CHAPTER 19

Accurate and Reliable Measurement Systems and Advanced Tools

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About This Chapter

In this chapter, we will discuss the use of tools to obtain information that will support the needed decision-making that leads to superior results. We will offer a framework for planning and gathering data that are required to answer the questions that lead to superior results. We provide guidelines for ensuring the relevance and accuracy of the data collected. Finally, we build on the core tools described in Chapter 18, Core Tools to Design, Control, and Improve Performance, and provide brief summaries of the most useful tools for collecting, analyzing, and presenting statistical data so that they clearly answer strategic and operational questions and provide a sound basis for decisions that deliver superior performance, the highest quality, loyal customers, and ultimately superior results.

High Points of This Chapter

1. Obtaining accurate, reliable, and relevant information happens when asking the right questions. Ask the right question, and you will get the right data.
2. Ten principles for effective measurement can help to develop accurate and reliable measures of performance.
3. When planning for data collection, the key issue is not how to collect data rather, the key issue is how to generate useful information. This is accomplished by a thorough understanding of the measurement system and comparative advantages among data collection and analysis choices, and beginning with the end in mind.
4. There are many tools useful to manage an organization that provides process improvement, design, and control. Tools for improvement require the testing of theories and finding root causes. Design tools require the collection of opinions and specifications, and then determine means to develop new services or products that are reliable. Control requires the use of statistical tools to help distinguish between common and special causes of variation to reduce risk, thereby facilitating appropriate intervention.
5. Chapter 18, Core Tools to Design, Control, and Improve Performance, covered some of the basic tools for planning, improving, and controlling quality. This chapter provides some additional tools for more detailed and complex analysis.

Measurement and Superior Results

In other chapters of this handbook, the reader will have seen many times the need for accurate, reliable, and relevant data in order to make the necessary decisions to achieve superior results. First and foremost, information must be directly *relevant* to the question being asked. If we wish to retain loyal customers, we require data on the actual loyalty and spending of the set of existing and potential customers. We will also need data that demonstrate the causative factors for customers' behavior. Next, the data must be *accurate*. As we will see, accuracy has two components: freedom from bias and sampling error (the uncertainty associated with using a sample of the whole) that is small enough to support the decision we must make. If we wish to improve the clinical status of the asthmatic population in a health plan, for example, we need to demonstrate that our measurement of that status is free from significant bias and that the samples we use to estimate the status are large enough so that our uncertainty arising from the samples size is small compared to the improvement we wish to achieve. Finally, the data must be *reliable*. Reliability encompasses both accuracy and relevance, but goes a step further, ensuring that the measurements will continue to be accurate and relevant on an ongoing basis within the operating and business environment so that we can continue to rely on it for decision-making. For example, if we have established that a process for manufacturing a complex electronic connector is capable of meeting customer requirements and that key variables of temperature, pressure, and speed must be controlled within proven limits, then our business success depends on those measures of temperature, pressure, and speed continuing to be both accurate and relevant in order to yield defect-free connectors.

Measurement and Analysis and the Juran Trilogy®

The Juran Trilogy® of Quality Planning, Quality Improvement, and Quality Control each rely on a foundation of accurate, reliable, and relevant information. While each is a distinct managerial process, they share a common need for information, apply many of the same tools, and often use the same data to ensure their ends. However, each has unique information requirements that form the basis for our pursuit of measurement and analysis for quality. The following sections list some of the key questions for each phase of the Juran Trilogy.

Quality Planning Measurement Questions

- What level of product market performance is required to meet strategic objectives?
- How does our product perform vis-à-vis the competition?
- How does our product perform with respect to customer expectations?
- What is the magnitude of the customer demand for the product (good or service) or process, and how much are they willing to pay?
- Who are the customers for the product (good or service) or process?
- How important is each customer?
- What are the needs/benefits for each significant customer?
- What is the relative importance of each of these needs and benefits?
- What is the impact of each product feature on each customer need?
- What are the mathematical tradeoffs among the various product features?
- What is the impact of each process feature/parameter on delivery of the product feature?
- What is the capability of the process to deliver the product?
- What are the optimal tolerances for the target of each product and process feature?
- How much of the strategic objective for the planning project was achieved?

Quality Improvement Measurement Questions

- What are the most important deficiencies driving customer disloyalty?
- What are the largest detailed categories of costs of poor quality?
- How much improvement in cost and customer loyalty is needed to meet strategic objectives?
- What are the major contributors to the identified problem?
- How much does each theory of cause contribute to the overall problem?
- Which theories are proven as root causes?
- How much improvement will the proposed remedy create?
- How much improvement did the project finally achieve?

Quality Control Measurement Questions

- What variables have the largest impact on the variability of the process?
- What is the normal random variation for the control variables?
- Is a variable exhibiting a sporadic spike in its variation due to an assignable cause?

Ten Principles of Effective Measurement

Quality measurement is central to quality control and improvement: "What gets measured, gets done." Before embarking on the details for good measurement and analysis, we need to consider the following principles that can help to develop effective measurements for quality:

1. Define the purpose and use that will be made of the measurement. An example of particular importance is the application of measurements in quality improvement. Final measurements must be supplemented with intermediate measurements for diagnosis.
2. Emphasize customer-related measurements; be sure to include both external and internal customers.
3. Focus on measurements that are useful—not just easy to collect. When quantification is too difficult, surrogate measures can at least provide a partial understanding of an output.
4. Provide for participation from all levels in both the planning and implementation of measurements. Measurements that are not used will eventually be ignored.
5. Provide for making measurements as close in time as possible to the activities they affect. This timing facilitates diagnosis and decision-making.
6. Provide not only concurrent indicators but also leading and lagging indicators. Current and historical measurements are necessary, but leading indicators help to look into the future.
7. Define in advance plans for data collection and storage, analysis, and presentation of measurements. Plans are incomplete unless the expected use of the measurements is carefully examined.
8. Seek simplicity in data recording, analysis, and presentation. Simple check sheets, coding of data, and automatic gauging are useful. Graphical presentations can be especially effective.
9. Provide for periodic evaluations of the accuracy, integrity, and usefulness of measurements. Usefulness includes relevance, comprehensiveness, level of detail, readability, and interpretability.
10. Realize that measurements alone cannot improve products and processes.

Measurements must be supplemented with the resources and training to enable people to achieve improvement.

Planning for Measurement and Data Collection

"Begin with the end in mind" is an appropriate maxim when starting any effort that requires collection of data. The "end" in this case is obtaining the information needed to effectively and efficiently plan, control, or improve. Before launching into a discourse on statistical analysis, we first will consider the need to plan for data collection. Part of this planning process is to consider the source of a set of data that we desire to analyze to solve a problem; the most common sources are historical data, newly collected operational data, and data from planned experimentation. These sources each have their advantages and drawbacks. Regardless of the source, all data need careful review before proceeding with an analysis and communication of the information gained from it.

Planning for Collection and Analysis of Data

In collecting and analyzing data, quality teams are seeking the answer to questions such as, How often does the problem occur? or What is causing the problem? In other words, they are seeking information. However, although good information always is based on data (the facts), simply collecting data does not necessarily ensure that useful information has been obtained. The key issue, then, is not, How do we collect data? Rather, the key issue is, How do we generate useful information? Although most organizations have vast stores of data about their operations, frequently, the data needed to provide truly useful information do not exist. The all-too-common practice at many organizations is to go "data diving," looking at much of or all of the data available to learn whatever they can about the process. While this practice can yield some useful information, it is inherently wasteful and can add time to the execution of a project. The process of planning the data collection with the end in mind that is described here is far more efficient and effective.

Information generation begins and ends with questions. To generate information, we need to

- Formulate precisely the question we are trying to answer. See general examples from each of the Juran Trilogy® processes above.
- Collect data relevant to that question.
- Analyze the data to determine the factual answer to the question.
- Present the data in a way that clearly communicates the answer to the question.

Learning to "ask the right questions" is the key skill in effective data collection. Accurate, precise data, collected through an elaborately designed statistical sampling plan, is useless if it is not relevant to answering a question that someone cares about.

Notice in Figure 19.1 how this planning process "works backwards" through the model. We start by defining the question. Then, rather than diving into the details of data collection,

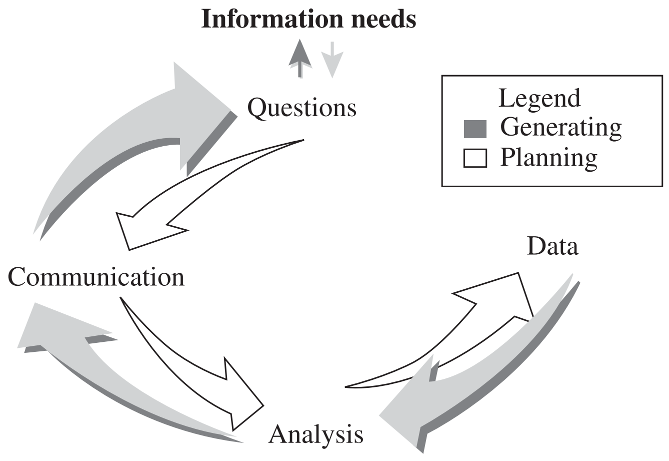


Figure 19.1 Planning for data collection.

we consider how we might communicate the answer to the question and what types of analysis we will need to perform. This helps us define our data needs and clarifies which characteristics are most important in the data. With this understanding as a foundation, we can deal more coherently with the where, who, how, and what of data collection.

To generate useful information, planning for good data collection, analysis, and communication proceeds through the following steps and associated considerations.

1. Establish data collection objectives and formulate the question in a specific statement:
   - What is your goal for collecting data?
   - What process or product will you monitor to collect the data?
   - What is the "theory" you are trying to test?
   - What is the question you are attempting to answer?
2. Decide what to measure, with consideration as to how the data will be communicated and analyzed:
   - What data do you need?
   - What type of measure is it? Time and physical measures such as length, mass, volume, and temperature are common; other measures include rankings (e.g., low-medium-high), ratios (e.g., speed), and indexes (e.g., case-mix adjusted hospital length of stay, refractive index). See the section "Types of Measures" for a discussion of scales of measurement.
   - What type of data is it? Variables data (readings on a scale of measurement) may be more expensive than attributes data (go or no-go data), but the information is much more useful.
   - What is the operational definition of each measure? An operational definition is a detailed description of a process, activity, or project term written to ensure common understanding among the members of a group.
   - How will the data be communicated and analyzed?
   - Are past data available that are applicable (however, bear in mind the hazards of historical data sets, discussed below)?
3. Decide how to measure a population or sample:
   - What measurement tool will you use? Calipers, Likert scale survey?
   - What is your sampling strategy? Simple random sampling? Stratified random sampling?
   - How much data will be collected? Calculate sample size considering the desired precision of the result, statistical risk, variability of the data, measurement error, economic factors, etc.
   - What is the measurement method?
4. Collect the data with a minimum of bias.
5. Define comprehensive data collection points:
   - Where in the process can we get appropriate data?
6. Select and train unbiased collectors:
   - Understand data collectors and their environment.
   - Who in the process can give us these data?

- How can we collect these data from these sources with minimum effort and least chance for error?

7. Design, prepare, and then test data collection methods, forms, and instructions:
   - What additional information should be captured for future analysis, reference, or traceability?
   - Conduct a measurement systems analysis (MSA) to confirm that the measures are accurate.
8. Audit the collection process and validate the results.
9. Screen the data.
10. Analyze the data.
11. Evaluate assumptions for determining the sample size and analyzing the data. Take corrective steps (including additional observations) if required.
12. Apply graphical and statistical techniques to evaluate the original problem.
13. Determine if further data and analysis are needed.
14. Consider a sensitivity analysis (e.g., by varying key sample estimates and other factors in the analysis and noting the effect on final conclusions).
15. Review the conclusions of the data analysis to determine if the original technical problem has been evaluated or if it has been changed to fit the statistical methods.
16. Present the results:
    - Write a report, including an executive summary.
    - State the conclusions in meaningful form by emphasizing results in terms of the original problem rather than the statistical indexes used in the analysis.
    - Present the results in graphic form where appropriate. Use simple statistical methods in the body of the report, and place complicated analyses in an appendix.
17. Determine if the conclusions of the specific problem apply to other problems or if the data and calculations could be a useful input to other problems.

Types of Measures

In planning for data collection, one needs to be clear about the characteristics of the data being collected and the implications of those characteristics for the questions to be answered. Two classifications of data types are useful here: the mathematical distinctions and the substantive quality questions answered.

The mathematical distinctions are typically known as measurement scales and are part of a system of measurement. The most useful scale is the *ratio scale* in which we record the actual amounts of a parameter such as weight. Ratio scales are also referred to as *continuous variables* data. An *interval scale* records ordered numbers but lacks an arithmetic origin such as zero—clock time is an example.

An *ordinal scale* records information in ranked categories—an example is customer preference for the flavor of various soft drinks. An unusual example of a measurement scale is the Wong-Baker FACES pain rating scale used widely in hospitals for children to communicate the intensity of pain felt to nurses (Wong and Baker 1998). The scale shows six faces to which a child can point, ranging from a very happy face (to indicate no hurt) to a very sad face (hurts most).

Finally, the *nominal scale* classifies objects into categories without an ordering or origin point—for example, the classification good or no-good, individual gender, color, the production shift, product, or geographic location.

Ordinal and nominal scales constitute a type of data referred to as *discrete* or *categorical* data.

The type of measurement scale determines the statistical analysis that can be applied to the data. In this regard, the ratio scale is the most powerful scale. For elaboration, see Emory and Cooper (1991).

For quality purposes, there are five general classes of quality measures:

- Defects (deficiencies, failures)
- Costs of poor quality
- Product and process features
- Customer needs
- Customer behavior

Units of measure for product deficiencies usually take the form of a fraction:

$$\frac{\text{Number of occurrences}}{\text{Opportunity for occurrence}}$$

The numerator may be in such terms as number of defects produced, number of field failures, or cost of warranty charges. The denominator may be in such terms as number of units produced, dollar volume of sales, number of units in service, or length of time in service. The deficiencies are determined by comparing the product delivered to its specification. In physical products, those specifications are in terms of physical dimensions, electrical or physical properties, or performance characteristics. In service products, the most common specification is in terms of timeliness. Other specifications usually relate to the actual performance versus the rules or specifications for the service—see the discussion of service features below.

Costs of poor quality are usually denominated in the currency of organization, but may also be expressed as fractions of sales, total costs, or gross margin.

Units of measure for product features are more difficult to create. The number and variety of these features may be large. Sometimes inventing a new unit of measure is a fascinating technical challenge. In one example, a manufacturer of a newly developed polystyrene product had to invent a unit of measure and a sensor to evaluate an important product feature. It was then possible to measure that feature of both the product and of competitors' products before releasing the product for manufacture. In another case, the process of harvesting peas in the field required a unit of measure for tenderness and the invention of a "tenderometer" gauge. A numerical scale was created, and measurements were taken in the field to determine when the peas were ready for harvesting.

Timeliness of execution is typically one important feature for a service product. Generally, the content of the service will also have certain performance features. A repair service will have features on the effectiveness and reliability of the repair.

Financial services will measure such features as the eligibility of the customer to receive a service or a specific return or interest rate. They also have specifications for calculating returns, payments, and value. These rules yield results that can be measured. The rules are extensively applied through automated decision engines, but the accuracy of these automated methods need to be validated, and there is often a human element in the setup and execution as well.

Health care has both process and outcome quality measures. The first describe the application of established standards of care for a given set of symptoms and signs. The outcomes measure the success of the treatment in restoring heath, avoiding further adverse episodes, and the safety of the patient from adverse events within the care setting, such as medication errors, falls, or procedural error.

Insurance pays claims according to the coverage of the policy and the nature of the insurable event. The insurance policy incorporates these rules for reimbursement for loss.

		Company X		Company A		Company B	
Attribute	**Relative Importance %**	**Rating**	**Weighted Rating**	**Rating**	**Weighted Rating**	**Rating**	**Weighted Rating**
Safety	28	6	168	5	140	4.5	126
Performance	20	6	120	7	140	6.5	130
Quality	20	6	120	7	140	4	80
Field service	12	4	48	8	96	5	60
Ease of use	8	4	32	6	48	5	40
Company image	8	8	64	4	32	4	32
Plant service	4	7.5	30	7.5	30	5	20
Total			582		626		488

(*Source: Quality Planning and Analysis*, Copyright 2007. Used by permission.)

Table 19.1 Multiattribute Study

"Claim engines" do most of the calculations, but require human specification and input. The accuracy of these payments can be expressed in monetary terms as well as in percent-defective terms.

Often a number of important product features exist. To develop an overall unit of measure, we can identify the important product features and then define the relative importance of each feature. In subsequent measurement, each feature receives a score. The overall measure is calculated as the weighted average of the scores for all features. This approach is illustrated in Table 19.1. In using such an approach for periodic or continuous measurement, some cautions should be cited (Early 1989). First, the relative importance of each feature is not precise and may change greatly over time. Second, improvement in certain features can result in an improved overall measure but can hide deterioration in one feature that has great importance.

The Sensor

The sensor is the means used to make the actual measurement. Most sensors are designed to provide information in terms of units of measure. For operational control subjects, the sensors are usually technological instruments or human beings employed as instruments (e.g., inspectors, auditors); for managerial and service subjects, the sensors are often data systems. Choosing the sensor includes defining how the measurements will be made—how, when, and who will make the measurements—and the criteria for taking action.

Clearly, sensors must be economical and easy to use. In addition, because sensors provide data that can lead to critical decisions on products and processes, sensors must be both accurate and precise, as discussed in the section "Measurement System Analysis."

Historical Data, Operational Data, and Experimental Data

Historical data are data that we already have and that may seem relevant to a question or problem at hand. Data often are saved during the production process, for example. If a satisfactory process goes out of control after some years of operation, it frequently is suggested that it would save both time and expense to analyze the historical data statistically rather than collect new data or perform a planned experiment to obtain new data that could lead to process correction. Thus, we have available data that may consist of measurements Y (such as a process yield, e.g., the strength of a material produced) and associated process variables $x1, x2, \ldots, xk$ (such as $x1$ = pressure and $x2$ = acid concentration, with $k = 2$). If such data do not exist, we might set up a data collection scheme to collect new operational data.

Historical or new operational data can both be invaluable for the following reasons:

- It is less time consuming and expensive to collect. Especially when multiple theories are at issue, even very lean eighth-fraction screening experimental designs can be prohibitive for some processes if they look at seven or more factors.
- For some types of operations that have a significant human performance component, the mere act of collecting new data, not to mention conducting experiments, can have unintended consequences on human behavior and, hence, the process—the famous Hawthorne effect.
- For out-of-control situations in previously stable processes, the information question is "what changed," which usually is a specific unique occurrence of an assignable cause that does not require significant experimentation.
- Substantial chronic random variation typically has root causes that are at least identifiable, and often quantifiable, from operational data.
- Although caveats need to be observed, operational data can be helpful in developing and testing the theories that will be used ultimately in an experiment.
- When dealing with either operational data or experimental data, the same pitfalls apply if one fails to test all the possible causes or extends results beyond the actual measured operating range.

Nevertheless, historical and operational data have potential drawbacks that include

- The x's may be highly correlated with each other in practice; hence, it may not be possible to separate the effects among them.
- The x's may cover a very small part of the possible operating range, so small that any indications of changes in Y attributable to changes in the x's may be overwhelmed by the size of the variability of the process.
- Other variables that affect the output of the process (e.g., time of day, atmospheric conditions, operator running the process, etc.) may not have been held constant and may in fact be the real causes of changes observed in the process.

In such cases, experimental data may be superior. Experiments are run at each of a number of combinations of settings that are selected in advance by statistical design criteria for each variable $x1, \ldots, xk$.

Measurement System Analysis

Control of a process, design of a new product, and elimination of chronic random variation all require accurate measurement of both the desired results and the contributing factors. A good measurement system that provides this critical information should have the following attributes:

- *Minimal bias*. Bias is the difference between the average measured value and a reference value. A reference value, in turn, is an agreed-upon standard, such as a traceable national standard. The reference standard is used to calibrate a measurement system, thereby bringing the reported measure in line with the accepted, known value. Bias sometimes is referred to as "accuracy." However, because accuracy has several meanings in the literature, "bias" is the recommended term in the present context.

- *Repeatability*. Repeatability is the variation in measurements obtained with one measurement instrument when used several times by an appraiser while measuring the identical characteristic on the same part.
- *Reproducibility*. Reproducibility is the variation in the average of the measurements made by different appraisers using the same measuring instrument when measuring the identical characteristic on the same part.
- *Stability*. Stability (or drift) is the total variation in the measurements obtained with a measurement system on the same master or parts when measuring a single characteristic over an extended period. A measurement system is stable if the same results are obtained at different points in time.
- *Linearity*. Linearity is the difference in bias values at different points along the expected operating range of a measurement instrument.
- *Precision*. Repeatability, reproducibility, and stability tend to be random, and the three together are often referred to as "precision." Refer to Figure 19.2 for a graphic depiction of the difference between bias and precision.

These five sources of measurement variation are illustrated in Figure 19.3, and are generally consistent with the definitions provided by the AIAG *Measurement Systems Analysis Reference Manual* (Automotive Industry Action Group, 2003).

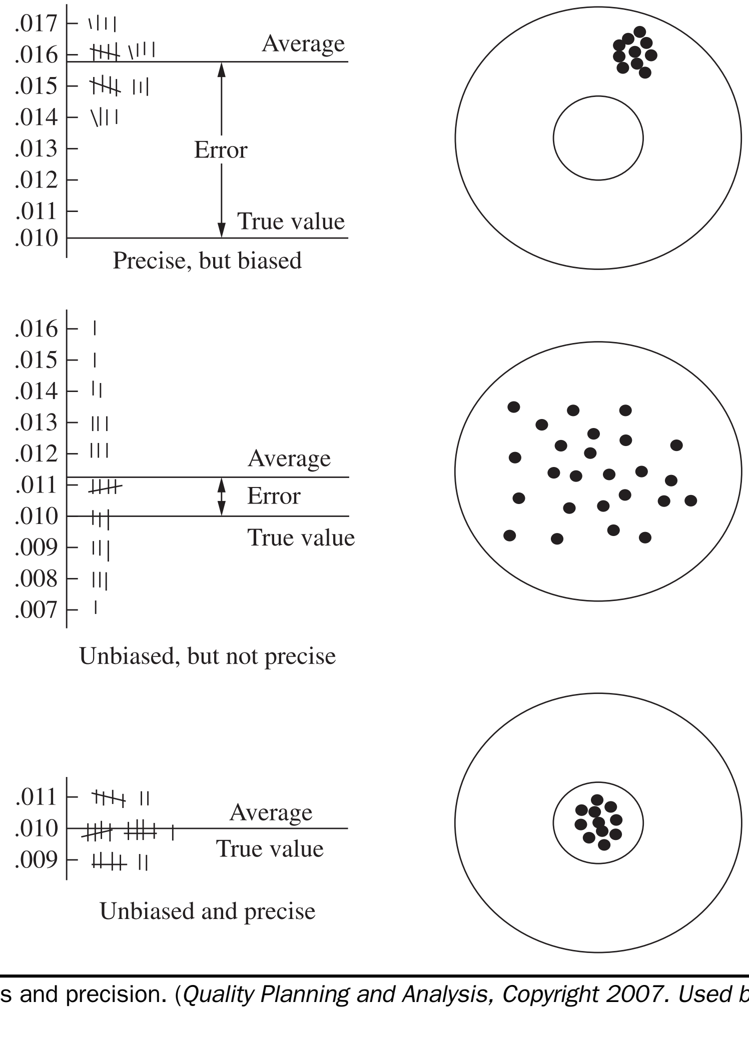
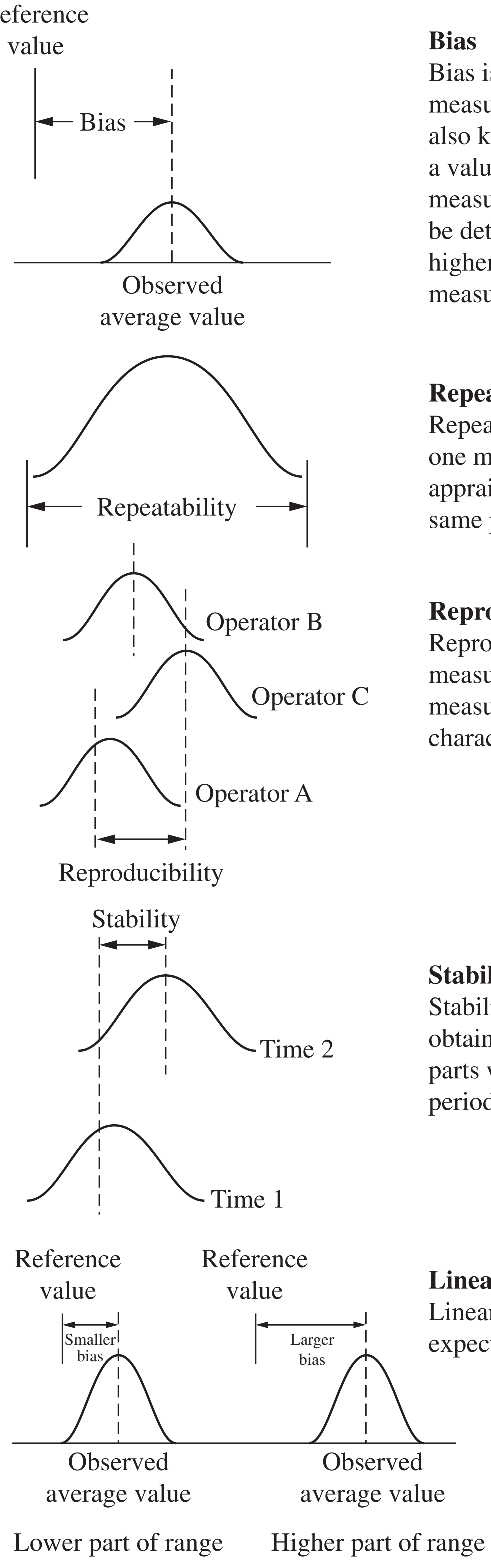


FIGURE 19.2 Bias and precision. (*Quality Planning and Analysis, Copyright 2007. Used by permission.*)



Bias

Bias is the difference between the observed average of measurements and the reference value. The reference value, also known as the accepted reference value or master value, is a value that serves as an agreed-upon reference for the measured values (ASTM D 3980–88). A reference value can be determined by averaging several measurements with a higher level (e.g., metrology lab or layout equipment) of measuring equipment.

Repeatability

Repeatability is the variation in measurements obtained with one measurement instrument when used several times by an appraiser while measuring the identical characteristic on the same part.

Reproducibility

Reproducibility is the variation in the average of the measurements made by different appraisers using the same measuring instrument when measuring the identical characteristic on the same part.

Stability

Stability (or drift) is the total variation in the measurements obtained with a measurement system on the same master or parts when measuring a single characteristic over an extended period.

Linearity

Linearity is the difference in the bias values through the expected operating range of the gauge.

FIGURE 19.3 Five sources of measurement variation. (*Reprinted with permission from the MSA Manual DaimlerChrysler, Ford, General Motors Supplier Quality Requirements Task Force.*)

Any statement of bias and precision must be preceded by three conditions:

1. Definition of the test method. This definition includes the step-by-step procedure, equipment to be used, preparation of test specimens, test conditions, etc.
2. Definition of the system of causes of variability, such as material, analysts, apparatus, laboratories, days, etc. American Society for Testing and Materials (ASTM) recommends that modifiers of the word "precision" be used to clarify the scope of the precision measure. Examples of such modifiers are single-operator, single-analyst, single-laboratory-operator-material-day, and multilaboratory.
3. Existence of a statistically controlled measurement process. The measurement process must have stability for the statements on bias and precision to be valid. This stability can be verified by a control chart.

Effect of Measurement Error On Acceptance Decisions. Error of measurement can cause incorrect decisions on (1) individual units of product and on (2) lots submitted to sampling plans. In one example of measuring the softening point of a material, the standard deviation of the test precision is 2°, yielding two standard deviations of ±4°. The specification limits on the material are ±3°. Imagine the incorrect decisions that are made under these conditions.

Two types of errors can occur in the classification of a product: (1) a nonconforming unit can be accepted (the consumer's risk) and (2) a conforming unit can be rejected (the producer's risk). In a classic paper, Eagle (1954) showed the effect of precision on each of these errors.

The probability of accepting a nonconforming unit as a function of measurement error (called test error, σ_{TE}, by Eagle) is shown in Figure 19.4. The abscissa expresses the test error as the standard deviation divided by the plus-or-minus value of the specification range (assumed equal to two standard deviations of the product). For example, if the measurement error is one-half of the tolerance range, the probability is about 1.65 percent that a nonconforming unit will be read as conforming (due to the measurement error) and therefore will be accepted.

Figure 19.5 shows the percentage of conforming units that will be rejected as a function of the measurement error. For example, if the measurement error is one-half of the plus-or-minus tolerance range, about 14 percent of the units that are within specifications will be rejected because the measurement error will show that these conforming units are outside specification.

The test specification can be adjusted with respect to the performance specification (see Figures 19.4 and 19.5). Moving the test specification inside the performance specification reduces the probability of accepting a nonconforming product but increases the probability of rejecting a conforming product. The reverse occurs if the test specification is moved outside the performance specification. Both risks can be reduced by increasing the precision of the test (i.e., by reducing the value of σ_{TE}).

Hoag et al. (1975) studied the effect of inspector errors on type I (α) and type II (β) risks of sampling plans (see the section "Hypothesis Testing" for definitions of type I and II risks). For a single sampling plan and an 80 percent probability of the inspector detecting a defect, the real value of β is two to three times that specified, and the real value of α is about one-fourth to one-half of that specified.

Case et al. (1975) investigated the effect of inspection error on the average outgoing quality (AOQ) of an attribute sampling procedure. They concluded that the AOQ values change and significant changes can occur in the shape of the AOQ curve.

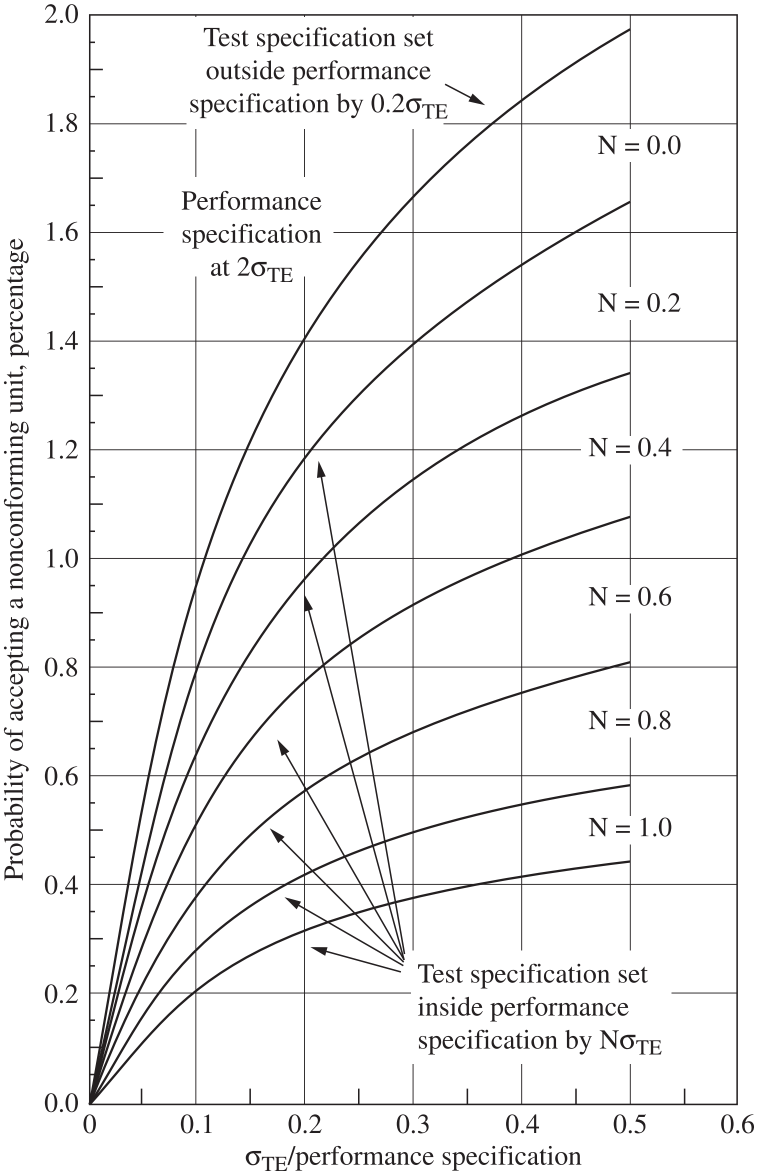


FIGURE 19.4 Probability of accepting a nonconforming unit.

The Automotive Industry Action Group (1995, p. 77) presents the concept of a gauge performance curve to determine the probability of accepting or rejecting a part when the gauge repeatability and reproducibility (R&R) are unknown.

All these investigations concluded that measurement error can be a serious problem.

Components of Variation. In drawing conclusions about measurement error, it is worthwhile to study the causes of variation in observed values. The relationship is

$$\sigma_{\text{observed}} = \sqrt{\sigma^2_{\text{causeA}} + \sigma^2_{\text{causeB}} + \ldots + \sigma^2_{\text{causeN}}}$$

The formula assumes that the causes act independently.

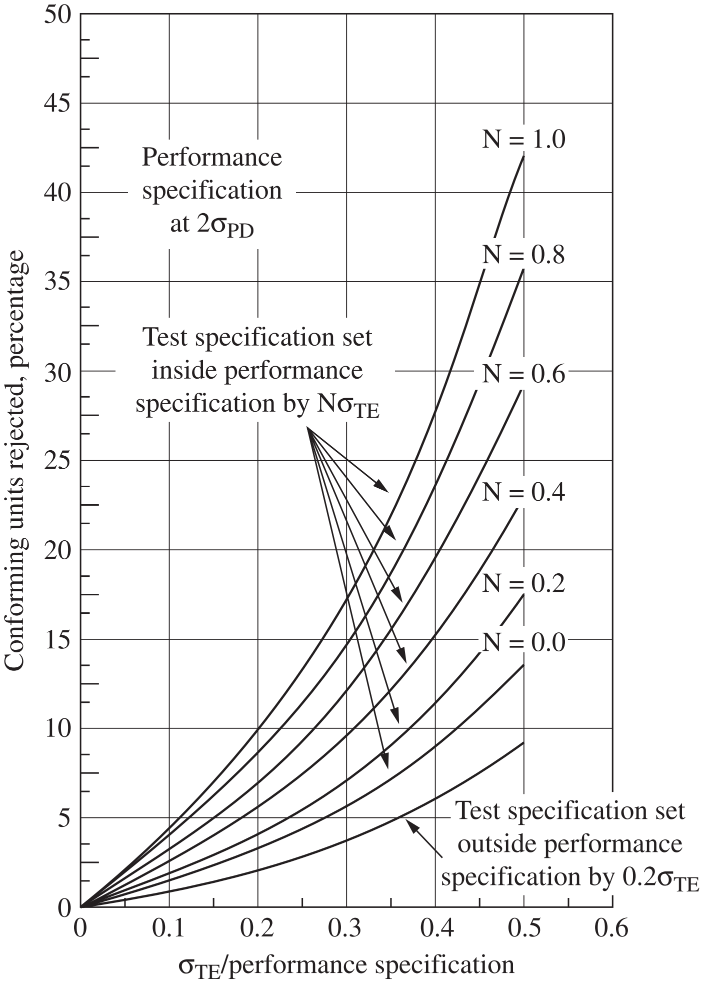


Figure 19.5 Conforming units rejected (percentage).

It is valuable to find the numerical values of the components of observed variation because the knowledge may suggest where effort should be concentrated to reduce variation in the product. A separation of the observed variation into product variation plus other causes of variation may indicate important factors other than the manufacturing process. Thus, if it is found that the measurement error is a large percentage of the total variation, this finding must be analyzed before proceeding with a quality improvement program. Finding the components (e.g., instrument, operator) of this error may help to reduce the measurement error, which in turn may completely eliminate a problem.

Observations from an instrument used to measure a series of different units of product can be viewed as a composite of (1) the variation due to the measuring method and (2) the variation in the product itself. This value can be expressed as

$$\sigma_O = \sqrt{\sigma_P^2 + \sigma_E^2}$$

where $\sigma_O = \sigma$ of the observed data
$\sigma_P = \sigma$ of the product
$\sigma_E = \sigma$ of the measuring method

Solving for σ_P yields

$$\sigma_P = \sqrt{\sigma_O^2 + \sigma_E^2}$$

The components of measurement error often focus on repeatability and reproducibility (R&R). Repeatability primarily concerns variation due to measurement gauges and equipment; reproducibility concerns variation due to human "appraisers" who use the gauges and equipment. Studies to estimate these components are often called "gauge R&R" studies.

A gauge R&R study can provide separate numerical estimates of repeatability and reproducibility. Two methods are usually used to analyze the measurement data. Each method requires a number of appraisers, a number of parts, and repeat trials of appraisers measuring different parts. For example, an R&R study might use three appraisers, ten parts, and two trials.

One method analyzes averages and ranges of the measurement study data. This method requires minimum statistical background and does not require a computer. The second method is the analysis of variance, ANOVA (see "Statistical Tools for Improvement"). Compared to the first method, ANOVA requires a higher level of statistical knowledge to interpret the results, but can evaluate the data for possible interaction between appraisers and parts. ANOVA is best done on a computer using Minitab or other software. Overall, the ANOVA method is preferred to analyzing the averages and ranges. Detailed illustrations of each method are provided in the Automotive Industry Action Group booklet *Measurement Systems Analysis* (1995). Also, see Tsai (1988) for an example using ANOVA and considering both no interaction and interaction of operators and parts. Burdick and Larsen (1997) provide methods for constructing confidence intervals on measures of variability in R&R studies.

When the total standard deviation of repeatability and reproducibility is determined from ANOVA, a judgment must then be made on the adequacy of the measurement process. A common practice is to calculate 5.15σ ($\pm 2.575\sigma$) as the total spread of the measurements that will include 99 percent of the measurements. If 5.15σ is equal to or less than 10 percent of the specification range for the quality characteristic, the measurement process is viewed as acceptable for that characteristic; if the result is greater than 10 percent, the measurement process is viewed as unacceptable. Engel and DeVries (1997) examine how the practice of comparing measurement error with the specification interval relates to making correct decisions in product testing.

Reducing and Controlling Errors of Measurement. Steps can be taken to reduce and control errors for all sources of measurement variation. The systematic errors that contribute to bias can sometimes be handled by applying a numerical correction to the measured data. If an instrument has a bias of 0.001, then, on average, it reads 0.001 too low. The data can be adjusted by adding 0.001 to each value of the data. Of course, it is preferable to adjust the instrument as part of a calibration program.

In a calibration program, the measurements made by an instrument are compared to a reference standard of known accuracy (a calibration program should include provisions for periodic audits). If the instrument is found to be out of calibration, an adjustment is made.

A calibration program can become complex for these reasons:

- The large number of measuring instruments
- The need for periodic calibration of many instruments

- The need for many reference standards
- The increased technological complexity of new instruments
- The variety of types of instruments (i.e., mechanical, electronic, chemical, etc.)

Precision in measurement can be improved through either or both of the following procedures:

- Discovering the causes of variation and remedying these causes. A useful step is to resolve the observed values into components of variation (see earlier). This process can lead to the discovery of inadequate training, perishable reagents, lack of sufficient detail in procedures, and other such problems. This fundamental approach also points to other causes for which the remedy is unknown or uneconomic (i.e., basic redesign of the test procedure).
- Using multiple measurements and statistical methodology to control the error in measurement. The use of multiple measurements is based on the following relationship:

$$\sigma_{\overline{X}} = \frac{\sigma}{\sqrt{n}}$$

As in all sampling schemes, halving the error in measurement requires quadrupling (not doubling) the number of measurements.

As the number of tests grows larger, a significant reduction in the error in measurement can be achieved only by taking a still larger number of additional tests. Thus, the cost of the additional tests versus the value of the slight improvement in measurement error becomes an issue. The alternatives of reducing the causes of variation must also be considered.

For an in-depth discussion of reducing other forms of measurement error, see Automotive Industry Action Group (2003) and Coleman et al. (2008).

A successful measurement system analysis (MSA) is critical not only for control but also for validating the measures used in quality planning and improvement, as illustrated by this Six Sigma improvement project (DMAIC) (courtesy of Steve Wittig and Chris Arquette at a Juran Institute client forum). It also illustrates the use and importance of attribute MSA studies for discrete variables.

Background. The paint line has a first run yield of 74 percent. This means that 26 percent of all frames need to be reworked at least once. Defects due to finish issues account for 15 percent, and material (wood) issues account for 11 percent. This project looks only at finish defects because this is readily within our control. Any rework is nonvalue-added and contributes to wasted paint/primer, labor, utilities, work in progress, capacity, and more hazardous waste. Our goal is to improve first-run yield to 90 percent for finish defects.

Summary of MSA Effort. The paint line is old and somewhat neglected. Our first MSA results were expectedly poor, and the appraisers were contributing to the defect rate by rejecting good frames. We improved this by continued training of the appraisers by quality control. We did two more MSAs with acceptable results. This will need to be an ongoing test/train routine. Figures 19.6 to 19.8 are attribute MSA results, and Figures 19.9 and 19.10 are results of a variable MSA.

Validate measurement system attribute data analysis – MSA 1

Sample #	Expert	Operator 1		Operator 2		Operator 3	
		Try 1	Try 2	Try 1	Try 2	Try 1	Try 2
1	Blister	Blister	Blister	Blister	Blister	Blister	Blister
2	Good	Light Ed.	Good	Good	Good	Good	Good
3	Drip	Drip	Drip	Dirt	Dirt	Drip	Drip
4	Dirt	Contam	Dirt	Dirt	Dirt	Dirt	Dirt
5	Contam	Contam	Contam	Good	Good	Over run	Over run
6	Blister	Blister	Blister	Blister	Blister	Dirt	Blister
7	Good	Good	Good	Good	Good	Good	Good
8	Dirt	Light Ed.	Contam	Good	Good	Dirt	Dirt
9	Good	Good	Drip	Dirt	Good	Drip	Drip
10	Good	Orange P.	Good	Good	Good	Good	Good
11	Dirt	Dirt	Good	Dirt	Dirt	Dirt	Dirt
12	Good	Contam	Light Ed.	Good	Good	Over run	Over run
13	Good	Light Ed.	Light Ed.	Good	Good	Light Ed.	Over run
14	Contam	Contam	Contam	Good	Good	Good	Good
15	Drip	Drip	Light Ed.	Dirt	Good	Drip	Drip
16	Light Ed.	Light Ed.	Light Ed.	Good	Good	Good	Good
17	Dirt	Contam	Contam	Good	Dirt	Dirt	Dirt
18	Dirt	Contam	Contam	Dirt	Dirt	Dirt	Dirt
19	Blister	Blister	Good	Good	Blister	Blister	Blister
20	Good	Good	Good	Good	Good	Orange P.	Orange P.

Figure 19.6 Baseline attribute MSA on appraisers' accept/reject decisions. (*Juran Institute, Inc.*)

Attribute data analysis-MSA 1 results

Within appraiser

Assessment agreement

Appraiser	# Inspected	# Matched	Percent (%)	95.0% Cl
1	20	11	55.0	(31.5, 76.9)
2	20	16	80.0	(56.3, 94.3)
3	20	18	90.0	(68.3, 98.8)

# Matched: Appraiser agrees with him/herself across trials.

Each appraiser vs standard

Assessment agreement

Appraiser	# Inspected	# Matched	Percent (%)	95.0% Cl
1	20	8	40.0	(19.1, 63.9)
2	20	11	55.0	(31.5, 76.9)
3	20	12	60.0	(36.1, 80.9)

# Matched: Appraisers' assessment across trials agrees with standard.

Between appraisers

Assessment agreement

# Inspected	# Matched	Percent (%)	95.0% Cl
20	2	10.0	(1.2, 31.7)

# Matched: All appraisers' assessments agree with each other.

All appraisers vs standard

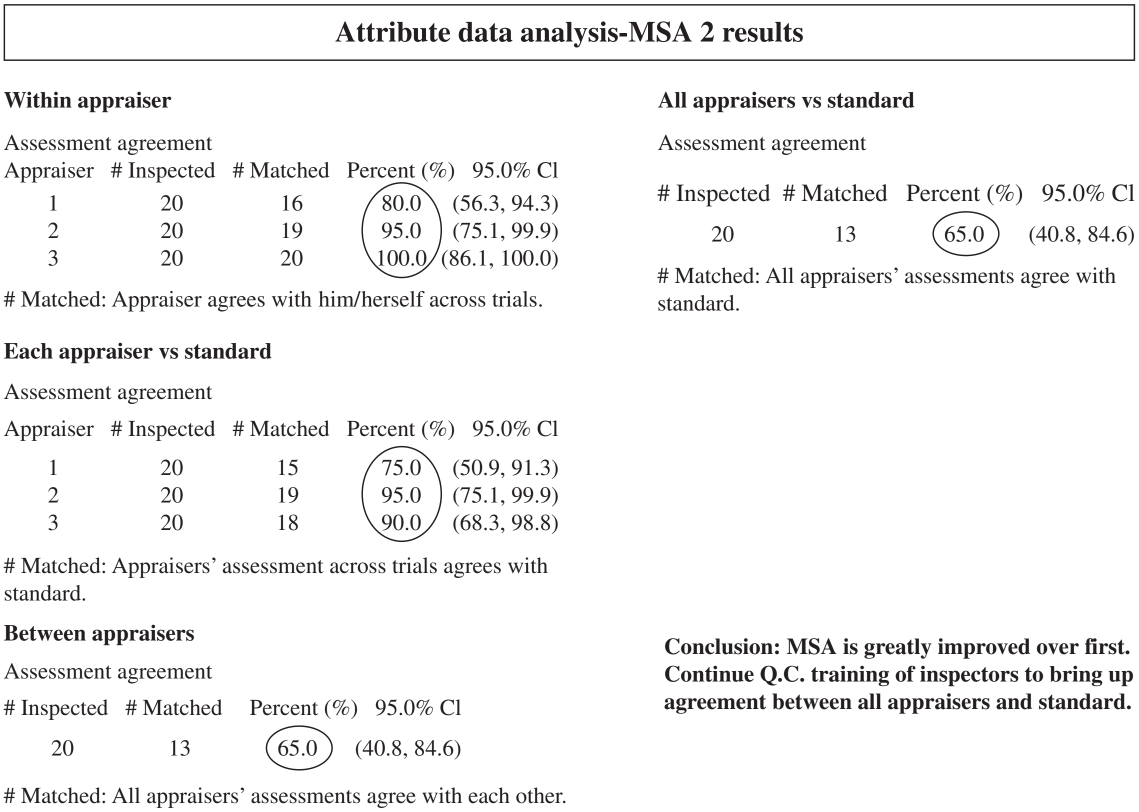
Assessment agreement

# Inspected	# Matched	Percent (%)	95.0% Cl
20	2	10.0	(1.2, 31.7)

# Matched: All appraisers' assessments agree with standard.

Note: 38% were called bad that were good. 22% were called good that were bad. This potentially could yield an improvement in the defect rate by 16%.

Figure 19.7 Results of baseline attribute MSA. Results are not acceptable. (*Juran Institute, Inc.*)



Attribute data analysis-MSA 2 results

Within appraiser

Assessment agreement

Appraiser	# Inspected	# Matched	Percent (%)	95.0% Cl
1	20	16	80.0	(56.3, 94.3)
2	20	19	95.0	(75.1, 99.9)
3	20	20	100.0	(86.1, 100.0)

# Matched: Appraiser agrees with him/herself across trials.

Each appraiser vs standard

Assessment agreement

Appraiser	# Inspected	# Matched	Percent (%)	95.0% Cl
1	20	15	75.0	(50.9, 91.3)
2	20	19	95.0	(75.1, 99.9)
3	20	18	90.0	(68.3, 98.8)

# Matched: Appraisers' assessment across trials agrees with standard.

Between appraisers

Assessment agreement

# Inspected	# Matched	Percent (%)	95.0% Cl
20	13	65.0	(40.8, 84.6)

# Matched: All appraisers' assessments agree with each other.

All appraisers vs standard

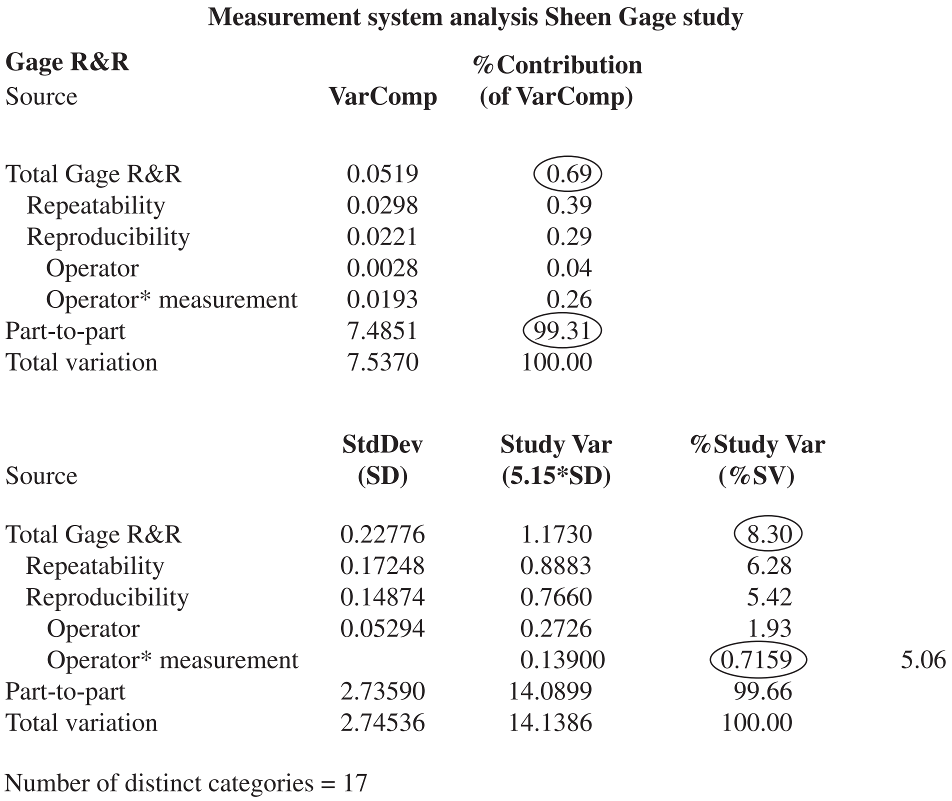
Assessment agreement

# Inspected	# Matched	Percent (%)	95.0% Cl
20	13	65.0	(40.8, 84.6)

# Matched: All appraisers' assessments agree with standard.

Conclusion: MSA is greatly improved over first. Continue Q.C. training of inspectors to bring up agreement between all appraisers and standard.

Figure 19.8 Attribute MSA after improvement. (*Juran Institute, Inc.*)



Measurement system analysis Sheen Gage study

Gage R&R Source	**VarComp**	**%Contribution (of VarComp)**
Total Gage R&R	0.0519	0.69
Repeatability	0.0298	0.39
Reproducibility	0.0221	0.29
Operator	0.0028	0.04
Operator* measurement	0.0193	0.26
Part-to-part	7.4851	99.31
Total variation	7.5370	100.00

Source	**StdDev (SD)**	**Study Var (5.15*SD)**	**%Study Var (%SV)**	
Total Gage R&R	0.22776	1.1730	8.30	
Repeatability	0.17248	0.8883	6.28	
Reproducibility	0.14874	0.7660	5.42	
Operator	0.05294	0.2726	1.93	
Operator* measurement		0.13900	0.7159	5.06
Part-to-part	2.73590	14.0899	99.66	
Total variation	2.74536	14.1386	100.00	

Number of distinct categories = 17

Figure 19.9 Results of baseline variable data MSA on sheen gage results are acceptable. (*Juran Institute, Inc.*)

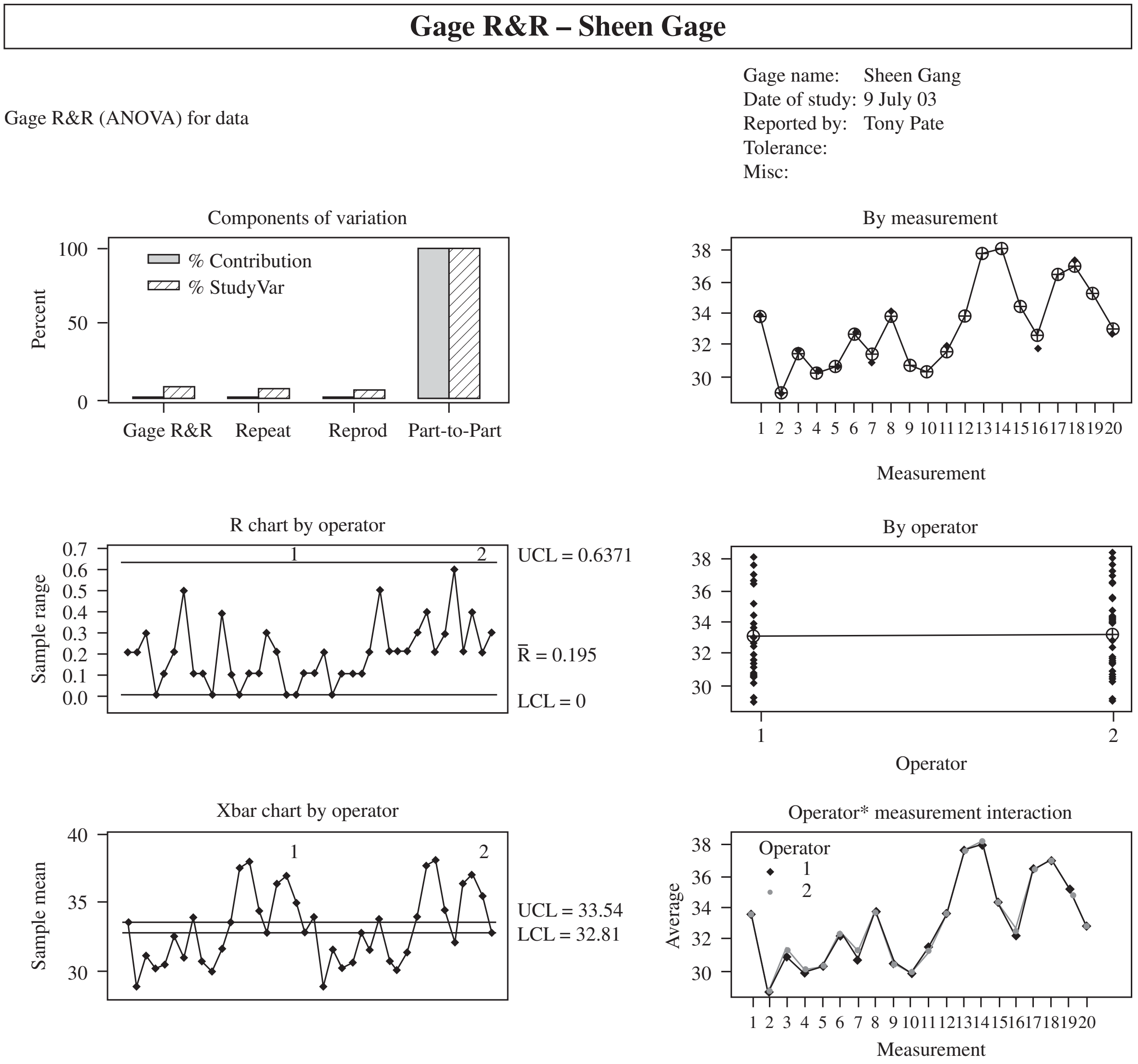


Figure 19.10 Gage R&R. (*Juran Institute, Inc.*)

Data Screening

As a practical matter, many data sets contain some instances of incorrectly transcribed values, values from points where an experiment went awry for some reason (such as equipment malfunction), and the measurement system failed, or other factors led to observational error. Procedures for finding these problems are called data screening and should be performed.

Data Screening Methods. Numerous tests are available to detect outliers, that is, "observation(s) [or (a)subset of observations] which appear to be inconsistent with the remainder of that set of data" (Barnett and Lewis 1994). One of the most common methods of data screening is to classify observations as outliers if they are outside an interval of *L* multiples of the standard deviation about the mean. The number *L* is commonly taken to be 2.5, 3, or 4. The larger *L* is, the less likely it is that outliers will be detected, while the smaller *L* is, the more good observations one will wrongly detect as potential outliers. For example, because approximately 99.73 percent of a population lies within ±3 standard deviations from the mean, application of $L = 3$ will yield (100) (0.0027) = 0.27 percent of the observations being further than 3 standard deviations from the mean even if there are no true outliers in the data set (this assumes a normal distribution for the observations). As the data set being considered becomes larger, the more possible outliers one will identify, even if there are no problems with the data. For this reason, outliers identified in this way should be deleted from the analysis only if they can be traced to specific causes (such as recording errors, experimental errors, and the like). Otherwise, there is a substantial risk of eliminating data that are, in a sense, "trying to tell you something."

Typically, one adjusts L based on the size of the data set to be screened; with $n = 1000$ points, $L = 3$ is reasonable; with $n = 100$, $L = 2.5$ can be used, and only (100) (0.0124) = 1.24 outliers will be expected to be found if the data have no problems. After bad data are deleted or replaced (this is desirable if the experiment can be rerun under comparable conditions to those specified in the experimental plan), the data should be screened again. With the "worst" points removed/corrected, less extreme cases may come to be identified as possible outliers, and should again be investigated.

Another commonly used method is to visualize the data in some way (e.g., to plot variables in box plots or scatter plots). Points visually distant from the others should be scrutinized and eliminated as outliers if (and only if) they are reasonably attributable to some specific cause unrelated to the question at hand. Regression analysis can be helpful as an additional step, using residuals (the differences between the observed and predicted values) to flag potential data points that are unusual (and may have undue leverage on the regression model). Regression is discussed later in this chapter.

Summarization of Data

A mantra for the data analyst is that the first three steps of any data analysis are to (1) plot the data, (2) plot the data, and (3) plot the data. Clearly important, many of the most practical methods of summarizing data are quite simple in concept. Depending on the goals of the data summarization, sometimes one method will provide a useful and complete summarization. More often, two or more methods will be needed to obtain the clarity of description that is desired. Several key methods are plots versus time order of data, frequency distributions and histograms, and sample characteristics such as measures of central tendency/location (mean, median, mode) and measures of dispersion (range, standard deviation, variance) displayed graphically

Plots versus Time Order of Data. Plotting the output Y against the time order in which the data were obtained (essentially a scatter plot of Y versus time) can reveal several possible phenomena:

- A few observations are far from the others. They should be investigated as to their cause and, if erroneous, corrected or discarded.
- There are trends or cycles within a time period—a day, week, etc. This may represent such phenomena as warming of a machine, operator fatigue, seasonal demand, customer timing preferences, or similar time-related trends.
- Variability decreases or increases with time; this may be due to a learning curve or raw material characteristics, as when one lot of material is used up and the next lot has lesser or greater heterogeneity. It may also reflect changes in customer behavior for services.

While the preceding trends may be apparent even in a plot of the original observations Y versus time, they are often more easily spotted in plots of the residuals of the observations after a regression analysis (see "Correlation and Regression Analysis" later in this chapter) or using a control chart.

Histograms. A frequency distribution is a tabulation of data arranged according to size. Presenting data in this form clarifies the central tendency and the dispersion along the scale of measurement, as well as the relative frequency of occurrence of the various values (i.e., the shape of the distribution of data). The shape of the distribution may suggest some theories of cause for variation in the process, and reduce the likelihood of others (see Chapter 18, Core Tools to Design, Control, and Improve Performance). Histograms usually require at least 40 data points to provide useful insight.

Box Plots. These also display frequency distribution and indications with regard to central tendency and the dispersion along the scale of measurement. They provide less rich detail than histograms, but can be used with as few as eight data points, and facilitate the comparison of many distributions. (See Chapter 18, Core Tools to Design, Control, and Improve Performance.)

Sample Characteristics. Descriptive statistics such as the mean (average), median, mode, range, variance, and standard deviation provide numerical ways of summarizing data, and should be used in conjunction with graphical displays of the type discussed previously.

Analysis

The emphasis in this section is on statistical tools used in the analysis of data for quality improvement, control, and planning. Statistics, for our purposes, is the use of a small sample of data to infer properties of a larger population or universe in which we are interested. Statistics is grounded in probability. Probability is a measure that describes the chance that an event will occur. Based on appropriately collected data, statistics and probability are used to understand explicitly the accuracy of the information we have for managing quality and assess the risks of both acting and not acting on the basis of that data.

The following are some types of problems that can benefit from statistical analysis:

- Determining the usefulness of a limited number of test results in predicting the true value of a product characteristic
- Determining the number of tests required to provide adequate data for evaluation
- Comparing test data between two alternative designs
- Predicting the amount of product that will fall within specification limits
- Predicting system performance
- Controlling process quality by early detection of process changes
- Planning experiments to discover the factors that influence a characteristic of a product or process (i.e., exploratory experimentation)
- Determining the quantitative relationship between two or more variables

The Concept of Statistical Variation

Variety is the so-called "spice of life," and this is no less true when it comes to statistics. The concept of variation is that no two items are perfectly identical. Variation is a fact of nature and a bane of industrial life. For example, even "identical" twins vary slightly in height and weight at birth. The dimensions of an integrated chip vary from chip to chip; cans of tomato soup vary slightly from can to can; the time required to assign a seat at an airline check-in counter varies from passenger to passenger. To disregard the existence of variation (or to rationalize falsely that it is small) can lead to incorrect decisions on major problems. Statistics helps to analyze data properly and draw conclusions, taking into account the existence of variation.

Statistical variation—variation due to random causes—is much greater than most people think. Often, we decide what action to take based on the most recent data point, and we forget that the data point is part of a history of data.

In order to make decisions and improve processes, statistical variation must be taken into account. Variation can be visualized through the use of histograms, box plots, and similar tools. Frequently, such tools are sufficient to draw practical conclusions because differences in central tendency are large and variation is relatively small. However, statistical tools become necessary when the picture (quite literally) is less clear.

Building on the foundation of descriptive statistics, we start with an overview of the probability distributions that underlie many statistical tools and are used to model data and allow estimation of probabilities. Terms are defined as they are encountered, including further discussion of enumerative and analytical studies. Following an introduction to statistical inference and hypothesis testing, specific methods are discussed by way of example.

Probability Distributions

Before diving in, we should make a distinction between a sample and a population. A population is the totality of the phenomenon under study. A sample is a limited number of items taken from that population. Measurements are made on the smaller subset of items, and we can calculate a sample statistic (e.g., the mean). A sample statistic is a quantity computed from a sample to estimate a population parameter. Samples for statistics must be random. Simple random samples require that every element of the population have the same equal probability of selection for the sample. More complex sampling, such as stratified sampling, requires still requires that each element have a known, but not necessarily equal, chance of selection.

A probability distribution function is a mathematical formula that relates the values of the characteristic with their probability of occurrence in the population. The collection of these probabilities is called a probability distribution. The mean (μ) of a probability distribution often is called the expected value. Some distributions and their functions are summarized in Figure 19.11. Distributions are of two types:

Continuous (for "Variable" Data). When the characteristic being measured can take on any value (subject to the fineness of the measuring process), its probability distribution is called a "continuous probability distribution." For example, the probability distribution of the resistance data in Table 19.2 is an example of a continuous probability distribution because the resistance could have any value, limited only by the fineness of the measuring instrument. Most continuous characteristics follow one of several common probability distributions: the normal distribution, the exponential distribution, or the Weibull distribution.

Discrete (for "Attribute" Data). When the characteristic being measured can take on only certain specific values (e.g., integers 0, 1, 2, 3), its probability distribution is called a "discrete probability distribution." For example, the distribution of the number of defects *r* in a sample of five items is a discrete probability distribution because *r* can be only 0, 1, 2, 3, 4, or 5 (and not 1.25 or similar intermediate values). The common discrete distributions are the Poisson and binomial.

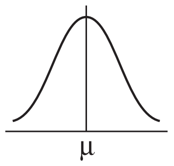
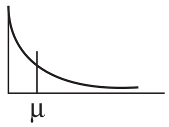
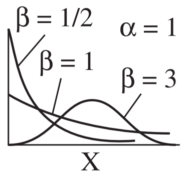
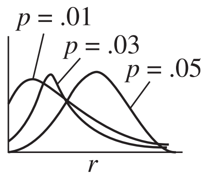
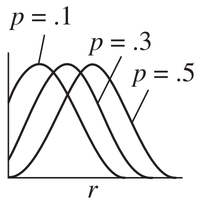
Distribution	Form	Probability function	
Normal		$y = \frac{1}{\sigma\sqrt{2\pi}}e^{-\frac{(x-\mu)^2}{2\sigma^2}}$ μ = Mean σ = Standard deviation	Applicable when there is a concentration of observations about the average and it is equally likely that observations will occur above and below the average. Variation in observations is usually the result of many small causes.
Exponential		$y = \frac{1}{\mu}\, e^{-\frac{x}{\mu}}$	Applicable when it is likely that more observations will occur below the average than above.
Weibull		$y = \alpha\beta(X-\gamma)^{\beta-1}e^{-\alpha(X-\gamma)^{\alpha}}$ α = Scale parameter β = Shape parameter γ = Location parameter	Applicable in describing a wide variety of patterns in variation, including departures from the normal and exponential.
Poisson*		$y = \frac{(np)^r e^{-np}}{r!}$ n = Number of trials r = Number of occurrences p = Probability of occurrence	Same as binomial but particularly applicable when there are many opportunities for occurrence of an event but a low probability (less than .10) on each trial.
Binomial*		$y = \frac{n!}{r!(n-r)!}\, p^r q^{n-r}$ n = Number of trials r = Number of occurrences p = Probability of occurrence $q = 1 - p$	Applicable in defining the probability of r occurrences in n trials of an event that has constant probability of occurrence on each independent trial.

FIGURE 19.11 Summary of common probability distributions. (*Quality Planning and Analysis, Copyright 2007. Used by permission.*)

3.37	3.34	3.38	3.32	3.33	3.28	3.34	3.31	3.33	3.34
3.29	3.36	3.30	3.31	3.33	3.34	3.34	3.36	3.39	3.38
3.35	3.36	3.30	3.32	3.33	3.35	3.35	3.34	3.32	3.38
3.32	3.37	3.34	3.38	3.36	3.37	3.36	3.31	3.33	3.30
3.35	3.33	3.38	3.37	3.44	3.32	3.36	3.32	3.29	3.35
3.38	3.39	3.34	3.32	3.30	3.39	3.36	3.40	3.32	3.33
3.29	3.41	3.27	3.36	3.41	3.37	3.36	3.37	3.33	3.66
3.31	3.33	3.35	3.34	3.35	3.34	3.31	3.36	3.37	3.35
3.40	3.35	3.37	3.35	3.32	3.36	3.38	3.35	3.31	3.34
3.35	3.36	3.39	3.31	3.31	3.30	3.35	3.33	3.35	3.31

(*Source: Quality Planning and Analysis,* Copyright 2007. Used by permission.)

TABLE 19.2 Resistance of 100 Coils, Ω

Statistical Inference

Statistical inference is the process of estimating, through sampling and application of statistical methods, certain characteristics of a population. In the world of quality, these estimates and statistical conclusions are used to draw practical conclusions, typically providing the practitioner confidence in taking subsequent action (or inaction) to improve a process.

Sampling Variation and Sampling Distributions

Suppose that a battery is to be evaluated to ensure that life requirements are met. A mean life of 30 hours is desired. Preliminary data indicate that the life follows a normal distribution and that the standard deviation is equal to 10 hours. A sample of four batteries is selected at random from the population and tested. If the mean of the four is close to 30 hours, it is concluded that the population of batteries meets the specification. Figure 19.12 plots the distribution of individual batteries from the population, assuming that the true mean of the population is exactly 30 hours.

If a sample of four is life-tested, the following lifetimes might result: 34, 28, 38, and 24, giving a mean of 31.0 hours. However, this random sample is selected from the many batteries made by the same process. Suppose that another sample of four is taken. The second sample of four is likely to be different from the first sample. Perhaps the results would be 40, 32, 18, and 29, giving a mean of 29.8 hours. If the process of drawing many samples (with four in each sample) is repeated over and over, different results would be obtained in most samples. The fact that samples drawn from the same process can yield different sample results illustrates the concept of sampling variation.

Returning to the problem of evaluating the battery, a dilemma exists. In the actual evaluation, let's assume only one sample of four can be drawn (e.g., because of time and cost limitations). Yet the experiment of drawing many samples indicates that samples vary. The question is, How reliable is the single sample of four that will be the basis of the decision? The final decision can be influenced by the "luck" of which sample is chosen. The key point is that the existence of sampling variation means that any one sample cannot always be relied upon to give an adequate decision. The statistical approach analyzes the results of the sample, taking into account the possible sampling variation that could occur.

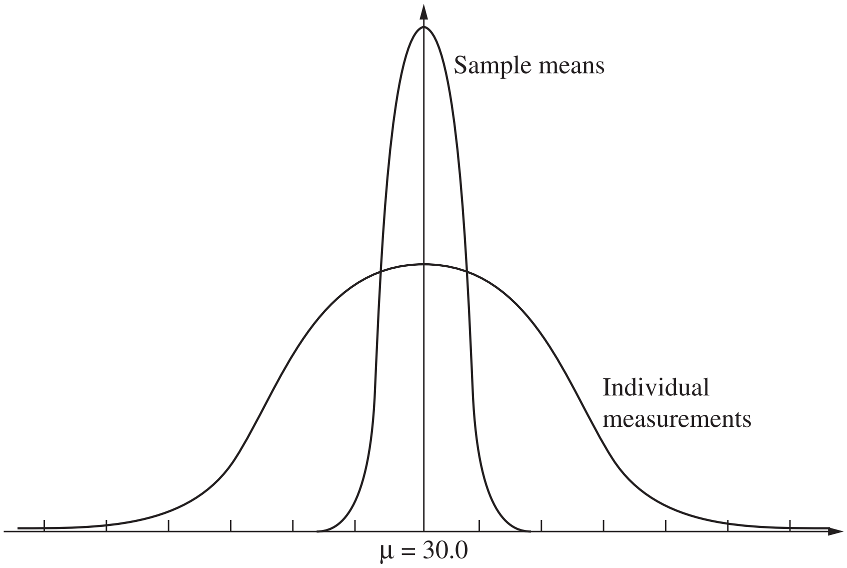


Figure 19.12 Distributions of individual measurements and sample means. (*Juran Institute, Inc., 1994.*)

Formulas have been developed to define the expected amount of sampling variation. In particular, the central limit theorem states that if $x_1, x_2, \ldots x_n$ are outcomes of a sample of n independent observations of a random variable x, then the mean of the samples of n will approximately follow a normal distribution, with mean μ and standard deviation $\sigma \bar{X} = \sigma\sqrt{n}$. When n is large ($n > 30$), the normal approximation is very close. For smaller samples, a modified Student-T distribution applies. The central limit theorem is very helpful to much practical statistical work. First, the variation of means is smaller than the variation of the underlying population, which makes conclusions easier. Second, because means are approximately normally distributed, we can apply the wide variety of techniques that rely on the assumption of normality.

Statistical Tools for Improvement

This concept of a sampling distribution is fundamental to the two major areas of statistical inference, estimation and tests of hypotheses, which are discussed next.

Statistical Estimation: Point Estimation and Confidence Intervals

Estimation is the process of analyzing a sample result to predict the corresponding value of the population parameter. In other words, the process is to estimate a desired population parameter by an appropriate measure calculated from the sample values. For example, the sample of four batteries previously mentioned had a mean life of 31.0 hours. If this is a representative sample from the process, what estimate can be made of the true average life of the entire population of batteries? The estimation statement has two parts:

1. The point estimate is a single value used to estimate the population parameter. For example, 31.0 hours is the point estimate of the average life of the population.
2. The confidence interval is a range of values that include (with a preassigned probability called a confidence level*) the true value of a population parameter. Confidence limits are the upper and lower boundaries of the confidence interval. Confidence limits should not be confused with other limits (e.g., control limits, statistical tolerance limits).

Table 19.3 summarizes confidence limit formulas for common parameters. The following example illustrates one of these formulas.

Problem Twenty-five specimens of brass have a mean hardness of 54.62 and an estimated standard deviation of 5.34. Determine the 95 percent confidence limits on the mean. The standard deviation of the population is unknown.

Solution Note that when the standard deviation is unknown and is estimated from the sample, the *t* distribution in Table 19.4 must be used. The *t* value for 95 percent confidence is found by entering the table at 0.975 and 25 – 1, or 24, degrees of freedom† and reading a *t* value of 2.064.

*A confidence level is the probability that an assertion about the value of a population parameter is correct. Confidence levels of 90, 95, or 99 percent are usually used in practice.

†A mathematical derivation of degrees of freedom is beyond the scope of this book, but the underlying concept can be stated. Degrees of freedom (DF) is the parameter involved when, for example, a sample standard deviation is used to estimate the true standard deviation of a universe. DF equals the number of measurements in the sample minus some number of constraints estimated from the data to compute the standard deviation. In this example, it was necessary to estimate only one constant (the population mean) to compute the standard deviation. Therefore, DF = 25 – 1 = 24.

Mean of a normal population (standard deviation known)	$\bar{X} \pm Z_{\alpha/2} \frac{\sigma}{\sqrt{n}}$ where $\bar{X}$ = sample average Z = normal distribution coefficient σ = standard deviation of population n = sample size
Mean of a normal population (standard deviation unknown)	$\bar{X} \pm t_{\alpha/2} \frac{s}{\sqrt{n}}$ where t = distribution coefficient (with $n - 1$ degrees of freedom) s = estimated σ (s is the sample standard deviation)
Standard deviation of a normal population	Upper confidence limit $= s\sqrt{\frac{n-1}{x^2_{\alpha/2}}}$ Lower confidence limit $= s\sqrt{\frac{n-1}{x^2_{1-\alpha/2}}}$ where x^2 = chi-square distribution coefficient with $n - 1$ degrees of freedom $1 - \alpha$ = confidence level
Population fraction defective	See charts: *Ninety-five percent confidence belts for population proportion* and *Binomial Distribution* at the end of this chapter, pages 670-672.
Difference between the means of two normal populations (standard deviations σ_1 and σ_2 known)	$(\bar{X}_1 - \bar{X}_2) \pm Z_{\alpha/2}\sqrt{\frac{\sigma_1^2}{n_1} + \frac{\sigma_2^2}{n_2}}$
Difference between the means of two normal populations ($\sigma_1 = \sigma_2$ but unknown)	$(\bar{X}_1 - \bar{X}_2) \pm t_{\alpha/2}\sqrt{\frac{1}{n_1} + \frac{1}{n_2}}$ $\times\sqrt{\frac{\Sigma(X - \bar{X}_1)^2 + \Sigma(X - \bar{X}_2)^2}{n_1 + n_2 - 2}}$
Mean time between failures based on an exponential population of time between failures	Upper confidence limit $= \frac{2rm}{x^2_{\alpha/2}}$ Lower confidence limit $= \frac{2rm}{x^2_{1-\alpha/2}}$ where r = number of occurrences in the sample (i.e., number of failures) m = sample mean time between failures DF = $2r$

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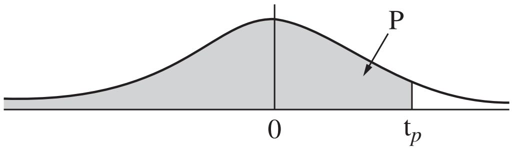
Table 19.3 Summary of Confidence Limit Formulas ($1 - \alpha$) (Confidence Level

Distribution of *t*

Value of *t* corresponding to certain selected probabilities (i.e., tail areas under the curve). To illustrate: the probability is .975 that a sample with 20 degrees of freedom would have *t* = +2.086 or smaller.



DF	$t_{.60}$	$t_{.70}$	$t_{.80}$	$t_{.90}$	$t_{.95}$	$t_{.975}$	$t_{.99}$	$t_{.995}$
1	0.325	0.727	1.376	3.078	6.314	12.706	31.821	63.657
2	0.289	0.617	1.061	1.886	2.920	4.303	6.965	9.925
3	0.277	0.584	0.978	1.638	2.353	3.182	4.541	5.841
4	0.271	0.569	0.941	1.533	2.132	2.776	3.747	4.604
5	0.267	0.559	0.920	1.476	2.015	2.571	3.365	4.032
6	0.265	0.553	0.906	1.440	1.943	2.447	3.143	3.707
7	0.263	0.549	0.896	1.415	1.895	2.365	2.998	3.499
8	0.262	0.546	0.889	1.397	1.860	2.306	2.896	3.355
9	0.261	0.543	0.883	1.383	1.833	2.262	2.821	3.250
10	0.260	0.542	0.879	1.372	1.812	2.228	2.764	3.169
11	0.260	0.540	0.876	1.363	1.796	2.201	2.718	3.106
12	0.259	0.539	0.873	1.356	1.782	2.179	2.681	3.055
13	0.259	0.538	0.870	1.350	1.771	2.160	2.650	3.012
14	0.258	0.537	0.868	1.345	1.761	2.145	2.624	2.977
15	0.258	0.536	0.866	1.341	1.753	2.131	2.602	2.947
16	0.258	0.535	0.865	1.337	1.746	2.120	2.583	2.921
17	0.257	0.534	0.863	1.333	1.740	2.110	2.567	2.898
18	0.257	0.534	0.862	1.330	1.734	2.101	2.552	2.878
19	0.257	0.533	0.861	1.328	1.729	2.093	2.539	2.861
20	0.257	0.533	0.860	1.325	1.725	2.086	2.528	2.845
21	0.257	0.532	0.859	1.323	1.721	2.080	2.518	2.831
22	0.256	0.532	0.858	1.321	1.717	2.074	2.508	2.819

TABLE 19.4 Distribution of *t*

23	0.256	0.532	0.858	1.319	1.714	2.069	2.500	2.807
24	0.256	0.531	0.857	1.318	1.711	2.064	2.492	2.797
25	0.256	0.531	0.856	1.316	1.708	2.060	2.485	2.787
26	0.256	0.531	0.856	1.315	1.706	2.056	2.479	2.779
27	0.256	0.531	0.855	1.314	1.703	2.052	2.473	2.771
28	0.256	0.530	0.855	1.313	1.701	2.048	2.467	2.763
29	0.256	0.530	0.854	1.311	1.699	2.045	2.462	2.756
30	0.256	0.530	0.854	1.310	1.697	2.042	2.457	2.750
40	0.255	0.529	0.851	1.303	1.684	2.021	2.423	2.704
60	0.254	0.527	0.848	1.296	1.671	2.000	2.390	2.660
120	0.254	0.526	0.845	1.289	1.658	1.980	2.358	2.617
∞	0.253	0.524	0.842	1.282	1.645	1.960	2.326	2.576

(*Source: Introduction to Statistical Analysis*, Copyright 1969, Used by permission.)

Table 19.4 (*Continued*)

$$\text{Confidence limits} = \bar{X} = \pm t\frac{s}{\sqrt{n}}$$

$$= 54.62 \pm (2.064)\frac{5.34}{\sqrt{25}}$$

$$= 52.42 \text{ and } 56.82$$

There is 95 percent confidence that the true mean hardness of the brass is between 52.42 and 56.82.

Determination of Sample Size

The only way to obtain the true value of a population parameter such as the mean is to measure (with a perfect measurement system) each and every individual within the population. This is not realistic (and is unnecessary when statistics are properly applied), so samples are taken instead. But how large a sample should be taken? The answer depends on (1) the sampling risks desired (alpha and beta risk, discussed further below and defined in Table 19.5), (2) the size of the smallest true difference that is desired to be detected, and (3) the variation in the characteristic being measured.

For example, suppose it was important to detect that the mean life of the battery cited previously was 35.0 hours (recall that the intended value is 30.0 hours). Specifically, we want to be 80 percent certain of detecting this difference (this is the "power" of the test, and has a corresponding risk of $\beta = 0.2$; this means we are willing to take a 20 percent chance of failing to detect the five-hour difference when, in fact, it exists). Further, if the true mean was

Null hypothesis (H_0): Statement of no change or no difference. This statement is assumed true until sufficient evidence is presented to reject it.

Alternative hypothesis (H_a): Statement of change or difference. This statement is considered true if H_0 is rejected.

Type I error: The error in rejecting H_0 when it is true or in saying there is a difference when there is no difference.

Alpha risk: The maximum risk or maximum probability of making a type I error. This probability is preset, based on how much risk the researcher is willing to take in committing a type I error (rejecting H_0 wrongly), and it is usually established at 5% (or .05). If the *p*-value is less than alpha, reject H_0.

Significance level: The risk of committing a type I error.

Type II error: The error in failing to reject H_0 when it is false or in saying there is no difference when there really is a difference.

Beta risk: The risk or probability of making a type II error or overlooking an effective treatment or solution to the problem.

Significant difference: The term used to describe the results of a statistical hypothesis test where a difference is too large to be reasonably attributed to chance.

p-value: The probability of obtaining different samples when there is really no difference in the population(s)—that is, the actual probability of committing a type I error. The *p*-value is the actual probability of incorrectly rejecting the null hypothesis (H_0) (i.e., the chance of rejecting the null when it is true). When the *p*-value is less than alpha, reject H_0. If the *p*-value is greater than alpha, fail to reject H_0.

Power: The ability of a statistical test to detect a real difference when there really is one, or the probability of being correct in rejecting H_0. Commonly used to determine if sample sizes are sufficient to detect a difference in treatments if one exists. Power = $(1 - \beta)$, or 1 minus the probability of making a type II error.

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Table 19.5 Hypothesis Testing Definitions

30.0 hours, we want to have only a 5 percent risk of wrongly concluding it is not 30.0 hours (a risk of $\alpha = 0.05$). Then, using the following formula:

$$n = \left[\frac{(Z_{\alpha/2} + Z_{\beta})_{\sigma}}{\mu - \mu_{o}} \right]^2$$

we plug in our values to obtain

$$n = \left[\frac{(1.96 + 0.84)10}{35 - 30} \right]^2 = 31.4$$

The required sample size is 32 (Gryna et al., 2007, p. 605).

Note that sample size sometimes is constrained by cost or time limitations; in addition, rules of thumb exist to estimate sample size. However, these potentially lead to gross under- or oversampling, with wasted time and effort. The recommended approach is to use power and sample size calculators (available online and in statistical software; these readily apply formulas appropriate for different sampling situations) in order to enter data collection and hypothesis testing with full knowledge of the statistically appropriate sample size.

Hypothesis Testing

A hypothesis, as used here, is an assertion about a population. Typically, the hypothesis is stated as a pair of hypotheses as follows: the null hypothesis (H_0) and an alternative hypothesis, H_a. The null hypothesis, H_0, is a statement of no change or no difference—hence, the term "null." The alternative hypothesis is the statement of change or difference—that is, if we reject the null hypothesis, the alternative is true by default.

For example, to test the hypothesis that the mean life of a population of batteries equals 30 hours, we state:

$$H_0: \mu = 30.0 \text{ hours}$$

$$H_a: \mu \neq 30.0 \text{ hours}$$

A hypothesis test is a test of the validity of the assertion, and is carried out by analyzing a sample of data. Sample results must be carefully evaluated for two reasons. First, there are many other samples that, by chance alone, could be drawn from the population. Second, the numerical results in the sample actually selected can easily be compatible with several different hypotheses. These points are handled by recognizing the two types of sampling errors, already alluded to above.

The Two Types of Sampling Errors. In evaluating a hypothesis, two errors can be made

- Reject the null hypothesis when it is true. This is called a type I error, or the level of significance. The maximum probability of a type I error is denoted by α.
- Fail to reject the null hypothesis when it is false. This is called type II error, and the probability is denoted by β.

These errors are defined in terms of probability numbers and can be controlled to desired values. The results possible in testing a hypothesis are summarized in Table 19.6. Definitions are found in Table 19.5. For additional detail on sampling errors in the context of quality, see Gryna at al (2007).

	Suppose the H_0 Is	
Suppose Decision of Analysis Is	**True**	**False**
Fail to reject H_0	Correct decision $p = 1 - \alpha$	Wrong decision $p = \beta$
Reject H_0	Wrong decision $p = \alpha$	Correct decision $p = 1 - \beta$

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Table 19.6 Type I (α) Error and Type II (β) Error

Steps to Hypothesis Testing. As emphasized earlier, it is important to plan for data collection and analysis; an investigator ideally should arrive at the point of actual hypothesis testing with elements such as sample size already defined. Hypothesis testing often is an iterative process, however, and as mentioned above in the opening discussion of data collection, further data may be needed after initial collection, for example, to bolster sample sizes to obtain the desired power so that both type I and type II errors are defined in advance.

Generally, then, the steps to test a hypothesis are as follows:

1. State the practical problem.
2. State the null hypothesis and alternative hypothesis.
3. Choose a value for α (alpha). Common values are 0.01, 0.05, and 0.10.
4. Choose the test statistic for testing the hypothesis.
5. Determine the rejection region for the test (i.e., the range of values of the test statistic that results in a decision to reject the null hypothesis).
6. Obtain a sample of observations, compute the test statistic, and compare the value to the rejection region to decide whether to reject or fail to reject the hypothesis.
7. Draw the practical conclusion.

Common Tests of Hypotheses. No single means of organizing hypothesis tests can convey all the information that may be of interest to an investigator. Table 19.7 summarizes some common tests of hypotheses in terms of the formulas. Table 19.8 categorizes tests according to the question being asked and type of data. Figure 19.13 provides similar information but in the form of a roadmap to assist in deciding what hypothesis test(s) are appropriate. Readers may find that the combination of these presentations will provide the best understanding of what is a multifaceted topic.

The hypothesis testing procedure is illustrated through the following example.

1. State the practical problem. To investigate a problem with warping wood panels, it was proposed that warping was caused by differing moisture content in the layers of the laminated product before drying. The sample data shown in Table 19.9 were taken between layers 1-2 and 2-3. Is there a significant difference in the moisture content?
2. State the null hypothesis and alternative hypothesis:

$$H_o: \mu 1\text{-}2 = \mu 2\text{-}3$$

$$H_a: \mu 1\text{-}2 \neq \mu 2\text{-}3$$

3. Choose a value for α. In this example, a type I error (α) of 0.05 will be assumed.
4. Choose the test statistic for testing the hypothesis.

Because we have two samples and desire to test for a difference in the means, a two-sample t-test is appropriate. (Note: A probability plot or test for normality will confirm the assumption of normality in the data. Also, an equal variance test concludes variances are approximately equal.)

1. Determine the rejection region for the test.

Hypothesis	Test Statistic and Distribution
H_o: $\mu = \mu_0$ (the mean of a normal population is equal to a specified value μ_0; σ is known)	$Z = \dfrac{\bar{X} - \mu_0}{\sigma / \sqrt{n}}$ Standard normal distribution
H_o: $\mu = \mu_0$ (the mean of a normal population is equal to a specified value μ_0; σ is estimated by s)	$t = \dfrac{\bar{X} - \mu_0}{s / \sqrt{n}}$ t distribution with $n - 1$ degrees of freedom (DF)
H_o: $\mu_1 = \mu_2$ (the mean of population 1 is equal to the mean of population 2; assume that $\sigma_1 = \sigma_2$ and that both populations are normal)	$t = \dfrac{\bar{X}_1 - \bar{X}_2}{\sqrt{1/n_1 + 1/n_2}\sqrt{\left[(n_1 - 1)s_1^2(n_2 - 1)s_2^2\right]} / (n_1 + n_2 - 2)}$ t distribution with DF = $n_1 + n_2 - 2$
H_o: $\sigma = \sigma_0$ (the standard deviation of a normal population is equal to a specified value σ_0)	$X^2 = \dfrac{(n-1)s^2}{\sigma_0^2}$ Chi-square distribution with DF = $n - 1$
H_o: $\sigma_1 = \sigma_2$ (the standard deviation of population 1 is equal to the standard deviation of population 2; assume that both populations are normal)	$F = \dfrac{s_1^2}{s_2^2}$ F distribution with $DF_1 = n_1 - 1$ and $DF_2 = n_2 - 1$
H_o: $\hat{p} = p_0$ (the fraction defective in a population is equal to a specified value p_0; assume that $np_0 \geq 5)\hat{p}$ = sample proportion	$Z = \dfrac{\hat{p} - p_0}{\sqrt{p_0(1 - p_0)/n}}$ Standard normal distribution
H_o: $p_1 = p_2$ (the fraction defective in population 1 is equal to the fraction defective in population 2; assume that n_1p_1 and n_2p_2 are each ≥ 5)	$Z = \dfrac{X_1/n_1 - X_2/n_2}{\sqrt{\hat{p}(1 - \hat{p})(1/n_1 + 1/n_2)}}$ $\quad \hat{p} = \dfrac{X_1 + X_2}{n_1 + n_2}$ Standard normal distribution
To test for independence in a J × K contingency table that cross-classifies the variable A and B H_o: A is independent of B H_a: A is dependent on B	$X^2 = \sum_{j=1}^{J}\sum_{k=1}^{K}\dfrac{(f_{jk} - e_{jk})^2}{e_{jk}}$ Chi-square distribution with DF = (J – 1) (K – 1) where f_{jk} = the observed frequency of data for category j of variable A and to category k of variable B e_{jk} = the expected frequency = $f_{j0}f_{0k}/f_{00}$ f_{j0} = frequency total for category j for variable A f_{0k} = frequency total for category k of variable B f_{00} = frequency total for J × K table

(*Source: Quality Planning and Analysis*, Copyright 2007. Used by permission.)

Table 19.7 Summary of Formulas on Tests of Hypotheses

Tests of hypotheses organized by the question being asked. All tests assume a categorical X in the Y= *f* (X) format. For example, X might be manufacturing plant, and there could be 1, 2 or more than two plants of interest in terms of output, Y. A continuous Y might be mean or standard deviation of daily units produced, a categorical Y might be proportion defective units produced in a single day.

Question: Is There a Difference in the Parameter	**Number of Sample Groups**	**Continuous Y (Normal)**		**Categorical Y**	
		Parameter of Interest	**Test**	**Parameter of Interest**	**Test**
Compared to a target?	1	μ σ	1-sample *t* Chi- square	Proportion	1-proportion test
between two groups?	2	μ σ	2-sample *t* F-test	Proportion	2-proportion test
among all groups?	≥2	μ σ	ANOVA* Bartlett's	Proportion	Chi-square test of Independence

*ANOVA assumes both equal variances and normality.
(*Source:* Juran Institute, Inc., Used by permission.)

Table 19.8 Hypothesis Testing Table

The critical value defining the rejection region is approximately 2.0 (see Table 19.4); if the absolute value of the calculated *t* is larger than the critical value, then we reject the null hypothesis.

1. Obtain a sample of observations, compute the test statistic, and compare the value to the rejection region to decide whether to reject or fail to reject the hypothesis.

A box plot (remember to plot the data!) suggests that the moisture content in Layer 1-2 tends to be higher than in Layer 2-3. Minitab output (see Figure 19.14) shows that the calculated *t* is 4.18, which is in the rejection region.

Because the calculated *t* is larger than the critical value, the associated *p*-value is $< \alpha$, and we reject the null hypothesis, H_0.

N	**Mean**	**StDev**	**SE Mean**	
Layer 1-2	25	5.350	0.613	0.12
Layer 2-3	25	4.689	0.499	0.10

Difference = μ (Layer 1-2) – μ (Layer 2-3)

Estimate for difference: 0.660901

95 percent CI for difference: (0.343158, 0.978644)

T-test of difference = 0 (vs. not =): *t*-value = 4.18 *p*-value = 0.000 DF = 48

Both use pooled StDev = 0.5587

1. Draw the practical conclusion. We conclude that the moisture content in Layer 1-2 is higher than the moisture content of Layer 2-3.

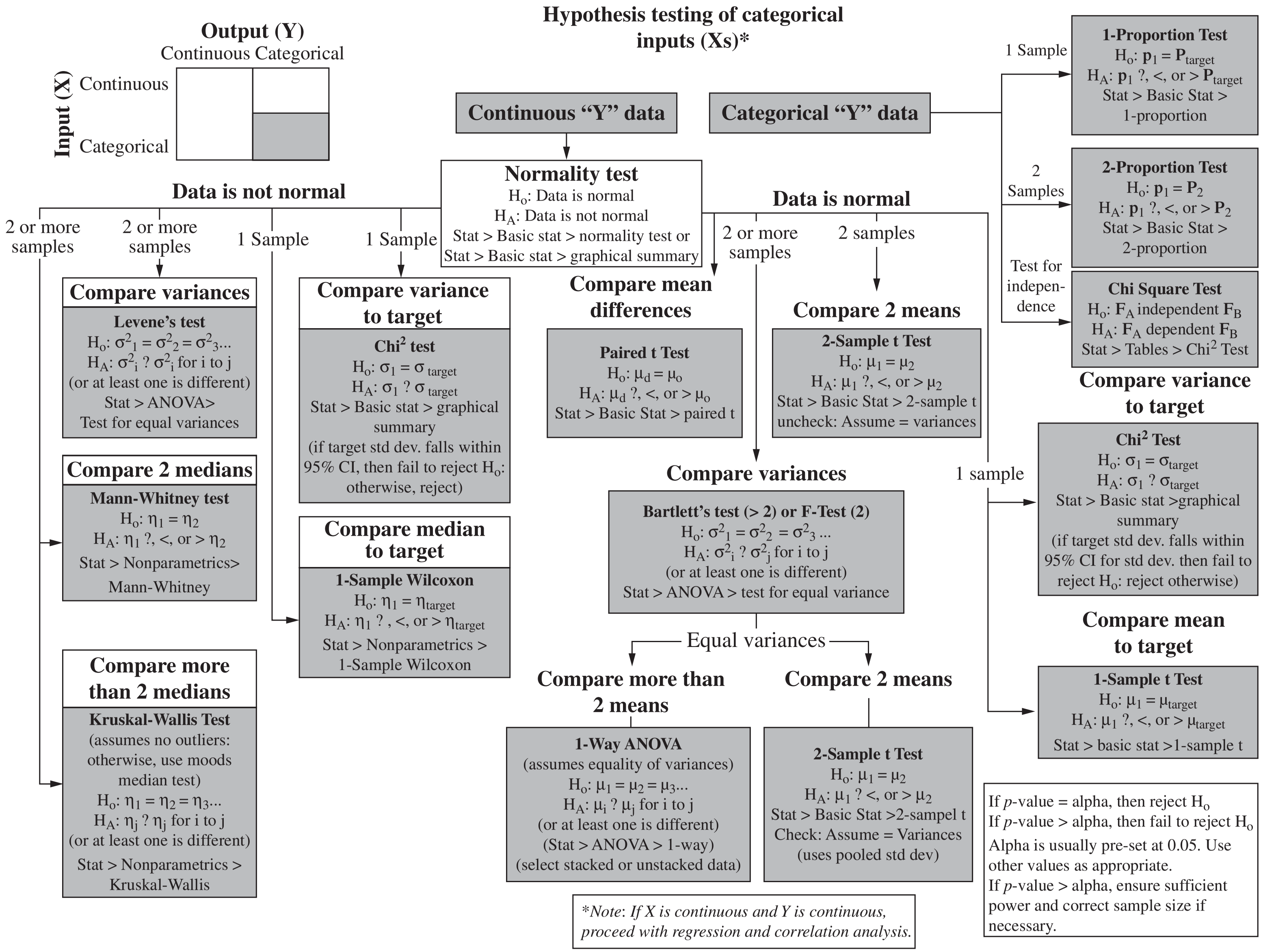
Output (Y)
Continuous Categorical
Input (X)
Continuous
Categorical
Hypothesis testing of categorical inputs (Xs)*
Continuous "Y" data
Categorical "Y" data
Normality test
H_o: Data is normal
H_A: Data is not normal
Stat > Basic stat > normality test or
Stat > Basic stat > graphical summary
Data is not normal
2 or more samples
2 or more samples
1 Sample
1 Sample
Compare variances
Levene's test
H_o: $\sigma^2_1 = \sigma^2_2 = \sigma^2_3$...
H_A: σ^2_i ? σ^2_i for i to j
(or at least one is different)
Stat > ANOVA>
Test for equal variances
Compare 2 medians
Mann-Whitney test
H_o: $\eta_1 = \eta_2$
H_A: η_1 ?, <, or > η_2
Stat > Nonparametrics>
Mann-Whitney
Compare more than 2 medians
Kruskal-Wallis Test
(assumes no outliers: otherwise, use moods median test)
H_o: $\eta_1 = \eta_2 = \eta_3$...
H_A: η_j ? η_j for i to j
(or at least one is different)
Stat > Nonparametrics >
Kruskal-Wallis
Compare variance to target
Chi^2 test
H_o: $\sigma_1 = \sigma_{target}$
H_A: σ_1 ? σ_{target}
Stat > Basic stat > graphical summary
(if target std dev. falls within 95% CI, then fail to reject H_o: otherwise, reject)
Compare median to target
1-Sample Wilcoxon
H_o: $\eta_1 = \eta_{target}$
H_A: η_1 ? , <, or > η_{target}
Stat > Nonparametrics >
1-Sample Wilcoxon
Data is normal
2 or more samples
2 samples
Compare mean differences
Paired t Test
H_o: $\mu_d = \mu_o$
H_A: μ_d ?, <, or > μ_o
Stat > Basic Stat > paired t
Compare 2 means
2-Sample t Test
H_o: $\mu_1 = \mu_2$
H_A: μ_1 ?, <, or > μ_2
Stat > Basic Stat > 2-sample t
uncheck: Assume = variances
Compare variances
Bartlett's test (> 2) or F-Test (2)
H_o: $\sigma^2_1 = \sigma^2_2 = \sigma^2_3$ ...
H_A: σ^2_i ? σ^2_j for i to j
(or at least one is different)
Stat > ANOVA > test for equal variance
Equal variances
Compare more than 2 means
1-Way ANOVA
(assumes equality of variances)
H_o: $\mu_1 = \mu_2 = \mu_3$...
H_A: μ_i ? μ_j for i to j
(or at least one is different)
(Stat > ANOVA > 1-way)
(select stacked or unstacked data)
Compare 2 means
2-Sample t Test
H_o: $\mu_1 = \mu_2$
H_A: μ_1 ? <, or > μ_2
Stat > Basic Stat >2-sampel t
Check: Assume = Variances
(uses pooled std dev)
1 sample
1 Sample
1-Proportion Test
H_o: $p_1 = P_{target}$
H_A: p_1 ?, <, or > P_{target}
Stat > Basic Stat >
1-proportion
2 Samples
2-Proportion Test
H_o: $p_1 = P_2$
H_A: p_1 ?, <, or > P_2
Stat > Basic Stat >
2-proportion
Test for indepen-dence
Chi Square Test
H_o: F_A independent F_B
H_A: F_A dependent F_B
Stat > Tables > Chi^2 Test
Compare variance to target
Chi^2 Test
H_o: $\sigma_1 = \sigma_{target}$
H_A: σ_1 ? σ_{target}
Stat > Basic stat >graphical summary
(if target std dev. falls within 95% CI for std dev. then fail to reject H_o: reject otherwise)
Compare mean to target
1-Sample t Test
H_o: $\mu_1 = \mu_{target}$
H_A: μ_1 ?, <, or > μ_{target}
Stat > basic stat >1-sample t
If p-value = alpha, then reject H_o
If p-value > alpha, then fail to reject H_o
Alpha is usually pre-set at 0.05. Use other values as appropriate.
If p-value > alpha, ensure sufficient power and correct sample size if necessary.
*Note: If X is continuous and Y is continuous, proceed with regression and correlation analysis.

Figure 19.13 Hypothesis testing.

Layer 1-2		Layer 2-3	
4.43	4.40	3.74	5.14
6.01	5.99	4.30	5.19
5.87	5.72	5.27	4.16
4.64	5.25	4.94	5.18
3.50	5.83	4.89	4.78
5.24	5.44	4.34	5.42
5.34	6.15	5.30	4.05
5.99	5.14	4.55	3.92
5.75	5.72	5.17	4.07
5.48	5.00	5.09	4.54
5.64	5.01	4.74	4.23
5.15	5.42	4.96	5.07
5.64		4.21	

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TABLE 19.9 Moisture Content

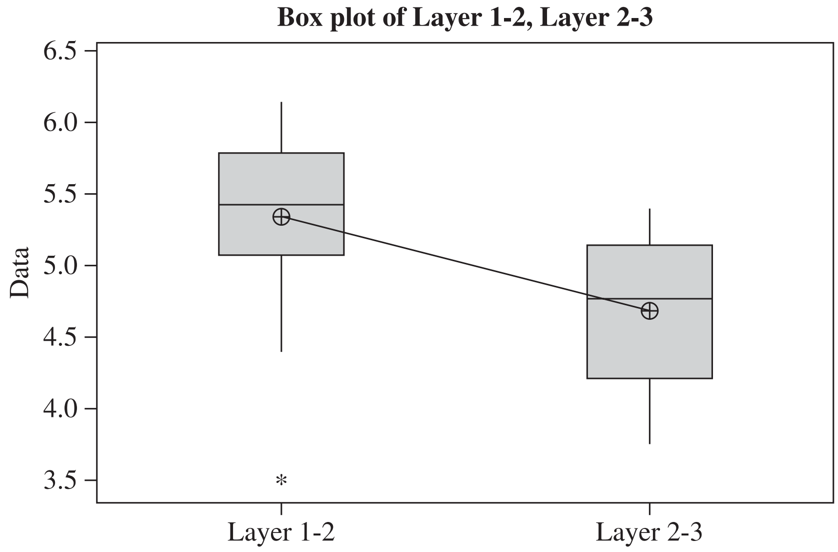


FIGURE 19.14 Box plot of Layer 1-2, Layer 2-3. (*Quality Planning and Analysis, Copyright 2007. Used by permission.*)

Nonparametric Hypothesis Tests, Data Transformation, and Bootstrapping

The preceding discussion has focused on "parametric" hypothesis tests (so-called because they rely on parameter estimation). Often, it is the case that one or more of the assumptions underlying the parametric tests are violated. In particular, practitioners frequently face skewed or otherwise nonnormal data, and application of parametric tests that assume bell-shaped data distribution may lead to erroneous conclusions and inappropriate action. Fortunately, options are available; these include nonparametric tests, data transformation, and bootstrapping.

Nonparametric hypothesis tests avoid violating key assumptions by virtue of being "distribution-free"; that is, they are not strictly dependent on particular distributions (such as a normal distribution); however, nonparametric tests have their own set of assumptions of which investigators should be aware). In effect, these methods typically transform the original data into ranks, and hypothesis tests then are carried out on the ranked data. Although nonparametric methods are not nearly as well developed and frequently are statistically less powerful compared to parametric tests, they are available for basic one-, two-, and two or more sample tests (see the bottom of Table 19.7 and the left side of the roadmap in Figure 19.13). See Sprent and Smeeton (2001) for more on traditional nonparametric methods. New methods continue to emerge, for example, wavelets and nonparametric Bayesian techniques; see Kvam and Vidakovic (2007).

Data transformation allows one to take data that violate some assumption of a parametric test and change them so that the assumption no longer is violated. For example, nonnormal data, or sample data with unequal variances can be changed to new numbers that are normal or have equal variances. Three common methods are

Power Functions. Traditionally, standard functions such as taking the square (x^2), square root ($x^{1/2}$), log (log10(x)), natural log (ln(x)), or inverse (x^{-1}) were used because they could easily be done with a calculator. Trial and error often is needed to find a function that appropriately transforms the data to meet the test assumptions.

Box-Cox Transformation. This method provides simultaneous testing of power functions to find an optimum value λ that minimizes the variance. Typically, one selects a power (value of λ) that is understandable and within a 95 percent confidence interval of the estimated λ (e.g., square: $\lambda = 2$; square root: $\lambda = 0.5$; natural log: $\lambda = 0$; inverse: $\lambda = -1$). The Box-Cox transformation does not work with negative numbers.

Johnson Transformation. This method selects an optimal function among three families of distributions (bounded, unbounded, lognormal). While effective in situations where Box-Cox does not work, the resulting transformation is not intuitive.

These methods are easy to apply (with software), and allow use of the more powerful parametric tests. However, the transformed data do not necessarily have intuitive meaning.

Bootstrapping is one of a broader class of computation-intensive resampling methods. Rather than assuming any particular distribution of a test statistic (such as normal), the distribution is determined empirically. More specifically, a statistic of interest (such as the mean) is repeatedly calculated from different samples drawn themselves, with replacements, from a sample. The distribution of these calculated statistics then is used as the basis for determining the probability of obtaining any particular value by chance. Itself a nonparametric approach, bootstrapping is a flexible method that gradually is gaining acceptance. For more information on the method and applications, see Davison and Hinkley (2006).

Correlation and Regression Analysis

Correlation and regression analysis help us understand relationships. More specifically, regression analysis is the modeling of the relationships between independent and dependent variables, while correlation analysis is a study of the strength of the linear relationships among variables. From a practical perspective, simple linear regression examines the distribution of one variable (the response, or dependent variable) as a function of one or more independent variables (the predictor, or independent variable) held at each of several levels.

X	Y	X	Y	X	Y	X	Y
90	41	100	22	105	21	110	15
90	43	100	35	105	13	110	11
90	35	100	29	105	18	110	6
90	32	100	18	105	20	110	10

(X, in feet per minute versus tool life; Y, in minutes)
(*Source: Quality Planning and Analysis*, Copyright 2007. Used by permission.)

Table 19.10 Cutting Speed

Note that the cause-and-effect relationship is stated explicitly, and it is this relationship that is tested to determine its statistical significance. In addition, regression analysis is used in forecasting and prediction based on the important independent variables, and in locating optimum operating conditions. In contrast, correlation typically looks at the joint variation of two variables that have not been manipulated by the experimenter, and there is no explicit cause-and-effect hypothesis.

For example, suppose that the life of a tool varies with the cutting speed of the tool and we want to predict life based on cutting speed. Thus, life is the dependent variable (Y) and cutting speed is the independent variable (X). Data are collected at four cutting speeds (Table 19.10).

Remembering to always plot the data, we note that a scatter plot (Figure 19.15) suggests that life varies with cutting speed (specifically, life decreases with an increase in speed) and also varies in a linear manner (i.e., increases in speed result in a certain decrease in life that is the same over the range of the data). Note that the relationship is not perfect—the points scatter about the line.

Often, it is valuable to obtain a regression equation. In this case, we have a linear relationship in the general form provided by

$$Y = \beta_0 + \beta_1 X + \varepsilon$$

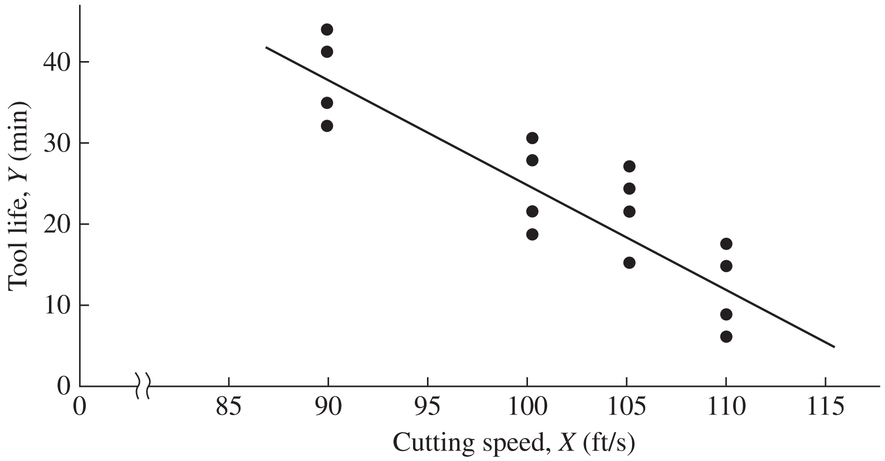


Figure 19.15 Tool life (Y) versus cutting speed (X). (*Quality Planning and Analysis, Copyright 2007. Used by permission.*)

where β_0 and β_1 are the unknown population intercept and slope, and ε is a random-error term that may be due to measurement errors and/or the effects of other independent variables. This model is estimated from sample data by the form

$$\hat{Y} = b_0 + b_1X$$

where $\hat{Y}$ is the predicted value of Y for a given value of X and b0 and b1 are the sample estimates of β_0 and β_1. Estimates usually are found by least-squares methods; formulas can be found in statistics books such as Kutner et al. (2004).

For this example, the resulting prediction equation is

$$\text{Tool life} = 106.90 - 1.3614\ (\text{cutting speed})$$

This equation can be used to predict tool life by plugging in values of cutting speed. Extreme caution should be used in making predictions outside the actual sample space (e.g., for cutting speeds above or below the tested maximum or minimum), however, as these are tenuous without confirmation by observation.

Although a prediction equation can be found mathematically, it should not be used without knowing how "good" it is. A number of criteria exist for judging the adequacy of the prediction equation. One common measure is R_2, the proportion of variation explained by the prediction equation. R_2, or the coefficient of determination, is the ratio of the variation due to the regression to the total variation. The higher R_2, the greater the probable utility of the prediction equation in estimating Y based on X.

Another measure of the degree of association between two variables is the simple linear correlation coefficient, *r*. This is the square root of the coefficient of determination, so that the values of *r* range from –1 to +1. A positive *r* is consistent with a positive relationship (an increase in one variable is associated with an increase in the other), whereas the opposite is true of a negative *r* (an increase in one variable is associated with a decrease in the other). Scatter plots are strongly recommended when interpreting correlations, especially as very different patterns can result in identical values of *r*. The significance level of *r* varies with sample size; statistical software is recommended to obtain exact significance levels.

The above discussion introduces simple linear correlation and regression—the direction and strength of a relationship between two variables, or prediction of a dependent variable, Y, from a single predictor variable, X. A natural extension of this is multiple regression that allows for two or more independent variables. For a discussion of how to estimate and examine a multiple regression prediction equation, see Kutner et al. (2004).

Analysis of Variance

Analysis of Variance (ANOVA) is an approach related to linear regression, falling into the class of what are called general linear models. However, unlike regression, the X is discrete rather than continuous (noting that general linear models actually can blend characteristics of both regression and ANOVA). In ANOVA, the total variation of all measurements around the overall mean is divided into sources of variation that are then analyzed for statistical significance. It is used in situations where the investigator is interested in comparing the means among two or more discrete groups. For example, an investigator may be interested in comparing performance among three different machine configurations. The ANOVA analysis detects a difference somewhere among the means (i.e., at least one mean is different from the others), and confidence intervals or follow-up tests such as pairwise comparisons can be applied to determine which mean (or means) is different. ANOVA is the basis for design of experiments, discussed next.

Design of Experiments

With origins in the pioneering work in agriculture of Sir Ronald A. Fisher, designed experiments have taken on an increasingly significant role in quality improvement in the business world. This section will first compare the classical and designed approaches to experimentation, thereby providing the reader with an understanding as to the limitations of traditional methods and the power of contemporary methods. Next, basic concepts and terminology will be introduced in the context of an example improvement problem, followed by an overview of different types of designs and the typical progression through a series of designed experiments. The section finishes with the related topic of Taguchi designs.

Contrast between the Classical and Contemporary Methods of Experimentation. The classical method of experimentation is to vary one factor at a time (sometimes called OFAT), holding everything else constant. By way of example, and to illustrate the need for designed experiments, consider the case of a certain fellow who decided he wanted to investigate the causes of intoxication. As the story goes, he drank some whiskey and water on Monday and became highly inebriated. The next day, he repeated the experiment holding all variables constant except one… he decided to replace the whiskey with vodka. As you may guess, the result was drunkenness. On the third day, he repeated the experiment for the last time. On this trial, he used bourbon in lieu of the whiskey and vodka. This time it took him two days just to be able to gather enough of his faculties to analyze the experimental results. After recovering, he concluded that water causes intoxication. Why? Because it was the common variable!

The contrast between this traditional method and the designed approach is striking. In particular, a designed approach permits the greatest information to be gained from the fewest data points (efficient experimentation), and allows the estimation of interaction effects among factors. Table 19.11 compares these two approaches in more detail for an experiment in which there are two factors (or variables) whose effects on a characteristic are being investigated (the same conclusions hold for an experiment with more than two factors).

Concepts and Terminology—An Example Designed Experiment. Suppose that three detergents (A, B, C) are to be compared for their ability to clean clothes in an automatic washing machine. The "whiteness" readings obtained by a special measuring procedure are the dependent, or response, variable. The independent variable under investigation (detergent) is a factor, and each variation of the factor is called a level; in this case, there are three levels. A treatment is a single level assigned to a single factor, detergent A. A treatment combination is the set of levels for all factors in a given experimental run. A factor may be qualitative (different detergents) or quantitative (water temperature). Finally, some experiments have a fixed-effects model (i.e., the levels investigated represent all levels of concern to the investigator—for example, three specific washing machines or brands). Other experiments have a random effects model, that is, the levels chosen are just a sample from a larger population (e.g., three operators of washing machines). A mixed-effects model has both fixed and random factors.

Figure 19.16 outlines six possible designs of experiments, starting with the classical design in Figure 19.16a. Here, all factors except detergent are held constant. Thus, nine tests are run, three with each detergent with the washing time, make of machine, water temperature, and all other factors held constant. One drawback of this design is that the conclusions about detergent brands apply only to the specific conditions of the experiment.

Figure 19.16b recognizes a second factor at three levels (i.e., washing machines brands I, II, and III). However, in this design, it would not be known whether an observed difference was due to detergents or washing machine (they are said to be confounded).

Criteria	Classical	Modern
Basic procedure	Hold everything constant except the factor under investigation. Vary that factor and note the effect on the characteristic of concern. To investigate a second factor, conduct a separate experiment in the same manner.	Plan the experiment to evaluate both factors in one main experiment. Include in the design measurements to evaluate the effect of varying both factors simultaneously.
Experimental conditions	Care should be taken to have material, workers, and machine constant throughout the entire experiment.	Realizes difficulty of holding conditions reasonably constant throughout an entire experiment. Instead, experiment is divided into several groups or blocks of measurements. Within each block, conditions must be reasonably constant (except for deliberate variation to investigate a factor).
Experimental error	Recognized but not stated in quantitative terms.	Stated in quantitative terms.
Basis of evaluation	Effect due to a factor is evaluated with only a vague knowledge of the amount of experimental error.	Effect due to a factor is evaluated by comparing variation due to that factor with the quantitative measure of an experimental error.
Possible bias due to sequence of measurements	Often assumed that sequence has no effect.	Guarded against by randomization.
Effect of varying both factors simultaneously ("interaction")	Not adequately planned into experiment. Frequently assumed that the effect of varying factor 1 (when factor 2 is held constant at some value) would be the same for any value of factor 2.	Experiment can be planned to include an investigation for interaction between factors.
Validity of results	Misleading and erroneous if interaction exists and is not realized.	Even if interaction exists, a valid evaluation of the main factors can be made.
Number of measurements	For a given amount of useful and valid information, more measurements are needed than in the modern approach.	Fewer measurements needed for useful and valid information.
Definition of problem	Objective of experiment frequently not defined as necessary.	Designing the experiment requires defining the objective in detail (how large an effect do we want to determine, what numerical risks can be taken, etc.).
Application of conclusions	Sometimes disputed as applicable only to the controlled conditions under which the experiment was conducted.	Broad conditions can be planned in the experiment, thereby making conclusions applicable to a wider range of actual conditions.

(*Source: Quality Planning and Analysis,* Copyright 2007. Used by permission.)

Table 19.11 Comparison of Classical and Modern Methods of Experimentation

A	B	C
-	-	-
-	-	-
-	-	-

(a)

I	II	III
A	B	C
A	B	C
A	B	C

(b)

I	II	III
C	B	B
A	C	B
A	A	C

(c)

I	II	III
B	A	C
C	C	A
A	B	B

(d)

	I	II	III
1	C	A	B
2	B	C	A
3	A	B	C

(e)

I	II	III
ABC	ABC	ABC
1 ---	---	---
2 ---	---	---
3 ---	---	---

(f)

FIGURE 19.16 Some experimental designs. (*Quality Planning and Analysis, Copyright 2007. Used by permission.*)

In Figure 19.16c, the nine tests are assigned completely at random, thus the name "completely randomized design." However, detergent A is not used with machine brand III, and detergent B is not used with machine brand I, thus complicating the conclusions.

Figure 19.16d shows a randomized block design. Here each block is a machine brand, and the detergents are run in random order within each block. This design guards against any possible bias due to the order in which the detergents are used and has advantages in the subsequent data analysis and conclusions. First, a test of hypothesis can be run to compare detergents and a separate test of hypothesis run to compare machines; all nine observations are used in both tests. Second, the conclusions concerning detergents apply for the three machines and vice versa, thus providing conclusions over a wider range of conditions.

Now suppose that another factor such as water temperature is also to be studied, using the Latin square design shown in Figure 19.16e. Note that this design requires using each

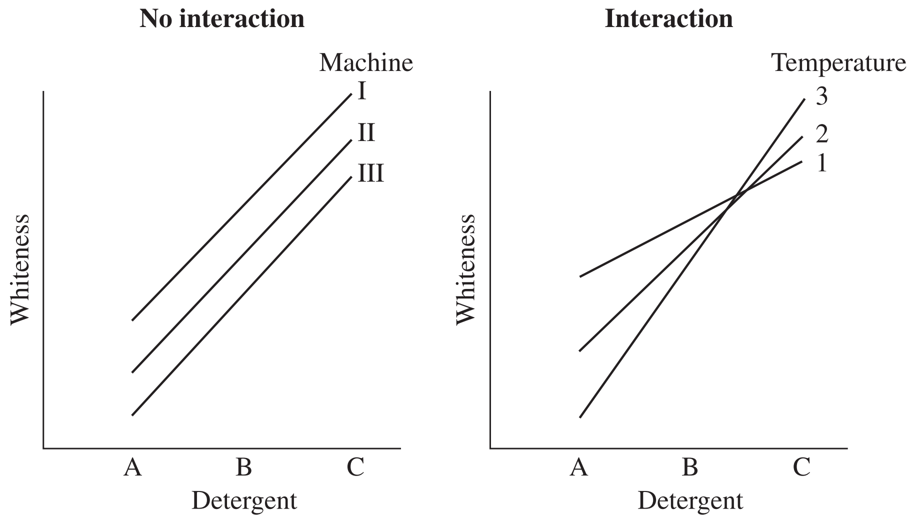


Figure 19.17 Interaction. (*Quality Planning and Analysis, Copyright 2007. Used by permission.*)

detergent only once with each machine and only once with each temperature. Thus, three factors can be evaluated (by three separate tests of hypothesis) with only nine observations. However, there is a danger. This design assumes no interaction among the factors. No interaction between detergent and machine means that the effect of changing from detergent A to B to C does not depend on which machine is used, and similarly for the other combinations of factors. The concept of interaction is shown in Figure 19.17. There is no interaction among the detergents and the machines. But the detergents do interact with temperature. At high temperatures, C is the best performer. At low temperatures, A performs best.

Finally, the main factors and possible interactions could be investigated by the factorial design in Figure 19.16f. Factorial means that at least one test is run for every combination of main factors, in this case 3 × 3 × 3 or 27 combinations. Separate tests of hypothesis can be run to evaluate the main factors and also possible interactions. Again, all the observations contribute to each comparison. When there are many factors, a portion of the complete factorial (i.e., a "fractional factorial") is useful when experimental resources are limited (see its application in a sequential testing approach, below).

Most problems can be handled with one of the standard experimental designs or a series of these. Designs can be classified by the number of factors to be investigated, the structure of the experimental design, and the kind of information the experiment is intended to provide (Table 19.12). For a description of both the design and analysis of various design structures, see Box et al. (2005). Another excellent general reference is Myers et al. (2009) for a detailed look at response surface designs.

A sequential approach to experimentation often can be helpful. Briefly, a typical sequence of designed experiments will allow an experimenter to quickly and efficiently narrow down a large number of possible factors (or X's in the Y = f(X) terminology of Lean Six Sigma) to find out which are most important, and then refine the relationships to find optimal settings for each of the vital few factors. The steps might be as follows:

1. *Screening experiment*. In this stage, a fractional factorial design may be applied that does not allow interactions to be detected, but can ferret out which of many factors have the greatest main effect.
2. *Fractional factorial design*. The smaller number of factors identified in the screening experiment are tested to allow detection of interaction effects.

Design	Type of Application
Completely randomized	Appropriate when only one experimental factor is being investigated
Factorial	Appropriate when several factors are being investigated at two or more levels and interaction of factors may be significant
Blocked factorial	Appropriate when number of runs required for factorial is too large to be carried out under homogeneous conditions
Fractional factorial	Appropriate when many factors and levels exist and running all combinations is impractical
Randomized block	Appropriate when one factor is being investigated and experimental material or environment can be divided into blocks or homogeneous groups
Balanced incomplete block	Appropriate when all the treatments cannot be accommodated in a block
Partially balanced incomplete block	Appropriate if a balanced incomplete block requires a larger number of blocks than is practical
Latin square	Appropriate when one primary factor is under investigation and results may be affected by two other experimental variables or by two sources of nonhomogeneity. It is assumed that no interactions exist.
Youden square	Same as Latin square, but number of rows, columns, and treatments need not be the same
Nested	Appropriate when objective is to study relative variability instead of mean effect of sources of variation (e.g., variance of tests on the same sample and variance of different samples)
Response surface	Objective is to provide empirical maps (contour diagrams) illustrating how factors under the experimenter's control influence the response
Mixture designs	Use when constraints are inherent (e.g., the sum of components in a paint must add to 100%)

(*Source*: Adapted from JQH5, Table 47.3.)

Table 19.12 Classification of Designs

3. *Full factorial design*. A small number of factors (usually no more than five) are tested to allow all main effects and higher-order (e.g., three-way, four-way) interactions to be detected and accounted for. Such designs also can detect curvature that indicates a potential optimum.
4. *Response surface design*. By adding data points in particular ways (e.g., a composite design), an experimenter can build on earlier experiments to fully characterize nonlinear relationships and pinpoint optimal settings.
5. *EVOP*. Once an improved process is in production mode, evolutionary operation techniques can be used to conduct many small experiments on production units over time. Although individual changes are small, the cumulative effect over time can be quite large, and exemplifies the power of continuous improvement. See Box and Draper (1969) for a classic text on this subject.

For a series of four papers on sequential experimentation, see Carter (1996). Emanuel and Palanisamy (2000) discuss sequential experimentation at two levels and a maximum of seven factors.

Taguchi Approach to Experimental Design

Professor Genichi Taguchi uses an approach to experimental design that has three purposes:

- Design products and processes that perform consistently on target and are relatively insensitive ("robust") to factors that are difficult to control.
- Design products that are relatively insensitive (robust) to component variation.
- Minimize variation around a target value.

Thus, although cited in this "improvement tools" section because of its association with DOE, the approach is meant to provide valuable information for product design and development (see "Statistical Tools for Designing for Quality" in this chapter). Taguchi divides quality control into online control (e.g., diagnosing and adjusting a process during production) and offline control that encompasses the engineering design process and its three phases: systems design, parameter design, and tolerance design. For an extensive bibliography and a summary of some controversial aspects of the Taguchi approach, see Box and Draper (1969, pp. 47.58 and 47.59).

Many books are available that cover DOE for engineering and manufacturing applications. For readers in nonmanufacturing environments, Ledolter and Swersey (2007) may be of interest. A recent text readers may find useful for not only classical but more contemporary techniques (e.g., Bayesian inference, kriging) is del Castillo (2007).

Discrete Event and Monte Carlo Simulation

Advances in user-friendly software make computer simulations increasingly accessible to quality practitioners that do not have a strong background in mathematics, programming, or modeling. Numerous types of simulation models exist, but two that may be of most interest to readers are discrete event and Monte Carlo simulations. These can be powerful methods for making process improvements; in particular, modeling provides a means of asking "what if?" questions and rapidly testing the effects of process changes and potential solutions in a safe, low-risk environment.

Discrete Event Simulation. Discrete event simulation (DES) attempts to mimic situations in which there are distinct, recognizable events and transactions. In a hospital, for example, arrival of patients at an emergency department and subsequent steps in patient care represent specific events that combine into a flow of transactions: arrival, registration, triage, nursing assessment, physician assessment, etc., through inpatient admission, discharge, or transfer. Discrete event simulation enables system components to be changed and tracks the resulting process flow over time to help understand the relationships among inputs, outputs, and process variables.

Typically, a process flow diagram (or process "map") that graphically displays the sequence and flow of activities forms the basis for a discrete event simulation. A discrete event simulation takes this basic flow diagram and adds inputs and process variables that govern the flow of transactions. Following on the hospital example, these include inputs (such as patient arrivals), human resources (e.g., number of nurses, physician schedules, overtime availability, skill levels, pay rates, etc.), equipment resources (e.g., types and number of beds, imaging equipment, etc.), rules for flow (the required sequence of steps, batching of inputs or outputs, priority rules, exceptions, decisions), resource acquisition (what resources are needed to complete an activity (e.g., one RN or one physician's assistant; two RNs; one RN and one physician, etc.), activity cycle times (work time, wait time), and similar details.

Once these details are built into the model, it "runs" by tracing the path of units (patients, in the hospital example) from arrival through to exit from the process. Patients are processed in accordance with the activities, rules, and constraints, and any relevant attributes (patient-specific characteristics) that may be assigned to them (e.g., acuity level, age, gender). The output consists of a multitude of descriptive statistics and measures that portray the collective behavior of the process as the various players interact and move through time.

Although every model is different and details vary, there are basic steps that should be a part of every simulation study. These steps and related questions are (adapted from Law and Kelton 2000):

1. State the problem and question(s) being asked. What is the business need for the simulation? What problem is to be fixed? What answers are being sought?
2. Prepare a plan for the simulation study. Who needs to be involved? What data are needed and how will data be collected? What alternative scenarios are to be tested? What are the milestones and timeline for completion?
3. Collect data. What is my current state? What are the data for alternative scenarios? Are there gaps in the data, and how will they be handled?
4. Build and validate a conceptual model. Given available data, what is the general structure of the model? What will be the inputs, process variables, and outputs? What statistical accumulators are needed, and where? If the model is built, will it provide the answers to the questions?
5. Build and validate an operational model. Are the model components necessary and sufficient? Does the model produce results consistent with the current state?
6. Design scenarios or experiments needed to answer the questions. What model parameters will be changed? Which are fixed? What combinations of factors need to be tested?
7. Run the scenarios or experiments to obtain the needed outputs. Are the results reproducible? Are additional scenarios or experiments suggested?
8. Analyze and interpret the data. What are the statistical results? Do the descriptive statistics and/or statistical tests indicate meaningful effects? What are the answers to the original questions? Are additional questions raised?

As emphasized at the beginning of this chapter, formulation of the question(s) being asked is a critical first step to the successful application of simulation modeling. Failure to have a clear understanding of what the model is being asked to do leads to poorly constructed models, models with insufficient inputs or process detail, or overly complicated models that take unnecessary time and effort to build and run. In addition, a clearly communicated business need will garner the stakeholder support needed to collect data, evaluate the model, and implement suggested changes.

Monte Carlo. Named after the famed gambling destination, this method seeks to account for uncertainty (variability) in inputs and carry this forward into probability distributions of outcomes. Essentially, instead of using single, fixed values in equations [such as Y = f(X)], distributions are used for the inputs (X's), and samples repeatedly are drawn from the distributions, yielding a distribution of outputs (Y values) instead of a single value. For example, while the forecasted net return on a new product could simply be stated as an expected $10 million, it would be useful to know the probability of achieving this, or that the uncertainty in the forecast is such that there is a high probability of a negative return.

By way of illustration, assume we have three components, A, B, and C that are assembled end-to-end to create a final product. If the mean lengths are 5, 10, and 15 mm, then we can simply add these together to arrive at an expected mean combined total length of 5 mm + 10 mm + 15 mm = 30 mm. However, we know from the concept of statistical variation that there will be variation in the components. Assuming we sample populations of each component and find the respective distributions for each of A, B, and C, what can we expect the overall distribution of assembled product length to look like? By repeatedly taking a random sample from each distribution and adding the lengths, Monte Carlo simulation generates a distribution of the total length Figure 19.18 shows the relative frequency distribution of the combined

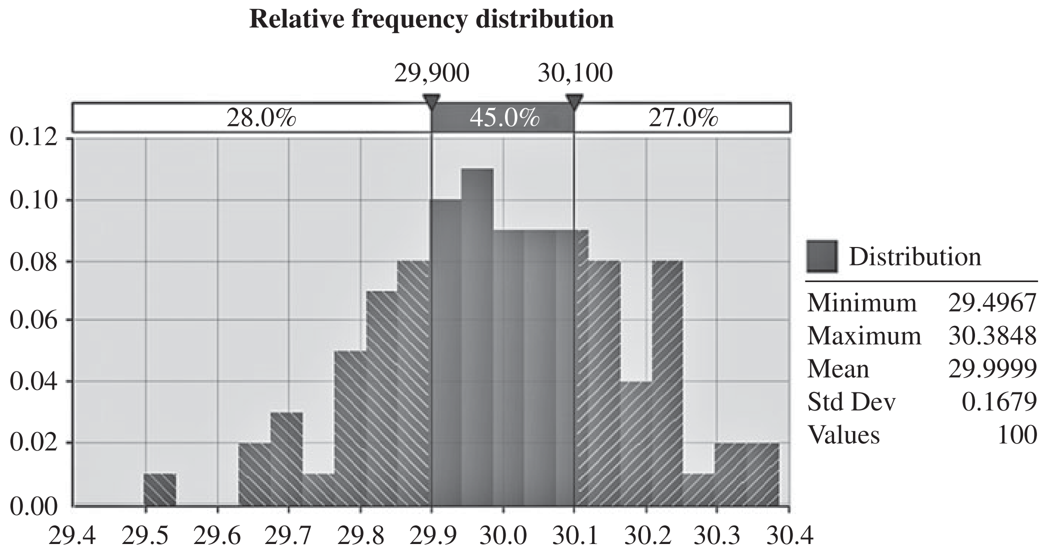


Figure 19.18 Result of Monte Carlo simulation showing a relative frequency distribution of combined total length of three components A, B and C that individually have normal distributions of 5, 10 and 15 mm, respectively, each with a standard deviation of 0.1 mm. The mean expected combined total length is approximately 30 mm, but the simulation shows the variation around this, e.g., that only 45% of assembled components are expected to be within +/– 0.1 mm of this mean value.

lengths of the three components from a Monte Carlo simulation with each of the three components having a standard deviation of of 0.1 mm. The mean expected combined total length is almost exactly 30 mm, but the simulation shows the variation around this, with only 45% of assembled components expected to be within +/– 0.1 mm of the total mean value. This approach provides substantially more information than the single estimate of 30 mm.

Simulated DOE. As tools evolve, they are being combined in new ways. One example is the combination of Monte Carlo, discrete event simulation, and DOE. Briefly, this approach involves a discrete event simulation (DES) that uses probability distributions for the input and/or process variables (Monte Carlo), and the investigator changes these variables (as factors) following a structured, designed approach (DOE). While any results and conclusions should be treated as preliminary until verified by actual experimentation, this can be particularly useful in environments where real-life changes may be difficult or dangerous to make.

Additional Advanced Analysis Tools

For practitioners faced with more complex scenarios such as multiple variables (more than one y and/or x), nonlinear data, or categorical outputs, extensions of the general linear models and other alternatives are available. In particular are methods for multivariate analysis; this refers to statistical techniques that simultaneously analyze multiple measurements on subjects. Many techniques are extensions of the univariate (single-variable distributions) and bivariate (correlation, regression) methods dealt with above. Beyond the scope of this chapter, these include:

- *Multiple regression*. Applies when the investigator has a single, continuous dependent variable and multiple, continuous independent variables (X's) of interest.
- *Nonlinear regression*. Useful when data cannot easily be treated by standard linear methods (note that curvilinear data do not necessarily require nonlinear methods).
- *Nonparametric linear regression*. Applies when the usual assumptions of regression are violated.

- *Multiple discriminant analysis*. Used in situations with a single, categorical (dichotomous or multichotomous) dependent variable (Y) and continuous independent variables (X's).
- *Logistic regression*. Also known as logit analysis, this is a combination of multiple regression and multiple discriminant analysis in which one or more categorical or continuous independent variables (X's) are used to predict a single, categorical dependent variable (Y). Odds ratios often are computed with this method.
- *Multivariate analysis of variance and covariance (MANOVA, MANCOVA)*. Dependence techniques that extend ANOVA to allow more than one continuous, dependent variable (Y) and several categorical independent variables (X's).
- *Principal component analysis (PCA) and common factor analysis*. These methods analyze interrelationships among a large number of variables and seek to condense the information into a smaller set of factors without loss of information.
- *Cluster analysis*. An interdependence technique that allows mutually exclusive subgroups to be identified based on similarities among the individuals. Unlike discriminant analysis, the groups are not predefined.
- *Canonical correlation analysis*. An extension of multiple regression that correlates simultaneously several continuous dependent variables (Y's) and several continuous independent variables (X's).
- *Conjoint analysis*. Often used in marketing analyses, this method helps assess the relative importance of both attributes and levels of complex entities (e.g., products). It is useful when trade-offs exist when making comparisons.
- *Multidimensional scaling*. An interdependence method (also called perceptual mapping), this seeks to transform preferences or judgments of similarity into a representation by distance in multidimensional space.
- *Correspondence analysis*. Another interdependence technique; this accommodates the perceptual mapping of objects (such as products) onto a set of categorical attributes. This method allows both categorical data and nonlinear relationships.

Readers are encouraged to research any techniques that appear to fit their need; although complex, these are powerful means of getting useful information from data. Some useful references include

Multivariate techniques:

Hair, J. F., Jr., Black, W. C., Babin, B. J., Anderson, R. E., and Tatham, R. L. (2006). *Multivariate Data Analysis*. Pearson Prentice-Hall, Upper Saddle River, NJ.

Affifi, A., Clark, V. A., and May, S. (2004). *Computer-Aided Multivariate Analysis* (4th ed.). Chapman and Hall/CRC Press, Boca Raton, FL.

Coleman, S, Greenfield, T., Stewardson, D., and Montgomery, D. C. (2008). *Statistical Practice in Business and Industry*. John Wiley & Sons, Hoboken, NJ. (see Chapter 13).

Hypothesis testing and DOE:

Box, G. E. P., Hunter, J. S., and Hunter, W. G. (2005). *Statistics for Experimenters: Design, Innovation and Discovery* (2nd ed.). Wiley-Interscience, Hoboken, NJ.

Logistic regression, Poisson regression, odds ratios:

Agresti, A. (1996). *An Introduction to Categorical Data Analysis*. John Wiley & Sons, New York.

Nonparametric:

Sprent, P., and Smeeton, N. C. (2001). *Applied Nonparametric Statistical Methods* (3rd ed.). Chapman and Hall/CRC Press, Boca Raton, FL.

Statistical Tools for Designing for Quality

Statistical tools for quality in the design and development process include techniques such as graphical summaries, probability distributions, confidence limits, tests of hypotheses, design of experiments, regression, and correlation analysis. These topics are covered in earlier sections of this chapter. To supplement these techniques, this section explains some statistical tools for reliability and availability, and tools for setting specification limits on product characteristics.

Failure Patterns for Complex Products

Methodology for quantifying reliability was first developed for complex products. Suppose that a piece of equipment is placed on test, is run until it fails, and the failure time is recorded. The equipment is repaired and again placed on test, and the time of the next failure is recorded. The procedure is repeated to accumulate the data shown in Table 19.13. The failure rate is calculated, for equal time intervals, as the number of failures per unit of time. When the failure rate is plotted against time, the result (Figure 19.19) often follows a familiar pattern of failure known as the bathtub curve. Three periods are apparent that differ in the frequency of failure and in the failure causation pattern:

- *The infant mortality period*. This period is characterized by high failure rates that show up early in use (see the lower half of Figure 19.18). Commonly, these failures

Time of Failure, Infant Mortality Period		Time of Failure, Constant Failure Rate Period		Time of Failure, Wear-Out Period	
1.0	7.2	28.1	60.2	100.8	125.8
1.2	7.9	28.2	63.7	102.6	126.6
1.3	8.3	29.0	64.6	103.2	127.7
2.0	8.7	29.9	65.3	104.0	128.4
2.4	9.2	30.6	66.2	104.3	129.2
2.9	9.8	32.4	70.1	105.0	129.5
3.0	10.2	33.0	71.0	105.8	129.9
3.1	10.4	35.3	75.1	106.5	
3.3	11.9	36.1	75.6	110.7	
3.5	13.8	40.1	78.4	112.6	
3.8	14.4	42.8	79.2	113.5	
4.3	15.6	43.7	84.1	114.8	
4.6	16.2	44.5	86.0	115.1	
4.7	17.0	50.4	87.9	117.4	
4.8	17.5	51.2	88.4	118.3	
5.2	19.2	52.0	89.9	119.7	
5.4		53.3	90.8	120.6	
5.9		54.2	91.1	121.0	
6.4		55.6	91.5	122.9	
6.8		56.4	92.1	123.3	
6.9		58.3	97.9	124.5	

(*Source: Quality Planning and Analysis*, Copyright 2007. Used by permission.)

TABLE 19.13 Failure History for a Unit

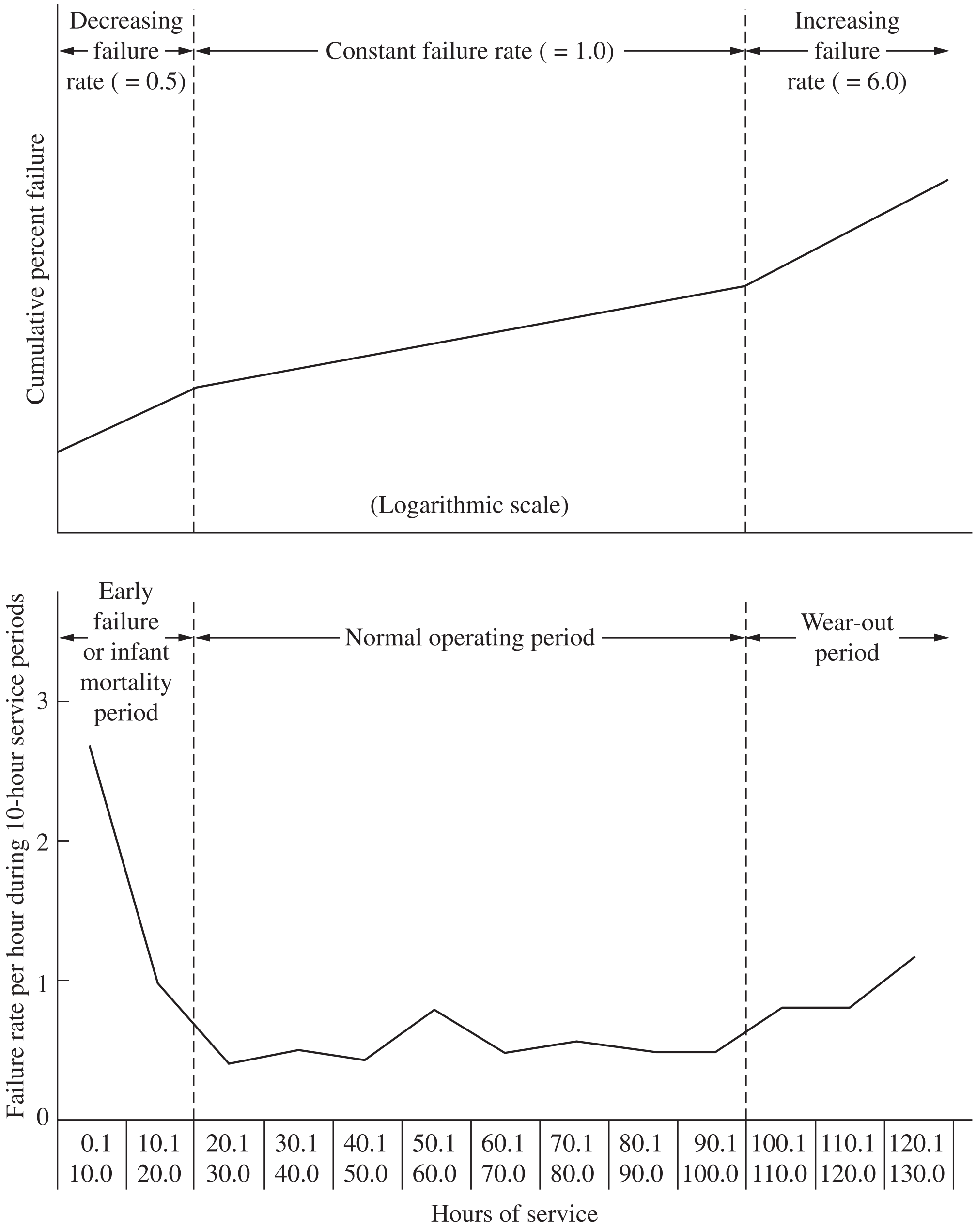


Figure 19.19 Failure rate vs. time. (*Quality Planning and Analysis, Copyright 2007. Used by permission.*)

are the result of blunders in design or manufacture, misuse, or misapplication. Once corrected, these failures usually do not occur again (e.g., an oil hole that is not drilled). Sometimes it is possible to "debug" the product by a simulated use test or by overstressing (in electronics this is known as burn-in). The weak units still fail, but the failure takes place in the test rig rather than in service. O'Connor (1995) explains the use of burn-in tests and environmental screening tests.

- *The constant-failure-rate period*. Here the failures result from the limitations inherent in the design, changes in the environment, and accidents caused by use or maintenance.

The accidents can be held down by good control of operating and maintenance procedures. However, a reduction in the failure rate requires basic redesign.

- *The wear-out period.* These failures are due to old age (e.g., a metal becomes embrittled or insulation dries out). A reduction in failure rates requires preventive replacement of these dying components before they result in catastrophic failure.

The top portion of Figure 19.19 shows the corresponding Weibull plot when $\alpha = 2.6$ was applied to the original data (Table 19.14). The values of the shape parameter, β, were approximately 0.5, 1.0, and 6.0, respectively. A shape parameter less than 1.0 indicates a decreasing failure rate, a value of 1.0 a constant failure rate, and a value greater than 1.0 an increasing failure rate.

The Distribution of Time Between Failures. Users desire low failure rates during the infant mortality period, and after this are concerned with the length of time that a product will perform without failure. Thus, for repairable products, the time between failures (TBF) is a critical characteristic. The variation in time between failures can be studied statistically. The corresponding characteristic for nonrepairable products is usually called the time to failure.

When the failure rate is constant, the distribution of time between failures is distributed exponentially. Consider the 42 failure times in the constant failure rate portion of Table 19.13. The time between failures for successive failures can be tallied, and the 41 resulting TBFs can be formed into the frequency distribution shown in Figure 19.20a. The distribution is roughly exponential in shape, indicating that when the failure rate is constant, the distribution of time between failures (not mean time between failures) is exponential. This distribution is the basis of the exponential formula for reliability.

The Exponential Formula for Reliability

The distribution of TBF indicates the chance of failure-free operation for the specified time period. The chance of obtaining failure-free operation for a specified time period or longer can be shown by changing the TBF distribution to a distribution showing the number of intervals equal to or greater than a specified time length (Figure 19.20b). If the frequencies are expressed as relative frequencies, they become estimates of the probability of survival. When the failure rate is constant, the probability of survival (or reliability) is

$$P_s = R = e^{-t/\mu} = e^{-t\lambda}$$

where $P_s = R$ = probability of failure-free operation for a time period equal to or greater than t
$e = 2.718$
t = specified period of failure-free operation
μ = mean time between failures (the mean of TBF distribution)
λ = failure rate (the reciprocal of μ)

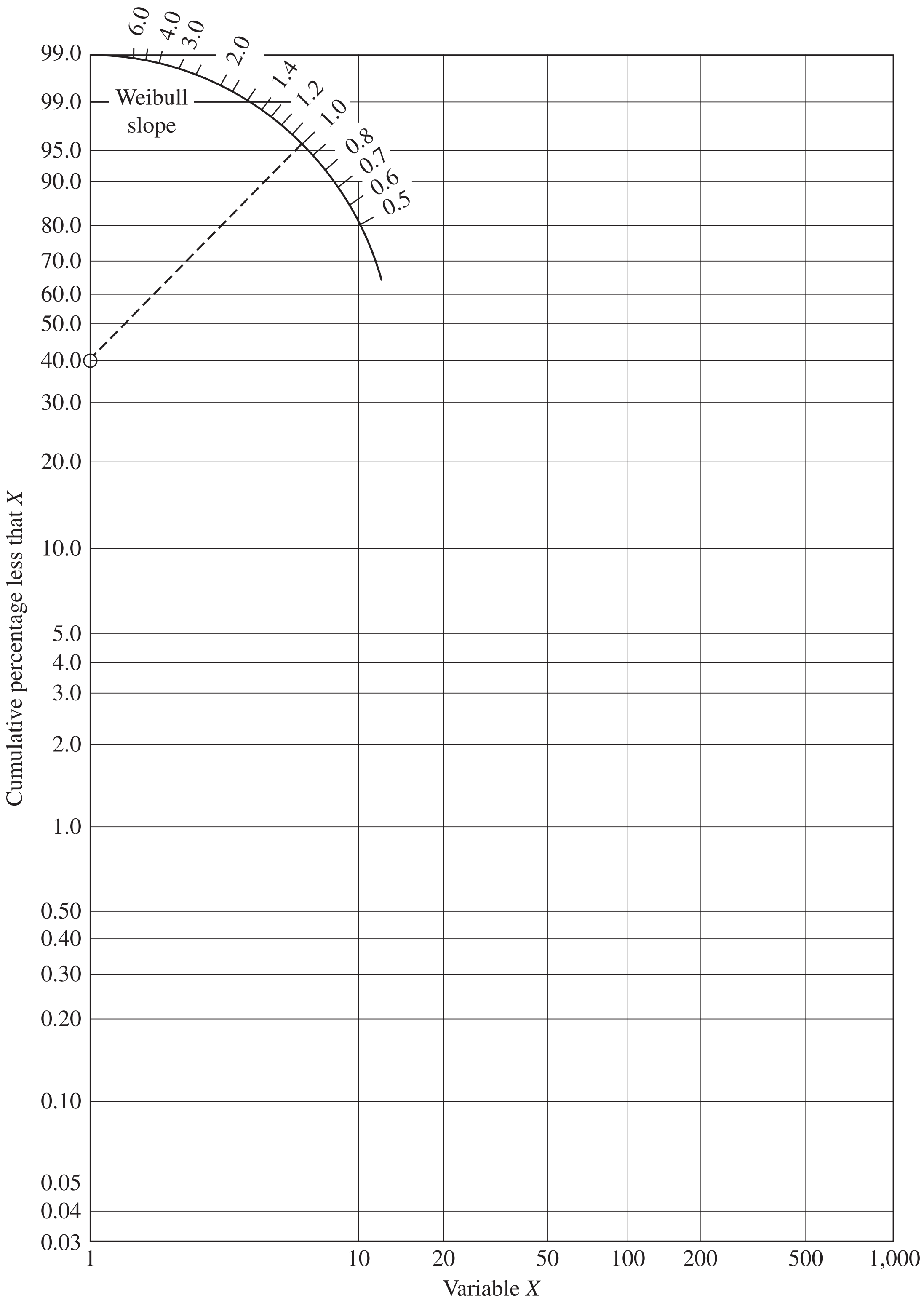
Note that this formula is simply the exponential probability distribution rewritten in terms of reliability.

Problem A washing machine requires 30 minutes to clean a load of clothes. The mean time between failures of the machine is 100 hours. Assuming a constant failure rate, what is the chance of the machine completing a cycle without failure?

Solution Applying the exponential formula, we obtain

$$R = e^{-t/\mu} = e^{-0.5/100} = 0.995$$

There is a 99.5 percent chance of completing a washing cycle.



(*Source: Quality Planning and Analysis*, Copyright 2007. Used by permission.)

Table 19.14 Weibull Paper

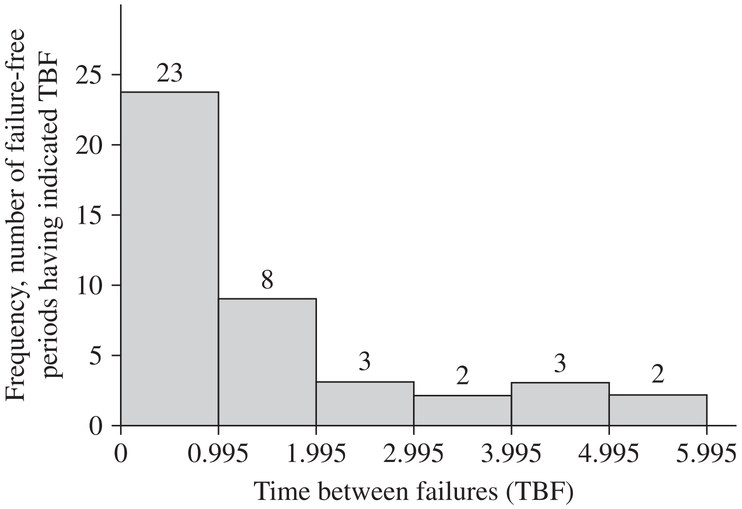


Figure 19.20*a* Histogram of TBF. (*Quality Planning and Analysis, Copyright 2007. Used by permission.*)

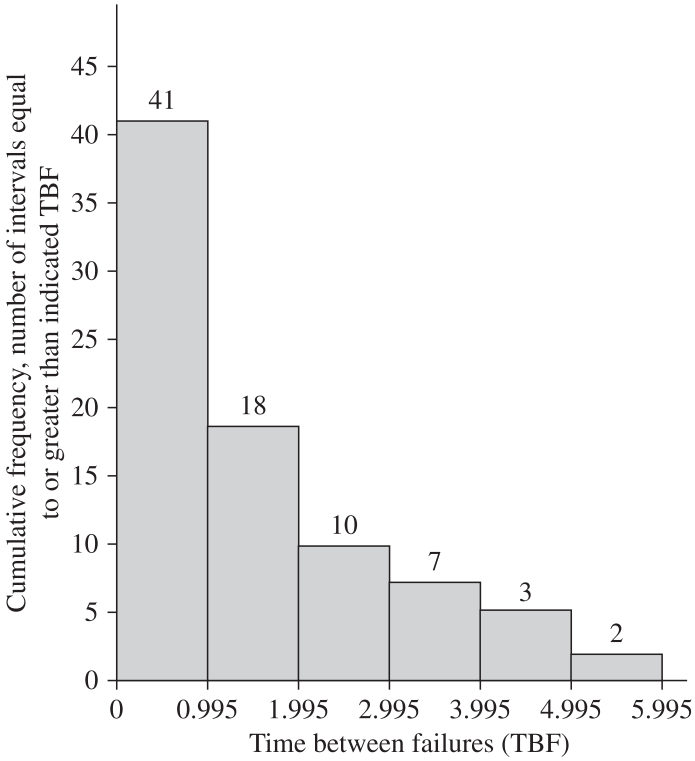


Figure 19.20*b* Cumulative histogram of TBF. (*Quality Planning and Analysis, Copyright 2007. Used by permission.*)

How about the assumption of a constant failure rate? In practice, sufficient data usually are not available to evaluate the assumption. However, experience suggests that this assumption often is true, particularly when (1) infant mortality types of failures have been eliminated before delivery of the product to the user, and (2) the user replaces the product or specific components before the wear-out phase begins.

The Meaning of Mean Time Between Failures. Confusion surrounds the meaning of mean time between failures (MTBF). Further explanation is warranted:

- The MTBF is the mean (or average) time between successive failures of a product. This definition assumes that the product in question can be repaired and placed back into operation after each failure. For nonrepairable products, the term “mean time to failure” (MTTF) is used.
- If the failure rate is constant, the probability that a product will operate without failure for a time equal to or greater than its MTBF is only 37 percent. This outcome is based on the exponential distribution (*R* is equal to 0.37 when *t* is equal to the MTBF). This result is contrary to the intuitive feeling that there is a 50-50 chance of exceeding an MTBF.
- MTBF is not the same as “operating life,” “service life,” or other indexes, which generally connote overhaul or replacement time.
- An increase in an MTBF does not result in a proportional increase in reliability (the probability of survival). If $t = 1$ hour, the following table shows the MTBF required to obtain various reliabilities.

MTBF	*R*
5	0.82
10	0.90
20	0.95
100	0.99

A fivefold increase in MTBF from 20 to 100 hours is necessary to increase the reliability by 4 percentage points compared with a doubling of the MTBF from 5 to 10 hours to get an 8 percentage point increase in reliability.

MTBF is a useful measure of reliability, but it is not correct for all applications. Other reliability indexes are listed in Chapter 28, Research & Development: More Innovation, Scarce Resources.

The Relationship Between Part and System Reliability

It often is assumed that system reliability (i.e., the probability of survival, P_s) is the product of the individual reliabilities of the *n* parts within the system:

$$P_s = P_1 P_2 \ldots P_n$$

For example, if a communications system has four subsystems with reliabilities of 0.970, 0.989, 0.995, and 0.996, the system reliability is the product, or 0.951. The formula assumes that (1) the failure of any part causes failure of the system and (2) the reliabilities of the parts are independent of one another (i.e., the reliability of one part does not depend on the functioning of another part).

These assumptions are not always true, but in practice, the formula serves two purposes. First, it shows the effect of increased complexity of equipment on overall reliability. As the number of parts in a system increases, the system reliability decreases dramatically (see Figure 19.21). Second, the formula often is a convenient approximation that can be refined as information on the interrelationships of the parts becomes available.

When it can be assumed that (1) the failure of any part causes system failure, (2) the parts are independent, and (3) each part follows an exponential distribution, then

$$P_s = e^{-t_1\lambda_1} e^{--t_2\lambda_2} \ldots e^{-t_n\lambda_n}$$

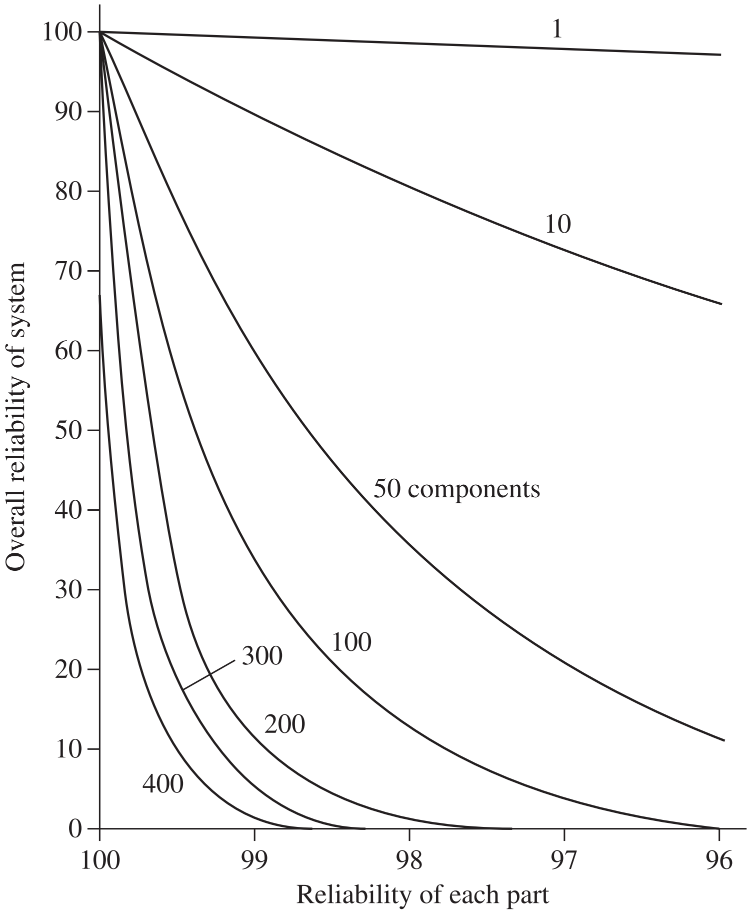


FIGURE 19.21 Relationship between part and system reliability. (*Quality Planning and Analysis, Copyright 2007. Used by permission.*)

Further, if t is the same for each part,

$$P_s = e^{-1\Sigma\lambda}$$

Thus, when the failure rate is constant (and therefore the exponential distribution can be applied), the reliability of a system can be predicted based on the addition of the part failure rates (see the section "Predicting Reliability during Design," next).

Sometimes designs are planned with redundancy so that the failure of one part will not cause system failure. Redundancy is an old (but still useful) design technique invented long before the advent of reliability prediction techniques. However, the designer can now predict the effect of redundancy on system reliability in quantitative terms.

Redundancy is the existence of more than one element for accomplishing a given task, where all elements must fail before there is an overall failure of the system. In parallel redundancy (one of several types of redundancy), two or more elements operate at the same time to accomplish the task, and any single element is capable of handling the job itself in case of failure of the other elements. When parallel redundancy is used, the overall reliability is calculated as follows:

$$P_s = 1 - (1 - \mathrm{P1})n$$

where P_s = reliability of the system
P1 = reliability of the individual elements in the redundancy
n = number of identical redundant elements

Problem Suppose that a unit has a reliability of 99.0 percent for a specified mission time. If two identical units are used in parallel redundancy, what overall reliability will be expected?

Solution Applying the formula above, we obtain

$$R = 1 - (1 - 0.99)(1 - 0.99) = 0.9999, \text{ or } 99.99 \text{ percent}$$

Predicting Reliability during Design

Reliability prediction methods continue to evolve, but include such standards as failure mode and effects analysis (FMEA) and testing. Ireson et al. (1996) provide an extensive discussion of reliability prediction, and should be consulted beyond the methods discussed in this handbook.

The following steps make up a reliability prediction method:

1. Define the product and its functional operation. The system, subsystems, and units must be precisely defined in terms of their functional configurations and boundaries. This precise definition is aided by preparation of a functional block diagram that shows the subsystems and lower-level products, their interrelationships, and the interfaces with other systems. Given a functional block diagram and a well-defined statement of the functional requirements of the product, the conditions that constitute failure or unsatisfactory performance can be defined.
2. Prepare a reliability block diagram. For systems in which there are redundancies or other special interrelationships among parts, a reliability block diagram is useful. This diagram is similar to a functional block diagram, but the reliability block diagram shows exactly what must function for successful operation of the system. The diagram shows redundancies and alternative modes of operation. The reliability block diagram is the foundation for developing the probability model for reliability. O'Connor (1995) provides further discussion.
3. Develop the probability model for predicting reliability. A simple model may add only failure rates; a complex model can account for redundancies and other conditions.
4. Collect information relevant to parts reliability. The data include information such as parts function, parts ratings, stresses, internal and external environments, and operating time. Many sources of failure-rate information state failure rates as a function of operating parameters. For example, failure rates for fixed ceramic capacitors are stated as a function of (1) expected operating temperature and (2) the ratio of the operating voltage to the rated voltage. Such data show the effect of derating (assigning a part to operate below its rated voltage) on reducing the failure rate.
5. Select parts reliability data. The required parts data consist of information on catastrophic failures and on tolerance variations with respect to time under known operating and environmental conditions. Acquiring these data is a major problem for the designer because there is no single reliability data bank comparable to handbooks such as those for physical properties of materials. Instead, the designer must build a data bank by securing reliability data from a variety of sources:

Field performance studies conducted under controlled conditions:

- Specified life tests
- Data from parts manufacturers or industry associations

- Customers' parts qualification and inspection tests
- Government agency data banks such as the Government Industry Data Exchange Program (GIDEP) and the Reliability Information Analysis Center (RIAC)

Combine all of the above to obtain the numerical reliability prediction.

Ireson et al. (1996) and O'Connor (1995) are excellent references for reliability prediction. Included are the basic methods of prediction, repairable versus nonrepairable systems, electronic and mechanical reliability, reliability testing, and software reliability. Box and Draper (1969) provides extensive discussion of reliability data analysis, including topics such as censored life data (not all test units have failed during the test) and accelerated-life test data analysis. Dodson (1999) explains how the use of computer spreadsheets can simplify reliability modeling using various statistical distributions.

Reliability prediction techniques based on component failure data to estimate system failure rates have generated controversy. Jones and Hayes (1999) present a comparison of predicted and observed performance for five prediction techniques using parts count analyses. The predictions differed greatly from observed field behavior and from each other. The standard ANSI/IEC/ASQC D60300-3-1-1997 (Dependability Management—Part 3: Application Guide—Section 1—Analysis Techniques for Dependability) compares five analysis techniques: FMEA/FMECA, fault tree analysis, reliability block diagram, Markov analysis, and parts count reliability prediction.

The reliability of a system evolves during design, development, testing, production, and field use. The concept of reliability growth assumes that the causes of product failures are discovered and action is taken to remove the causes, thus resulting in improved reliability of future units ("test, analyze, and fix"). Reliability growth models provide predictions of reliability due to such improvements. For elaboration, see O'Connor (1995). Also, ANSI/IEC/ASQC D601164-1997 (Reliability Growth—Statistical Test and Estimation Methods) and the related IEC 61164 Ed. 2.0 (2004) (Reliability growth—Statistical test and estimation methods) describe methods of estimating reliability growth.

Predicting Reliability Based on the Exponential Distribution

When the failure rate is constant and when study of a functional block diagram reveals that all parts must function for system success, then reliability is predicted to be the simple total of failure rates. An example of a subsystem prediction is shown in Table 19.15. The prediction for the subsystem is made by adding the failure rates of the parts; the MTBF is then calculated as the reciprocal of the failure rate.

For further discussion of reliability prediction, including an example for an electronic system, see Gryna et al. (2007).

Predicting Reliability Based on the Weibull Distribution

Prediction of overall reliability based on the simple addition of component failure rates is valid only if the failure rate is constant. When this assumption cannot be made, an alternative approach based on the Weibull distribution can be used.

1. Graphically, use the Weibull distribution to predict the reliability R for the time period specified. $R = 100 - \%$ failure. Do this for each component (Table 19.14).
2. Combine the component reliabilities using the product rule and/or redundancy formulas to predict system reliability.

Predictions of reliability using the exponential distribution or the Weibull distribution are based on reliability as a function of time. Next we consider reliability as a function of stress and strength.

Part Description	Quantity	Generic Failure Rate per Million Hours	Total Failure Rates per Million Hours
Heavy-duty ball bearing	6	14.4	86.4
Brake assembly	4	16.8	67.2
Cam	2	0.016	0.032
Pneumatic hose	1	29.28	29.28
Fixed displacement pump	1	1.464	1.464
Manifold	1	8.80	65.0
Guide pin	5	13.0	65.0
Control valve	1	15.20	15.20
Total assembly failure rate			273.376

MTBF = 1/0.000273376 = 3.657.9 hours

(*Source:* Adapted from Ireson et al., p. 19.9. *Quality Planning and Analysis*, Copyright 2007. Used by permission.)

Table 19.15 Example of Mechanical Parts and Subsystem Failure Rates

Reliability as a Function of Applied Stress and Strength

Failures are not always a function of time. In some cases, a part will function indefinitely if its strength is greater than the stress applied to it. The terms "strength" and "stress" here are used in the broad sense of inherent capability and operating conditions applied to a part, respectively.

For example, operating temperature is a critical parameter, and the maximum expected temperature is 145°F (63°C). Further, capability is indicated by a strength distribution having a mean of 172°F (78°C) and a standard deviation of 13°F (7°C) (Figure 19.22). With knowledge of only the maximum temperatures, the safety margin is

$$\frac{172-145}{13}=2.08$$

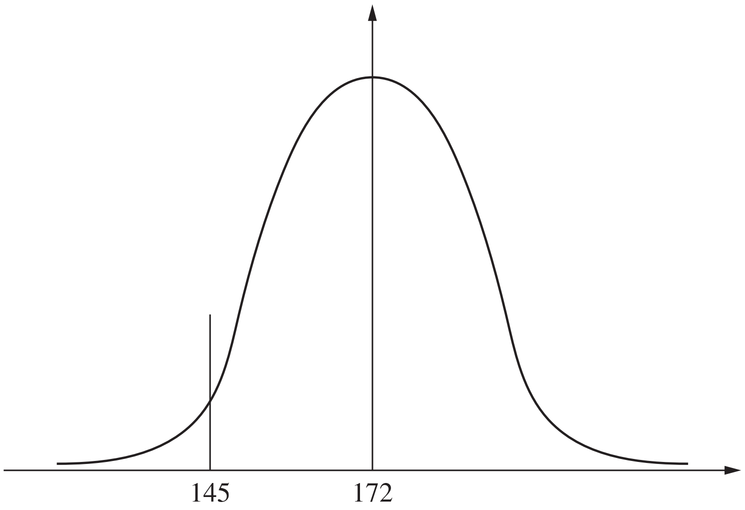


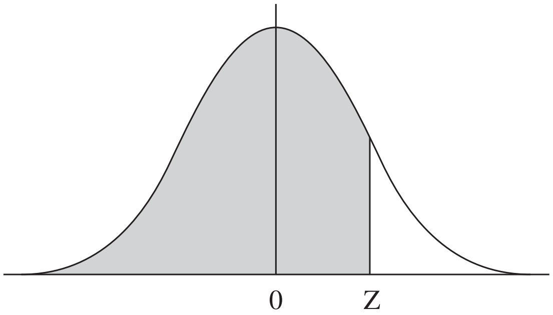
Figure 19.22 Distribution of strength.

The safety margin says that the average strength is 2.08 standard deviations above the maximum expected temperature of 145°F (63°C). Table 19.16 can be used to calculate a reliability of 0.981 [the area beyond 145°F (63°C)].

This calculation illustrates the importance of variation in addition to the average value during design. Designers have always recognized the existence of variation by using a safety factor in design. However, the safety factor is often defined as the ratio of average strength to the worst stress expected.

TABLE A

Normal distribution



Proportion of total areas under the curve from $-\infty$ to $Z = \frac{X-\mu}{\sigma}$, To illustrate when $Z = 2$, the probability is .9773 of obtaining a value equal to or less then X.

Z	0.09	0.08	0.07	0.06	0.05	0.04	0.03	0.02	0.01	0.00
−3.0	.00100	.00104	.00107	.00111	.00114	.00118	.00122	.00126	.00131	.00135
−2.9	.0014	.0014	.0015	.0015	.0016	.0016	.0017	.0017	.0018	.0019
−2.8	.0019	.0020	.0021	.0021	.0022	.0023	.0023	.0024	.0025	.0026
−2.7	.0026	.0027	.0028	.0029	.0030	.0031	.0032	.0033	.0034	.0035
−2.6	.0036	.0037	.0038	.0039	.0040	.0041	.0043	.0044	.0045	.0047
−2.5	.0048	.0049	.0051	.0052	.0054	.0055	.0057	.0059	.0060	.0062
−2.4	.0064	.0066	.0068	.0069	.0071	.0073	.0075	.0078	.0080	.0082
−2.3	.0084	.0087	.0089	.0091	.0094	.0096	.0099	.0102	.0104	.0107
−2.2	.0110	.0113	.0116	.0119	.0122	.0125	.0129	.0132	.0136	.0139
−2.1	.0143	.0146	.0150	.0154	.0158	.0162	.0166	.0170	.0174	.0179
−2.0	.0183	.0188	.0192	.0197	.0202	.0207	.0212	.0217	.0222	.0228
−1.9	.0233	.0239	.0244	.0250	.0256	.0262	.0268	.0274	.0281	.0287
−1.8	.0294	.0301	.0307	.0314	.0322	.0329	.0336	.0344	.0351	.0359
−1.7	.0367	.0375	.0384	.0392	.0401	.0409	.0418	.0427	.0436	.0446
−1.6	.0455	.0465	.0475	.0485	.0495	.0505	.0516	.0526	.0537	.0548
−1.5	.0559	.0571	.0582	.0594	.0606	.0618	.0630	.0643	.0655	.0668
−1.4	.0681	.0694	.0708	.0721	.0735	.0749	.0764	.0778	.0793	.0808
−1.3	.0823	.0838	.0853	.0869	.0885	.0901	.0918	.0934	.0951	.0968
−1.2	.0985	.1003	.1020	.1038	.1057	.1075	.1093	.1112	.1131	.1151
−1.1	.1170	.1190	.1210	.1230	.1251	.1271	.1292	.1314	.1335	.1357

(*Source: Quality Planning and Analysis*, Copyright 2007. Used by permission.)

TABLE 19.16 Normal Distribution

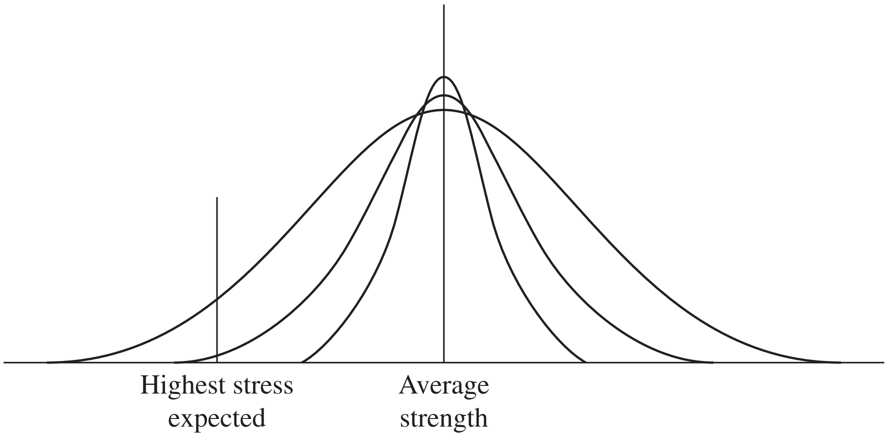


Figure 19.23 Variation and safety factor. (*Quality Planning and Analysis, Copyright 2007. Used by permission.*)

Note that in Figure 19.23, all designs have the same safety factor. Also note that the reliability (probability of a part having a strength greater than the stress) varies considerably. Thus, the uncertainty often associated with this definition of safety factor is, in part, due to its failure to reflect the variation in both strength and stress. Such variation is partially reflected in a safety margin, defined as

$$\frac{\text{Average strength} - \text{worst stress}}{\text{Standard deviation of strength}}$$

This recognizes the variation in strength but is conservative because it does not recognize a variation in stress.

Availability

Availability has been defined as the probability that a product, when used under given conditions, will perform satisfactorily when called upon. Availability considers the operating time of the product and the time required for repairs. Idle time, during which the product is not needed, is excluded.

Availability is calculated as the ratio of operating time to operating time plus downtime. However, downtime can be viewed in two ways:

- *Total downtime*. This period includes active repair (diagnosis and repair time), preventive maintenance time, and logistics time (time spent waiting for personnel, spare parts, etc.). When total downtime is used, the resulting ratio is called operational availability (A_0).
- *Active repair time*. The resulting ratio is called intrinsic availability (A_i). Under certain conditions, availability can be calculated as:

$$A_0 = \frac{\text{MTBF}}{\text{MTBF+MDT}} \qquad \text{and} \qquad A_i = \frac{\text{MTBF}}{\text{MTBF+MTTR}}$$

where MTBF = mean time between failures
MDT = mean downtime
MTTR = mean time to repair

This is known as the steady-state formula for availability. The steady-state formula for availability has the virtue of simplicity. However, the formula is based on several assumptions that are not always met in the real world. The assumptions are

- The product is operating in the constant failure rate period of the overall life. Thus, the failure-time distribution is exponential.
- The downtime or repair-time distribution is exponential.
- Attempts to locate system failures do not change the overall system failure rate.
- No reliability growth occurs (such growth might be due to design improvements or through debugging of bad parts).
- Preventive maintenance is scheduled outside the time frame included in the availability calculation.

More precise formulas for calculating availability depend on operational conditions and statistical assumptions. These formulas are discussed by Ireson et al. (1996).

Setting Specification Limits

A major step in the development of physical products is the conversion of product features into dimensional, chemical, electrical, and other characteristics of the product. Thus, a heating system for an automobile will have many characteristics for the heater, air ducts, blower assembly, engine coolant, etc.

For each characteristic, the designer must specify (1) the desired average (or "nominal value") and (2) the specification limits (or "tolerance limits") above and below the nominal value that individual units of product must meet. These two elements relate to parameter design and tolerance design, as discussed in Gryna et al. (2007).

The specification limits should reflect the functional needs of the product, manufacturing variability, and economic consequences. These three aspects are addressed in the next three sections. For greater depth in the statistical treatment of specification limits, see Anand (1996).

Specification Limits and Functional Needs

Sometimes data can be developed to relate product performance to measurements of a critical component. For example, a thermostat may be required to turn on and shut off a power source at specified low and high temperature values, respectively. A number of thermostat elements are built and tested. The prime recorded data are (1) turn-on temperature, (2) shut-off temperature, and (3) physical characteristics of the thermostat elements. We can then prepare scatter diagrams (Figure 19.24) and regression equations to help establish critical component tolerances on a scientific basis within the confidence limits for the numbers involved. Ideally, the sample size is sufficient, and the data come from a statistically controlled process—two conditions that are both rarely achieved. O'Connor (1995) explains how this approach can be related to the Taguchi approach to develop a more robust design.

Specification Limits and Manufacturing Variability

Generally, designers will not be provided with information on process capability. Their problem will be to obtain a sample of data from the process, calculate the limits that the process can meet, and compare these to the limits they were going to specify. If they do not have any limits in mind, the capability limits calculated from process data provide a set of limits that are realistic from the viewpoint of producibility. These limits must then be evaluated against the functional needs of the product.

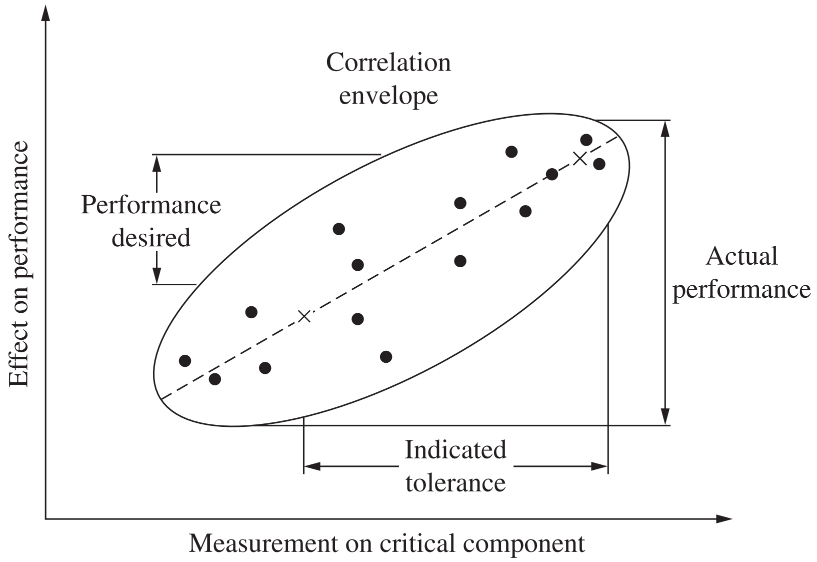


Figure 19.24 Approach to functional tolerancing. (*Quality Planning and Analysis, Copyright 2007. Used by permission.*)

Statistically, the problem is to predict the limits of variation of individual items in the total population based on a sample of data. For example, suppose that a product characteristic is normally distributed with a population average of 5.000 in (12.7 cm) and a population standard deviation of 0.001 in (0.00254 cm). Limits can then be calculated to include any given percentage of the population. Figure 19.25 shows the location of the 99 percent limits. Table 19.16 indicates that 2.575 standard deviations will include 99 percent of the population. Thus, in this example, a realistic set of tolerance limits would be

$$5.000 \pm 2.575(0.001) = \frac{5.003}{4.997}$$

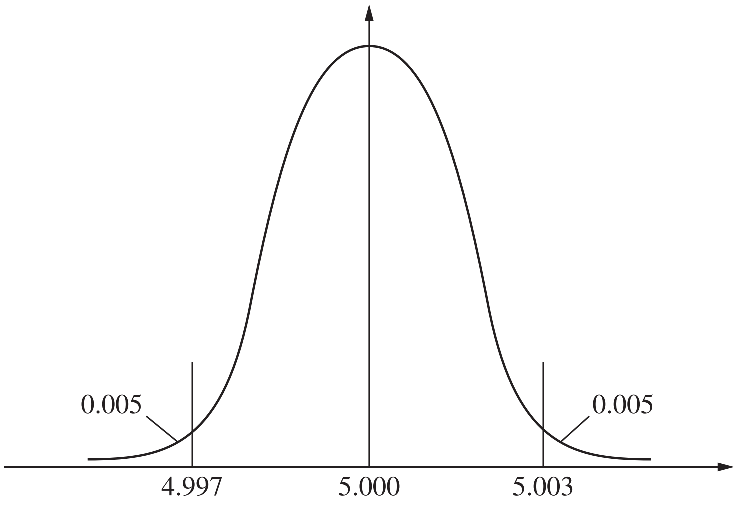


Figure 19.25 Distribution with 99 percent limits. (*Quality Planning and Analysis, Copyright 2007. Used by permission.*)

Ninety-nine percent of the individual pieces in the population will have values between 4.997 and 5.003.

In practice, the average and standard deviation of the population are not known but must be estimated from a sample of product from the process. As a first approximation, tolerance limits are sometimes set at

$$\overline{X} \pm 3s$$

Here, the average $\overline{X}$ and standard deviation s of the sample are used directly as estimates of the population values. If the true average and standard deviation of the population happen to be equal to those of the sample, and if the characteristic is normally distributed, then 99.73 percent of the pieces in the population will fall within the limits calculated. These limits are frequently called natural tolerance limits (limits that recognize the actual variation of the process and therefore are realistic). This approximation ignores the possible error in both the average and standard deviation as estimated from the sample.

Methodology has been developed for setting tolerance limits in a more precise manner. For example, formulas and tables are available for determining tolerance limits based on a normally distributed population. Table 19.17 provides factors for calculating tolerance limits that recognize the uncertainty in the sample mean and sample standard deviation. The tolerance limits are determined as

$$\overline{X} \pm Ks$$

The factor K is a function of the confidence level desired, the percentage of the population to be included within the tolerance limits, and the number of data values in the sample.

For example, suppose that a sample of 10 resistors from a process yielded an average and standard deviation of 5.04 and 0.016, respectively. The tolerance limits are to include 99 percent of the population, and the tolerance statement is to have a confidence level of 95 percent. Referring to Table 19.17, the value of K is 4.433, and tolerance limits are then calculated as

$$5.04 \pm 4.433(0.016) = \frac{5.11}{4.97}$$

We are 95 percent confident that at least 99 percent of the resistors in the population will have resistance between 4.97 and 5.11 Ω. Tolerance limits calculated in this manner are often called statistical tolerance limits. This approach is more rigorous than the 3*s* natural tolerance limits, but the two percentages in the statement are a mystery to those without a statistical background.

For products in some industries (e.g., electronics), the number of units outside of specification limits is stated in terms of parts per million (ppm). Thus, if limits are set at three standard deviations, 2700 ppm (100 to 99.73 percent) will fall outside the limits. For many applications (e.g., a personal computer with many logic gates), such a level is totally unacceptable. Table 19.18 shows the ppm for several standard deviations. These levels of ppm assume that the process average is constant at the nominal specification. A deviation from the nominal value will result in a higher ppm value. To allow for modest shifts in the process average, some manufacturers follow a guideline for setting specification limits at ±6σ.

Designers often must set tolerance limits with only a few measurements from the process (or more likely from the development tests conducted under laboratory conditions).

Tolerance Factors for Normal Distributions (Two Sided)										
P	γ = 0.75					γ = 0.90				
N	**0.75**	**0.90**	**0.95**	**0.99**	**0.999**	**0.75**	**0.90**	**0.95**	**0.99**	**0.999**
2	4.498	6.301	7.414	9.531	11.920	11.407	15.978	18.800	24.167	30.227
3	2.501	3.538	4.187	5.431	6.844	4.132	5.847	6.919	8.974	11.309
4	2.035	2.892	3.431	4.471	5.657	2.932	4.166	4.943	6.440	8.149
5	1.825	2.599	3.088	4.033	5.117	2.454	3.494	4.152	5.423	6.879
6	1.704	2.429	2.889	3.779	4.802	2.196	3.131	3.723	4.870	6.188
7	1.624	2.318	2.757	3.611	4.593	2.034	2.902	3.452	4.521	5.750
8	1.568	2.238	2.663	3.491	4.444	1.921	2.743	3.264	4.278	5.446
9	1.525	2.178	2.593	3.400	4.330	1.839	2.626	3.125	4.098	5.220
10	1.492	2.131	2.537	3.328	4.241	1.775	2.535	3.018	3.959	5.046
11	1.465	2.093	2.493	3.271	4.169	1.724	2.463	2.933	3.849	4.906
12	1.443	2.062	2.456	3.223	4.110	1.683	2.404	2.863	3.758	4.792
13	1.425	2.036	2.424	3.183	4.059	1.648	2.355	2.805	3.682	4.697
14	1.409	2.013	2.398	3.148	4.016	1.619	2.314	2.756	3.618	4.615
15	1.395	1.994	2.375	3.118	3.979	1.594	2.278	2.713	3.562	4.545
16	1.383	1.977	2.355	3.092	3.946	1.572	2.246	2.676	3.514	4.484
17	1.372	1.962	2.337	3.069	3.917	1.552	2.219	2.643	3.471	4.430
18	1.363	1.948	2.321	3.048	3.891	1.535	2.194	2.614	3.433	4.382
19	1.355	1.936	2.307	3.030	3.867	1.520	2.172	2.588	3.399	4.339
20	1.347	1.925	2.294	3.013	3.846	1.506	2.152	2.564	3.368	4.300
21	1.340	1.915	2.282	2.998	3.827	1.493	2.135	2.543	3.340	4.264
22	1.334	1.906	2.271	2.984	3.809	1.482	2.118	2.524	3.315	4.232
23	1.328	1.898	2.261	2.971	3.793	1.471	2.103	2.506	3.292	4.203
24	1.322	1.891	2.252	2.950	3.778	1.462	2.089	2.480	3.270	4.176
25	1.317	1.883	2.244	2.948	3.764	1.453	2.077	2.474	3.251	4.151
26	1.313	1.877	2.236	2.938	3.751	1.444	2.065	2.460	3.232	4.127
27	1.309	1.871	2.229	2.929	3.740	1.437	2.054	2.447	3.215	4.106
30	1.297	1.855	2.210	2.904	3.708	1.417	2.025	2.413	3.170	4.049
35	1.283	1.834	2.185	2.871	3.667	1.390	1.988	2.368	3.112	3.974
40	1.271	1.818	2.166	2.846	3.635	1.370	1.959	2.334	3.066	3.917
100	1.218	1.742	2.075	2.727	3.484	1.275	1.822	1.172	2.854	3.646
500	1.177	1.683	2.006	2.636	3.368	1.201	1.717	2.046	2.689	3.434
1000	1.169	1.671	1.992	2.617	3.344	1.185	1.695	2.019	2.654	3.390
∞	1.150	1.645	1.960	2.576	3.291	1.150	1.645	1.960	2.576	3.291

Table 19.17 Tolerance Factors for Normal Distributions

γ = 0.95					γ = 0.99				
0.75	**0.90**	**0.95**	**0.99**	**0.999**	**0.75**	**0.90**	**0.95**	**0.99**	**0.999**
22.858	32.019	37.674	48.430	60.573	114.363	160.363	188.491	242.300	303.054
5.922	8.380	9.916	12.861	16.208	13.378	18.930	22.401	29.055	36.616
3.779	5.369	6.370	8.299	10.502	6.614	9.398	11.150	14.527	18.383
3.002	4.275	5.079	6.634	8.415	4.643	6.612	7.855	10.260	13.015
2.604	3.712	4.414	5.775	7.337	3.743	5.337	6.345	8.301	10.548
2.361	3.369	4.007	5.248	6.676	3.233	4.613	5.488	7.187	9.142
2.197	3.136	3.732	4.891	6.226	2.905	4.147	4.936	6.468	8.234
2.078	2.967	3.532	4.631	5.899	2.677	3.822	4.550	5.966	7.600
1.987	2.839	3.379	4.433	5.649	2.508	3.582	4.265	5.594	7.129
1.916	2.737	3.259	4.277	5.452	2.378	3.397	4.045	5.308	6.766
1.858	2.655	3.162	4.150	5.291	2.274	3.250	3.870	5.079	6.477
1.810	2.587	3.081	4.044	5.158	2.190	3.130	3.727	4.893	6.240
1.770	2.529	3.012	3.955	5.045	2.120	3.029	3.608	4.737	6.043
1.735	2.480	2.954	3.878	4.949	2.060	2.945	3.507	4.605	5.876
1.705	2.437	2.903	3.812	4.865	2.009	2.872	3.421	4.492	5.732
1.679	2.400	2.858	3.754	4.791	1.965	2.808	3.345	4.393	5.607
1.655	2.366	2.819	3.702	4.725	1.926	2.753	3.279	4.307	5.497
1.635	2.337	2.784	3.656	4.667	1.891	2.703	3.221	4.230	5.399
1.616	2.310	2.752	3.615	4.614	1.860	2.659	3.168	4.161	5.312
1.599	2.286	2.723	3.577	4.567	1.833	2.620	3.121	4.100	5.234
1.584	2.264	2.697	3.543	4.523	1.808	2.584	3.078	4.044	5.163
1.570	2.244	2.673	3.512	4.484	1.795	2.551	3.040	3.993	5.098
1.557	2.225	2.651	3.483	4.447	1.764	2.522	3.004	3.947	5.039
1.545	2.208	2.631	3.457	4.413	1.745	2.494	2.972	3.904	4.985
1.534	2.193	2.612	3.432	4.382	1.727	2.460	2.941	3.865	4.935
1.523	2.178	2.595	3.409	4.353	1.711	2.446	2.914	3.828	4.888
1.497	2.140	2.549	3.350	4.278	1.668	2.385	2.841	3.733	4.768
1.462	2.090	2.490	3.272	4.179	1.613	2.306	2.748	3.611	4.611
1.435	2.052	2.445	3.213	4.104	1.571	2.247	2.677	3.518	4.493
1.311	1.874	2.233	2.934	3.748	1.383	1.977	2.355	3.096	3.954
1.215	1.737	2.070	2.721	3.475	1.243	1.777	2.117	2.783	3.555
1.195	1.709	2.036	2.676	3.418	1.214	1.736	2.068	2.718	3.472
1.150	1.645	1.960	2.576	3.291	1.150	1.645	1.960	2.576	3.291

[*] Table H—Tolerance factors for normal distributions" from *Selected Techniques of Statistical Analysis—OSRD* by C. Eisenhart, M. W. Hastay, and W. A. Wallis, Copyright 1947 by The McGraw-Hill Companies, Inc. Reprinted by permission of The McGraw-Hill Companies, Inc.

γ = confidence level

P = percentage of population within tolerance limits

N = number of values in sample

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Table 19.17 (*Continued*)

Number of Standard Deviations	Part per Million (ppm)
±3σ	2700
±4σ	63
±5σ	0.57
±6σ	0.002

*If the process is not centered and the mean shifts by up to 1.5σ, then ±6σ will be 3.4 ppm.

(*Source: Quality Planning and Analysis*, Copyright 2007. Used by permission.)

Table 19.18 Standard Deviations and PPM (centered process)*

In developing a paint formulation, for example, the following values of gloss were obtained: 76.5, 75.2, 77.5, 78.9, 76.1, 78.3, and 77.7. A group of chemists was asked where they would set a minimum specification limit. Their answer was 75.0—a reasonable answer for those without statistical knowledge. Figure 19.26 shows a plot of the data on normal probability paper. If the line is extrapolated to 75.0, the plot predicts that about 11 percent of the population will fall below 75.0, even though all of the sample data exceed 75.0. Of course, a larger

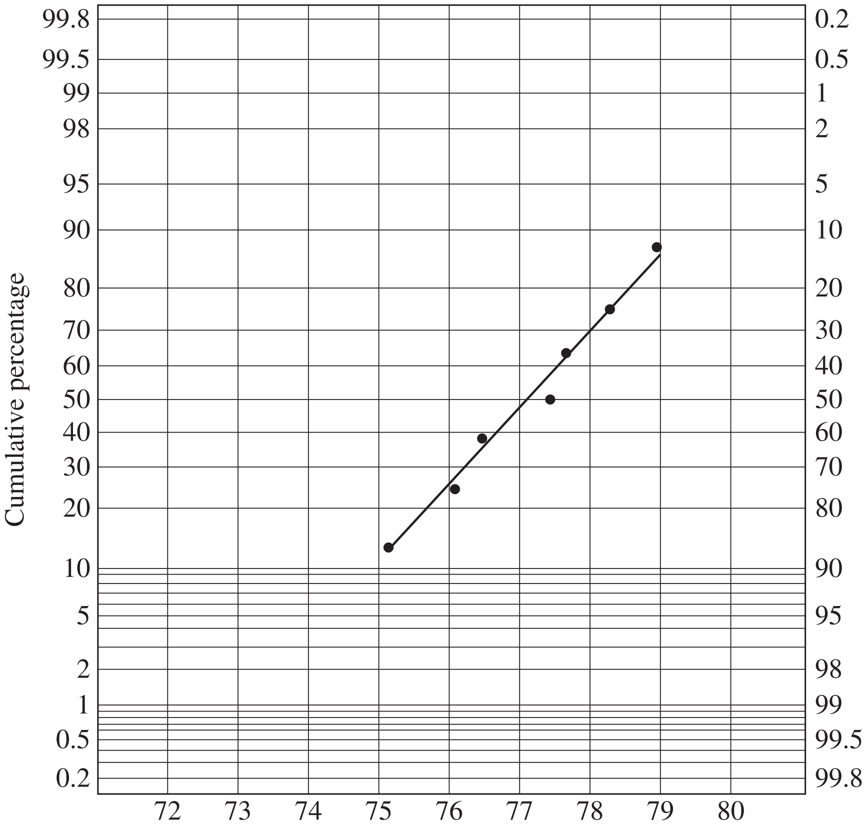

Figure 19.26 Probability plot of development data. (*Quality Planning and Analysis, Copyright 2007. Used by permission.*)

Name of Limit	Meaning
Tolerance	Set by the engineering design function to define the minimum and maximum values allowable for the product to work properly
Statistical tolerance	Calculated from process data to define the amount of variation that the process exhibits; these limits will contain a specified proportion of the total population
Prediction	Calculated from process data to define the limits which will contain all of *k* future observations
Confidence	Calculated from data to define an interval within which a population parameter lies
Control	Calculated from process data to define the limits of chance (random) variation around some central value

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Table 19.19 Distinctions Among Limits

sample size is preferred and further statistical analyses could be made, but the plot provides a simple tool for evaluating a small sample of data.

All methods of setting tolerance limits based on process data assume that the sample of data represents a process that is sufficiently stable to be predictable. In practice, the assumption is often accepted without any formal evaluation. If sufficient data are available, the assumption should be checked with a control chart.

Statistical tolerance limits are sometimes confused with other limits used in engineering and statistics. Table 19.19 summarizes the distinctions among five types of limits (see also Box, pp. 44.47–44.58).

Specifications Limits and Economic Consequences

In setting traditional specification limits around a nominal value, we assume that there is no monetary loss for product falling within specification limits. For product falling outside the specification limits, the loss is the cost of replacing the product.

Another viewpoint holds that any deviation from the nominal value causes a loss. Thus, there is an ideal (nominal) value that customers desire, and any deviation from this ideal results in customer dissatisfaction. This loss can be described by a loss function (Figure 19.27).

Many formulas can predict loss as a function of deviation from the target. Taguchi proposes the use of a simple quadratic loss function:

$$L = k(X - T)^2$$

where L = loss in monetary terms
k = cost coefficient
X = value of quality characteristic
T = target value

Ross (1996) provides an example to illustrate how the loss function can help to determine specification limits. In automatic transmissions for trucks, shift points are designed to

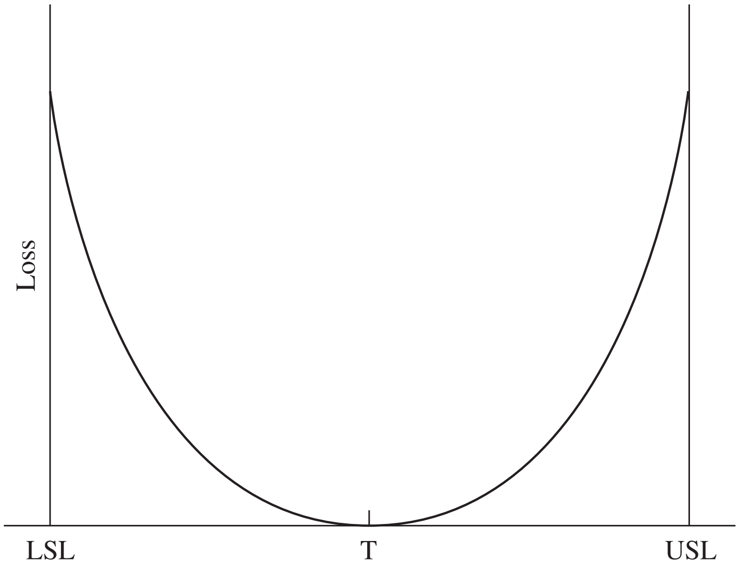


Figure 19.27 Loss function. (*Quality Planning and Analysis, Copyright 2007. Used by permission.*)

occur at a certain speed and throttle position. Suppose it costs the producer $100 to adjust a valve body under warranty when a customer complains of the shift point. Research indicates that the average customer would request an adjustment if the shift point is off from the nominal by 40 rpm transmission output speed on the first-to-second gear shift. The loss function is then

$$\text{Loss} = k(X - T)^2$$
$$100 = k(40)^2$$
$$k = \$0.0625$$

This adjustment can be made at the factory at a lower cost, about $10. The loss function is now used to calculate the specification limits:

$$\$10 = 0.0625(X - T)^2$$
$$(X - T) = \pm 12.65 \text{ or } \pm 13 \text{ rpm}$$

The specification limits should be set at 13 rpm around the desired nominal value. If the transmission shift point is further than 13 rpm from the nominal, adjustment at the factory is less expensive than waiting for a customer complaint and making the adjustment under warranty in the field. Ross (1996) discusses how the loss function can be applied to set one-sided specification limits (e.g., a minimum value or a maximum value).

Specification Limits for Interacting Dimensions

Interacting dimensions mate or merge with other dimensions to create a final result. Consider the simple mechanical assembly shown in Figure 19.28. The lengths of components A, B, and C are interacting dimensions because they determine the overall assembly length.

Suppose the components were manufactured to the specifications indicated in Figure 19.28. A logical specification for the assembly length would be 3.500 ± 0.0035, giving limits of

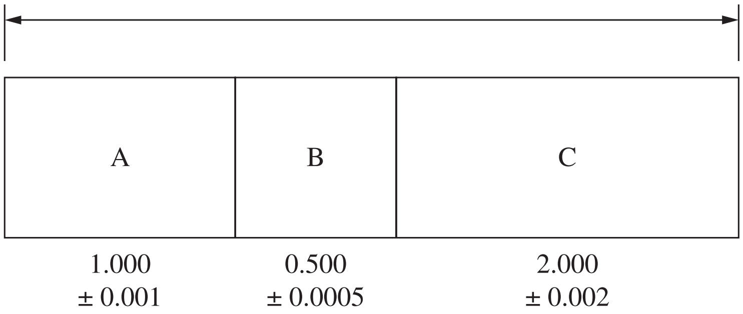


Figure 19.28 Mechanical assembly. (*Quality Planning and Analysis, Copyright 2007. Used by permission.*)

3.5035 and 3.4965. This logic may be verified from the two extreme assemblies shown in the following table.

Maximum	Minimum
1.001	0.999
0.5005	0.4995
2.002	1.998
3.5035	3.4965

The approach of adding component tolerances is mathematically correct, but is often too conservative. Suppose that about 1 percent of the pieces of component A are expected to be below the lower tolerance limit for component A and suppose the same for components B and C. If a component A is selected at random, there is, on average, 1 chance in 100 that it will be on the low side, and similarly for components B and C. The key point is this: If assemblies are made at random and if the components are manufactured independently, then the chance that an assembly will have all three components simultaneously below the lower tolerance limit is

$$\frac{1}{100} \times \frac{1}{100} \times \frac{1}{100} = \frac{1}{1{,}000{,}000}$$

There is only about one chance in a million that all three components will be too small, resulting in a small assembly. Thus, setting component and assembly tolerances based on the simple addition formula is conservative in that it fails to recognize the extremely low probability of an assembly containing all low (or all high) components.

The statistical approach is based on the relationship between the variances of a number of independent causes and the variance of the dependent or overall result. This may be written as

$$\sigma_{\text{result}} = \sqrt{\sigma^2{}_{\text{causeA}} + \sigma^2{}_{\text{causeB}} + \sigma^2{}_{\text{causeC}} + \ldots}$$

In terms of the assembly example, the formula is:

$$\sigma_{\text{assembly}} = \sqrt{\sigma_A^2 + \sigma_B^2 + \sigma_C^2}$$

Now suppose that for each component, the tolerance range is equal to three standard deviations (or any constant multiple of the standard deviation). Because σ is equal to T divided by 3, the variance relationship may be rewritten as

$$\frac{T}{3} = \sqrt{\left(\frac{T_A}{3}\right)^2 + \left(\frac{T_B}{3}\right)^2 + \left(\frac{T_C}{3}\right)^2}$$

or

$$T_{\text{assembly}} = \sqrt{T_A^2 + T_B^2 + T_C^2}$$

Thus, the squares of tolerances are added to determine the square of the tolerance for the overall result. This formula compares to the simple addition of tolerances commonly used.

The effect of the statistical approach is dramatic. Listed below are two possible sets of component tolerances that will yield an assembly tolerance equal to 0.0035 when used with the previous formula.

Component	Alternative 1	Alternative 2
A	±0.002	±0.001
B	±0.002	±0.001
C	±0.002	±0.003

With alternative 1, the tolerance for component A has been doubled, the tolerance for component B has been quadrupled, and the tolerance for component C has been kept the same as the original component tolerance based on the simple addition approach. If alternative 2 is chosen, similar significant increases in the component tolerances may be achieved. This formula, then, may result in a larger component tolerance with no change in the manufacturing processes and no change in the assembly tolerance.

The risk of this approach is that an assembly may fall outside the assembly tolerance. However, this probability can be calculated by expressing the component tolerances as standard deviations, calculating the standard deviation of the result, and finding the area under the normal curve outside the assembly tolerance limits. For example, if each component tolerance is equal to $3s$, then 99.73 percent of the assemblies will be within the assembly tolerance, that is, 0.27 percent, or about 3 assemblies in 1000 taken at random would fail to meet the assembly tolerance. The risk can be eliminated by changing components for the few assemblies that do not meet the assembly tolerance.

The tolerance formula is not restricted to outside dimensions of assemblies. Generalizing, the left side of the equation contains the dependent variable or physical result, and the right side of the equation contains the independent variables of physical causes. If the result is placed on the left and the causes on the right, the formula always has plus signs under the square root—even if the result is an internal dimension (such as the clearance between a shaft and hole). The causes of variation are additive wherever the physical result happens to fall.

The formula has been applied to a variety of mechanical and electronic products. The concept may be applied to several interacting variables in an engineering relationship. The nature of the relationship need not be additive (assembly example) or subtractive (shaft-and-hole example). The tolerance formula can be adapted to predict the variation of results that are the product and/or the division of several variables.

Assumptions of the formula. The formula is based on several assumptions:

- The component dimensions are independent and each component to be assembled is chosen randomly. These assumptions are usually met in practice.
- Each component dimension should be normally distributed. Some departure from this assumption is permissible.
- The actual average for each component is equal to the nominal value stated in the specification. For the original assembly example, the actual averages for components A, B, and C must be 1.000, 0.500, and 2.000, respectively. Otherwise, the nominal value of 3.500 will not be achieved for the assembly and tolerance limits set at about 3.500 will not be realistic. Thus it is important to control the average value for interacting dimensions. Consequently, process control techniques are needed using variables measurement.

Use caution if any assumption is violated. Reasonable departures from the assumptions may still permit applying the concept of the formula. Notice that in the example, the formula resulted in the doubling of certain tolerances. This much of an increase may not even be necessary from the viewpoint of process capability.

Bender (1975) has studied these assumptions for some complex assemblies and concluded, based on a "combination of probability and experience," that a factor of 1.5 should be included to account for the assumptions:

$$T_{\text{result}} = 1.5\sqrt{T_A^2 + T_B^2 + T_C^2 + \cdots}$$

Graves (1997) suggests developing different factors for initial versus mature production, high versus low volume production, and mature versus developing technology and measurement processes.

Finally, variation simulation analysis is a technique that uses computer simulation to analyze tolerances. This technique can handle product characteristics with either normal or nonnormal distributions. Dodson (1999) describes the use of simulation in the tolerance design of circuits; Gomer (1998) demonstrates simulation to analyze tolerances in engine design. For an overall text on reliability, see Meeker and Escobar (1998).

Statistical Tools for Control

In addition to the fundamental control charts introduced in Chapter 18, Core Tools to Design, Control, and Improve Performance, there are some special-purpose methods for control that are sometimes helpful.

PRE-Control

PRE-Control is a statistical technique for detecting process conditions and changes that may cause defects (rather than changes that are statistically significant). PRE-Control focuses on controlling conformance to specifications, rather than statistical control. PRE-Control starts a process centered between specification limits and detects shifts that might result in making some of the parts outside a specification limit. It requires no plotting and no computations, and it needs only three measurements to give control information. The technique uses the normal distribution curve to determine significant changes in either the aim or the spread of a production process that could result in increased production of defective work.

The relative simplicity of PRE-Control versus statistical control charts can have important advantages in many applications. The concept, however, has generated some controversy. For a comparison of PRE-Control versus other approaches and the most appropriate applications of PRE-Control, see Ledolter and Swersey (1997) and Steiner (1997). For a complete story, also see the references in both of these papers.

Short-Run Control Charts

Some processes are carried out in such short runs that the usual procedure of collecting 20 to 30 samples to establish a control chart is not feasible. Sometimes these short runs are caused by previously known assignable causes that take place at predetermined times (such as a frequent shift in production from one product to another, as may be the case in lean production systems). Hough and Pond (1995) discuss four ways to construct control charts in these situations:

1. Ignore the systematic variability, and plot on a single chart.
2. Stratify the data, and plot them on a single chart.
3. Use regression analysis to model the data, and plot the residuals on a chart.
4. Standardize the data, and plot the standardized data on a chart.

The last option has received the most consideration. It involves transforming the data via the Z-transformation:

$$Z = \frac{X - \mu}{\sigma}$$

to remove any systematic changes in level and variability (thereby normalizing the data to a common baseline). This standardization of Shewhart charts has been discussed by Nelson (1989), Wheeler (1991), and Griffith (1996). Pyzdek (1993) also provides a good discussion of short and small runs.

Cumulative Sum Control Chart

The cumulative sum (CUMSUM or CUSUM) control chart is a chronological plot of the cumulative sum of deviations of a sample statistic (e.g., $\overline{X}$, p, number of nonconformities) from a reference value (e.g., the nominal or target specification). By definition, the CUMSUM chart focuses on a target value rather than on the actual average of process data. Each point plotted contains information from all observations (i.e., a cumulative sum). CUMSUM charts are particularly useful in detecting small shifts in the process average (say, 0.5σ to 2.0σ). The chart shown in Figure 19.29 is one way of constructing CUMSUM charts. The method is as follows:

1. Compute the control statistic (x-bar for the example in Figure 19.29).
2. Determine the target value T (10 in Figure 19.29).
3. Compute the standard deviation s (1.96 in Figure 19.29).
4. Draw a reference line at zero and upper and lower control limits (UCL and LCL respectively) at ±4s.
5. Compute the upper cumulative sum C_U for each sample point k as follows:

$$C_{U,k} = \text{Maximum}\left\{0, \sum_{i=1}^{k}[\overline{x}_i - (T + s/2)]\right\}$$

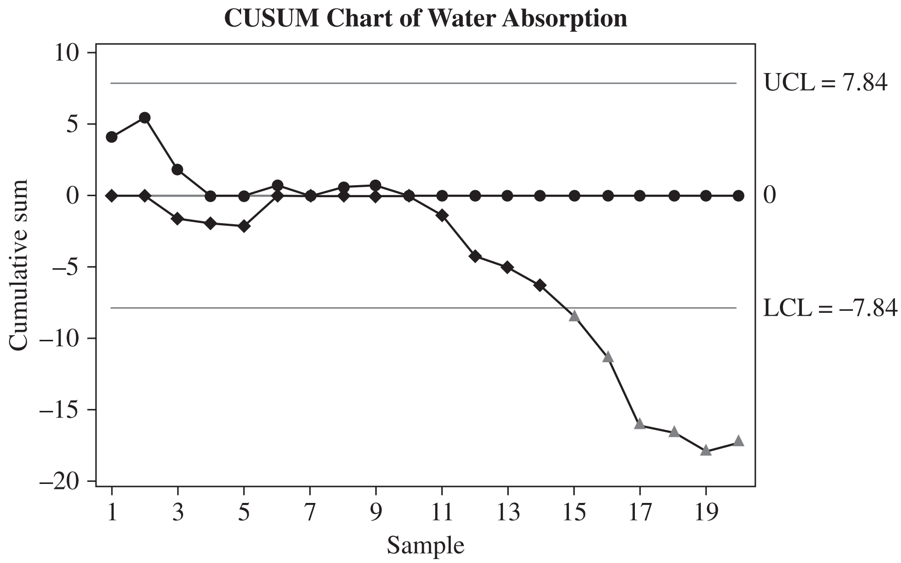


Figure 19.29 Cumulative sum control chart. (*Juran Institute, Inc. Copyright 1994. Used by permission.*)

6. Compute the upper cumulative sum C_L for each sample point k as follows:

$$C_{L,k} = \text{Minimum}\left\{0, \sum_{i=1}^{k} [\bar{x}_i - (T - s/2)]\right\}$$

7. Plot C_U and C_L as two separate lines.
8. When C_U exceeds the UCL, then an upward shift has occurred. When C_L drops below LCL, then a downward shift has occurred.

Moving Average Control Charts

Another special chart is the moving average chart. This chart is a chronological plot of the moving average, which is calculated as the average value updated by dropping the oldest individual measurement and adding the newest individual measurement. Thus, a new average is calculated with each individual measurement. A further refinement is the exponentially weighted moving average (EWMA) chart. In the EWMA chart, the observations are weighted, and the highest weight is given to the most recent data. Moving average charts are effective in detecting small shifts, highlighting trends, and using data in processes in which it takes a long time to produce a single item.

Box-Jenkins Manual Adjustment Chart

Still another chart is the Box-Jenkins manual adjustment chart. The average and range, CUMSUM, and EWMA charts for variables focus on monitoring a process and reducing variability due to special causes of variation identified by the charts. Box-Jenkins charts have a different objective: to analyze process data to regulate the process after each observation and thereby minimize process variation. For elaboration on this advanced technique, see Box and Luceño (1997).

Multivariate Control Charts

Finally, we consider the concept of multivariate control charts. When there are two or more quality characteristics on a unit of product, these could be monitored independently with separate control charts. Then the probability that a sample average on either control chart exceeds three sigma limits is 0.0027. But the joint probability that both variables exceed their control limits simultaneously when they are both in control is (0.0027)(0.0027) or 0.00000729, which is much smaller than 0.0027. The situation becomes more distorted as the number of characteristics increases. For this and other reasons, monitoring several characteristics independently can be misleading. Multivariate control charts and statistics (e.g., Hotelling's T^2 charts, multivariate EWMA) address this issue. See Montgomery (2000, Section 8.4) for a highly useful discussion.

Process Capability

In planning the quality aspects of operations, nothing is more important than advance assurance that the processes will meet the specifications. In recent decades, a concept of process capability has emerged to provide a quantified prediction of process adequacy. This ability to predict quantitatively has resulted in widespread adoption of the concept as a major element of quality planning. Process capability is the measured, inherent variation of the product turned out by a process.

Basic definitions. Each key word in this definition must itself be clearly defined because the concept of capability has an enormous extent of application, and nonscientific terms are inadequate for communication within the industrial community.

- Process refers to some unique combination of machine, tools, methods, materials, and people engaged in production. It is often feasible and illuminating to separate and quantify the effect of the variables entering this combination.
- Capability refers to an ability, based on tested performance, to achieve measurable results.
- Measured capability refers to the fact that process capability is quantified from data that, in turn, are the results of measurement of work performed by the process.
- Inherent capability refers to the product uniformity resulting from a process that is in a state of statistical control (i.e., in the absence of time-to-time "drift" or other assignable causes of variation). "Instantaneous reproducibility" is a synonym for inherent capability.
- The product is measured because product variation is the end result.

Uses of process capability information. Process capability information serves multiple purposes:

- Predicting the extent of variability that processes will exhibit. Such capability information, when provided to designers, provides important information in setting realistic specification limits.
- Choosing from among competing processes that are most appropriate to meet the tolerances.
- Planning the interrelationship of sequential processes. For example, one process may distort the precision achieved by a predecessor process, as in hardening of gear teeth. Quantifying the respective process capabilities often points the way to a solution.
- Providing a quantified basis for establishing a schedule of periodic process control checks and readjustments.
- Assigning machines to classes of work for which they are best suited.

- Testing theories of causes of defects during quality improvement programs.
- Serving as a basis for specifying the quality performance requirements for purchased machines.

These purposes account for the growing use of the process capability concept.

Planning for a process capability study. Capability studies are conducted for various reasons, for example, to respond to a customer request for a capability index number or to evaluate and improve product quality. Prior to data collection, clarify the purpose for making the study and the steps needed to ensure that it is achieved.

In some cases, the capability study will focus on determining a histogram and capability index for a relatively simple process. Here the planning should ensure that process conditions (e.g., temperature, pressure) are completely defined and recorded. All other inputs must clearly be representative (i.e., specific equipment, material, and, of course, personnel).

For more complex processes or when defect levels of 1 to 10 parts per million are desired, the following steps are recommended:

1. Develop a process description, including inputs, process steps, and output quality characteristics. This description can range from simply identifying the equipment to developing a mathematical equation that shows the effect of each process variable on the quality characteristics.
2. Define the process conditions for each process variable. In a simple case, this step involves stating the settings for temperature and pressure. But for some processes, it means determining the optimum value or aim of each process variable. The statistical design of experiments provides the methodology. Also, determine the operating ranges of the process variables around the optimum because the range will affect the variability of the product results.
3. Make sure that each quality characteristic has at least one process variable that can be used to adjust it.
4. Decide whether measurement error is significant. This can be determined from a separate error of measurement study. In some cases, the error of measurement can be evaluated as part of the overall study.
5. Decide whether the capability study will focus only on variability or will also include mistakes or errors that cause quality problems.
6. Plan for the use of control charts to evaluate the stability of the process.
7. Prepare a data collection plan, including adequate sample size that documents results on quality characteristics along with the process conditions (e.g., values of all process variables) and preserves information on the order of measurements so that trends can be evaluated.
8. Plan which methods will be used to analyze data from the study to ensure that before starting the study, all necessary data for the analysis will be available. The analyses should include process capability calculations on variability and also analysis of attribute or categorical data on mistakes and analysis of data from statistically designed experiments built into the study.
9. Be prepared to spend time investigating interim results before process capability calculations can be made. These investigations can include analysis of optimum values and ranges of process variables, out-of-control points on control charts, or other unusual results. The investigations then lead to the ultimate objective, that is, improvement of the process.

Note that these steps focus on improvement rather than just on determining a capability index.

Standardized process capability formula. The most widely adopted formula for process capability is:

$$\text{Process capability} = \pm 3\sigma \text{ (a total of } 6\sigma)$$

where σ is the standard deviation of the process under a state of statistical control (i.e., under no drift and no sudden changes). If the process is centered at the nominal specification and follows a normal probability distribution, 99.73 percent of production will fall within 3σ of the nominal specification.

Relationship to product specifications. A major reason for quantifying process capability is to compute the ability of the process to hold product specifications. For processes that are in a state of statistical control, a comparison of the variation of 6*s* to the specification limits permits ready calculation of percentage defective by conventional statistical theory.

Planners try to select processes with the 6*s* process capability well within the specification width. A measure of this relationship is the capability ratio:

$$C_p = \text{capability ratio} = \frac{\text{specification range}}{\text{process capability}} = \frac{\text{USL} - \text{LSL}}{6\text{s}}$$

where USL is the upper specification limit and LSL is the lower specification limit.

Note that 6*s* is used as an estimate of 6σ.

Some companies define the ratio as the reciprocal. Some industries now express defect rates in terms of parts per million. A defect rate of one part per million requires a capability ratio (specification range over process capability) of about 1.63.

Figure 19.30 shows four of many possible relations between process variability and specification limits and the likely courses of action for each. Note that in all of these cases, the average of the process is at the midpoint between the specification limits.

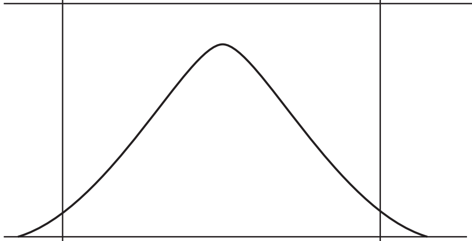
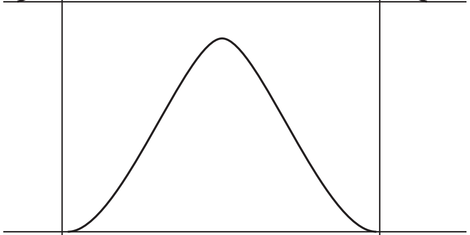
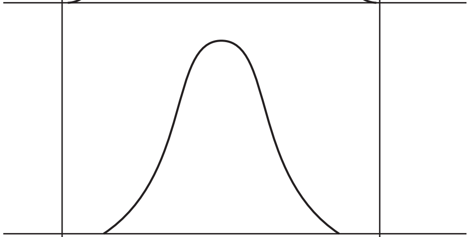
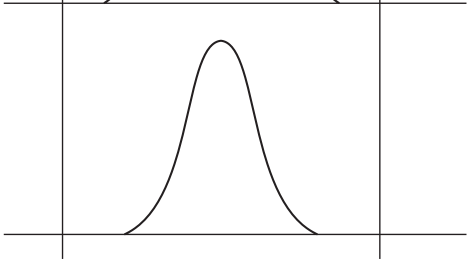
Table 19.20 shows selected capability ratios and the corresponding level of defects, assuming that the process average is midway between the specification limits. A process that is just meeting specification limits (specification range ±3σ) has a C_p of 1.0. The criticality of many applications and the reality that the process average will not remain at the midpoint of the specification range suggest that C_p should be at least 1.33. Note that a process operating at $C_p = 2.0$ over the short term (and centered midway between the specification limits) will correspond to a process sigma capability measure of $3C_p$, or 6 sigma (allowing for a 1.5s shift over the long term. This corresponds to 6*s* – 1.5*s* = 4.5*s*, which is expected to produce 3.4 ppm outside of the two-sided specification limits over the long term).

Note that the C_p index measures whether the process variability can fit within the specification range. It does not indicate whether the process is actually running within the specification because the index does not include a measure of the process average (this issue is addressed by another measure, C_{pk}).

Three capability indexes commonly in use are shown in Table 19.21. Of these, the simplest is C_p. The higher the value of any indexes, the lower the amount of product outside the specification limits.

Pignatiello and Ramberg (1993) provide an excellent discussion of various capability indexes. Bothe (1997) provides a comprehensive reference book that includes extensive discussion of the mathematical aspects. These references explain how to calculate confidence bounds for various process capability indexes.

The C_{pk} capability index. Process capability, as measured by C_{pk}, refers to the variation in a process about the average value. This concept is illustrated in Figure 19.31. The two processes have equal capabilities (C_p) because 6σ is the same for each distribution, as indicated by the

Process	C_p	Total amount outside limits	Typical actions to be taken
	<1.0	≥5.0%	Heavy process control, sorting, rework, etc.
	1.0	0.3%	Heavy process control, inspection
	1.33	64 ppm	Reduced inspection, selected use of control charts
	1.63	1 ppm	Spot checking, selected use of control charts

LSL USL

FIGURE 19.30 Four examples of process variability. (*Quality Planning and Analysis, Copyright 2007. Used by permission.*)

widths of the distribution curves. The process aimed at μ2 is producing defectives because the aim is off center, not because of the inherent variation about the aim (i.e., the capability).

Thus, the C_p index measures potential capability, assuming that the process average is equal to the midpoint of the specification limits and the process is operating in statistical control; because the average is often not at the midpoint, it is useful to have a capability index that reflects both variation and the location of the process average. Such an index is C_{pk}.

C_{pk} reflects the current process mean's proximity to either the USL or LSL. C_{pk} is estimated by

$$\hat{C}_{pk} = \min\left[\frac{\bar{X} - \text{LSL}}{3s}, \frac{\text{USL} - \bar{X}}{3s}\right]$$

In an example from Kane (1986),

$$\text{USL} = 20 \quad \bar{X} = 16$$
$$\text{LSL} = 8 \quad s = 2$$

Process Capability Index (C_p)	Total Product Outside Two-Sided Specification Limits*
0.5	13.36%
0.67	4.55%
1.00	0.3%
1.33	64 ppm
1.63	1 ppm
2.00	0

*Assuming that the process is centered midway between the specification limits.
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Table 19.20 Process Capability index (C_p) and Product Outside Specification Limits

Process Capability	Process Performance
$C_p = \dfrac{\text{USL}-\text{LSL}}{6\sigma}$	$P_p = \dfrac{\text{USL}-\text{LSL}}{6s}$
$C_{pk} = \min\left[\dfrac{\text{USL}-\mu}{3\sigma}, \dfrac{\mu-\text{LSL}}{3\sigma}\right]$	$P_{pk} = \min\left[\dfrac{\text{USL}-\bar{X}}{3s}, \dfrac{\bar{X}-\text{LSL}}{3s}\right]$
$C_{pm} = \dfrac{\text{USL}-\text{LSL}}{6\sqrt{\sigma^2+(\mu-T)^2}}$	$P_{pm} = \dfrac{\text{USL}-\text{LSL}}{6\sqrt{s^2+(\bar{X}-T)^2}}$

(*Source: Quality Planning and Analysis*, Copyright 2007. Used by permission.)

Table 19.21 Process Capability and Process Performance Indexes

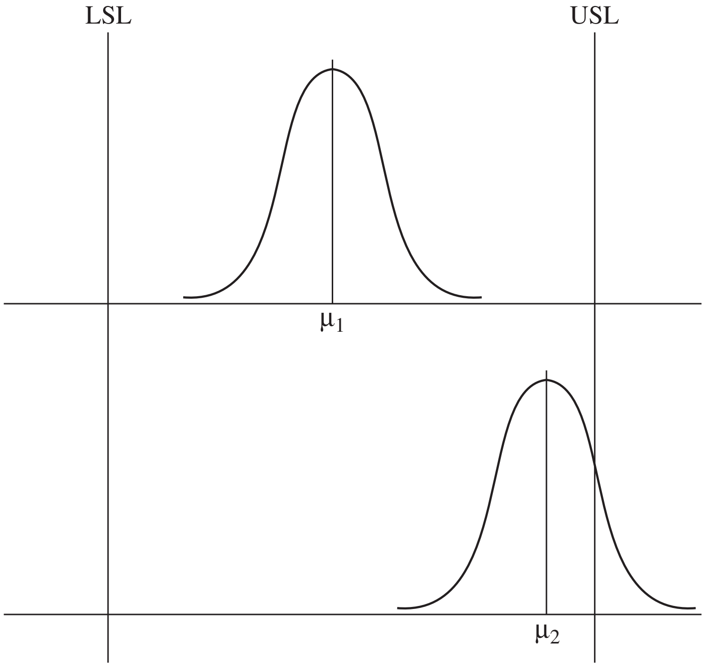


Figure 19.31 Process with Equal Process Capability but Different Aim. (*Quality Planning and Analysis. Copyright 2007. Used by permission.*)

The standard capability ratio is estimated as

$$\frac{\text{USL} - \text{LSL}}{6\sigma} = \frac{20 - 8}{12} = 1.0$$

which implies that if the process were centered between the specification limits (at 14), then only a small proportion (about 0.27 percent) of product would be defective.

However, when we calculate C_{pk}, we obtain

$$\hat{C}_{pk} = \min\left[\frac{16-8}{6}, \frac{20-16}{12}\right] = 0.67$$

which indicates that the process mean is currently nearer the USL. (Note that if the process were centered at 14, the value of C_{pk} would be 1.0.) An acceptable process will require reducing the standard deviation and/or centering the mean. Also note that if the actual average is equal to the midpoint of the specification range, then $C_{pk} = C_p$.

The higher the value of C_p, the lower the amount of product outside specification limits. In certifying suppliers, some organizations use C_{pk} as one element of certification criteria. In these applications, the value of C_{pk} desired from suppliers can be a function of the type of commodity purchased.

A capability index can also be calculated around a target value rather than the actual average. This index, called C_{pm} or the Taguchi index, focuses on reduction of variation from a target value rather than reduction of variability to meet specifications.

Most capability indexes assume that the quality characteristic is normally distributed. Krishnamoorthi and Khatwani (2000) propose a capability index for handling normal and nonnormal characteristics by first fitting the data to a Weibull distribution.

Two types of process capability studies are as follows:

1. *Study of process potential*. In this study, an estimate is obtained of what the process can do under certain conditions (i.e., variability under short-run defined conditions for a process in a state of statistical control). The C_p index estimates the potential process capability.
2. *Study of process performance*. In this study, an estimate of capability provides a picture of what the process is doing over an extended period. A state of statistical control is also assumed. The C_{pk} index estimates the performance capability.

Estimating inherent or potential capability from control chart analysis. In a process potential study, data are collected from a process operating without changes in material batches, workers, tools, or process settings. This short-term evaluation uses consecutive production over one time period. Such an analysis should be preceded by a control chart analysis in which any assignable causes have been detected and eliminated from the process.

Because specification limits usually apply to individual values, control limits for sample averages cannot be compared to specification limits. To make a comparison, we must first convert *R* to the standard deviation for individual values, calculate the 3*s* limits, and compare them to the specification limits. This process is explained below.

If a process is in statistical control, it is operating with the minimum amount of variation possible (the variation due to chance causes). If, and only if, a process is in statistical control, the following relationship holds for using *s* as an estimate of σ:

$$s = \frac{\bar{R}}{d_2}$$

Tables 19.22 and 19.23 provide values of d_2. If the standard deviation is known, process capability limits can be set at ±3σ, and this value used as an estimate of 3σ.

Factors for $\bar{X}$ and R Control Charts;[*] Factors for Estimating s from R[†]

Number of Observations in Sample	A_2	D_3	D_4	Factor for Estimate from $\bar{R}$: $d_2 = \bar{R}/s$
2	1.880	0	3.268	1.128
3	1.023	0	2.574	1.693
4	0.729	0	2.282	2.059
5	0.577	0	2.114	2.326
6	0.483	0	2.004	2.534
7	0.419	0.076	1.924	2.704
8	0.373	0.136	1.864	2.847
9	0.337	0.184	1.816	2.970
10	0.308	0.223	1.777	3.078
11	0.285	0.256	1.744	3.173
12	0.266	0.284	1.717	3.258
13	0.249	0.308	1.692	3.336
14	0.235	0.329	1.671	3.407
15	0.223	0.348	1.652	3.472

$$\begin{cases} \text{Upper control limit for } \bar{X} = \text{UCL}_{\bar{X}} = \bar{\bar{X}} + A_2\bar{R} \\ \text{Lower control limit for } \bar{X} = \text{LCL}_{\bar{X}} = \bar{\bar{X}} - A_2\bar{R} \end{cases}$$

$$\begin{cases} \text{Upper control limit for } R = \text{UCL}_R = D_4\bar{R} \\ \text{Lower control limit for } R = \text{LCR}_R = D_3\bar{R} \end{cases}$$

$$s = \bar{R}/d_2$$

From *1950 ASTM Manual on Quality Control of Materials* and *ASTM Manual on Presentation of Data, 1945.* American Society for Testing and Materials. Copyright ASTM International. Reprinted with permission. (*Source: Quality Planning and Analysis*, Copyright 1997. Used by permission.)

Table 19.22 Factors for $\bar{X}$ and R Control Charts

n	A_2	D_3	D_4	d_2
2	1.880	0	3.268	1.128
3	1.023	0	2.574	1.693
4	0.729	0	2.282	2.059
5	0.577	0	2.114	2.326
6	0.483	0	2.004	2.534
7	0.419	0.076	1.924	2.704
8	0.373	0.136	1.864	2.847
9	0.337	0.184	1.816	2.970
10	0.308	0.223	1.777	3.079

(*Source: Quality Planning and Analysis*, Copyright 2007. Used by permission.)

Table 19.23 Constants for $\bar{X}$ and R Chart

For the data shown in Figure 19.32 (machine N-5),

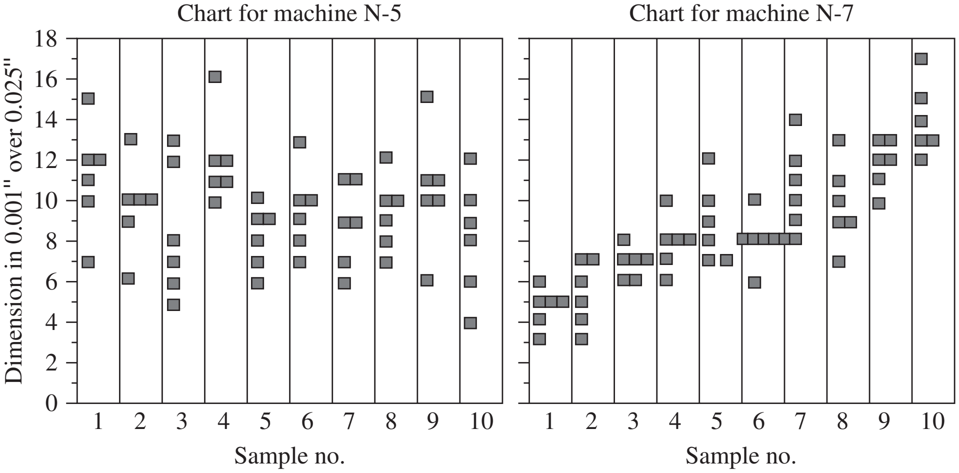
$$s = \frac{\bar{R}}{d_2} = \frac{6.0}{2.534} = 2.37$$

and

$$\pm 3s = \pm 3(2.37) = 7.11$$

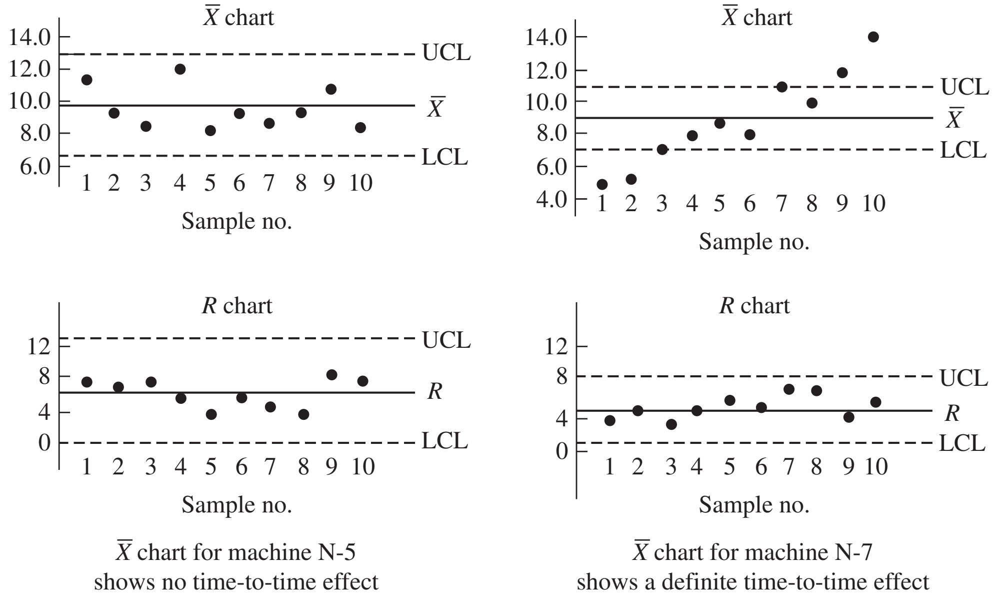
or

$$6s = 14.22 \text{ (or 0.0124 in the original data units)}$$



For machine N-5:

Sample	1	2	3	4	5	6	7	8	9	10
$\bar{X}$	11.2	9.7	8.5	12.0	8.2	9.5	8.8	9.3	10.5	8.2
R	8.0	7.0	8.0	6.0	4.0	6.0	5.0	5.0	9.0	8.0



$\bar{X}$ chart for machine N-5 shows no time-to-time effect

$\bar{X}$ chart for machine N-7 shows a definite time-to-time effect

FIGURE 19.32 $\bar{X}$ and R charts confirm. (*Quality Planning and Analysis. Copyright 2007. Used by permission.*)

The specification limit was 0.258 ± 0.005.

Thus,

$$\text{USL} = 0.263$$
$$\text{LSL} = 0.253$$

Then

$$C_p = \frac{\text{USL} - \text{LSL}}{6s} = \frac{0.263 - 0.253}{0.0142} = 0.72$$

Even if the process is perfectly centered at 0.258 (and it was not), it is not capable.

The assumption of statistical control and its effect on process capability. All statistical predictions assume a stable population. In a statistical sense, a stable population is one that is repeatable (i.e., a population that is in a state of statistical control). The statistician rightfully insists that this be the case before predictions can be made. The manufacturing engineer also insists that the process conditions (feeds, speeds, etc.) be fully defined.

In practice, the original control chart analysis will often show that the process is out of statistical control. (It may or may not be meeting product specifications.) However, an investigation may show that the causes cannot be economically eliminated from the process. In theory, process capability should not be predicted until the process is in statistical control. However, in practice, some kind of comparison of capability to specifications is needed. The danger in delaying the comparison is that the assignable causes may never be eliminated from the process. The resulting indecision will thereby prolong interdepartmental bickering on whether "the specification is too tight" or "manufacturing is too careless."

A good way to start is by plotting individual measurements against specification limits. This step may show that the process can meet the product specifications even with assignable causes present. If a process has assignable causes of variation but is able to meet the specifications, usually no economic problem exists. The statistician can properly point out that a process with assignable variation is unpredictable. This point is well taken, but in establishing priorities of quality improvement efforts, processes that are meeting specifications are seldom given high priority.

If a process is out of control and the causes cannot be economically eliminated, the standard deviation and process capability limits can nevertheless be computed (with the out-of-control points included). These limits will be inflated because the process will not be operating at its best. In addition, the instability of the process means that the prediction is approximate.

It is important to distinguish between a process that is in a state of statistical control and a process that is meeting specifications. A state of statistical control does not necessarily mean that the product from the process conforms to specifications. Statistical control limits on sample averages cannot be compared to specification limits because specification limits refer to individual units. For some processes that are not in control, the specifications are being met and no action is required; other processes are in control, but the specifications are not being met, and action is needed.

In summary, we need processes that are both stable (in statistical control) and capable (meeting product specifications).

The increasing use of capability indexes has also led to the failure to understand and verify some important assumptions that are essential for statistical validity of the results. Five key assumptions are:

1. *Process stability*. Statistical validity requires a state of statistical control with no drift or oscillation.
2. *Normality of the characteristic being measured*. Unless nonparametric methods or alternative distributions are used, normality is needed to draw statistical inferences about the population.

3. *Sufficient data*. Sufficient data are necessary to minimize the sampling error for the capability indexes.
4. *Representativeness of samples*. Random samples must be included.
5. *Independent measurements*. Consecutive measurements cannot be correlated.

These assumptions are not theoretical refinements—they are important conditions for properly applying capability indexes. Before applying capability indexes, readers are urged to read the paper by Pignatiello and Ramberg (1993). It is always best to compare the indexes with the full data versus specifications depicted in a histogram.

Measuring process performance. A process performance study collects data from a process that is operating under typical conditions but includes normal changes in material batches, workers, tools, or process settings. This study, which spans a longer term than the process potential study, also requires that the process be in statistical control.

The capability index for a process performance study is

$$C_{pk} = \min\left[\frac{\bar{X} - \text{LSL}}{3s}, \frac{\text{USL} - \bar{X}}{3s}\right]$$

Problem Consider a pump cassette used to deliver intravenous solutions (Baxter Travenol Laboratories, 1986). A key quality characteristic is the volume of solution delivered in a predefined time. The specification limits are

$$\text{USL} = 103.5 \quad \text{LSL} = 94.5$$

A control chart was run for one month, and no out-of-control points were encountered. From the control chart data, we know that

$$\bar{X} = 98.2 \text{ and } s = 0.98$$

Figure 19.33 shows the process data and the specification limits.

Solution The capability index is

$$C_{pk} = \min\left[\frac{98.2 - 94.5}{3(0.98)}, \frac{103.5 - 98.2}{3(0.98)}\right]$$

$$C_{pk} = 1.26$$

For many applications, 1.26 is an acceptable value of C_{pk}.

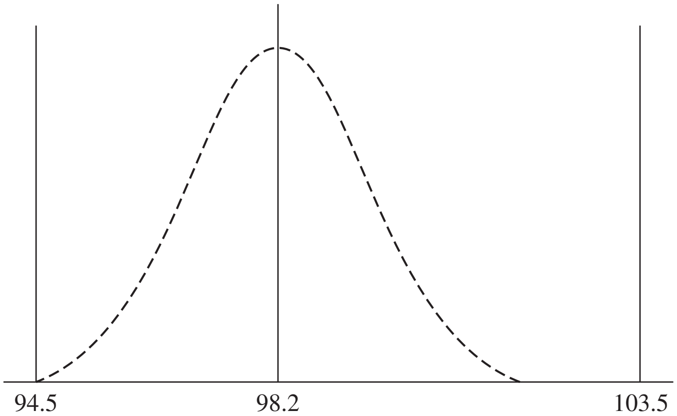


Figure 19.33 Delivered volume of solution.

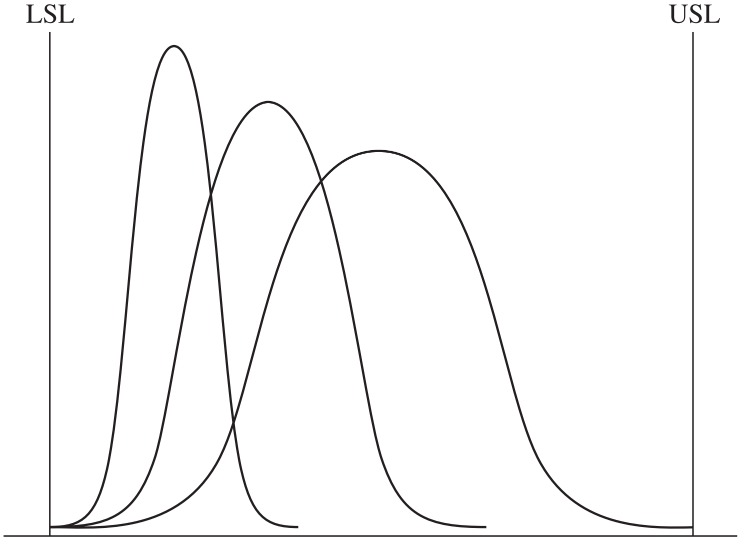


Figure 19.34 Three Processes with $C_{pk} = 1$. (*Quality Planning and Analysis. Copyright 2007. Used by permission.*)

Interpretation of C_{pk}. In using C_{pk} to evaluate a process, we must recognize that C_{pk} is an abbreviation of two parameters—the average and the standard deviation. Such an abbreviation can inadvertently mask important detail in these parameters. For example, Figure 19.34 shows that three extremely different processes can all have the same C_{pk} (in this case $C_{pk} = 1$).

Increasing the value of C_{pk} may require a change in the process average, the process standard deviation, or both. For some processes, increasing the value of C_{pk} by changing the average value (perhaps by a simple adjustment of the process aim) may be easier than reducing the standard deviation (by investigating the many causes of variability). The histogram of the process should always be reviewed to highlight both the average and the spread of the process.

Note that Table 19.21 also includes the capability index C_{pm}. This index measures the capability around a target value T rather than the mean value. When the target value equals the mean value, the C_{pm} index is identical to the C_{pk} index.

Attribute (or categorical) data analysis. The methods discussed earlier assume that numerical measurements are available from the process. Sometimes, however, the only data available are in attribute or categorical form (i.e., the number of nonconforming units and the number acceptable).

The data in Table 19.24 on errors in preparing insurance policies also can be used to illustrate process capability for attribute data. The data reported 80 errors from six policy writers, or 13.3 errors per writer—the current performance. The process capability can be calculated by excluding the abnormal performance identified in the study—type 3 errors by worker B, type 5 errors, and errors of worker E. The error data for the remaining five writers becomes 4, 3, 5, 2, and 5, with an average of 3.8 errors per writer. The process capability estimate of 3.8 compares with the original performance estimate of 13.3.

This example calculates process capability in terms of errors or mistakes rather than the variability of a process parameter. Hinckley and Barkan (1995) point out that in many processes, nonconforming product can be caused by excessive variability or by mistakes (e.g., missing parts, wrong parts, wrong information, or other processing errors). For some processes, mistakes can be a major cause of failing to meet customer quality goals. The actions required to reduce mistakes are different from those required to reduce variability of a parameter.

Readers are directed to DeVor et al. (1992) for a good background in process control charting.

	Policy Writer						
Error Type	A	B	C	D	E	F	Total
1	0	0	1	0	2	1	4
2	1	0	0	0	1	0	2
3	0	16	1	0	2	0	19
4	0	0	0	0	1	0	1
5	2	1	3	1	4	2	13
6	0	0	0	0	3	0	3
.							
.							
.							
27							
28							
29							
Total	6	20	8	3	36	7	80

(*Source: Quality Planning and Analysis*, Copyright 2007. Used by permission.)

Table 19.24 Matrix of Errors by Insurance Policy Writers

Software

While many of the tools mentioned in this chapter can be applied using programs such as Microsoft Excel, numerous software packages are available that provide more specialized assistance. Some of these packages and vendors are listed here, according to their primary emphasis. Most vendors have multiple software options.

Basic statistics:

- QI Macros
- SigmaXL
- StatPlus

Advanced statistics:

- JMP
- Minitab
- Systat

Design of experiments:

- StatSoft STATISTICA
- Stat-Ease
- STRATEGY
- Statgraphics

Monte Carlo, discrete event simulation:

- @Risk
- Crystal Ball
- iGrafx

Reliability, availability:

- Isograph
- Relex 2009
- ReliaSoft

Control charting:

- CHARTRunner
- Statit

References

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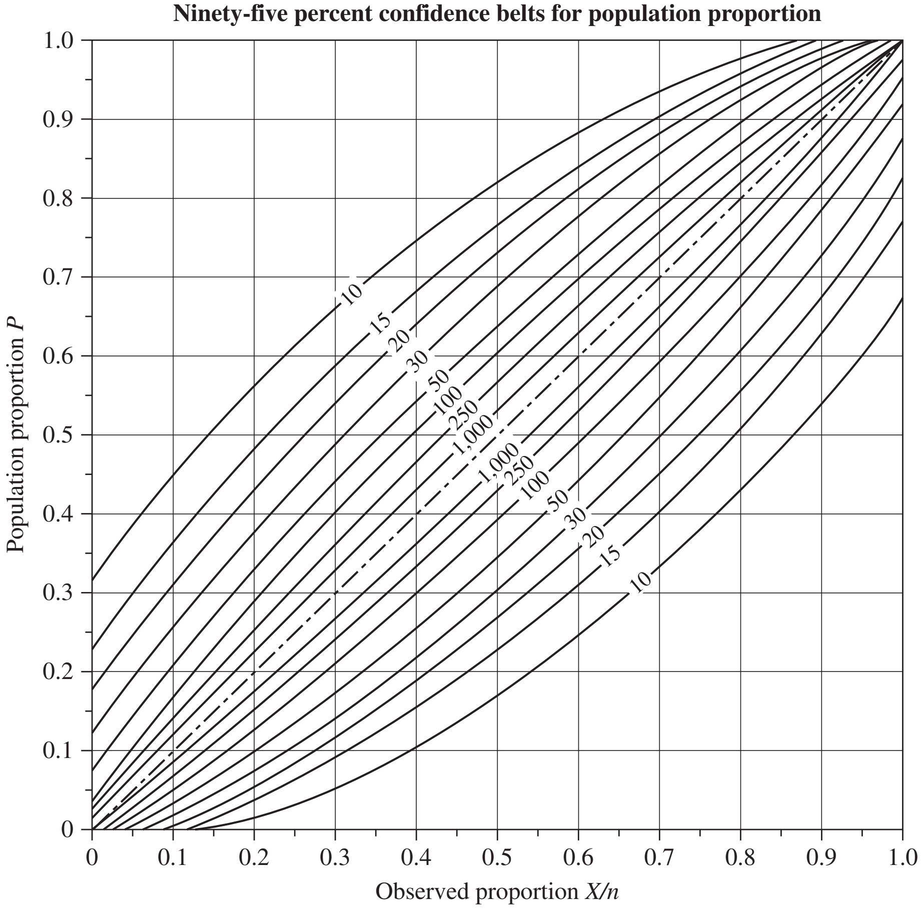
Reference Charts for Table 19.3



Example in a sample of 10 items, 8 were defective (*X/n* – 8/10). The 95% confidence limits on the population proportion defective are read from the two curves (for *n* – 10) as 0.43 and 0.98.

–Ninety-five percent confidence belts for population proportion” from *Selected Techniques of Statistical analysis–OSRD* by C. Eisenhart, M.W. Hastay, and W.A. Wallis. Copyright 1947 by the McGraw-Hill Companies, Inc. Reprinted by permission of The McGraw-Hill Companies, Inc.

Binomial Distribution*

Probability of r or fewer occurrences of an event in n trials, where p is the probability of occurrence on each trial.

		P									
n	***r***	**0.05**	**0.10**	**0.15**	**0.20**	**0.25**	**0.30**	**0.35**	**0.40**	**0.45**	**0.50**
2	0	0.9025	0.8100	0.7225	0.6400	0.5625	0.4900	0.4225	0.3600	0.3025	0.2500
	1	0.9975	0.9900	0.9775	0.9600	0.9375	0.9100	0.8775	0.8400	0.7975	0.7500
3	0	0.8574	0.7290	0.6141	0.5120	0.4219	0.3430	0.2746	0.2160	0.1664	0.1250
	1	0.9928	0.9720	0.9392	0.8960	0.8438	0.7840	0.7182	0.6480	0.5748	0.5000
	2	0.9999	0.9990	0.9966	0.9920	0.9844	0.9730	0.9571	0.9360	0.9089	0.8750
4	0	0.8145	0.6561	0.5220	0.4096	0.3164	0.2401	0.1785	0.1296	0.0915	0.0625
	1	0.9860	0.9477	0.8905	0.8192	0.7383	0.6517	0.5630	0.4752	0.3910	0.3125
	2	0.9995	0.9963	0.9880	0.9728	0.9492	0.9163	0.8735	0.8208	0.7585	0.6875
	3	1.0000	0.9999	0.9995	0.9984	0.9961	0.9919	0.9850	0.9744	0.9590	0.9375
5	0	0.7738	0.5905	0.4437	0.3277	0.2373	0.1681	0.1160	0.0778	0.0503	0.0312
	1	0.9774	0.9185	0.8352	0.7373	0.6328	0.5282	0.4284	0.3370	0.2562	0.1875
	2	0.9988	0.9914	0.9734	0.9421	0.8965	0.8369	0.7648	0.6826	0.5931	0.5000
	3	1.0000	0.9995	0.9978	0.9933	0.9844	0.9692	0.9460	0.9130	0.8688	0.8125
	4	1.0000	1.0000	0.9999	0.9997	0.9990	0.9976	0.9947	0.9898	0.9815	0.9688
6	0	0.7351	0.5314	0.3771	0.2621	0.1780	0.1176	0.0754	0.0467	0.0277	0.0156
	1	0.9672	0.8857	0.7765	0.6554	0.5339	0.4202	0.3191	0.2333	0.1636	0.1094
	2	0.9978	0.9842	0.9527	0.9011	0.8306	0.7443	0.6471	0.5443	0.4415	0.3438
	3	0.9999	0.9987	0.9941	0.9830	0.9624	0.9295	0.8826	0.8208	0.7447	0.6562
	4	1.0000	0.9999	0.9996	0.9984	0.9954	0.9891	0.9777	0.9590	0.9308	0.8906
	5	1.0000	1.0000	1.0000	0.9999	0.9998	0.9993	0.9982	0.9959	0.9917	0.9844
7	0	0.6983	0.4783	0.3206	0.2097	0.1335	0.0824	0.0490	0.0280	0.0152	0.0078
	1	0.9556	0.8503	0.7166	0.5767	0.4449	0.3294	0.2338	0.1586	0.1024	0.0625
	2	0.9962	0.9743	0.9262	0.8520	0.7564	0.6471	0.5323	0.4199	0.3164	0.2266
	3	0.9998	0.9973	0.9879	0.9667	0.9294	0.8740	0.8002	0.7102	0.6083	0.5000
	4	1.0000	0.9998	0.9988	0.9953	0.9871	0.9712	0.9444	0.9037	0.8471	0.7734
	5	1.0000	1.0000	0.9999	0.9996	0.9987	0.9962	0.9910	0.9812	0.9643	0.9375
	6	1.0000	1.0000	1.0000	1.0000	0.9999	0.9998	0.0994	0.9984	0.9963	0.9922
8	0	0.6634	0.4305	0.2725	0.1678	0.1001	0.0576	0.0319	0.0168	0.0084	0.0039
	1	0.9428	0.8131	0.6572	0.5033	0.3671	0.2553	0.1691	0.1064	0.0632	0.0352
	2	0.9942	0.9619	0.8948	0.7969	0.6785	0.5518	0.4278	0.3154	0.2201	0.1445
	3	0.9996	0.9950	0.9786	0.9437	0.8862	0.8059	0.7064	0.5941	0.4770	0.3633
	4	1.0000	0.9996	0.9971	0.9896	0.9727	0.9420	0.8939	0.8263	0.7396	0.6367

	5	1.0000	1.0000	0.9998	0.9988	0.9958	0.9887	0.9747	0.9502	0.9115	0.8555
	6	1.0000	1.0000	1.0000	0.9999	0.9996	0.9987	0.9964	0.9915	0.9819	0.9648
	7	1.0000	1.0000	1.0000	1.0000	1.0000	0.9999	0.9998	0.9993	0.9983	0.9961
9	0	0.6302	0.3874	0.2316	0.1342	0.0751	0.0404	0.0207	0.0101	0.0046	0.0020
	1	0.9288	0.7748	0.5995	0.4362	0.3003	0.1960	0.1211	0.0705	0.0385	0.0195
	2	0.9916	0.9470	0.8591	0.7382	0.6007	0.4628	0.3373	0.2318	0.1495	0.0898
	3	0.9994	0.9917	0.9661	0.9144	0.8343	0.7297	0.6089	0.4826	0.3614	0.2539
	4	1.0000	0.9991	0.9944	0.9804	0.9511	0.9012	0.8283	0.7334	0.6214	0.5000
	5	1.0000	0.9999	0.9994	0.9969	0.9900	0.9747	0.9464	0.9006	0.8342	0.7461
	6	1.0000	1.0000	1.0000	0.9997	0.9987	0.9957	0.9888	0.9750	0.9502	0.9102
	7	1.0000	1.0000	1.0000	1.0000	0.9999	0.9996	0.9986	0.9962	0.9909	0.9805
	8	1.0000	1.0000	1.0000	1.0000	1.0000	1.0000	0.9999	0.9997	0.9992	0.9980
10	0	0.5987	0.3487	0.1969	0.1074	0.0563	0.0282	0.0135	0.0060	0.0025	0.0010
	1	0.9139	0.7361	0.5443	0.3758	0.2440	0.1493	0.0860	0.0464	0.0232	0.0107
	2	0.9885	0.9298	0.8202	0.6778	0.5256	0.3828	0.2616	0.1673	0.0996	0.0547
	3	0.9990	0.9872	0.9500	0.8791	0.7759	0.6496	0.5138	0.3823	0.2660	0.1719
	4	0.9999	0.9984	0.9901	0.9672	0.9219	0.8497	0.7515	0.6331	0.5044	0.3770
	5	1.0000	0.9999	0.9986	0.9936	0.9803	0.9527	0.9051	0.8338	0.7384	0.6230
	6	1.0000	1.0000	0.9999	0.9991	0.9965	0.9894	0.9740	0.9452	0.8980	0.8281
	7	1.0000	1.0000	1.0000	0.9999	0.9996	0.9984	0.9952	0.9877	0.9726	0.9453
	8	1.0000	1.0000	1.0000	1.0000	1.0000	0.9999	0.9995	0.9983	0.9955	0.9893
	9	1.0000	1.0000	1.0000	1.0000	1.0000	1.0000	1.0000	0.9999	0.9997	0.9990