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Special Topics in Quality

OVERVIEW OF STATISTICAL METHODS

Statistics is a mathematical science pertaining to the collection, analysis, interpretation or explanation, and presentation of data. It is applicable to a wide variety of academic disciplines, from the natural and social sciences to the humanities, and to government and business.

Statistical methods can be used to summarize or describe a collection of data; this is called *descriptive statistics*. In addition, patterns in the data may be modeled in a way that accounts for randomness and uncertainty in the observations, and then used to draw inferences about the process or population being studied; this is called *inferential statistics*. Both descriptive and inferential statistics comprise applied statistics. There is also a discipline called *mathematical statistics*, which is concerned with the theoretical basis of the subject.

The word *statistics* is also the plural of *statistic* (singular), which refers to the result of applying a statistical algorithm to a set of data, as in economic statistics, crime statistics, and so on.

History

Some scholars pinpoint the origin of statistics to 1662, with the publication of "Observations on the Bills of Mortality" by John Graunt. Early applications of statistical thinking revolved around the needs of states to base policy on demographic and economic data. The scope of the discipline of statistics broadened in the early nineteenth century to include the collection

and analysis of data in general. Today, statistics is widely employed in government, business, and the natural and social sciences.

Because of its empirical roots and its applications, statistics is generally considered not to be a subfield of pure mathematics, but rather a distinct branch of applied mathematics. Its mathematical foundations were laid in the seventeenth century with the development of probability theory by Blaise Pascal and Pierre de Fermat. Probability theory arose from the study of games of chance. The method of least squares was first described by Carl Friedrich Gauss around 1794. The use of modern computers has expedited large-scale statistical computation, and has also made possible new methods that are impractical to perform manually.

Overview

In applying statistics to a scientific, industrial, or societal problem, one begins with a process or population to be studied. This might be a population of people in a country, of crystal grains in a rock, or of goods manufactured by a particular factory during a given period. It may instead be a process observed at various times; data collected about this kind of "population" constitute what is called a *time series*.

For practical reasons, rather than compiling data about an entire population, one usually studies a chosen subset of the population, called a *sample*. Data are collected about the sample in an observational or experimental setting. The data are then subjected to statistical analysis, which serves two related purposes: description and inference.

Descriptive statistics can be used to summarize the data, either numerically or graphically, to describe the sample. Basic examples of numerical descriptors include the mean and standard deviation. Graphical summarizations include various kinds of charts and graphs.

Inferential statistics is used to model patterns in the data, accounting for randomness and drawing inferences about the larger population. These inferences may take the form of answers to yes/no questions (hypothesis testing), estimates of numerical characteristics (estimation), descriptions of association (correlation), or modeling of relationships (regression). Other modeling techniques include analysis of variance (ANOVA), time series, and data mining.

The concept of correlation is particularly noteworthy. Statistical analysis of a data set may reveal that two variables (that is, two properties of the

population under consideration) tend to vary together, as if they are connected. For example, a study of annual income and age of death among people might find that poor people tend to have shorter lives than affluent people. The two variables are said to be correlated (which is a positive correlation in this case). However, one cannot immediately infer the existence of a causal relationship between the two variables. The correlated phenomena could be caused by a third, previously unconsidered phenomenon, called a *lurking variable* or *confounding variable*.

If the sample is representative of the population, then inferences and conclusions made from the sample can be extended to the population as a whole. A major problem lies in determining the extent to which the chosen sample is representative. Statistics offers methods to estimate and correct for randomness in the sample and in the data collection procedure, as well as methods for designing robust experiments in the first place. The fundamental mathematical concept employed in understanding such randomness is probability. Mathematical statistics (also called *statistical theory*) is the branch of applied mathematics that uses probability theory and analysis to examine the theoretical basis of statistics.

The use of any statistical method is valid only when the system or population under consideration satisfies the basic mathematical assumptions of the method. Misuse of statistics can produce subtle but serious errors in description and interpretation—subtle in the sense that even experienced professionals sometimes make such errors, and serious in the sense that they may affect, for instance, social policy, medical practice, and the reliability of structures such as bridges. Even when statistics is correctly applied, the results can be difficult for the nonexpert to interpret. For example, the statistical significance of a trend in the data, which measures the extent to which the trend could be caused by random variation in the sample, may not agree with one's intuitive sense of its significance. The set of basic statistical skills (and skepticism) needed by people to deal with information in their everyday lives is referred to as *statistical literacy*.

Statistical Methods

Experimental and Observational Studies

A common goal for a statistical research project is to investigate causality, and in particular to draw a conclusion on the effect of changes in the

values of predictors or independent variables on response or dependent variables. There are two major types of causal statistical studies, experimental studies and observational studies. In both types of studies, the effects of differences of an independent variable (or variables) on the behavior of the dependent variable are observed. The difference between the two types lies in how the study is actually conducted. Each can be very effective.

An experimental study involves taking measurements of the system under study, manipulating the system, and then taking additional measurements using the same procedure to determine if the manipulation has modified the values of the measurements. In contrast, an observational study does not involve experimental manipulation. Instead, data are gathered and correlations between predictors and response are investigated.

An example of an experimental study is the famous Hawthorne studies, which attempted to test the changes to the working environment at the Hawthorne plant of the Western Electric Company. The researchers were interested in determining whether increased illumination would increase the productivity of the assembly line workers. The researchers first measured the productivity in the plant, then modified the illumination in an area of the plant and checked if the changes in illumination affected the productivity. It turned out that the productivity indeed improved (under the experimental conditions). However, the study is heavily criticized today for errors in experimental procedures, specifically for the lack of a control group and blindedness.

An example of an observational study is a study which explores the correlation between smoking and lung cancer. This type of study typically uses a survey to collect observations about the area of interest, and then performs statistical analysis of the observational data. In this case, the researchers would collect observations of both smokers and nonsmokers, perhaps through a case-control study, and then look for the number of cases of lung cancer in each group.

The basic steps of an experiment are as follows:

- Planning the research, including determining information sources, research subject selection, and ethical considerations for the proposed research and method
- Designing experiments, concentrating on the system model and the interaction of independent and dependent variables

- Summarizing a collection of observations to feature their commonality by suppressing details (descriptive statistics)
- Reaching consensus about what the observations tell about the world being observed (statistical inference)
- Documenting and presenting the results of the study

Levels of Measurement

There are four types of measurements, levels of measurement, or measurement scales used in statistics: nominal, ordinal, interval, and ratio. They have different degrees of usefulness in statistical research. Ratio measurements have both a zero value and the distances between different measurements defined; they provide the greatest flexibility in statistical methods that can be used for analyzing the data. Interval measurements have meaningful distances between measurements defined, but have no meaningful zero value (as in the case with IQ measurements or with temperature measurements in Fahrenheit). Ordinal measurements have imprecise differences between consecutive values, but have a meaningful order to those values. Nominal measurements have no meaningful rank order among values.

Since variables conforming only to nominal or ordinal measurements cannot be reasonably measured numerically, sometimes they are referred to as categorical variables, whereas ratio and interval measurements are grouped together as quantitative or continuous variables due to their numerical nature.

Statistical process control (SPC) is an effective method of monitoring a process through the use of control charts. Control charts enable the use of objective criteria for distinguishing background variation from events of significance based on statistical techniques. Much of SPC's power lies in the ability to monitor both the process center and its variation about that center. By collecting data from samples at various points within the process, variations in the process that may affect the quality of the end product or service can be detected and corrected, thus reducing waste as well as the likelihood that problems will be passed on to the customer. With its emphasis on early detection and prevention of problems, SPC has a distinct advantage over quality methods such as inspection, that apply resources to detecting and correcting problems in the end product or service.

In addition to reducing waste, SPC can lead to a reduction in the time required to produce the product or provide the service from end to end.

TABLE 6.1
Statistical Formulas

Statistic	Formula	Used for
Continuous Statistics		
Mean	$\mu = \frac{\sum x}{n}$	The center of a set of data
Range	$r = x_{\max} - x_{\min}$	The dispersion of data around the center
Variance	$\sigma^2 = \frac{\sum (\mu - x)^2}{n-1}$	The dispersion of data around the center
Standard Deviation	$\sigma = \sqrt{\frac{\sum (\mu - n)^2}{n-1}}$	The dispersion of data around the center
Normal Distribution	$f(x) = \frac{1}{\sigma\sqrt{2\pi}} \bullet e^{-\frac{1}{2}\left(\frac{\mu - x}{\sigma}\right)^2}$	Used to perform estimations
Standard Normal Value	$z = \frac{\mu - x}{\sigma}$	Used to determine normalcy
Hypothesis Test of Means	$z = \frac{\mu_1 - \mu_2}{\sigma / \sqrt{n}}$	Used to determine differences

t Test	$t = \dfrac{\left(\bar{x}_1 - \bar{x}_2\right) - \left(\mu_1 - \mu_2\right)}{\sqrt{s_p^2\left(\dfrac{1}{n_1} + \dfrac{1}{n_2}\right)}}$ where $s_p^2 = \dfrac{\left(n_1 - 1\right)s_1^2 - \left(n_2 - 1\right)s_2^2}{n_1 + n_2 - 2}$ $df = n_1 + n_2 - 2$	Used to determine differences
Regression	$r = \dfrac{\sum xy - \dfrac{\left(\sum x\right)\left(\sum y\right)}{n}}{\sqrt{\left[\sum x^2 - \dfrac{\sum\left(x\right)^2}{n}\right] - \left[\sum y^2 - \dfrac{\sum\left(y\right)^2}{n}\right]}}$	Used to determine differences
Confidence Limits	$\mu \pm z\dfrac{\sigma}{\sqrt{n}}$ where $n \geq 30$; or $\mu \pm t\dfrac{\sigma}{\sqrt{n}}$ where $n < 30$	Used to determine differences

Continued

TABLE 6.1. (continued)
Statistical Formulas

Statistic	Formula	Used for
Discrete Statistics		
Proportion	$p = \frac{\sum r}{\sum x}$	Used to determine percentage nonconforming
Binomial Distribution	$\mu = \frac{n!}{r!(n-r)!} p^r q^{(n-r)}$	Used to determine average percentage nonconforming
Poisson Distribution	$\mu = \frac{\lambda^x e^{-\lambda}}{x!}$	Used to determine average percentage nonconforming
Hypergeometric Distribution	$\mu = \frac{C_d^D C_{n-d}^{N-D}}{C_n^N}$ where n = sample size, N = lot size, D = number of failures, and d = probability of a failure	Used in statistical sampling
$p = p_0$ Hypothesis Test	$\mu = \frac{\hat{p} - p_0}{\sqrt{\frac{p_0(1-p_0)}{n}}}$	Used to determine differences

$p_1 - p_2 = 0$ Hypothesis Test	$\mu = \dfrac{\left(\hat{p}_1 - \hat{p}_2\right) - 0}{\sqrt{\hat{p}\left(1-\hat{p}\right)\left(\dfrac{1}{n_1}+\dfrac{1}{n_2}\right)}}$ where $n \times \hat{p}$ and $n\left(1-\hat{p}\right)$ are at least 5	Used to determine differences
Chi-Square Distribution	$x^2 = \sum \dfrac{\left(O_i - E_i\right)^2}{E_i}$ Where $E_i = \dfrac{R_1 \bullet C_i}{n}$	Used to analyze survey data
Confidence Limits	$\mu = z\sqrt{\dfrac{\hat{p}\left(1-\hat{p}\right)}{n}}$ where $n\hat{p}$ and $n\left(1-\hat{p}\right)$ are at least 5	Used to determine differences

This is partially due to a diminished likelihood that the final product will have to be reworked, but it may also result from using SPC data to identify bottlenecks, wait times, and other sources of delays within the process. Process cycle time reductions coupled with improvements in yield have made SPC a valuable tool from both a cost reduction and a customer satisfaction standpoint.

History of SPC

Statistical process control was pioneered by Walter A. Shewhart in the early 1920s. W. Edwards Deming later applied SPC methods in the United States during World War II, thereby successfully improving quality in the manufacture of munitions and other strategically important products. Deming was also instrumental in introducing SPC methods to Japanese industry after the war had ended.

Shewhart created the basis for the control chart and the concept of a state of statistical control by carefully designed experiments. While Dr. Shewhart drew from pure mathematical statistical theories, he understood that data from physical processes seldom produce a *normal distribution curve* (a Gaussian distribution, also commonly referred to as a *bell curve*). He discovered that observed variation in manufacturing data did not always behave the same way as with data in nature (for example, Brownian motion of particles). Dr. Shewhart concluded that while every process displays variation, some processes display controlled variation that is natural to the process (common causes of variation), while others display uncontrolled variation that is not present in the process causal system at all times (special causes of variation).

General

The following description relates to manufacturing rather than to the service industry, although the principles of SPC can be successfully applied to either. SPC has also been successfully applied to detecting changes in organizational behavior, with social network change detection introduced by McCulloh (2007).

In mass manufacturing, the quality of the finished article was traditionally achieved through postmanufacturing inspection of the product, accepting or rejecting each article (or samples from a production lot) based

on how well it met its design specifications. In contrast, SPC uses statistical tools to observe the performance of the production process in order to predict significant deviations that may later result in rejected product.

Two kinds of variations occur in all manufacturing processes; both these process variations cause subsequent variations in the final product: The first are known as *natural* or *common causes* of variation and may be variations in temperature, specifications of raw materials or electrical current, and so on. These variations are small, and are generally near to the average value. The pattern of variation will be similar to those found in nature, and the distribution forms the bell-shaped normal distribution curve (see Figure 6.1). The second kind is known as *special causes*, and happens less frequently than the first.

For example, a breakfast cereal–packaging line may be designed to fill each cereal box with 500 grams of product, but some boxes will have slightly more than 500 grams, and some will have slightly less, in accordance with a distribution of net weights. If the production process, its inputs, or its environment changes (for example, the machines doing the manufacture begin to wear), this distribution can change. For example, as its cams and pulleys wear out, the cereal-filling machine may start putting more cereal into each box than specified. If this change is allowed to continue unchecked, more and more product will be produced that falls outside the tolerances of the manufacturer or consumer, resulting in waste. While in this case, the waste is in the form of "free" product for the consumer, typically waste consists of rework or scrap.

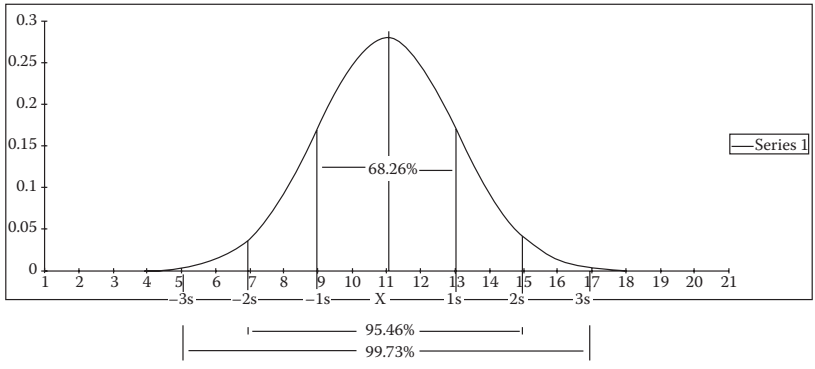

FIGURE 6.1
Normal curve.

TABLE 6.2

Statistical Methods Applied to Operations

Statistic	Formula	Used For
Attribute Control Charts		
P Chart	$CL = \bar{p} \pm 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}}$	Process; tracking proportion nonconforming
C Chart	$CL = \bar{c} \pm 3\sqrt{\bar{c}}$	Process: tracking nonconformities
Np Chart	$CL = n\bar{p} \pm 3\sqrt{n\bar{p}(1-p)}$	Process: tracking multiple nonconformities per unit
U Chart	$CL = \bar{u} \pm 3\sqrt{\frac{\bar{u}}{n}}$	Process: tracking multiple nonconformities per sample
Variable Control Charts		
$\bar{X}$ Chart	$CL = \bar{\bar{X}} \pm A_2\bar{R}$	Product: tracking product consistency and accuracy
$\bar{R}$ Chart	$CL = D_4\bar{R}$	Product: tracking product consistency and accuracy
$\bar{\bar{X}}_s$ Chart	$CL = \bar{\bar{X}} \pm A_3\bar{S}$	Product: tracking product consistency and accuracy
$\bar{S}$ Chart	$CL = B_4\bar{S}$	Product: tracking product consistency and accuracy

Where n = sample size, $\bar{S}$ = average of sample standard deviations, A_2, B_4, D_4 = constants, $\bar{\bar{X}}$ = average of samples averages, and $\bar{R}$ = average of sample ranges.

TABLE 6.3

SPC Constants

N	D4	B4	A2	k1	k2	d2
2	3.268	3.267	1.860	4.56	3.65	1.128
3	2.574	2.568	1.023	3.05	2.70	1.693
4	2.282	2.266	0.729	2.50	2.30	2.059
5	2.115	2.089	0.577			2.326
6	2.004	1.970	0.483			2.534

By observing at the right time what happened in the process that led to a change, the quality engineer or any member of the team responsible for the production line can troubleshoot the root cause of the variation that has crept into the process and correct the problem.

TABLE 6.4

Quality-Engineering Formulas

Name	Equation	Used For
Process Capability	$Cp = \frac{US - LS}{6\sigma}$	Product design versus process
Upper Capability	$Cp_u = \frac{US - \bar{\bar{X}}}{3\hat{\sigma}}$	Product design versus process
Lower Capability	$Cp_L = \frac{\bar{\bar{X}} - LS}{3\hat{\sigma}}$	Product design versus process
Sigma Estimation	$\hat{\sigma} = \bar{R} / d_2$	Product design versus process
Part per Million	$PPM = \frac{R_e}{n} \times 1{,}000{,}000$	Process
Repeatability and Reproducibility	$R\&R = \sqrt{\left(\bar{\bar{R}} \times k_1\right)^2 + \sqrt{\left(\bar{X}_{diff} \times k_2\right)^2 - \left[\left(\bar{R} \times k_1\right)^2 / \left(n \times r\right)\right]}}$ $\%R\&R = 100\left(\left(R\&R\right) / \left(US - LS\right)\right)$ $\quad \sigma_c = \sqrt{\left(\sigma_a\right)^2 + \left(\sigma_b\right)^2}$	Measurement analysis

Where US = upper specification, LS = lower specification, n = number of parts, r = number of trials, R_e = number of nonconformities, and k_1, k_2, and d_2 = constants.

TABLE 6.5
Statistical Sampling Plan

Lot Size		Acceptable Nonconformance Levels and Sample Sizes			
From	**To**	**2.5%**	**4.0%**	**6.5%**	**10%**
2	8	5	3	2	2
9	15	5	3	2	2
16	25	5	3	3	2
26	50	5	5	5	3
51	90	7	6	5	4
91	150	11	7	6	5
151	280	13	10	7	6
281	500	16	11	9	7
501	1,200	19	15	11	8
1,201	3,200	23	18	13	9
3,201	10,000	29	22	15	9
10,001	35,000	35	29	15	9
35,001	150,000	40	29	15	9
150,001	500,000	40	29	15	9
500,001	>500,001	40	29	15	9

Reject on one nonconformity and accept on zero nonconformities.

SPC indicates when an action should be taken in a process, but it also indicates when *no* action should be taken. An example is a person who would like to maintain a constant body weight and takes weight measurements weekly. A person who does not understand SPC concepts might start dieting every time his or her weight increased, or eat more every time his or her weight decreased. This type of action could be harmful and possibly generate even more variation in body weight. SPC would account for normal weight variation and better indicate when the person is in fact gaining or losing weight.

RISK ANALYSIS

Risk analysis is the science of risks and their probability and evaluation.

The term *cindynics* (from the Greek *kindunos*, "danger") has been proposed for this field. This term is used in France, but has not been widely

adopted in the English-speaking world. Probabilistic risk assessment is the analysis strategy usually employed in science and engineering.

Risk Analysis and the Risk Workshop

As part of the risk management process, risk analysis for each project should be performed. The data from this would be based on risk discussion workshops to identify potential issues and risks ahead of time before these were to pose negative cost and/or schedule impacts (see the article on cost contingency for a discussion of the estimation of cost impacts).

The risk workshops should be chaired by a small group, ideally between 6 and 10 individuals from the various departmental functions (e.g., project manager, construction manager, site superintendent, and representatives from operations, procurement, [project] controls, etc.) so as to cover every risk element from different perspectives.

The outcome of the risk analysis would be the creation and review of the risk register to identify and quantify risk elements to the project and their potential impact.

Given that risk management is a continuous and iterative process, the risk workshop members would regroup at regular intervals and project milestones to review the risk register mitigation plans, make changes to it as appropriate, and, following those changes, rerun the risk model. By constantly monitoring risks, they can successfully mitigate them, resulting in a cost and schedule savings with a positive impact on the project.

Probabilistic risk assessment (PRA) (or probabilistic safety assessment or analysis) is a systematic and comprehensive methodology to evaluate risks associated with a complex engineered technological entity (such as airliners or nuclear power plants). Risk in a PRA is defined as a feasible detrimental outcome of an activity or action. In a PRA, risk is characterized by two quantities:

The magnitude (severity) of the possible adverse consequence(s)
The likelihood (probability) of occurrence of each consequence

Consequences are expressed numerically (e.g., the number of people potentially hurt or killed), and their likelihoods of occurrence are expressed as probabilities or frequencies (i.e., the number of occurrences

or the probability of occurrence per unit time). The total risk is the sum of the products of the consequences multiplied by their probabilities. The spectrums of risks across classes of events are also of concern, and are usually controlled in licensing processes (it would be of concern if rare but high-consequence events were found to dominate the overall risk).

Probabilistic risk assessment usually answers three basic questions:

What can go wrong with the studied technological entity, or what are the initiators or initiating events (undesirable starting events) that lead to adverse consequence(s)?

What and how severe are the potential detriments or the adverse consequences that the technological entity may be eventually subjected to as a result of the occurrence of the initiator?

How likely to occur are these undesirable consequences, or what are their probabilities or frequencies?

Two common methods of answering this last question are event tree analysis and fault tree analysis—for explanations of these, see safety engineering.

In addition to the above methods, PRA studies require special but often very important analysis tools like human reliability analysis (HRA) and common cause or failure (CCF) analysis. HRA deals with methods for modeling human error, while CCF analysis deals with methods for evaluating the effect of intersystem and intrasystem dependencies which tend to cause simultaneous failures and thus significant increases in overall risk.

PRA studies have been successfully performed for complex technological systems at all phases of the life cycle from concept definition and predesign through safe removal from operation. For example, the Nuclear Regulatory Commission (NRC) required that each nuclear power plant in the United States perform an individual plant examination (IPE) to identify and quantify plant vulnerabilities to hardware failures and human faults in design and operation. Although no method was specified for performing such an evaluation, the NRC requires risk analysis (Business).

Risk analysis is a technique to identify and assess factors that may jeopardize the success of a project or the achievement of a goal. This technique also helps to define preventive measures to reduce the probability of these factors from occurring, as well as identify countermeasures to successfully

deal with these constraints when they develop to avert possible negative effects on the competitiveness of the company.

One of the more popular methods to perform a risk analysis in the computer field is called the *facilitated risk analysis process* (FRAP).

Facilitated Risk Analysis Process

FRAP analyzes one system, application, or segment of business processes at a time.

Practitioners of FRAP believe that additional efforts to develop precisely quantified risks are not cost-effective because

such estimates are time-consuming;

risk documentation becomes too voluminous for practical use; and

specific loss estimates are generally not needed to determine if controls are needed.

After identifying and categorizing risks, the FRAP team identifies the controls that could mitigate the risk. The decision for what controls are needed lies with the business manager. The team's conclusions as to what risks exist and what controls are needed are documented, along with a related action plan for control implementation.

Three of the most important risks a software company faces are unexpected changes in (1) revenue, (2) costs from those budgeted, and (3) the amount of specialization of the software planned. Risks that affect revenues can be unanticipated competition, privacy, intellectual property rights problems, and unit sales that are less than forecasted; unexpected development costs also create risk that can be in the form of more rework than anticipated, security holes, and privacy invasions.

Narrow specialization of software with a large amount of research and development expenditures can lead to both business and technological risks, since specialization does not lead to lower unit costs of software (Messerschmidt and Szyperski 2004). Combined with the decrease in the potential customer base, specialization risk can be significant for a software firm. After probabilities of scenarios have been calculated with risk analysis, the process of risk management can be applied to help manage the risk.

Methods like applied information economics add to and improve on risk analysis methods by introducing procedures to adjust subjective

probabilities, compute the value of additional information, and use the results in part of a larger portfolio management problem.

RELIABILITY ENGINEERING

Reliability Theory

Reliability theory is the foundation of reliability engineering. For engineering purposes, *reliability* is defined as the probability that a device will perform its intended function during a specified period of time under stated conditions.

Mathematically, this may be expressed as

$$R_{(t)} = \int_{t}^{\infty} f\left(x\right)dx$$

where $f\left(x\right)$ is the failure probability density function, and t is the length of the period (which is assumed to start from time zero).

Reliability engineering is concerned with four key elements of this definition:

First, reliability is a probability. This means that failure is regarded as a random phenomenon: it is a recurring event, and we do not express any information on individual failures, the causes of failures, or relationships between failures, except that the likelihood for failures to occur varies over time according to the given probability function. Reliability engineering is concerned with meeting the specified probability of success, at a specified statistical confidence level.

Second, reliability is predicated on "intended function": generally, this is taken to mean operation without failure. However, even if no individual part of the system fails, but the system as a whole does not do what was intended, then the failure is still charged against the system reliability. The system requirements specification is the criterion against which reliability is measured.

Third, reliability applies to a specified period of time. In practical terms, this means that a system has a specified chance that it will operate

without failure before a specified time. Reliability engineering ensures that components and materials will meet the requirements during the specified time. Units other than time may sometimes be used: the automotive industry might specify reliability in terms of miles; the military might specify reliability of a gun for a certain number of rounds fired; or a piece of mechanical equipment may have a reliability rating value in terms of cycles of use.

Fourth, reliability is restricted to operation under stated conditions. This constraint is necessary because it is impossible to design a system for unlimited conditions. A Mars Rover will have different specified conditions than the family car. The operating environment must be addressed during design and testing.

Reliability Program Plan

Many tasks, methods, and tools can be used to achieve reliability. Every system requires a different level of reliability. A commercial airliner must operate under a wide range of conditions. The consequences of failure are grave, but there is a correspondingly higher budget. A pencil sharpener may be more reliable than an airliner, but it has a much different set of operational conditions, insignificant consequences of failure, and a much lower budget.

A reliability program plan is used to document exactly what tasks, methods, tools, analyses, and tests are required for a particular system. For complex systems, the reliability program plan is a separate document. For simple systems, it may be combined with the systems engineering management plan. The reliability program plan is essential for a successful reliability program and is developed early during system development. It specifies not only what the reliability engineer does, but also the tasks performed by others. The reliability program plan is approved by top program management.

Reliability Requirements

For any system, one of the first tasks of reliability engineering is to adequately specify the reliability requirements. Reliability requirements address the system itself, test and assessment requirements, and associated tasks and documentation. Reliability requirements are included in the appropriate system and subsystem requirement specifications, test plans, and contract statements.

System Reliability Parameters

Requirements are specified using reliability parameters. The most common reliability parameter is mean time between failure (MTBF), which can also be specified as the failure rate or the number of failures during a given period. These parameters are very useful for systems that are operated on a regular basis, such as most vehicles, machinery, and electronic equipment. Reliability increases as the MTBF increases. The MTBF is usually specified in hours, but can also be used with other units of measurement such as miles or cycles.

In other cases, reliability is specified as the probability of mission success. For example, reliability of a scheduled aircraft flight can be specified as a dimensionless probability or a percentage.

A special case of mission success is the single-shot device or system. These are devices or systems that remain relatively dormant and operate only once. Examples include automobile airbags, thermal batteries, and missiles. Single-shot reliability is specified as a probability of success, or is subsumed into a related parameter. Single-shot missile reliability may be incorporated into a requirement for the probability of hit.

For such systems, the probability of failure on demand (PFD) is the reliability measure. This PFD is derived from failure rate and mission time for nonrepairable systems. For repairable systems, it is obtained from failure rate and mean time to recovery (MTTR) and test interval. This measure may not be unique for a given system, as the measure depends on the kind of demand. In addition to system-level requirements, reliability requirements may be specified for critical subsystems. In all cases, reliability parameters are specified with appropriate statistical confidence intervals.

Reliability Modeling

Reliability modeling is the process of predicting or understanding the reliability of a component or system. Two separate fields of investigation are common: the physics of failure approach uses an understanding of the failure mechanisms involved, such as crack propagation or chemical corrosion; and the parts stress modeling approach is an empirical method for prediction based on counting the number and type of components of the system, and the stress they undergo during operation.

For systems with a clearly defined failure time (which is sometimes not given for systems with a drifting parameter), the empirical distribution function of these failure times can be determined. This is done in general in an accelerated experiment with increased stress. These experiments can be divided into two main categories.

Early failure rate studies determine the distribution with a decreasing failure rate over the first part of the bathtub curve. Here, in general, only moderate stress is necessary. The stress is applied for a limited period of time in what is called a *censored test*. Therefore, only the part of the distribution with early failures can be determined.

In so-called zero-defect experiments, only limited information about the failure distribution is acquired. Here the stress, stress time, or the sample size is so low that not a single failure occurs. Due to the insufficient sample size, only an upper limit of the early failure rate can be determined. At any rate, it looks good for the customer if there are no failures.

In a study of the intrinsic failure distribution, which is often a material property, higher stresses are necessary to achieve failure in a reasonable period of time. Several degrees of stress have to be applied to determine an acceleration model. The empirical failure distribution is often parameterized with a Weibull or a log-normal model.

It is a general praxis to model the early failure rate with an exponential distribution. This less complex model for the failure distribution has only one parameter: the constant failure rate. In such cases, the chi-square distribution can be used to find the goodness of fit for the estimated failure rate. Compared to a model with a decreasing failure rate, this is quite pessimistic. Combined with a zero-defect experiment, this becomes even more pessimistic. The effort is greatly reduced in this case: one does not have to determine a second model parameter (e.g., the shape parameter of a Weibull distribution) or its confidence interval (e.g., by a maximum likelihood approach, or MLE), and the sample size is much smaller.

Reliability Test Requirements

Because reliability is a probability, even highly reliable systems have some chance of failure. However, testing reliability requirements is problematic for several reasons. A single test is insufficient to generate enough statistical data. Multiple tests or long-duration tests are usually very expensive. Some tests are simply impractical. Reliability engineering

is used to design a realistic and affordable test program that provides enough evidence that the system meets its requirements. Statistical confidence levels are used to address some of these concerns. A certain parameter is expressed along with a corresponding confidence level: for example, an MTBF of 1,000 hours at a 90 percent confidence level. From this specification, the reliability engineer can design a test with explicit criteria for the number of hours and number of failures until the requirement is met or failed.

Actual mean time between failures is calculated as follows:

$$MTBF = \frac{\sum units \times \sum hours}{\sum Failures} \text{ (60\% failure rate)}$$

System survivability is calculated as follows:

$$R_s = e^{\left(-t/MTBF\right)}$$

where $-t$ is the operational hours of concern and $e = 2.18$.

The combination of reliability parameter value and confidence level greatly affects the development cost and the risk to both the customer and producer. Care is needed to select the best combination of requirements. Reliability testing may be performed at various levels, such as the component, subsystem, and system levels. Also, many factors must be addressed during testing, such as extreme temperature and humidity, shock, vibration, and heat. Reliability engineering determines an effective test strategy so that all parts are exercised in relevant environments. For systems that must last many years, reliability engineering may be used to design an accelerated life test.

Requirements for Reliability Tasks

Reliability engineering must also address requirements for various reliability tasks and documentation during system development, testing, production, and operation. These requirements are generally specified in the contract statement of work and depend on how much leeway the customer wishes to provide to the contractor. Reliability tasks include various

analyses, planning, and failure reporting. Task selection depends on the criticality of the system as well as cost. A critical system may require a formal failure-reporting and failure review process throughout development, whereas a noncritical system may rely on final test reports. The most common reliability program tasks are documented in reliability program standards, such as MIL-STD-785 (U.S. Air Force 1986) and IEEE 1332 (Institute of Electrical and Electronics Engineers 1998).

Design for Reliability

Design for reliability (DFR) is an emerging discipline that refers to the process of designing reliability into products. This process encompasses several tools and practices, and describes the order of their deployment that an organization needs to have in place in order to drive reliability into their products. Typically, the first step in the DFR process is to set the system's reliability requirements. Reliability must be "designed into" the system. During system design, the top-level reliability requirements are then allocated to subsystems by design and reliability engineers working together.

Reliability design begins with the development of a model. Reliability models use block diagrams and fault trees to provide a graphical means of evaluating the relationships between different parts of the system. These models incorporate predictions based on parts-count failure rates taken from historical data. While the predictions are often not accurate in an absolute sense, they are valuable to assess relative differences in design alternatives.

Fault Tree Diagrams

One of the most important design techniques is redundancy. This means that if one part of the system fails, there is an alternate success path, such as a backup system. An automobile brake light might use two light bulbs. If one bulb fails, the brake light still operates using the other bulb. Redundancy significantly increases system reliability, and is often the only viable means of doing so. However, redundancy is difficult and expensive, and is therefore limited to critical parts of the system. Another design technique, the physics of failure, relies on understanding the physical processes of stress, strength, and failure at a very detailed level. The material

or component can then be redesigned to reduce the probability of failure. Another common design technique is component derating: selecting components whose tolerance significantly exceeds the expected stress, as by using a heavier gauge wire that exceeds the normal specification for the expected electrical current.

Many tasks, techniques, and analyses are specific to particular industries and applications. Commonly these include the following:

Built-in test (BIT)
Failure mode and effects analysis (FMEA)
Reliability simulation modeling
Thermal analysis
Reliability block diagram analysis
Fault tree analysis
Sneak circuit analysis
Accelerated testing
Reliability growth analysis
Weibull analysis
Electromagnetic analysis
Statistical interference

Results are presented during the system design reviews and logistics reviews. Reliability is just one requirement among many system requirements. Engineering trade studies are used to determine the optimum balance between reliability and other requirements and constraints.

Reliability Testing

A Reliability Sequential Test Plan

The purpose of reliability testing is to discover potential problems with the design as early as possible and, ultimately, provide confidence that the system meets its reliability requirements.

Reliability testing may be performed at several levels. Complex systems may be tested at the component, circuit board, unit, assembly, subsystem, and system levels. (The test-level nomenclature varies among applications.) For example, performing environmental stress–screening tests at lower levels, such as with piece parts or small assemblies, catches

problems before they cause failures at higher levels. Testing proceeds during each level of integration through full-up system testing, developmental testing, and operational testing, thereby reducing program risk. System reliability is calculated at each test level. Reliability growth techniques and failure-reporting, analysis, and corrective action systems (FRACAS) are often employed to improve reliability as testing progresses. The drawbacks to such extensive testing are time and expense. Customers may choose to accept more risk by eliminating some or all lower levels of testing.

It is not always feasible to test all system requirements. Some systems are prohibitively expensive to test; some failure modes may take years to observe; some complex interactions result in a huge number of possible test cases; and some tests require the use of limited test ranges or other resources. In such cases, different approaches to testing can be used, such as accelerated life testing, the design of experiments, and simulations.

The desired level of statistical confidence also plays an important role in reliability testing. Statistical confidence is increased by increasing either the test time or the number of items tested. Reliability test plans are designed to achieve the specified reliability at the specified confidence level with the minimum number of test units and test time. Different test plans result in different levels of risk to the producer and consumer. The desired reliability, statistical confidence, and risk levels for each side influence the ultimate test plan. Good test requirements ensure that the customer and developer agree in advance on how reliability requirements will be tested.

A key aspect of reliability testing is to define *failure*. Although this may seem obvious, there are many situations where it is not clear whether a failure is really the fault of the system. Variations in test conditions, operator differences, weather, and unexpected situations create differences between the customer and the system developer. One strategy to address this issue is to use a scoring conference process. A scoring conference includes representatives from the customer, the developer, the test organization, and the reliability organization, and sometimes independent observers. The scoring conference process is defined in the statement of work. Each test case is considered by the group and "scored" as a success or failure. This scoring is the official result used by the reliability engineer.

As part of the requirements phase, the reliability engineer develops a test strategy with the customer. The test strategy makes trade-offs between the needs of the reliability organization, which wants as much data as possible,

and constraints such as cost, schedule, and available resources. Test plans and procedures are developed for each reliability test, and results are documented in official reports.

Accelerated Testing

The purpose of accelerated life testing is to induce field failure in the laboratory at a much faster rate by providing a harsher, but nonetheless representative, environment. In such a test, the product is expected to fail in the lab just as it would have failed in the field—but in much less time. The main objective of an accelerated test is either of the following:

To discover failure modes
To predict the normal field life from the high-stress lab life

Accelerated testing needs planning as follows:

Define the objective and scope of the test.
Collect required information about the product.
Identify the stress(es).
Determine the level of stress(es).
Conduct the accelerated test, and analyze the accelerated data.

Common ways to determine a life stress relationship are the following:

Arrhenius model
Eyring model
Inverse power law model
Temperature-humidity model
Temperature nonthermal model

Software Reliability

Software reliability is a special aspect of reliability engineering. System reliability, by definition, includes all parts of the system, including hardware, software, operators, and procedures. Traditionally, reliability engineering focuses on critical hardware parts of the system. Since the widespread use of digital integrated circuit technology, software

has become an increasingly critical part of most electronics and, hence, nearly all present-day systems. There are significant differences, however, in how software and hardware behave. Most hardware unreliability is the result of a component or material failure that results in the system not performing its intended function. Repairing or replacing the hardware component restores the system to its original unfailed state. However, software does not fail in the same sense that hardware fails. Instead, software unreliability is the result of unanticipated results of software operations. Even relatively small software programs can have astronomically large combinations of inputs and states that are infeasible to exhaustively test. Restoring software to its original state only works until the same combination of inputs and states results in the same unintended result. Software reliability engineering must take this into account.

Despite this difference in the source of failure between software and hardware—software doesn't wear out—some in the software reliability–engineering community believe statistical models used in hardware reliability are nevertheless useful as a measure of software reliability, describing what we experience with software: the longer you run software, the higher the probability you'll eventually use it in an untested manner and find a latent defect that results in a failure (Shooman 1987; Musa 2005; Denney 2005).

As with hardware, software reliability depends on good requirements, design, and implementation. Software reliability engineering relies heavily on a disciplined software-engineering process to anticipate and design against unintended consequences. There is more overlap between software quality engineering and software reliability engineering than between hardware quality and reliability. A good software development plan is a key aspect of the software reliability program. The software development plan describes the design and coding standards, peer reviews, unit tests, configuration management, software metrics, and software models to be used during software development.

A common reliability metric is the number of software faults, usually expressed as faults per thousand lines of code. This metric, along with software execution time, is key to most software reliability models and estimates. The theory is that the software reliability increases as the number of faults (or fault density) goes down. Establishing a direct connection between fault density and MTBF is difficult, however, because of the way software faults are distributed in the code, their severity, and

the probability of the combination of inputs necessary to encounter the fault. Nevertheless, fault density serves as a useful indicator for the reliability engineer. Other software metrics, such as complexity, are also used.

Testing is even more important for software than hardware. Even the best software development process results in some software faults that are nearly undetectable until tested. As with hardware, software is tested at several levels, starting with individual units, through integration and full-up system testing. Unlike with hardware, it is inadvisable to skip levels of software testing. During all phases of testing, software faults are discovered, corrected, and retested. Reliability estimates are updated based on the fault density and other metrics. At the system level, MTBF data are collected and used to estimate reliability. Unlike with hardware, performing the exact same test on the exact same software configuration does not provide increased statistical confidence. Instead, software reliability uses different metrics such as test coverage.

Eventually, the software is integrated with the hardware in the top-level system, and software reliability is subsumed by system reliability. The Software Engineering Institute's *capability maturity model* is a common means of assessing the overall software development process for reliability and quality purposes.

Reliability Operational Assessment

After a system is produced, reliability engineering during the system operation phase monitors, assesses, and corrects deficiencies. Data collection and analysis are the primary tools used. When possible, system failures and corrective actions are reported to the reliability engineering organization. The data are constantly analyzed using statistical techniques, such as Weibull analysis and linear regression, to ensure the system reliability meets the specification. Reliability data and estimates are also key inputs for system logistics. Data collection is highly dependent on the nature of the system. Most large organizations have quality control groups that collect failure data on vehicles, equipment, and machinery. Consumer product failures are often tracked by the number of returns. For systems in dormant storage or on standby, it is necessary to establish a formal surveillance program to inspect and test random samples. Any changes

to the system, such as field upgrades or recall repairs, require additional reliability testing to ensure the reliability of the modification.

Reliability Organizations

Systems of any significant complexity are developed by organizations of people, such as a commercial company or a government agency. The reliability-engineering organization must be consistent with the company's organizational structure. For small, noncritical systems, reliability engineering may be informal. As complexity grows, the need arises for a formal reliability function. Because reliability is important to the customer, the customer may even specify certain aspects of the reliability organization.

There are several common types of reliability organizations. The project manager or chief engineer may employ one or more reliability engineers directly. In larger organizations, there is usually a product assurance or specialty-engineering organization, which may include reliability, maintainability, quality, safety, human factors, logistics, and so on. In such case, the reliability engineer reports to the product assurance manager or specialty-engineering manager.

In some cases, a company may wish to establish an independent reliability organization. This is desirable to ensure that the system reliability, testing of which is often expensive and time-consuming, is not unduly slighted due to budget and schedule pressures. In such cases, the reliability engineer works on the project on a day-to-day basis, but is actually employed and paid by a separate organization within the company.

Because reliability engineering is critical to early system design, it has become common for reliability engineers; however, the organization is structured to work as part of an integrated product team.

Certification

The American Society for Quality (ASQ) has a program to become a certified reliability engineer, or CRE. Certification is based on education, experience, and a certification test; periodic recertification is required. The body of knowledge for the test includes reliability management, design evaluation, product safety, statistical tools, design and development, modeling, reliability testing, collecting and using data, and so on.

Reliability Engineering Education

Some universities offer graduate degrees in reliability engineering (e.g., the University of Maryland). Reliability engineers typically have an engineering degree, which can be in any field of engineering, from an accredited university or college program. Many engineering programs offer reliability courses, and some universities have entire reliability-engineering programs. A reliability engineer may be registered as a professional engineer by the state, but this is not required by most employers. There are many professional conferences and industry training programs available for reliability engineers. Several professional organizations exist for reliability engineers, including the IEEE Reliability Society, the ASQ, and the Society of Reliability Engineers (SRE).

SYSTEMS ANALYSIS

System analysis is the branch of electrical engineering that characterizes electrical systems and their properties. Although many of the methods of system analysis can be applied to nonelectrical systems, it is a subject often studied by electrical engineers because it has direct relevance to many other areas of their discipline, most notably signal processing and communication systems.

Characterization of Systems

A system is characterized by how it responds to input signals. In general, a system has one or more input signals and one or more output signals. Therefore, one natural characterization of systems is by how many inputs and outputs they have:

Single input, single output (SISO)
Single input, multiple outputs (SIMO)
Multiple inputs, single output (MISO)
Multiple inputs, multiple outputs (MIMO)

It is often useful (or necessary) to break up a system into smaller pieces for analysis. Therefore, we can regard a SIMO system as multiple SISO

systems (one for each output), and the same applies for a MIMO system. By far, the greatest amount of work in system analysis has been with SISO systems, although many parts inside SISO systems have multiple inputs (such as adders).

Signals can be continuous or discrete in time, as well as continuous or discrete in the values they take at any given time:

- Signals that are continuous in time and continuous in value are known as *analog signals*.
- Signals that are discrete in time and discrete in value are known as *digital signals*.
- Signals that are discrete in time and continuous in value are called *discrete time signals*. While important mathematically, systems that process discrete time signals are difficult to physically realize. The methods developed for analyzing discrete time signals and systems are usually applied to digital and analog signals and systems.
- Signals that are continuous in time and discrete in value are sometimes seen in the timing analysis of logic circuits, but have little to no use in system analysis.

With this categorization of signals, a system can then be characterized as to which type of signals it deals with:

- A system that has analog input and analog output is known as an *analog system*.
- A system that has digital input and digital output is known as a *digital system*.

Systems with analog input and digital output or digital input and analog output are possible. However, it is usually easiest to break up these systems into their analog and digital parts for analysis, as well as the necessary analog-to-digital or digital-to-analog converter.

Another way to characterize systems is by whether their output at any given time depends only on the input at that time, or perhaps on the input at some time in the past (or in the future!).

Memoryless systems do not depend on any past input.
Systems with memory do depend on past input.
Causal systems do not depend on any future input.
Noncausal or anticipatory systems do depend on future input.

Note: It is not possible to physically realize a noncausal system operating in "real time." However, from the standpoint of analysis, these systems are important for two reasons. First, the ideal system for a given application is often a noncausal system, which although not physically possible, can give insight into the design of a derivated causal system to accomplish a similar purpose. Second, there are instances when a system does not operate in "real time" but rather is simulated "offline" by a computer.

Analog systems with memory may be further classified as lumped or distributed. The difference can be explained by considering the meaning of memory in a system. Future output of a system with memory depends on future input and a number of state variables, such as values of the input or output at various times in the past. If the number of state variables necessary to describe future output is finite, the system is lumped; if it is infinite, the system is distributed.

Finally, systems may be characterized by certain properties which facilitate their analysis:

A system is linear if it has superposition and scaling properties.
A system that is not linear is nonlinear.
If the output of a system does not depend explicitly on time, the system is said to be time-invariant; otherwise, it is time-variant,
A system that will always produce the same output for a given input is said to be deterministic.
A system that will produce different outputs for a given input is said to be stochastic.

There are many methods of analysis developed specifically for linear time-invariant (LTI) deterministic systems. Unfortunately, in the case of analog systems, none of these properties are ever perfectly achieved. Linearity implies that operation of a system can be scaled to arbitrarily large magnitudes, which is not possible. Time-invariance is violated by aging effects that can change the outputs of analog systems over time (usually years or even decades). Thermal noise and other random phenomena ensure that the operation of any analog system will have some degree of stochastic behavior. Despite these limitations, however, it is usually reasonable to assume that deviations from these ideals will be small.

LTI Systems

As mentioned above, there are many methods of analysis developed specifically for LTI systems. This is due to their simplicity of specification. An LTI system is completely specified by its transfer function (which is a rational function for digital and lumped analog LTI systems). Alternatively, we can think of an LTI system as being completely specified by its frequency response. A third way to specify an LTI system is by its characteristic linear differential equation (for analog systems) or linear difference equation (for digital systems). Which description is most useful depends on the application.

The distinction between lumped and distributed LTI systems is important. A lumped LTI system is specified by a finite number of parameters, be it the zeros and poles of its transfer function, or the coefficients of its differential equation, whereas specification of a distributed LTI system requires a complete function.

AUDITING

Quality audit is the process of systematic examination of a quality system carried out by an internal or external quality auditor or an audit team. It is an important part of an organization's quality management system and is a key element in the ISO quality system standard, ISO 9001.

Quality audits are typically performed at predefined time intervals and ensure that the institution has clearly defined internal quality-monitoring procedures linked to effective action. This can help determine if the organization complies with the defined quality system processes and can involve procedural or results-based assessment criteria.

With the upgrade of the ISO 9000 series of standards from the 1994 to 2000 series, the focus of the audits has shifted from purely procedural adherence toward measurement of the actual effectiveness of the quality management system (QMS) and the results that have been achieved through the implementation of a QMS.

Quality audits can be an integral part of compliance for regulatory requirements. One example is the U.S. Food and Drug Administration, which requires quality auditing to be performed as part of its Quality System Regulation (QSR) for medical devices (Title 21 of the U.S. Code of Federal Regulations, part 820).

Several countries have adopted quality audits in their higher education system (New Zealand, Australia, Sweden, Finland, Norway, and the United States). Initiated in the UK, the process of quality audit in the education system focused primarily on procedural issues rather than on the results or the efficiency of a quality system implementation.

Audits can also be used for safety purposes. Evans and Parker (2008) describe auditing as one of the most powerful safety-monitoring techniques and "an effective way to avoid complacency and highlight slowly deteriorating conditions," especially when the auditing focuses not just on compliance but also on effectiveness.

Audit Planning and Scheduling

Auditor Education and Training

An auditor must possess and maintain sufficient basic education and training in order to perform audits in a professional manner.

Audit Initiation

Audits are initiated by the client either by request or through approval of a program of audits submitted by the auditing department or group. The audit must be assigned to and be accepted by a qualified auditor.

Audit Scope

The scope of audits depends on the need as determined by the client and/or auditing organization. In most cases, the scope of the quality system is defined in the top-level quality manual.

Audit Objective

Audits determine compliance or noncompliance with established standards and assess the effectiveness of such standards. The secondary objective of a quality audit can be to determine opportunities and needs for improvements in the operation and control systems, review performances and results, and facilitate communication. The intent of an audit is that the auditor obtains sufficient evidence to draw conclusions relative to the stated audit objective.

PLAN, SCHEDULE, AND RESULTS

1. Audit plan		2. Schedule		3. Report (Result)			
				Conformed?			
Element	**Auditor(s) Assigned**	**Date(s) Audited**	**Next Audit**	**N/A**	**Yes**	**No**	**AR**
4.22 Quality manual				☐	☐	☐	
4.2.3 Control of documents				☐	☐	☐	
4.2.4 Control of records				☐	☐	☐	
5.1 Management commitment				☐	☐	☐	
5.2 Customer focus				☐	☐	☐	
5.3 Quality focus				☐	☐	☐	
5.4.1 Quality objectives				☐	☐	☐	
5.4.2 Quality planning				☐	☐	☐	
5.5.1 Responsibility and authority				☐	☐	☐	
5.5.3 Internal communications				☐	☐	☐	
5.6 Management review				☐	☐	☐	
6.2.2 Competence awareness and training				☐	☐	☐	
6.3 Infrastructure				☐	☐	☐	
7.2 Customer related process				☐	☐	☐	
7.3 Design and development				☐	☐	☐	
7.4 Purchasing				☐	☐	☐	
7.5.1 Production provision				☐	☐	☐	
7.5.2 Validation of process				☐	☐	☐	
7.5.3 Indentification and traceablity				☐	☐	☐	
7.5.4.Customer property				☐	☐	☐	
7.5.5 Preservation of product				☐	☐	☐	
7.6 Calibration				☐	☐	☐	
8.2.1 Customer satisfaction				☐	☐	☐	
8.2.2 Internal audit				☐	☐	☐	
8.2.3 Monitoring and measurement of processes				☐	☐	☐	
8.2.4 Monitoring and measurement of product				☐	☐	☐	
8.4 Analysis of data				☐	☐	☐	
8.5.3. Preventative action				☐	☐	☐	
				☐	☐	☐	

COMMENTS & OBSERVATIONS

FIGURE 6.2
Audit plan and report.

Frequency and Timing

Audit frequency may be determined by law or regulation, by the audit program, by standards, or by the need of the client.

The timing should be chosen with due regard to availability of evidential material, unbiased observations, adequate cooperation and support from the auditee, sufficiency of the audit resources, and least cost.

Long-term planning provides a framework for an annual audit program. The individual audit assignments in the program must be further planned in detail.

Long-Term Planning

This is usually carried out by the audit department or group. The resulting plan or program (see Figure 6.2) should be approved by the client. The plan, or program, should include the name of the organizational unit, the object of the audit, and the expected duration and timing of each audit element.

Pre-Audit Review of System

Audits should be planned and carried out only where a quality system is established. Pre-audit reviews are to verify the existence of a system or individual documented procedure that can be audited.

The planning should be conducted by the auditor, or lead auditor with the assistance of the auditors assigned to the team. Audit elements assigned to the individual auditors should be coordinated and integrated in the audit plan.

Working Papers

These are all of the documents required for an effective and orderly execution of the audit plan (see Figure 6.3).

Result

Sampling Plans

Sampling plans are used in the audit to ensure applicability, validity, and reliability of the observation being made (see Figure 6.4).

AUDITOR		DATE:
Activity	Comments	Rating
Quality management system 4.1. General requirements The organization shall establish, document, implement, and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard. The organization shall a) Identify the processes needed for the quality management system and their application throughout organization (see 12). b) Determine the sequence and interaction of these processes. c) Determine criteria and methods needed to ensure that both the operation and control of these processes are effective. d) Ensure the availibility of resources and information necessary to support the operation and monitoring of these processes. e) Monitor, measure and analyze these processes. f) Implement actions necessary to achieve planned results and continual improvement of these processes. These processes shall be managed by the organization in accordance with the requirements of this International Standard. When an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsource processes shall be identified within the quality management system. Note: Process needed for the quality mangement system referred to above should include processes for management activities.		

FIGURE 6.3
Audit working paper.

C=0 SAMPLING PLAN

This table is read starting at the left-hand column, reading down and to the right, and finding the correct sample size under the appropriate AQL. The lot is rejected if one non-conformance is found.

LOT SIZE		AQLs/SAMPLE SIZES			
FROM	TO	2.2	4	6.5	10
2	8	5	3	2	2
9	15	5	3	2	2
16	25	5	3	3	2
26	50	5	5	5	3
51	90	7	6	5	4
91	150	11	7	6	5
151	280	13	10	7	6
281	500	16	11	9	7
501	1,200	19	15	11	8
1,201	3,200	23	18	13	9
3,201	10,000	29	22	15	9
10,001	35,000	35	29	15	9
35,001	150,000	40	29	15	9
150,001	500,000	40	29	15	9
500,001	>500,001	40	29	15	9

FIGURE 6.4
C = 0 sampling plan.

Audit Implementation Steps

The audit plan should be implemented through the following steps:

Notification to the auditee
Orientation of auditors and auditee
Examination
Follow-up and close-out
Reporting of results (management review)

Notification to Auditee

Advance notification allows the auditee to make final preparations for the audit. The audit plan should be forwarded with the notification.

Opening Meeting

The audit team should meet when final preparation and decisions need to be made. A brief meeting with the management of the organization to be audited serves for clarification of the audit plan, introduction of the auditors, and finalization of procedures and meetings.

Information, Verification, and Evaluation

The auditor must obtain sufficient, relevant information and evidence that permit a valid and reliable verification and evaluation (see Figure 6.5).

Audit Observations

Audit observations are significant conclusions and results of the examination.

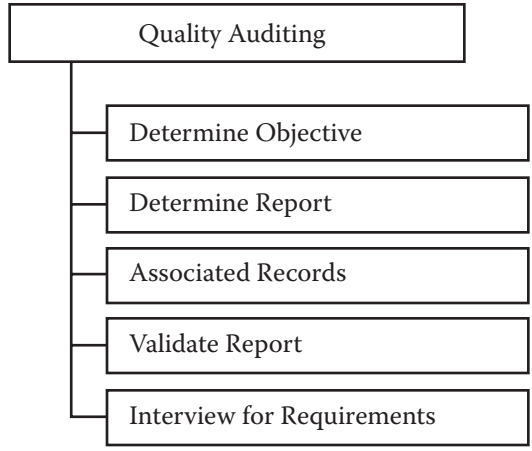

FIGURE 6.5
Audit steps: Any process.

Audit Supervision

At the conclusion of the audit and prior to preparing the audit report, a meeting should be held by the auditor or lead auditor with the auditee's senior management. The main purpose of the meeting is to present and clarify all audit observations to be reported, along with supporting evidence, so that the auditee can initiate necessary corrective action effectively without delay.

Audit Follow-Up

Follow-up consists of verification of corrective action resulting from observations.

Preparation of the Report

Standards for the form and content of the report should be established and followed.

Content of the Report

The audit report should include the following:

Purpose, objective, and scope of the audit
Details of the audit plan, auditors, dates, and organization audited
Standards used
Observations and evidence
Noteworthy comments and recommendations
Follow-up corrective actions

Reporting the Audit

Review and Distribution

Management of the auditing organization should review and approve the report prior to submitting it to the client. The client decides on the distribution of copies of the report.

Audit Completion

An audit assignment is completed upon submission of the audit report to the client, except in special circumstances when verification of corrective action is explicitly included in the audit assignment and plan.

Record Retention

The auditor, lead auditor, or audit organization is responsible for custody and retention of audit documents and records.

COST OF QUALITY

In management accounting, cost accounting is the process of tracking, recording, and analyzing costs associated with the products or activities of an organization. Managers use cost accounting to support decision making to reduce a company's costs and improve its profitability. As a form of management accounting, cost accounting need not follow standards such as generally accepted accounting principles (GAAP), because its primary use is for internal managers, rather than external users, and what to compute is instead decided pragmatically.

Costs are measured in units of nominal currency by convention. Cost accounting can be viewed as translating the supply chain (the series of events in the production process that, in concert, result in a product) into financial values.

There are at least four approaches:

Standardized cost accounting
Activity-based costing
Throughput accounting
Marginal costing, or cost-volume-profit analysis

Classical cost elements are as follows:

Raw materials
Labor
Allocated overhead

TABLE 6.6

Cost-of-Quality Statement

		Cost	Subtotal	
Failure Costs				
	Raw material nonconformance	$3,276		
	Repairs	$70,299		
	Scrap	$2,000		
	Returns	$300,000		
	Rework	$20,000		
			$395,575	
Appraisal Costs				
	Product audits	$32,000		
	Receiving inspection	$25,000		
	In-process inspection	$25,000		
	Final inspection	$50,000		
			$132,000	
Prevention Costs				
	Design reviews	$9,000		
	Quality assurance	$25,000		
			$34,000	
Total				$561,575

Origins

Cost accounting has long been used to help managers understand the costs of running a business. Modern cost accounting originated during the Industrial Revolution, when the complexities of running a large-scale business led to the development of systems for recording and tracking costs to help business owners and managers make decisions.

In the early industrial age, most of the costs incurred by a business were what modern accountants call *variable costs* because they varied directly with the amount of production. Money was spent on labor, raw materials, power to run a factory, and so on, in direct proportion to production. Managers could simply total the variable costs for a product and use this as a rough guide for decision-making processes.

Some costs tend to remain the same even during busy periods, unlike variable costs, which rise and fall with volume of work. Over time, the importance of these "fixed costs" has become more important to managers.

Examples of fixed costs include the depreciation of plant and equipment, and the cost of departments such as maintenance, tooling, production control, purchasing, quality control, storage and handling, plant supervision, and engineering. In the early twentieth century, these costs were of little importance to most businesses. However, in the twenty-first century, these costs are often more important than the variable cost of a product, and allocating them to a broad range of products can lead to bad decision making. Managers must understand fixed costs in order to make decisions about products and pricing.

The concept of quality costs (see Table 6.6) is a means to quantify the total cost of quality-related efforts and deficiencies. It was first described by Armand V. Feigenbaum in a 1956 *Harvard Business Review* article.

Prior to its introduction, the general perception was that higher quality requires higher costs, either by buying better materials or machines, or by hiring more labor. Furthermore, while cost accounting had evolved to categorize financial transactions into revenues, expenses, and changes in shareholder equity, it had not attempted to categorize costs relevant to quality. By classifying quality-related entries from a company's general ledger, management and quality managers can evaluate investments in quality based on cost improvement and profit enhancement.

Internal failure costs: These are costs associated with nonconformities that are found during receiving, in-process inspection, and finished-goods inventory prior to shipping to the customer. Examples would be the following:

Scrap
Rework
Supplier scrap or rework
Sorting
Retest and reinspection
Regrading

External failure costs: These are costs associated with nonconformities that are found by the customer. Examples would be the following:

Warranty charges
Service time and material allowances
Returned material costs

Appraisal costs: These are the costs associated with product verification and validation. Examples would be as follows:

Product audits
Receiving inspection
In-process inspection
Final inspection
Calibration

Prevention costs: These are the costs associated with activities associated with preventing nonconformities from occurring. Examples would be as follows:

Planning
Reviews
Management controls
Organizing
Internal audits
Supplier audits
Training