THE ASQ

CERTIFIED QUALITY PROCESS ANALYST

THIRD EDITION

HANDBOOK

SANDRA L. FURTERER, Editor

The ASQ Certified Quality Process Analyst Handbook

Third Edition

Sandra L. Furterer, editor

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To my family—husband Dan, and children Kelly, Erik, and Zach—for the love, support, and care that you provide each and every day; and to Demi, Lily, and Louis, my rescue dogs and cat, who bring joy and hang with me when I'm writing.

Sandra L. Furterer

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Sandra L. Furterer

Introduction

This handbook is designed as a reference for the Certified Quality Process Analyst (CQPA) Body of Knowledge (BoK), providing the basic information needed to prepare for the CQPA examination. However, it can also be leveraged to learn and deepen the understanding of a quality process analyst, which is the first step to becoming a quality engineer.

There are five main sections in the CQPA Body of Knowledge, further subdivided into related subsections:

- Quality Concepts and Team Dynamics
- Quality Tools and Process Improvement Techniques
- Data Analysis
- Customer–Supplier Relations
- Corrective and Preventative Action

Part I of the handbook describes the fundamental elements of a quality system. The section begins with the quality principles embodied by the ASQ Code of Ethics. It then covers the importance of quality to improve processes, products, and services. Lastly, it describes quality planning, standards, requirements, and specifications; documentation and the Cost of Quality (COQ), quality audits, team dynamics, and training and evaluation.

Part II focuses on quality tools and process improvement techniques, including Lean-Six Sigma, benchmarking, risk management and business process management, management and planning tools, and project management tools. Part III provides the analytical methods to interpret and compare data sets and model processes. Basic statistics, probability, reliability concepts, data types, data collection and data integrity, sampling methods, measurement systems analysis, statistical process control (SPC), advanced statistical analysis tools, regression and correlation, hypothesis testing, design of experiments (DOE), Taguchi concepts, and analysis of variance are explained in this section. Customer-supplier relations are covered in Part IV, including internal and external customers and suppliers, customer satisfaction methods, product and process approval systems, supplier management, material identification, status, and traceability. Finally, as discussed in Part V, an overall effective quality management system must employ a corrective and preventive action (CAPA) system.

The relevant portion of the CQPA Body of Knowledge is excerpted at the beginning of each BoK section in the text as a guide for the reader.

Part I

Quality Concepts and Team Dynamics

Chapter 1

Professional Conduct and Ethics

Identify and apply behaviors that are aligned with the ASQ Code of Ethics. (Apply)

Body of Knowledge I.A

CODE OF ETHICS

Introduction

The purpose of the American Society for Quality (ASQ) Code of Ethics is to establish global standards of conduct and behavior for its members, certification holders, and anyone else who may represent or be perceived to represent ASQ. In addition to the code, all applicable ASQ policies and procedures should be followed. Violations to the Code of Ethics should be reported. Differences in work style or personalities should be first addressed directly with others before escalating to an ethics issue.

The ASQ Professional Ethics and Qualifications Committee, appointed annually by the ASQ Board of Directors, is responsible for interpreting this code and applying it to specific situations, which may or may not be specifically called out in the text. Disciplinary actions will be commensurate with the seriousness of the offense and may include permanent revocation of certifications and/or expulsion from the society.

Fundamental Principles

ASQ requires its representatives to be honest and transparent. Avoid conflicts of interest and plagiarism. Do not harm others. Treat them with respect, dignity, and fairness. Be professional and socially responsible. Advance the role and perception of the Quality professional.

Expectations of a Quality Professional

A. **Act with Integrity and Honesty**

1. Strive to uphold and advance the integrity, honor, and dignity of the Quality profession.

2. Be truthful and transparent in all professional interactions and activities.
3. Execute professional responsibilities and make decisions in an objective, factual, and fully informed manner.
4. Accurately represent and do not mislead others regarding professional qualifications, including education, titles, affiliations, and certifications.
5. Offer services, provide advice, and undertake assignments only in your areas of competence, expertise, and training.

B. **Demonstrate Responsibility, Respect, and Fairness**

1. Hold paramount the safety, health, and welfare of individuals, the public, and the environment.
2. Avoid conduct that unjustly harms or threatens the reputation of the Society, its members, or the Quality profession.
3. Do not intentionally cause harm to others through words or deeds. Treat others fairly, courteously, with dignity, and without prejudice or discrimination.
4. Act and conduct business in a professional and socially responsible manner.
5. Allow diversity in the opinions and personal lives of others.

C. **Safeguard Proprietary Information and Avoid Conflicts of Interest**

1. Ensure the protection and integrity of confidential information.
2. Do not use confidential information for personal gain.
3. Fully disclose and avoid any real or perceived conflicts of interest that could reasonably impair objectivity or independence in the service of clients, customers, employers, or the Society.
4. Give credit where it is due.
5. Do not plagiarize. Do not use the intellectual property of others without permission. Document the permission as it is obtained.

As a Certified Quality Process Analyst (CQPA), you will be expected to perform your process analysis duties as a professional, which includes acting in an ethical manner. The ASQ Code of Ethics has been carefully drafted to serve as a guide for ethical behavior of its members and those individuals who hold certifications in its various disciplines.

Specifically, the Code of Ethics requires that CQPAs are honest and impartial and serve the interests of their employers, clients, and the public with dedication. CQPAs should join with other quality process analysts to increase the competence and prestige of the profession. CQPAs should use their knowledge and skill for the advancement of human welfare and to promote the safety and reliability of products for public use. They should earnestly strive to aid the work of the

American Society for Quality in its efforts to advance the interests of the quality process analyst profession.

Performing your duties in an ethical manner is not always easy. Ethical choices are often not clear-cut, and the right course of action is not always obvious. The ASQ Code of Ethics is not meant to be the one final answer to all ethical issues you may encounter. In fact, the code has been revised and will continue to be revised from time to time to keep it current as new perspectives and challenging dilemmas arise.

To improve relations with the public, CQPAs should do whatever they can to promote the reliability and safety of all the products and services that fall within their jurisdiction. They should endeavor to extend public knowledge of the work of ASQ and its members as it relates to the public welfare. They should be dignified and modest in explaining quality process analysis work and its merit. CQPAs should preface any public statements they make by clearly indicating on whose behalf they are made.

An example of the CQPA's obligation to serve the public at large arose when a process analyst found that her manufacturing facility was disposing hazardous waste materials in an illegal fashion. Naturally, she wrote up the violation and sent her report to the director of manufacturing. Her manager told her a few days later to "just forget about" the report she had written. This CQPA considered the incident a significant violation of her personal ethics, and she told her boss that she felt the larger public interest outweighed the company's practice in this case. Her arguments were persuasive, and eventually the company reversed its former practice of disposing of the hazardous materials in an illegal manner.

To advance relations with employers and clients, CQPAs should act in professional matters as faithful agents or trustees of each employer or client. They should inform each client or employer of any business connections, interests, and affiliations that might influence the CQPA's judgment or impair the equitable character of his or her services. CQPAs should indicate to his or her employer or client the adverse consequences to be expected if his or her judgment is overruled. CQPAs should not disclose information concerning the business affairs or technical processes of any present or former employer or client without formal consent. CQPAs should not accept compensation from more than one party for the same service without the consent of all parties. For example, if the CQPA is employed, he or she should not engage in supplementary employment in consulting practice without first gaining the consent of the employer.

Another example of an ethical issue concerning loyalty to employers and clients occurred when a quality consultant was asked to give another client in a competing firm a short description of the first client's product. The information that the second company was requesting was readily available on the internet, but this CQPA felt that he should not be the source of information about a competitor's project since that information was obtained while engaged by the competitor.

To improve relations with peers, CQPAs should give credit for the work of others to those to whom it is due. CQPAs should endeavor to aid the professional development and advancement of those in his or her employ or under his or her supervision. Finally, CQPAs must not compete unfairly with others. They should extend friendship and confidence to all associates and to those with whom he or she has business relations.

An example of a potential violation of the ASQ Code of Ethics as it relates to dealing with peers occurred when a consulting quality process analyst was asked to do a job that required more work than she could do on her own. She properly enlisted the support of a peer, a highly qualified and very senior Certified Quality Engineer (CQE). The CQE so impressed the client that they asked him to take the lead on the engagement. The CQE, however, chose not to violate the Code of Ethics. Instead, he discussed the situation openly with the CQPA and the client, and it was agreed to keep the leadership for this engagement in the CQPA's domain.

Chapter 2
Quality Concepts

QUALITY

> Describe how using quality techniques to improve processes, products, and services can benefit all parts of an organization. Describe what quality means to various stakeholders (e.g., employees, organization, customers, suppliers, community) and how each can benefit from quality. (Understand)
>
> **Body of Knowledge I.B.1**

Definitions of Quality

In this section, we will first discuss the concept of a system, and a value chain, which provides a high-level perspective of the value provided to customers from a manufacturing and a service organization. This will provide the foundation and context for how quality is defined from the perspective of the various customers and stakeholders in the organization.

System Definition

Dr. W. E. Deming, the quality guru, defined a system as:

> *an interconnected complex of functionally related components, divisions, teams, platforms, whatever you call them, that work together to try to accomplish the aim of the system. A system must have an aim. Without an aim there is no system. The aim of the system must be clear to everyone in the system. The aim includes plans for the future.* (Deming and Orsini 2013, Chapter 5)[1]

In order to achieve quality of a product or service, the system, with its processes, people, and technology, must be well understood. A way to understand a system is to model it from the perspective of a value chain.

Value System and Value Chains

The *value chain* is a chain of activities that provide value to your customer and enable competitive advantage. The concept of a value chain was first

described and popularized by Michael Porter (Porter 1985).[2] The industry-wide synchronized interactions of those local value chains create an extended value chain, sometimes global in extent. Porter terms this larger interconnected system of value chains the "value system." A value system includes the value chains of a firm's supplier (and their suppliers, etc.), the firm itself, the firm's distribution channels, and the firm's buyers (and presumably extended to the buyers of their products, and so on). Value systems can consist of value activities, also called primary activities, and support activities. Value activities are the key critical activities that provide value to the customer and that can differentiate an organization from its competitors. The support activities are necessary but do not provide core value to customers.

Porter's value chains include the following primary activities for a manufacturing organization:

- Inbound logistics: includes receiving the materials, storing and managing inventory, and scheduling transportation
- Operations: all of the operational processes required to make the product
- Outbound logistics: the distribution activities to ship the finished product, including warehousing, order management, transportation, and distribution
- Marketing and sales: marketing and sales of the product
- Service: customer service, repair, installation, and training

The support activities in Porter's model include these activities:

- Procurement: purchasing raw materials and components
- Technology development: Research and development, and product design
- Human resource management: recruiting, development, retention, and employee compensation activities
- Firm infrastructure: includes all of the managerial support functions including legal, accounting, finance, quality management, strategic planning, and so on

For a service value system, we define the concept somewhat differently than Porter's model. We define a value system as an aggregation of the value chains that provide value to the customers. The value chains are the sets of activities that provide a specific service delivery or product line to the customer. In a manufacturing organization, the majority of the product lines would use the same activities and value chains to create the product, so multiple sets of value chains would not be necessary. For a service organization, the activities that are part of the value chain could vary for different service lines more than a manufacturing organization's value chains. By defining our value system differently, we enable our model to be used for a manufacturing and a service organization.[3]

To further illustrate the distinction, a healthcare organization's value system could consist of the following value chains for value activities for service delivery value chains:

- Provide emergency services
- Provide inpatient services
- Provide outpatient services
- Provide surgical services
- Provide women's services

Some examples of support value chains that support the clinical service delivery systems include:

- Provide supply chain services: activities that provide supplies, equipment, and instruments to the organization for clinical and nonclinical services
- Provide human resources services: activities that support the employees, including recruiting, training and development, career and succession planning, performance evaluation, reward, and recognition
- Provide infrastructure services: includes all managerial support functions such as legal, accounting, finance, quality management, strategic planning, and more

As an example, the highest-level business functions of the emergency services value chain is shown in Figure 2.1.

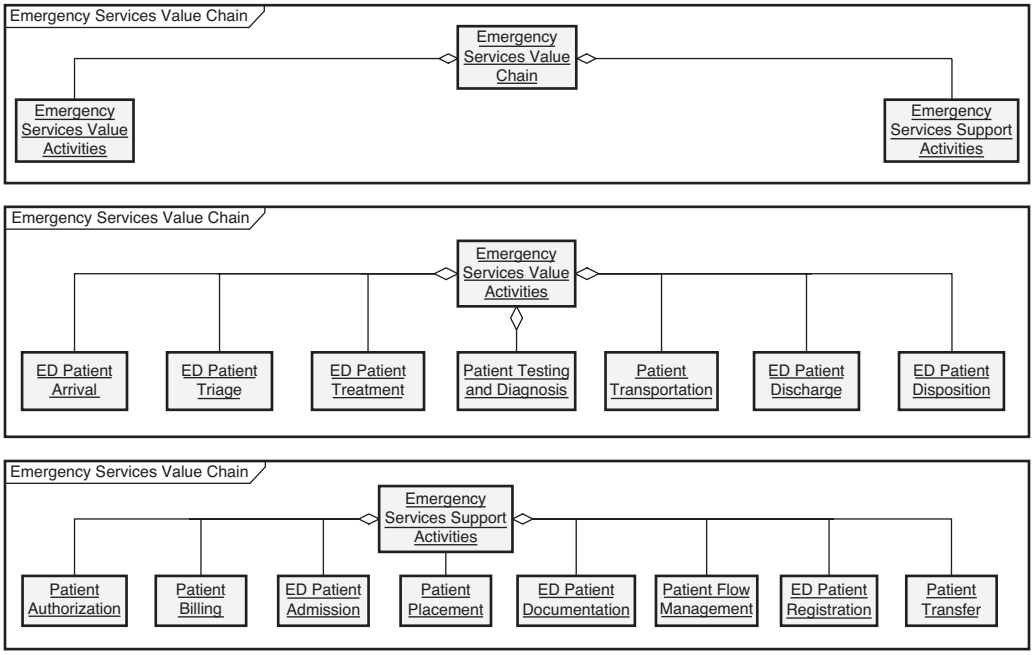


Figure 2.1 Emergency services value chain.

Source: Created by Sandra L. Furterer.[4]

SIPOC

There are many different definitions of quality, especially as defined by different stakeholders within the system. The SIPOC (suppliers–inputs–process–outputs–customers) tool helps us to define the customers and stakeholders involved in performing a process. The five to seven high-level process steps correspond roughly to the high-level activities in the value chain model. The suppliers in the SIPOC model are stakeholders (they can also be customers) that provide an input into the process, and the customers are also stakeholders that receive an output from the process. These suppliers and customers are the stakeholders that have a stake in the process and can be responsible for some level of quality within their process or receive a quality product or service as an external customer. An example of the SIPOC for the emergency services process is shown in Figure 2.2.

SIPOC				
Explain the customer/supplier relationship in the process. Identify where the process begins and where it ends as well as the activities included within the scope of the process to be improved.				
Suppliers	**Inputs**	**Process**	**Outputs**	**Customers**
Patient EMS Physicians Other facilities	Request for ED care Referrals Patient information	**Triage patient**	Acuity level Triage decision	Medical staff Patient
Patient Medical staff	Patient information Acuity level Triage decision	**Register patient**	Registered patient	Registration Medical staff ED physicians
Patient Medical staff ED physicians	Patient information Acuity level Triage decision	**Treat patient**	Patient information Physician orders	Patient Medical staff Ancillary staff ED physicians
Patient Medical staff ED physicians Ancillary staff	Patient information Physician orders Patient medical record	**Test/diagnose patient**	Test results Specimens Diagnosis Patient medical record	Patient Medical staff Ancillary staff
Patient Medical staff Ancillary staff	Test results Diagnosis	**Disposition patient**	Diagnosis Patient medical record	Patient Medical staff ED physicians Admitting & consulting physicians Ancillary staff
Patient Medical staff ED physicians Ancillary staff	Diagnosis Patient medical record	**Transport patient**	Transported patient Patient medical record	Patient Ancillary staff Medical staff
Patient Ancillary staff Medical staff	Patient Patient medical record	**Discharge or admit patient**	Discharged or admitted patient Bill	Patient Insurance companies Medicare/Medicaid

Figure 2.2 Emergency services SIPOC.

Source: Created by Sandra L. Furterer.

Stakeholder Analysis The stakeholder analysis is a tool that can be used to define the people and their roles that are impacted by the process. The stakeholder analysis includes a listing of the stakeholders, type of stakeholder, primary roles that have a stake in the process, potential impact/concerns, and receptivity (see Figure 2.3).[5]

Stakeholder Analysis

Identify the internal and external customer roles and concerns to ensure their expectations are addressed. Define roles, impacts, concerns, and receptivity.

Stakeholder	Type	Primary role	Potential impacts/ concerns	Initial receptivity	Future receptivity
ED patients	**Primary**	Patients who go through the Emergency Department. Includes patients who are seen and discharged, admitted, or who leave without being seen	Quality of care Low waiting time Patient satisfaction	Neutral	Neutral
ED physicians	**Primary**	Physicians who provide care for ED patients	Efficient processes Patient satisfaction Patient throughput Patient capacity	Strongly support	Strongly support
Medical staff	**Primary**	Nurses, technicians, transport, lab, radiology, pharmacy, other inpatient areas who provide care for ED patients	Efficient processes Patient satisfaction	Moderately support	Strongly support
Administration	**Primary**	Administration of the hospital	Efficient use of resources Patient satisfaction Patient throughput	Strongly support	Strongly support
EMS	**Secondary**	Emergency Medical Services who transport patients to the ED from outside the hospital	Quality of care Low waiting time Patient satisfaction	Neutral	Neutral
Registration	**Primary**	Register the patient	Correct registration Accurate billing	Moderately support	Strongly support
Admitting physicians and consultants	**Secondary**	Physicians and specialty consultants who admit patients to the hospital or provide care for the patients that go through the ED	Patient satisfaction Quality of care	Neutral	Strongly support
Regulatory agencies	**Secondary**	Regulatory agencies who define regulatory criteria	Quality of care Revenue integrity	Neutral	Neutral
Ancillary support	**Secondary**	Support staff, environmental services, central supply, dietary, insurance, payors	Efficient processes Patient satisfaction Patient throughput	Moderately support	Strongly support

Figure 2.3 Emergency services stakeholder analysis.

Source: Created by Sandra L. Furterer.

Stakeholder (Group Name): The stakeholder group name describes the function that the stakeholder group holds related to the process. The stakeholder name should never be a specific person but the function that they perform. People change jobs or functions, but the function usually persists.

Type: If there are many stakeholders, they can be categorized as primary or secondary types. Primary stakeholders are those who are directly impacted by the system being developed and may be operating the system or benefit directly from the system. Secondary stakeholders are those who are impacted by the system but not as directly as the primary stakeholders.

Primary Role: The role of each stakeholder group with respect to the process is described.

Potential Impacts/Concerns: The project sponsor, team lead, or systems engineer should interview stakeholder representatives to understand their primary concerns regarding the process and/or how they are impacted by the process or system.

Initial and Future Receptivity: The project sponsor and team lead should assess how receptive the stakeholders are to changes in the process. They should also assess how receptive the stakeholders need to be when the process or system is deployed or revised for use. The receptivity is typically assessed based on a rating scale, from strongly support, moderately support, neutral, moderately against, and strongly against. How does the project sponsor and the team leader assess the stakeholders' receptivity to the project? Assessing receptivity can be done in several ways: (1) talk to the stakeholders to assess their receptivity, (2) monitor body language and conversations of the stakeholders within and outside of meetings, and (3) talk with other people who know the stakeholders.

Supportive and engaged stakeholders, team members, and leaders:

- attend meetings and are prompt and engaged
- have a positive outlook and willingness to participate
- exude genuine interest in the project and system
- share ideas in meetings and brainstorming sessions
- perform tasks outside of meetings without being prompted
- offer management perspective to help the team with improvement ideas

Unsupportive and unengaged stakeholders, team members, and leaders:

- complain within and outside of meetings
- have a confrontational tone in meetings
- discourage most ideas
- may not provide ideas in meetings and brainstorming sessions
- do not encourage (or even frown upon) out-of-the-box thinking

Some examples of unsupportive body language include crossed arms, eye rolling, always on phone, holding head in hands, or putting hands out in front of body as if to stop someone from advancing.

Quality Definitions

Quality can be defined based upon the impacts or concerns identified from the voice of the customer data collection as the stakeholder analysis is performed.

James Evans and William Lindsay define quality based upon the view of the stakeholders within the system. They have six quality definitions based upon these different perspectives:[6]

- **Transcendent:** Quality transcends or rises above normal or average quality. This definition represents excellence in quality. This is not a very useful definition, because it is difficult to measure due to the subjective and judgmental nature of the perspective. An example of a product defined as excellent in a transcendent manner can be a Lexus automobile or an Apple iPhone.
- **Product:** This definition relates quality to a quantity of product or service attributes. An example could be a coffee maker that has a timer to automatically brew your coffee, with the ability to make espresso and a latte all with the same machine. The more attributes or features, the supposed higher quality. This may not always be true, though. The author likes brewed tea and once bought a very fancy tea maker with a temperature gage, timed heating, and a glass carafe. Well, the controls and buttons to start, set, and turn on and off the unit were so complicated it hardly constituted a high-quality product, in addition to the glass carafe being easily chipped. She quickly returned to her tried-and-true (and much less expensive) stainless steel percolator, minus the fancy features.
- **User or Fitness for Intended Use:** This definition, advocated by the quality guru Joseph Juran, defines quality based upon how well the product or service achieves the users' intended use or functionality. One user may want an athletic watch with many features, to track multiple types of activities, such as walking, running, swimming, biking, and more, while another user may just want the old-fashioned watch that tells them the date and time. Quality is defined by the functions that the user wants in the product.
- **Value:** The value definition defines quality based upon the trade-off between price and benefits that the product or service provides. An example is the difference and expectations between the quality of the food at a fast-food restaurant—getting lower quality, although it may be consistent lower quality, for a lower price—compared to a high-end restaurant, which is more expensive, includes lovely ambience, and offers much higher-quality food. The user determines the trade-off between price and quality or value for the product or service that they choose.
- **Manufacturing:** The manufacturing of a product to specifications, or conformance to specifications, defines quality from how the product is consistently made to meet the specifications, derived from the customers' needs or requirements. The quality of a car door can be measured to achieve no defects on the door when produced. A quality

of a service can also be defined based on meeting certain specifications, such as being in an emergency room for less than three hours while receiving high-quality medical care.

- **Customer:** This definition defines quality based upon the ability to meet or exceed customers' expectations. The customers in this definition can consist of both internal and external customers or consumers of the final product or service. The value chain model and the SIPOC tools help us to define the chain of customers throughout the system of activities, departments, suppliers, and customers involved in making a product or delivering a service. The voice of the customer data collection helps us to understand the customers' needs in each step of the process, which can help the organization ensure that these needs are met. An example is a mortgage department providing a loan to a consumer purchasing a home. Ultimately, the customer wants to close a loan within 30 days or less, with minimal documentation and a smooth process. Each department can have requirements for the prior department to perform their work in a timely and quality manner (without errors).

The definition used depends upon the stakeholders and the activity being performed in the value chain. The customers may typically measure quality from a *transcendent*, *product*, or *customer* perspective. The customer needs are commonly translated by the marketing department, which defines quality based upon the *user* perspective. The design engineers apply the *value* perspective to make trade-offs between costs of materials and meeting desired customer needs from a value perspective. They translate the customers' requirements into technical or design requirements. The manufacturing and industrial engineers set up manufacturing processes to meet the manufacturing specifications and measure quality based on the *manufacturing* perspective.

In our healthcare emergency services example, the patient may use the *transcendent*, *product*, or *customer* perspective to define quality, completing a patient satisfaction survey based upon their perception of excellence or how their experience in the emergency department transcended their expectations. They also may have selected the hospital's emergency room based upon the product attributes or specialty services that the emergency room is known to provide, such as having a stroke center, a heart center, a trauma center, and the like. They may also assess quality from a customer perspective, that the emergency room met their needs by providing emergency services in a timely manner. The *user* perspective can be used by marketing to market the hospital, providing information on how the hospital has state-of-the-art technology, the latest MRI or CT machines, or laser technology used to provide surgical services.

There probably is not a great deal of the *value* definition applied in a hospital setting, since lack of price transparency comparing like procedures is still not advanced enough to provide the patient the ability to compare from hospital-to-hospital. However, at some point in the future it could be possible as data analytics progresses for the patient to apply a value definition, having a trade-off decision between price and quality of the patient experience. The manufacturing or conformance to specifications can be used within the processes for each major

activity in the value chain to be assessed against a target, such as the patient will see a healthcare professional within five minutes of their arrival, or they will be triaged within seven minutes of their arrival, or their total length of stay will be under three hours for discharged patients and five hours for patients who are admitted to the hospital. The different quality definitions can effectively be used based upon the different stakeholders and the value chain activity being performed.

Benefits of Quality

Quality has many benefits for any organization. A number of research studies have shown that quality can provide a competitive advantage and enhanced business results. A study by PIMS Inc. found that there are nine major strategic drivers of profitability and cash flow. One of these is customer preference for the product or service offered, which aligns to the customer-focused definition of quality:

> *Customer preference for the products and/or services offered: The specifying customers' preference for the non-price attributes of the business's product/service package, compared to those of competitors, has a generally favourable impact on all measures of performance.*[7]

In another study, the researchers compared the Malcolm Baldrige National Quality Award winners to the performance of the S&P 500 as a whole. The Baldrige winners outperformed the S&P 500 overall. Beyond the financial results, the drive for achieving high quality can transform the culture on its journey to performance excellence.[8] Quality can have a positive impact on product or service design as well as improved quality of conformance. The improved quality of design can lead to higher perceived value in the marketplace, leading to increased market share and higher prices. The higher prices can lead to increased revenues and higher profitability. The improved quality of conformance can lead to lower manufacturing and service costs and subsequently higher profitability.[9] These relationships are illustrated in Figure 2.4.

The pursuit for high quality can also enhance the employees' experience with the organization. It can have a positive impact on the culture, the ability of the employees to be able to do their jobs, through having documented processes and procedures, leading to less frustration and errors. Higher employee satisfaction can lead to lower turnover rates for these employees.[10]

Quality of products and services can enhance the organization.[11] Deming's chain reaction supports this point. Improved quality can lead to decreased costs due to less rework and scrap, fewer mistakes and delays, and better use of resources. Decreased costs can improve productivity, which can help to capture higher market share due to better quality and lower prices. Higher market share enhances the ability of the organization to stay in business, enabling the organization to provide more jobs.[12] Figure 2.5 illustrates these relationships.

Customers are critical to any organization. An important part of developing a quality system is to define methods for understanding the customers' needs or listening to the voice of the customer (VOC): eliciting requirements, listening

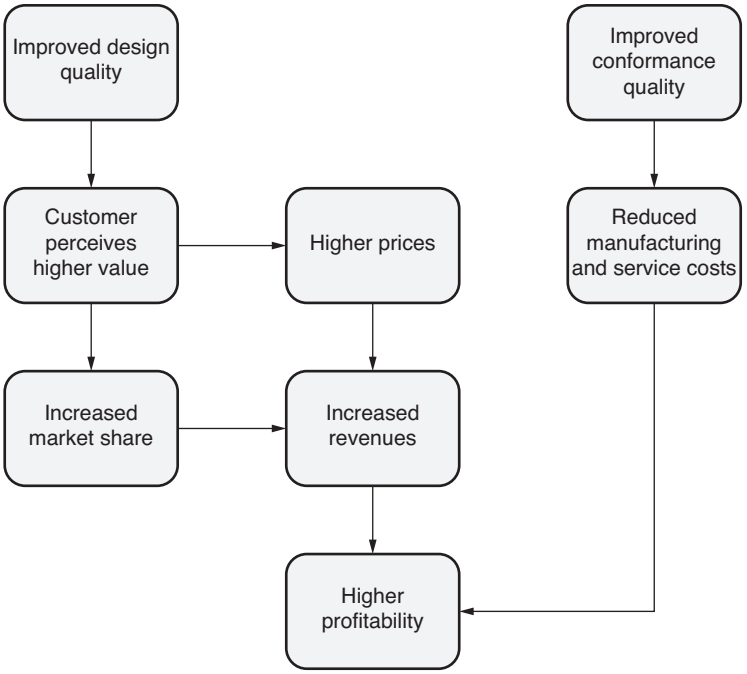


Figure 2.4 Quality impact.

Source: Adapted from Evans and Lindsay.[12]

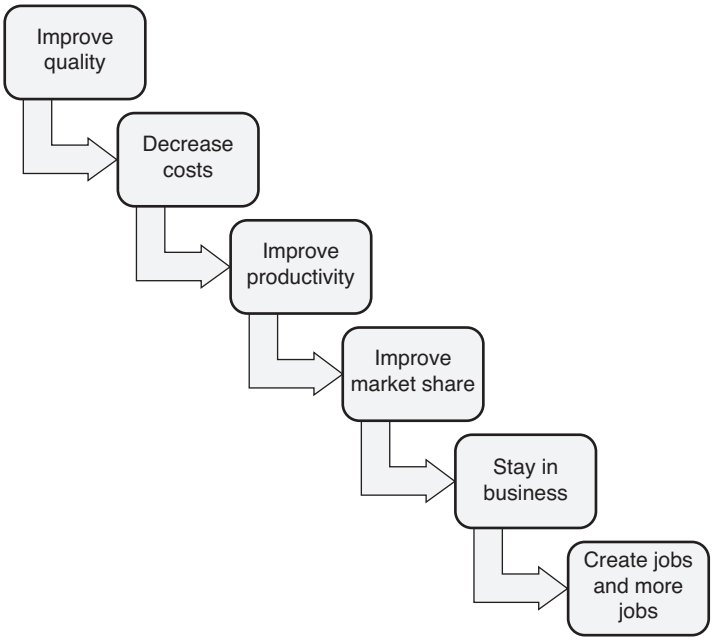


Figure 2.5 Deming's chain reaction of quality.

Source: Adapted from Evans and Lindsay.[12]

to the customer by monitoring and resolving customer complaints, and improving customer satisfaction and—perhaps, most importantly—customer loyalty. Having a customer for a lifetime provides a huge benefit. It is much easier to keep a customer than gain new ones. Suppliers are important stakeholders to the organization. Selecting and certifying suppliers based on quality, not just price, is an important part of ensuring the quality of the product or service. Partnering with suppliers to seamlessly connect the needs of the customer with the supplied parts or services is also critical. Where would a hospital be if they didn't seamlessly design and provide services with their partner physicians, vendors, and other suppliers? Finally are the community benefits from the quality orientation of an organization. Employees, organizations, customers, and suppliers are taxpayers who contribute to the communities in which they live and work, enhancing the viability of these communities.[13]

QUALITY PLANNING

> Define a quality plan, describe its purpose for the organization as a whole, and know who has responsibility for contributing to its development. (Understand)
>
> **Body of Knowledge I.B.2**

To get things done, an organization needs a plan. Plans may be very simple, with merely a goal to be reached and a list of the steps necessary to achieve the goal. But effective organizational quality plans have many of the following elements:

1. Defined responsibilities of all the people associated with the quality plan
2. Alignment to quality policy
2. Clear goals or objectives
3. Logical steps to reach the goals or objectives
4. Identification of necessary resources
5. An implementation approach:
    a. Deployment of the goals or objectives
    b. Conveying priorities and rationale to stakeholders and performers
    c. Measures of progress
    d. Milestones (checkpoints in the schedule to check progress)
6. Measures of success

Responsibilities

Top-level management in an organization is responsible for establishing the firm's commitment to quality. It is this commitment from top management that constitutes total quality management. Armand Feigenbaum[14] defined total quality control as follows:

> *Total quality control's organization-wide impact involves the managerial and technical implementation of customer-oriented quality activities as a prime responsibility of general management and of the mainline operations of marketing, engineering, production, industrial relations, finance, and service as well as of the quality control function itself.*

Kaoru Ishikawa defined *companywide quality control* (CWQC) this way:[15]

> *To practice quality control is to develop, design, produce, and service a quality product which is most economical, most useful, and always satisfactory to the customer.*

Juran called the function or department responsible for quality the Quality and Excellence Office, which could also be known as the Quality or Quality Assurance Department. In highly regulated industries, such as medical device or pharmaceutical companies, it can be referred to as Quality Assurance/Regulatory Assurance.[16] In addition to top management endorsing its commitment to quality and having a separate quality department, most organizations appoint a group to develop guidelines, measure progress, and assist in implementing the quality objectives. A cross-functional team of members representing the key functions in an organization to help assure quality is often referred to as a *quality council*. Many organizations call it by different names or merely include the quality council function in the roles of the executive committee. The council acts as a steering committee for the corporate quality initiative. In addition to ensuring that the quality initiative is implemented, the quality council must incorporate total quality strategies into the strategic business plan. Some of the specific responsibilities of the quality council may include the following:[17]

- Developing an educational module: The modules may be different in content and duration for different organizational levels.
- Defining quality objectives for each division of the organization: This encompasses what improvement methods to employ, who is responsible, and what measures will be used.
- Developing and helping implement the company improvement strategy: Roadblocks and system problems must be resolved, and the quality council is in a unique position to influence these decisions.
- Determining and reporting quality cost: There is no better way to encourage quality improvement than to show that poor quality costs a great deal. Evaluating the dollar value associated with poor quality in terms of prevention, appraisal, and failure costs helps management to measure quality using an easily understood denominator.

- Developing and maintaining an awareness program: The awareness program should be built slowly. It should not be a surge of slogans, posters, and banners that will subsequently fade away. Continuous emphasis on excellence, sharing of success stories, recognition, and setting standards are all part of this process.

Problems identified by the quality council provide opportunities for improvement. For a condition to qualify as a problem, it must meet the following three criteria:

1. Variable performance from an established standard
2. Deviation from the perception and the facts
3. The cause is unknown; if we know the cause, there is no problem

Identifying problems for improvement is not difficult, as there often are many more than can be analyzed. The quality council or work group must prioritize them using the following selection criteria:

1. Is the problem important and not superficial? Why?
2. Will problem solution contribute to the attainment of goals?
3. Can the problem be defined clearly using objectives measures?

Whenever possible, the planning process should include the people who will ultimately implement the plan. There are two reasons for this:

1. The people who will ultimately implement the plan probably have more realistic expectations of what is feasible.
2. People who feel that they participated in planning the work to be done are often more committed to performing it later.

The focus of this perspective is for organizations to continually improve their products, services, processes, and practices, with an emphasis on reducing variation and reducing cycle time. This approach implies extensive use of the quality management tools, including cost of quality, process management approaches, and measurement techniques.

Aligned to Quality Policy

A quality policy provides a guide to managerial action related to quality. It is important to define a clear and concise quality policy that serves as a guide to the quality system. The quality policy statement should be short and concise, as well as align to the organization's strategic direction and core values.

According to the ISO 9001: 2015 standard regarding a quality policy: *Top management shall establish, implement, and maintain a quality policy that: (a) Is appropriate to the purpose and context of the organization and supports its strategic direction. (b) Provides a framework for setting quality objectives. (c) Includes a commitment to satisfy applicable requirements. (d) Includes a commitment to continual improvement of the quality management system.*[18]

Set Goals/Objectives

Quality planning always begins with establishing what needs to be accomplished or what products and services need to be provided. This is often not an easy task since the various stakeholders in any process often have significantly different perspectives of what needs to be accomplished. Therefore, it is almost always necessary to negotiate the goals that will be the objectives of the quality project or effort.

Quality goals should be set for the organization and for each quality project to be performed. The quality council may establish these for the organization, but corporate quality goals can be often derived from the corporation's strategic mission, which is influenced by customers and top management. The quality goals must be consistent with the organization's mission and should be included in the corporate strategic plan. Quality goals, like all strategic goals, should be SMART:

S = Specific

M= Measurable

A = Achievable

R = Realistic

T = Time-bound or timely

To be SMART, the goal must identify who is responsible, what must be accomplished, where the goal is to be achieved, and when the goal is to be accomplished.

To be *measurable*, the goal must be quantified. Goals that are not quantified are not measurable and are not SMART.

The goal must be *achievable*. It must be possible to reach the goal, at least in theory. If the goal is not feasible, it is not reasonable to expect people to try to achieve it. The goal should stretch the organization slightly so that everyone reaches for higher levels of performance, but it must not be beyond the organization's ability to reach. Breaking difficult long-term goals into simpler, attainable steps so the managers and workforce believe that what they are doing is possible is a good management practice.

To be *realistic*, a goal must represent an objective that is both important and *feasible*, given the capabilities of the organization. In establishing goals, it is necessary to consider the abilities of the individuals who will achieve them and to consider the capability of the organization's processes. If the organization does not have the skills, materials, tools, training, processes, and knowledge to achieve the goal, it is unrealistic to expect that the organization can achieve it.

For a goal to be *timely*, it should be accomplished in a timely manner, having a due date or time frame assigned for each goal/objective. This drives a sense of urgency and ensures achievement of goals and objectives.

Here is an example of a customer satisfaction goal that is specific, measurable, attainable, realistic, and timely:

> *To ensure that we are satisfying our customers, 90% of our customers will give us 5s or 6s on our customer satisfaction survey by January 2024.*

According to Juran,[19] total quality control should be a structured process and should include the following:

- A quality council
- Quality policies
- Strategic quality goals
- Deployment of quality goals
- Resources for control
- Measurement of performance
- Quality audits

Quality goals must be linked to product or service satisfaction, customer satisfaction, or cost of quality.

Logical Steps to Reaching the Goals

Stated goals alone are not sufficient for a plan. The plan must provide a road map for reaching the goals. The job must be broken into specific tasks that, when performed in sequence, will result in the goals being met. The project management tools and practices described in Chapter 9 of this handbook will aid in breaking the quality initiative into specific, interrelated tasks.

Resources

All the personnel, equipment, materials, facilities, and processes necessary to perform the tasks must be identified in the plan. The company's total quality processes must include the means for identifying and procuring the resources necessary.

Anyone who is involved with the quality programs should be identified in the corporate quality plan. Individuals must be assigned specific tasks to plan, implement, measure, and improve the quality program in the organization. It is imperative that those assigned specific responsibilities be held accountable for performing the assigned tasks. Holding individuals responsible for their actions is the role of the individual's supervisor or manager, though this process may be monitored by the quality council and senior management.

An Implementation Approach

For a plan to be of any real value to an organization, it is essential that the plan be implemented. "Deployment of the plan" means informing the individuals who will execute the plan of their responsibilities and holding them accountable for implementing the plan. Plan deployment is necessary, or the plan is merely a document that has no impact on the organization's activities.

Measures of Success

Finally, for a plan to be effective, it must include measures of success. The success of corporate quality planning can include these measures:

- Are products or services delivered on time?
- Are the costs of developing/delivering the products or services less than the price charged?
- Are any of the products produced unsold (overproduction)?
- Are the customers' requirements and expectations met?
- Are the customers satisfied with the service provided?
- Was documentation provided (if expected)?

QUALITY STANDARDS, REQUIREMENTS, AND SPECIFICATIONS

> Define and distinguish between national or international standards, customer requirements, and product or process specifications. (Understand)
>
> **Body of Knowledge I.B.3**

The *quality assurance* (QA) function may include design, development, production, installation, servicing, and documentation. The phrases "fit for use" and "do it right the first time" arose from the quality movement in Asia and the United States. The quality goal is to assure quality at every step of a process, from raw materials, assemblies, products and components, services related to production, and management, production, and inspection processes through delivery to the customer, including a feedback loop at each step for continuous improvement. For a service delivery process, the steps include service process design, deployment and delivery of the services, and providing feedback for continuous improvement.

One of the most widely used paradigms for QA management is the *plan–do–check–act* (PDCA) cycle, also known as the Shewhart cycle. The main goal of QA is to ensure that the product fulfills or exceeds customer expectations, also known as *customer requirements*.

A companywide quality approach places an emphasis on four aspects:

- Infrastructure (as it enhances or limits functionality)
- Elements (e.g., controls, job management, adequate processes, performance and integrity criteria, and identification of records)
- Competence (e.g., knowledge, skills, experience, and qualifications)
- Soft elements (e.g., personnel integrity, confidence, organizational culture, motivation, team spirit, and quality relationships)

The quality of the outputs is at risk if any of these four aspects are deficient in any way.

In manufacturing and construction activities, these business practices can be equated to the models for quality assurance defined by the international standards contained in the ISO 9000 series for quality systems. From the onset of the Industrial Revolution through World War II, companies' quality systems relied primarily on shop floor inspection or final lot inspection. This quality philosophy lacked a proactive approach and held the potential that if a product made it to final lot inspection and defects were found, the entire lot was rejected, sometimes at considerable cost and waste of personnel and material resources. The quality problem was not addressed and corrected during manufacture. With the pressures of raw material costs and limited resources, most businesses adopted the more recent quality philosophy to limit adding value to a product or activity as soon as poor quality is observed, and to implement check steps along the process to observe and correct as early as possible. This led to the *quality assurance* or *total quality control* philosophy.

The key to any process, product, or service is to understand and provide what the customer wants. There are three major process, product, or service characteristics:

- Reliability
- Maintainability
- Safety

Various industries have lost market share due to a failure to adequately understand *customer requirements* and failure to translate those requirements into *technical requirements* or *specifications* that a company would need in order to be able to satisfy the customer requirements.

Specifications are typically an engineering function and are critical in the product design, planning, and realization phases.

In addition to physical, measurable specifications, there may be other customer expectations, such as appearance. This may be included as a quality requirement that the quality function would establish, document, and implement.

For instance, parameters for a pressure vessel must include not only the material and dimensions, but also operating, environmental, safety, reliability, and maintainability requirements. Moreover, external standards outside of the company and the customer may dictate further requirements that the product must meet. They may be published federal environmental standards or statistical sampling standards, such as ASQ Z1.4-2003, or performance and testing method standards published by a professional association such as the American Society for Testing and Materials (ASTM).[20]

QUALITY DOCUMENTATION

> Identify and describe common elements of various document control systems, including configuration management, and describe the relationship between quality manuals, procedures, and work instructions. (Understand)
>
> **Body of Knowledge I.B.4**

To the quality professional—and other business support personnel—documentation systems are essential although often underappreciated tools. There are three purposes for a documentation system in an organization:

1. Guide individuals in the performance of their duties
2. Standardize the work processes throughout the organization
3. Provide a source of evidence regarding practices

New employees, people recently reassigned to fulfill new responsibilities, and candidates for appointment to new jobs need a reference for the policies, materials, tools, resources, and practices necessary to do their new job. Documentation serves as the basis for training new employees in both formal training settings and on-the-job training. Documentation also provides more-seasoned individuals a reference for the work they are doing.

For an organization to function effectively, the practices of all of the individuals must be standardized so that others will know what to expect from each person. Failure to standardize is one of the most prevalent reasons for confusion and friction in processes involving multiple departments, functions, or teams. As will be stressed in the discussion of configuration management, the documentation system must permit changes so that improvements can be made and to serve the unique needs of specific customers, but the documentation system must standardize the common elements of the work being done by everyone.

Finally, the documentation system serves as a source of evidence for practices in which the organization is engaged. Documents must be available to support appropriate responses under the following conditions:

1. When legal or regulatory challenges are made
2. When marketing and sales requires proof of the organization's capabilities
3. When senior managers and project managers need to plan and estimate future performance
4. When quality personnel need to spot opportunities for improvement, sources of waste, and problems

Nearly all quality certification programs require the organization being certified to demonstrate that it employs a documentation system to control its documents.

For example, ISO 9001:201521 criteria include a requirement that registered organizations possess documented information. The extent of the documented information depends upon the organization and the following factors:[21]

- Size of the organization, type of activities, processes, products, and services
- Complexity and interactions of the processes
- Competence of personnel

The ISO 9001:2015 requirements address the control of documented information as follows:[22]

> 7.5.3 Control of documented information
>
> 7.5.3.1 Documented information required by the quality management system and by this International Standard shall be controlled to ensure:
>
> a) it is available and suitable for use, where and when it is needed; and
>
> b) it is adequately protected (e.g., from loss of confidentiality, improper use, or loss of integrity).

The ISO 9001:2015 standard changed the terminology related to documentation. The ISO 9001:2008 used the term "records," whereas the ISO 9001:2015 standard uses the term "retained documented information." The 2008 standard refers to documentation, quality manual, documented procedures and records, whereas the 2015 standard instead uses the term "documented information." However, there is no requirement that the information is documented, but it is instead up to the organization to decide if the information needs to be documented.[23]

Need for a Flexible and Current Documentation System

No documentation system is perfect. While every effort must be made to ensure that the documents in the system are complete, the manner in which jobs are performed changes over time, and the documents describing the work are seldom 100% up to date. Accordingly, the documentation system must be flexible.

When individuals retrieve a document and discover that it is out of date, they will be reluctant to retrieve documents from the documentation system in the future. It is essential that the documents in the system are kept current even though it is often an expensive and difficult activity.

Library

Every organization needs to have a library of documents necessary for the organization to perform its functions. ISO 9001:2015 has several documentation requirements, including documentation of the quality management system. Items typically contained in the quality manual or in the organization's library may include the following, but are not all necessarily required:[24]

- Policies and procedures
- Work instructions
- Contracts
- Design inputs
- Process details
- Engineering changes
- Final inspection data
- Warranty changes
- Legal agreements
- History of defects
- Disposition of customer complaints
- Warranties
- Document descriptions and blueprints
- Histories of supplier performance

There is an expense associated with archiving and maintaining the library. The cost of building and maintaining the library must be borne by the organization. Companies that have tried to eliminate the costs associated with the documentation system have often discovered that this was a serious mistake when they were later unable to respond to an environmental agency challenge or were sued and unable to produce evidence of their practices in court.

Configuration Management

Organizations that produce products (hardware or software) control their documents with a *configuration management* (CM) program. Examples of organizations that produce products include

- a manufacturing firm that produces electronic components,
- a software firm that makes and sells computer games, and
- a consulting firm that produces training materials for courses to prepare candidates for ASQ certifications.

The organization's documentation system must be flexible to permit changes to be made to documents when changes are made to products or their design. To allow documents to be modified in a systematic and intelligent fashion, most product-producing organizations adopt configuration management. The CM system ensures that all the documentation describing the product reflects all of the changes that have been made to it during design, development, or installation.

For example, if an electronic component manufacturing firm designs a capacitor to satisfy a customer requirement for handling 12.5 amps, but later is

Table 2.1 Example document traceability matrix.

CPI Program 7267.39 Requirements						
Control number	**Requirement**	**ORD**	**SS**	**CPCI specification**	**VCRM**	**Test document**
CN 301	Sense change signal	3.1.7	2.1.2	3.4.1.2	4.1.2	4.1.2
CN 302	Assemble control data	3.1.8	2.1.5	3.1.3	4.1.2.1	4.1.2.1
CN 303	Transfer data to external module	3.1.9	2.7.6	3.4.1.3	4.1.3	4.1.3
CN 304	Calculate new delay time	3.1.10	2.1.4	3.7.9	4.1.4	4.1.4
CN 305	Inform control module	3.1.11	2.1.7	3.4.1.4	4.1.5	4.1.5
CN 306	Return to search mode	3.1.12	2.1.8	3.4.1.5	4.1.5.1	4.1.5.1

informed that this requirement must be increased to 13.0 amps, the customer and the company must be certain that this change in the requirement has been reflected everywhere that it appears. Of course, the requirement will be changed in the *operational requirement document* (ORD) and the *system specification* (SS). It must also be changed in the component specification, in the installation instructions, and in any training documents that have been generated. The purpose of a configuration management system is to make sure the requirements are changed in all the documents, not just some of them. Failure to make the changes universally will result in confusion and perhaps serious failure.

Configuration management is an established discipline. Most professional organizations have adopted configuration management to control their policies, standards, practices, and manuals. For example, ASQ practices CM to control its handbooks, certification requirements, bodies of knowledge, and other documents. The IEEE also has a standard, 729 1983, for software CM.[8, 25]

CM is often administered by a *configuration control board* in the organization. This is a team of personnel responsible for ensuring that document revisions are universally incorporated throughout all the organization's documents. At a minimum, there must be a *document traceability matrix*, a spreadsheet that traces each requirement. An example of a simplified requirements document traceability matrix is shown in Table 2.1.

Documentation Control

All organizations should employ some version of a *documentation control* (DC) system. The DC system is very much like the CM system that manufacturers and product providers require. But even if the organization does not provide customers with products, it is highly desirable that the organization's documents all be organized and kept current and available. Revising the documents should follow a simple procedure that ensures that all of the agencies and individuals who are affected by any proposed changes have an opportunity to review the revisions before they are made, and that the changes, once they are made, are reflected universally in all relevant documents. ISO 9001:2015[25] requires that

revisions to documents be controlled with version control, stored, and preserved. Change markings can occur throughout the document. For example, additions may be shown underlined and deleted words can be shown as lined through—features all word processors provide.

A word of caution: Individuals should be discouraged from making hard copies or soft/electronic copies of documents to keep handy since these documents will not reflect the latest changes that have been made. Once a documentation control system is in place, it should be adhered to by everyone in the organization; if it has been automated, the continued use of hard copies and local copies on someone's own computer hard drives or shared drives should be discouraged.

COST OF QUALITY (COQ)

> Define and describe the four basic cost of quality categories: prevention, appraisal, internal failure, external failure. (Understand)
>
> **Body of Knowledge I.B.5**

Cost of quality (COQ) is a term that's widely used—and widely misunderstood.

The "cost of quality"[26] isn't the price of creating a quality product or service. It's the cost of *not* creating a quality product or service. It is also referred to as the cost of poor quality (COPQ).

Every time work is redone, the cost of quality increases. Here are some obvious examples:

- The reworking of a manufactured item
- The retesting of an assembly
- The rebuilding of a tool
- The correction of a bank statement
- The reworking of a service, such as the reprocessing of a loan operation or the replacement of a food order in a restaurant

In short, any cost that would not have been expended if quality were perfect contributes to the cost of quality.

Total Quality Costs

As Figure 2.6 shows, quality costs are the total of the costs incurred by

- investing in the prevention of nonconformance to requirements,
- appraising a product or service for conformance to requirements, and
- failing to meet requirements.

Prevention Costs

The costs of all activities specifically designed to prevent poor quality in products or services.

Examples are the costs of:

- New product review
- Quality planning
- Supplier capability surveys
- Process capability evaluations
- Quality improvement team meetings
- Quality improvement projects
- Quality education and training

Appraisal Costs

The costs associated with measuring, evaluating, or auditing products or services to assure conformance to quality standards and performance requirements.

These include the costs of:

- Incoming and source inspection/test of purchased material
- In-process and final inspection/test
- Product, process, or service audits
- Calibration of measuring and test equipment
- Associated supplies and materials

Failure Costs

The costs resulting from products or services not conforming to requirements or customer/user needs. Failure costs are divided into internal and external failure categories.

Internal Failure Costs

Failure costs occurring prior to delivery or shipment of the product, or the furnishing of a service, to the customer.

Examples are the costs of:

- Scrap
- Rework
- Reinspection
- Retesting
- Material review
- Downgrading

External Failure Costs

Failure costs occurring after delivery or shipment of the product—and during or after furnishing of a service—to the customer.

Examples are the costs of:

- Processing customer complaints
- Customer returns
- Warranty claims
- Product recalls

Total Quality Costs

The sum of the above costs. This represents the difference between the actual cost of a product or service and what the reduced cost would be if there were no possibility of substandard service, failure of products, or defects in their manufacture.

Figure 2.6 Quality costs—general description.

Chapter 3
Quality Audits

AUDIT TYPES

> Define and distinguish between basic audit types, including internal and external audits; product, process, and systems audits; and first-, second-, and third-party audits. (Understand)
>
> **Body of Knowledge I.C.1**

An audit is an evaluation of an organization, its processes, or its products. Audits are performed by an independent and objective person or team who are called *auditors*. The purpose of an audit is to provide decision makers such as senior managers with unbiased information on which decisions can be made. Audits can be concerned with a single aspect of the business, such as its financial status, or they can assess performance in many or all of the functions engaged in a business process, such as an audit of a supplier's operation to determine if a contract award should be made. Auditors collect data from their observations and interviews with personnel who function within the audited area. The data are compared to standards, regulations, or practices that have been established for the organization. The results of the audit will be communicated to management for the purpose of assessing their organization's performance and the effectiveness of their quality management system.

There are two major classifications of audits:

- *Internal audits* are engaged by the company being audited. The auditors may be specially trained members of the audited firm's staff, or they may be consultants or contracted personnel who are capable of collecting and analyzing the necessary audit data. Internal auditors should be independent of the activities that are being audited to ensure the audit is unbiased. The results of an internal audit are delivered to the audited company's management so that these managers can make decisions or direct changes based on the audit results. Nearly always, if a firm is anticipating an external audit, it will arrange for an internal

audit to prepare for the external one. One of the procedures required for an organization to be certified to ISO 9001 is to have an internal audit procedure. Also known as a *first-party audit*, an internal audit is basically an organization auditing itself.

- *External audits* are engaged by an agency outside the audited company, such as a government agency or an independent auditing firm. There are regional, national, and international accounting firms and auditing corporations that are capable of performing extensive and thorough audits of finance, quality, safety, and compliance with regulations such as environmental and hazardous waste disposal restrictions. The board of directors of a company may engage an external audit, or an external agency may require that an organization have an external audit to grant a certification or for some other reason. An audit performed by any person or organization outside the organization that is being audited is considered an external audit and can be further defined as either a *second-party audit* or a *third-party audit*. Third-party audits are performed by auditors who are independent of both the auditee and the requesting agency. When an organization is seeking ISO 9001:2008 certification, an external certification body or registrar performs the audit and certification. ISO (International Organization for Standardization) does not perform certification (or registration), and so a company cannot be certified by ISO. A second-party audit is performed by a customer to verify that the supplier conforms to applicable requirements.

Auditing is an integral part of any organization's quality control program. ISO 9001:2015 certification requires external audits in order to register a company as compliant with its standards. A fundamental requirement of ISO 9001:2015 is that a company demonstrates that it conducts routine internal audits; it is a key continuous improvement tool to monitor and improve its quality management system.

Ordinarily, the auditee is informed that the audit will occur and when. This is necessary since the auditors will need to interview workers, staff, and managers in the audited organization, and they will need to look at data that may not be immediately available. In order to minimize the time spent auditing (which impacts routine performance of the audited organization), it is nearly always necessary to notify the auditee in advance. However, sometimes an unannounced audit is appropriate. A third-party or external audit team can arrive and announce that they are present to conduct an unannounced audit. Firms that are subject to such unannounced audits must be prepared at all times for such an audit to interrupt their normal duties. They should perform frequent, routine internal audits and have sufficient margin in their schedules and budgets to accommodate these otherwise disruptive audits.

There are three types of quality audits:

1. Product audit
2. Process audit
3. System audit

The *product audit* assesses the final product or service to determine its quality before it is used by the customer. It is an assessment of conformance to required product or service specifications. A product audit may be an external audit performed by the customer or an internal audit such as a final production inspection. Product audits usually take less time than a process or system audit since they assess a single product at a time.

The *process audit* is an assessment in which steps are traced for process flow to assure the process is being implemented as planned and the company has the ability to produce the desired results. It is, accordingly, more complex than a product audit but ordinarily less difficult and time-consuming than a system audit. The process audit may be performed as an internal or an external audit. The focus of a process audit is a single function, such as all of the steps in manufacturing a product or all of the steps in servicing a type of customer. The audit appraises completeness, correctness of conditions, and probable effectiveness.

The *system audit* is an assessment of the entire system or all of the functions of an organization. These audits typically cannot be conducted rapidly. It is not uncommon for a full system audit to take from two to five days and include several auditors who engage dozens of individuals from the audited organization's staff in interviews. ISO 9001:2015 audits by a team of registrar auditors and a pre-award audit to determine if a new supplier can be awarded a large contract to provide materials are examples of system audits. System audits are often performed by third parties. However, as has already been suggested, organizations often perform internal audits even of the entire system in order to better prepare for an external full system audit.

For more information about quality audits, consult *The ASQ Certified Quality Auditor Handbook*.[1]

AUDIT COMPONENTS

> Identify various elements of the audit process, including audit purpose and scope, the standard to audit against, audit planning (preparation) and performance, opening and closing meetings, final audit report, and verification of corrective actions. (Understand)
>
> **Body of Knowledge I.C.2**

The audit process is described in four phases:

1. Preparation
2. Performance
3. Reporting
4. Closure

Preparation

When preparing for any quality audit, the following actions should be taken:

Receive Formal Authorization. The first step in the audit process is obtaining formal authorization from someone in a leadership position, usually someone in upper management, for the audit. The authorization provides the audit team leader the authority to execute the audit, the permission to the audited organization to cooperate with the auditors, and the organization resources necessary to plan and execute the audit.

Establish the Purpose of the Audit. Audits are conducted to improve processes, implement a continuous improvement program, take corrective action, and many other reasons. Ultimately, the audit purpose must be made clear to the auditors and auditees alike.

Determine the Audit Type. There are three audit types: product audits, process audits, and system audits. In addition, audits may be customized to specific auditing needs.

Establish the Scope of the Audit. To avoid the audit's scope growing over time (scope creep), the scope should be clearly defined during the preparation phase. Organizations have processes that sustain production, support, and external interfaces. Processes in these three areas should be examined:

- *Production* processes make goods and services, such as teaching, operating, and assembling.
- *Support* processes can be administrative or help production, such as purchasing, quality, IT (information technology), and accounting.
- *External interface* processes are customer or supplier based and can include various departments such as customer service, purchasing, and regulatory affairs.

Once the audit is underway, the scope may change, but a clear understanding of the scope that was agreed to at the beginning of the project will provide a basis for orderly and systematic change rather than chaos.

As far as timing, a new audit can be based on past experiences—consult the records of past audits to determine how long it took to perform them, and then adjust the estimates derived from the actual time and effort required to perform them in the past with what is known about the new audit. For example, if a similar audit was performed in the past by three people in three days, but the three people felt that was not sufficient time, the new audit may be scheduled to take three people four days.

Identify the Necessary Resources. The personnel, equipment, materials, documentation (that is, standards and quality manual), training, tools, and procedures that are required to perform the audit must be stated.

Form a Team. The auditors should be identified and then provided an opportunity to develop into a team before the audit commences. It may be useful to employ a facilitator to expedite the team-building process.

Assign Team Roles and Responsibilities. Once the auditors have been identified, it is necessary to assign them to specific roles and to identify each of their responsibilities. The team leader is identified and given the responsibility of leading the team, facilitating the audit process, and constituting the remainder of the audit team. Other audit team members are normally assigned responsibilities within their areas of expertise in auditing methods and practices or in specific technical areas. The audit team leader should attempt to assign individuals to duties they are capable of performing and arrange for instruction or training in areas that the team members will need during the audit.

Identify the Audit Requirements. In Deming's plan–do–check–act cycle, auditing is the *checking* cycle. An audit measures to performance standards or requirements (the *plan* part of the cycle). It is important to be prepared by reading the procedures and reviewing process information and previous audit information. Specific audit activities and deliverables, including audit forms to be completed, working papers (that is, checklists), and detailed questions to be asked during interviews, debriefing activities, and reports, all constitute the audit requirements.

Schedule the Audit Activities. A final component of the audit plan is a detailed audit time schedule. This schedule must include not only dates and times for the delivery of required documents and reports but must also identify milestones. Milestones are checkpoints in the schedule at which time the status of the audit activities can be assessed to determine progress.

Communicate. The audit plan is communicated to the audit team members and also presented to the organization being audited ahead of time for agreement. If there are objections by the auditee, they need to be brought to the auditor's attention for clarification and/or revision of the plan. It is the auditee's responsibility to communicate to their organization any relevant information to help prevent surprises and be prepared. This can facilitate cooperation and prevent delays.

Performance

The execution of the audit constitutes the *performance* phase. The following activities are required during this phase:

- The *opening meeting* is for the auditing staff and the senior management of the organization being audited. The auditor presents the scope and time frame along with notification of potential interviews.
- *Interviewing* by asking open-ended questions is more useful in obtaining relevant information than yes/no-type questions.
- *Examining* records and observing activities helps gather objective evidence—both conforming (good) and nonconforming (bad).
- *Discussion*—it is important to have daily briefings and team meetings to communicate progress and issues. Analyze data to find patterns and trends and to create findings.

Reporting

Audit results will need to be reported to management and should include reference to procedures and standards that have not been met or that need follow-up for improvement. The reporting should be balanced to give both negative and positive feedback.

- *Findings sheets* will have a statement of the problem with the supporting facts.
- Nonconformities are documented when it's been demonstrated that a requirement is not being met.
- *Positive practices* help reinforce the good things that are being done (conformances).
- The audit report should be objective, providing conformances, nonconformances, and observations for improvements.

Closure

The audit team works with the audit coordinator to finalize the audit report. The team leader assures there is information for the background, executive summary, and request for corrective actions. The following reports are presented at the closing meeting:

- Final report
- Final report with exceptions
- Terms and conditions for closure (agreements between the agent authorizing the audit and the auditee regarding what constitutes closure)

It is important to thank the organization being audited for their cooperation. This can be done at the closing meeting as well as in the final report. Thanking the audit team for their participation is also valuable—along with feedback and lessons learned—and can be done in the presence of the audit team members. An audit is considered closed when both parties involved with the audit are satisfied that all corrective actions have been verified and successfully completed. For more on corrective actions, see Chapter 21.

AUDIT ROLES AND RESPONSIBILITIES

> Identify and describe the roles and responsibilities of key audit participants: lead auditor, audit team member, client, and auditee. (Understand)
>
> **Body of Knowledge I.C.3**

The roles and responsibilities for each participant in an audit are listed in this section.

Agent Authorizing the Audit (Client)

This may be an external agency, registrar, certifying body, board of directors, customer purchasing department, process manager, or product manager.

- Authorize the audit
- State the audit purpose
- Determine the audit type
- Establish the scope of the audit
- Approve the schedule
- Approve the closure terms and conditions

Senior Management

- Authorize resources
- Direct the organization to cooperate with and assist the auditors

Audit Team Leader (Lead Auditor)

- Create the audit plan for approval by senior management and the agent authorizing the audit
- Manage and administer the audit process
- Form the team
- Assign the team members' roles and responsibilities
- State the audit requirements
- Schedule the audit activities, deliverables, and milestones
- Administer documents during the execution phase
- Call and lead the kickoff, progress, and exit meetings

Auditor (Audit Team)

- Participate in planning the audit
- Participate in team-building activities
- Collect data
- Analyze data

- Prepare working papers
- Attend meetings
- Give reports
- Document findings

Auditee

- Be available when the audit is scheduled
- Provide all evidence requested by the auditor, such as documents, work in progress, and computer data normally employed in the performance of the auditee's duties
- Answer all questions posed by the auditor (normally, auditees should not volunteer information not requested by the auditor)

Chapter 4
Team Dynamics

TYPES OF TEAMS

> Distinguish between various types of teams: process improvement teams, work groups/ work cells, self-managed teams, temporary/ ad hoc project teams, and cross-functional teams. (Analyze)
>
> **Body of Knowledge I.D.1**

A *team* is a group of people who perform interdependent tasks to work toward a common mission.

Some teams have a limited life, for example, a design team developing a new product or a process improvement team organized to solve a particular problem. Others are ongoing, such as a department team that meets regularly to review goals, activities, and performance. Understanding the many interrelationships that exist between organizational units and processes, and the impact of these relationships on quality, productivity, and cost, makes the value of teams apparent.

Many of today's team concepts originated in the United States during the 1970s through the use of quality circles or employee involvement initiatives. But the initiatives were often seen as separate from normal work activities, in addition to daily tasks.

Team design has since evolved into a broader concept that includes many types of teams formed for different purposes.[1] Although they may take different names in different industries or organizations, this text presents eight types of teams:

- Process improvement teams
- Work groups
- Work cells (cellular teams)
- Self-managed teams
- Temporary/ad hoc teams

- Cross-functional teams
- Special project teams
- Virtual teams

Process Improvement Teams

Process improvement teams focus on improving or developing specific business processes and are more likely to be trying to accomplish breakthrough-level improvement (as explained in Chapter 8). Process improvement team

- are typically cross-functional—different functions/skills related to the process;
- have a management sponsor who charters the team, ensures that the team has appropriate resources, and ensures that the team has organizational support;
- achieve a specific goal;
- are guided by a well-defined project plan; and
- have a negotiated beginning and end.

The leader of a process improvement team is usually selected by the project's sponsor, and the team meets on a regular basis to accomplish the following:

- Plan activities that will occur outside the meeting
- Review information gathered since the previous meeting
- Make decisions to implement process changes

In cases where a team member does not have the expertise, an independent facilitator (not associated with the specific process) may be asked to work with the team.

There are many organizations that have implemented the *kaizen* approach for productivity improvement, with its main goal of eliminating waste (kaizen is discussed further in Chapter 6). An organization taking the kaizen approach may also use *kaizen events* or *kaizen blitzes* to concentrate on process improvement through an accelerated team process that focuses on a narrow project implementing the recommended changes within a three- to five-day period. In these cases, the team facilitator typically has more authority than with most teams.[2]

A *quality process analyst* (QPA) will often be a member of a process improvement team. Because it is challenging enough to support the development and deployment of organizational change, it is always good to first ensure that the mission has been accepted and approved by upper management and that its purpose is well-defined and measurable. Two of the challenges a QPA might experience include dedicating enough time to work on a specific project and employees being reluctant to provide data or information. Once a solution is provided, employees may be unwilling to embrace the change that needs to happen in order for the solution to be effective for quality improvement. To promote the change process, the QPA

can communicate the positive benefits of the change to their peers. Including and encouraging fellow employees to participate when possible will make them more inclined to support the mission.

Work Groups

Also called *natural teams*, work groups bring together employees in a participative environment. Work groups have an ongoing charter to continually improve the work processes over which they have direct responsibility and ownership. The team leader is usually the individual responsible for the work area, such as a department supervisor.

Work groups function similarly to quality circles, in which department personnel meet weekly or monthly to review the performance of their process. They may

- monitor feedback from customers,
- track internal performance measures of processes, and
- track internal performance measures of suppliers.

Work groups are similar to process improvement teams, with the key differences being that work groups are neither cross-functional nor temporary. Should they need additional support, a facilitator is usually available, and outside resources may be brought in on a temporary basis if necessary.

Since work groups are an ongoing organizational structure, it is critical that the organizational systems and values support the effort. Certain basic elements should be considered when an organization is attempting to initiate work groups:

- Top management support
- Clear communication
- Improvement objectives and expectations
- Team training
- Appropriate competencies
- Supportive compensation and performance appraisal systems

Other issues to consider include the following:

- Team's scope of responsibility and authority
- Degree of autonomy
- Information needed by team and where obtained
- Decision-making process
- Performance measures and success factors
- Recognition and rewards for performance
- Competencies that must be developed

- Selection process for leaders and facilitators
- Risk management process

An implementation plan including the necessary support systems should be defined before initiating such groups. If work groups are being implemented in an existing organization where a participative management style has not been used before, a pilot program in a department where they are likely to succeed is highly recommended.[3]

Work Cells (Cellular Teams)

Processes can be organized into *work cells*, or *cellular teams*, where the layout of workstations and/or machines used in a designated part of a process is typically arranged in a U-shaped configuration (see Figure 4.1). This allows operators to perform progressive activities on the same part, moving from a machine to produce a whole product or a major subassembly.

The team that operates the cell is usually completely cross-trained on every step in the series. Team effectiveness depends on coordination, timing, and cooperation. Team members' competencies must be as closely matched as possible to maintain a reasonable and consistent work pace.

Cellular team members usually assume ownership and responsibility for establishing and improving the work processes. Leadership of the cellular team may be by a person designated as lead operator or a similar title. In some cases, the role of lead operator may be rotated among the members. The lead operator is usually responsible for training new team members, reporting team output, and balancing the flow of work through the process. A cellular team is a specialized form of a self-directed work group.[4]

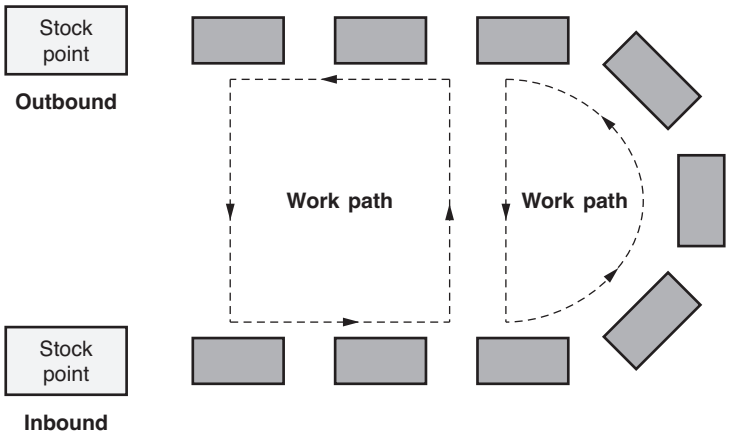


Figure 4.1 Typical U-shaped cell layout.

Source: R. T. Westcott, *The Certified Manager of Quality/Organizational Excellence Handbook*, 3rd ed. (Milwaukee, WI: ASQ Quality Press, 2006), 403.

Self-Managed Teams

Also called *self-directed teams* or *high-performance teams* because of their broader scope of responsibilities, *self-managed teams* are groups of employees involved in directly managing the day-to-day operation of their particular process or department. Some of their responsibilities are those that are traditionally held for managers. Self-managed teams

- are authorized to make decisions on a wide range of issues (for example, safety, quality, maintenance, scheduling, and personnel),
- set goals,
- allocate assignments, and
- resolve conflict.[5]

Because the team members have broader responsibilities, they assume ownership of a work process. The leader of a self-managed team is usually selected by the team members; in many cases, the role is rotated among the members over time. Other positions (entailing scheduling or safety, for example) are also often rotated among the team members. Self-managed teams require up-front planning, support structures, and nurturing. Figure 4.2 highlights a number of guidelines that can increase the success of self-managed teams.

With the various roles that self-managed teams take on, training is necessary to move from a traditional work environment to a self-managed work environment. Often, even the managers need training to transition from their current role to the new support role. For self-managed teams to be successful, they will need training. For example, one Fortune 500 company provides training in the following subjects:

- How to maintain focus on the customer
- How to develop a vision and mission that are integrated with the larger organizational mission
- Understanding roles and operating guidelines

- Have a well–thought out vision of how the team will fit into the entire organization
- Ensure that the organizational culture can and will support the team
- Ensure that the organization has the resources to commit to this type of change
- Train team members in skills that will allow them to function together
- Set performance expectations for the team
- Develop a method for providing feedback to the team
- Set boundaries in which the team will be allowed to operate
- Recognize that the self-managed team is not leaderless and that they may need management intervention

Figure 4.2 Guidelines for successful self-managed teams.

Source: ASQ's Foundations in Quality Self-Directed Learning Series, Certified Quality Manager, Module 1 (Milwaukee, WI: ASQ Quality Press, 2001), 1–58.

- Skills required for working together to make decisions, plan work, resolve differences, and conduct meetings
- The concepts and strategies for empowerment
- Setting goals (objectives) and solving problems for continuous improvement[6]

Attempts to transition from a traditional work environment to a self-managed work environment require a culture change. This culture change can be very dramatic and is best approached by first implementing cross-functional process improvement teams and/or work teams as learning mechanisms. Self-managed teams are more likely to be successful as part of a startup of a new facility.

Temporary/Ad Hoc Teams

These types of teams are often initiated to address a specific problem or situation. The team would be formed based on the work to be performed. It might not use the usual formal structure (e.g., agenda, regular meeting frequency), but the same general principles and processes still apply. Organizations open to using ad hoc teams must be flexible.

An empowered organization will use temporary teams when deemed useful to carry out a short-term mission, such as conducting internal audits. Some companies, for example engineering design companies, may form ad hoc teams with other engineering, design, and/or manufacturing experts to meet their customers' needs. Various situations can arise that require immediate and dedicated attention, in which case ad hoc teams would have to be formed, such as in the following situations:

- Preparing for a major customer's audit team coming to do an assessment on the adequacy of your quality management system
- Disaster relief—fire occurring and the process of needing to relocate
- Recovery from your organization's information management computer system being compromised by an outside virus

Usually, management will designate a person to

- form a small, cross-functional team;
- address the situation to the team; and
- call on other technical expertise as needed.

Cross-Functional Teams

Cross-functional teams are teams that have members from multiple departments or functions within the organization. The purpose of the team could be to bring subject matter experts from across different disciplines or functions, such as a new product design team, a process improvement team, or a problem-solving team. These teams are designed to connect knowledge across the teams, to eliminate

silos that departmental boundaries create, and to engage members from different skill sets. Here is an example of a cross-functional team:

> *The emergency department of a hospital is not meeting its patient length-of-stay (LOS) key performance indicator (KPI) goal. It forms a cross-functional continuous improvement team to improve the process. The team consists of members from the emergency department (nursing, physicians), radiology, laboratory, registration services, compliance, information technology, pharmacy, environmental services, and patient transport. The team members apply the Lean-Six Sigma methodology and tools to successfully improve the process and implement the improvements within the emergency department and in their own departments and processes as applicable. Some of the improvements also have a positive impact on other patients throughout the hospital, where the improved processes cross the multiple services and patient types, including inpatients, surgical patients, and outpatients.*[7]

Special Project Teams

This type of team is used when a need develops to form a long-term, totally dedicated project team to implement a major new product, system, or process.

These are some examples:

- Reengineering an entire process
- Relocating a major segment of an operation
- Mergers, acquisitions, or divestitures
- Replacing a major information system
- Entering a new market with a new product
- Preparing to apply for the Malcolm Baldrige National Quality award

Such special project teams may operate as a parallel organization during their existence. They may even be located away from the main organization or exempt from some of the constraints of the main organization. The core team members are usually drafted for the duration of the project. Persons with additional expertise may be called into the team on a temporary, as-needed basis. Usually, the project is headed by an experienced project manager. Depending on the nature of the team's objectives, external specialists or consultants may be retained to augment the core competencies of the team members.[8]

Virtual Teams

In today's global and electronic business environment, it may be expedient to have team members who do not work in the same geographic location. These virtual teams also require many of the same roles and processes, but the substitution of electronic communications (e.g., e-mail, videoconferencing) for face-to-face meetings provides an additional challenge to team leadership. A key competency of team members is the ability and motivation to self-manage their time and priorities.

Virtual teams have special needs, some of which include the following:

- Telephones, pagers, local area networks, satellites, videoconferencing
- Computers, high-speed and wireless connections, internet technology, e-mail, web-based chat rooms/forums
- Software for communications, meeting facilitation, time management, project management, groupware, and access to online databases

There are many benefits of virtual teams:

- Team members can work from anywhere, at any time of day
- Team members are selected for their competence, not for their geographic location
- Expenses may be reduced or eliminated, such as travel, lodging, parking, and renting/leasing or owning a building[9]

TEAM DEVELOPMENT

> Identify various elements in team-building, such as inviting team members to share information about themselves during the initial meeting, using icebreaker activities to enhance team membership, and developing a common vision and agreement on team objectives. (Apply)
>
> **Body of Knowledge I.D.2**

The *Certified Manager of Quality/Organizational Excellence Handbook* (2021) explains how team processes have two major groups of components to consider: task type and maintenance type. Team-building techniques enhance both groups. *Task-type* processes keep teams focused and on the path toward meeting their goals. *Maintenance-type* processes help maintain or protect the well-being of relationships among team members.

Key task-type components include

- documenting and reviewing the team's objective;
- having an agenda and staying on task during every team meeting;
- defining or selecting and following a technical process that fits the particular project mission;
- using decision-making techniques appropriate to the situation; and
- defining action items, responsibilities, and timing, and holding team members accountable.[10]

Maintenance-type components also have a dramatic impact on team performance. The dynamics of interactions between team members are just as critical as the tasks that keep the team on the path toward meeting its objectives. Team maintenance helps alleviate the problems created by the fact that each team member has his or her own perspectives and priorities. These are shaped by individual personalities, current issues in each member's personal life, and the attitudes of both the formal and informal groups within the organization to which the team member may belong. Although the team may have specific objectives and agendas, each individual may interpret them differently.

The first team meeting can set the tone for the entire team effort. With good planning, the first meeting will include these elements:

- Team member introductions, where members share information about themselves
- Team members getting acquainted
- The sponsor attending the meeting and emphasizing the importance of the meeting
- Defining the team's mission and scope
- Defining the structure for future meetings
- Defining or selecting the technical process improvement methodology/model to be used
- Drafting the team's objectives
- Defining/reviewing the project plan and schedule
- Setting the meeting ground rules (norms)
- Working out decision-making issues
- Clarifying team members' roles[11]

Handling Team Introductions

There are various methods to ease the anxiety team members might be having about working with one another as they approach their initial meeting. The manager can conduct team introductions by asking team members to share basic information with the group, such as name and job title, the thing they like best about their job, or an interest outside of work.

Conducting special exercises, or "icebreakers," during the first meeting makes it easier for the team members to feel more comfortable in their new environment. The introductions promote spontaneous interaction and conversation. A very simple icebreaker is one where the team members get into small groups of two or three people and share a recent photo that they've taken that is special to them, and explain to the team why this photo is special. This creates wonderful discussion and quickly shares something of special meaning to each team member, whether it is a family member, a pet, or a recent memorable vacation photo. Another quick, yet powerful icebreaker is again done in small groups.

Everyone gets some M&M candies. They may eat all but one M&M, which they save to identify a theme of a story to share with their group, aligning it to the M&M color, as follows:[12]

- Blue = proud
- Orange = failure
- Yellow = scared
- Green = embarrassed
- Brown = success/accomplishment
- Red = aspiration

Each person has two minutes to prepare the story and two minutes to share it with the group. Depending upon the time available, stories can also be shared with the larger team.

Another idea is to initiate building camaraderie among the team members by coming up with a team name. Also, allowing the team members to share their individual good or bad experiences of working on other teams is a great way to expose their personality and values. This kind of sharing can bring team members closer together.

Setting Team Goals and Objectives

Team goals must flow from organizational goals and departmental goals to ensure that team members and the entire organization are moving in the same direction.

Objectives are defined as quantitative statements of future expectations that include a deadline for completion. Team objectives should be approached the "SMART WAY," as described in Figure 4.3.[13]

Specific:	Focus on *specific* needs and opportunities
Measurable:	Make each objective *measurable*
Achievable:	Ensure that objectives are challenging yet *achievable*
Realistic:	Stretching is fine, but the objective should be *realistic*
Time frame:	Every objective should indicate a *time frame* for achievement
Worthwhile:	Every objective should be *worth doing*
Assigned:	*Assign* responsibility for each objective
Yield results:	Ensure that all objectives *yield* desired results

Figure 4.3 Objectives made the SMART WAY.

Source: ASQ's Foundations in Quality Self-Directed Learning Series, Certified Quality Manager, Module 1 (Milwaukee, WI: ASQ Quality Press, 2001), 1–66. Reproduced with permission from R. T. Westcott & Associates.

Preventing Problems

Team members need basic guidelines to add predictability to their work environment, along with creating a sense of safety around team interactions. Having ground rules, or *norms*, working out decision-making issues, and having assigned roles are common ways of preventing problems associated with team dynamics.

Ground Rules or Rules of Engagement

Ground rules should be considered group norms regarding how meetings will be run, how team members will interact, and what kind of behavior is acceptable. Each member is expected to respect these rules during the project's duration. Some areas to consider when establishing ground rules are provided in Table 4.1.

A sample rules of engagement is shown in Figure 4.4. The parking lot issues in the rules of engagement include issues brought up in meetings that must be resolved at a later time and can be logged for further tracking and resolution.

Decision-Making Method

"Consensus decision making is the process recommended for major project issues. The approach is more time-consuming, and demanding, but provides the most thorough and cohesive results. It allows the team to work out different points of

Table 4.1 Meeting ground rules.

Area	Topics to consider
Logistics	• Regular meeting time and place • Procedure for notifying members of meetings • Responsibilities for taking notes, setting up the room, and so on
Attendance	• Legitimate reasons for missing a meeting • Procedure for informing the team leader when a meeting will be missed • Procedure for bringing absent members up to speed
Promptness	• Agreed-upon definition of "on time" • Value of promptness • Ways to encourage promptness
Participation	• Basic conversational courtesies (e.g., listening attentively, holding one conversation at a time) • Tolerable interruptions (e.g., phone calls, operational emergencies) • Confidentiality guidelines • Value of timely task completion

Source: ASQ's Foundations in Quality Self-Directed Learning Series, Certified Quality Manager, Module 1 (Milwaukee, WI: ASQ Quality Press, 2001), 1–65.

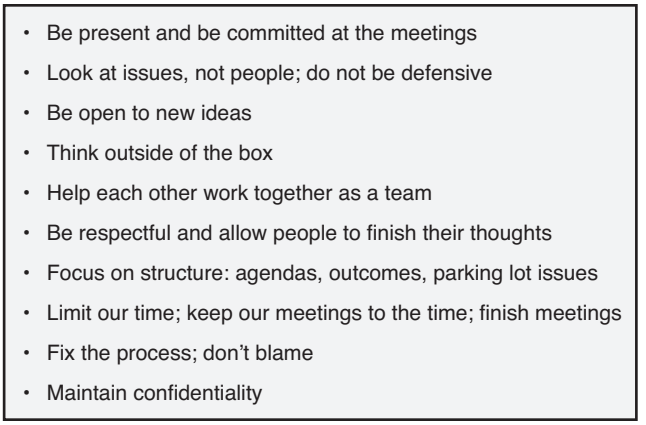


Figure 4.4 Sample rules of engagement.
Source: Sandra L. Furterer

view on an issue and come to a conclusion that is acceptable. Consensus means that the decision is acceptable enough that all team members will support it. To achieve consensus, all team members must be allowed to express their views and must also objectively listen to the views of others. The decision and alternatives should be discussed until consensus is reached."[14]

TEAM STAGES

Describe the classic stages of team evolution: forming, storming, norming, performing, and adjourning. (Understand)

Body of Knowledge I.D.3

According to the Tuckman model, there are typical stages that a team goes through as the members work together over time and the team grows and matures. Understanding these development stages is valuable for effective management of the team process:[15]

Stage 1: Forming. The team usually clarifies its purpose, identifies roles for each member, and defines rules of acceptable behavior (often called *norms*). Members can be proud that they were chosen for the team, but they also have some fear of the unknown. It is common for members to question why they are on the team. They also try to determine acceptable team behavior and establish team rules; they may even complain about the organization and the tasks. Leadership can help teams through this stage by helping members get to know each other, through icebreakers, as we previously discussed. They should provide clear direction and purpose, and involve the team members in developing plans and rules of engagement.[16]

Stage 2: Storming. Team members are still thinking primarily as individuals and are therefore basing decisions on their individual experiences rather than pooling information with other members. Collaboration is not yet the norm, which can lead to behavior that may involve confrontations. This stage can be the most difficult for the team. They feel like they are thrashing about, without much direction. The team could fall apart if they are not coached adequately through this stage. Team members may feel frustrated or anxious, and they may even withdraw from engaging with the team. To guide the team through this stage, leadership should help the team resolve issues of power and authority, teaching them how to make team decisions. If team ground rules weren't adequately developed, they should be now, or reviewed and refreshed as needed.[17]

Stage 3: Norming. The team's focus at this stage has shifted to meeting the team-related challenges. Team members are more agreeable, working out their differences for the sake of the team, resulting in more cooperation and dialogue. In this stage, team members have begun to accept the norms of behavior established through the ground rules, and emotional turmoil is reduced. Team members will begin to joke, laugh, and confide in each other. To help the team get through this stage, leadership should encourage and acknowledge members' respect for each other, encourage members to work collaboratively, and modify ground rules if needed.[18]

Stage 4: Performing. The team at this point has a better appreciation of their processes. The team's members are supportive of each other, allowing the team to make significant progress toward achieving its goals. In this stage the team has settled into its relationships, norms, and expectations. The members perform consistently and start making change happen and get work done. To continue the team as a performing team, leadership can help them to understand how to manage change, advocate for the team with other groups and individuals, and celebrate team achievements.[19]

Stage 4: Adjourning. This final stage of a team is when the team disbands. Leadership should ensure that the tasks are complete and that the team's goals have been met before breaking up the team.[20]

If needed, team members should have training on how to interact with one another in a positive manner, deal with difficult people or situations, contribute to accomplishing the team's goals, and give and receive constructive feedback. With a basic understanding of these techniques, team members will be more productive, enhancing the development and performance of their team.

TEAM ROLES AND RESPONSIBILITIES

> Describe the roles and responsibilities of various team stakeholders: sponsor, champion, facilitator, team leader, and team member. (Understand)
>
> **Body of Knowledge I.D.4**

Process analysts will inevitably be asked to participate on teams since most work in organizations—including quality processes—is performed by working teams.

Seven team roles are listed in Table 4.2. Of the seven roles described, those of timekeeper and scribe are the only ones that are optional, depending upon the mission of the team. While the remaining five roles are essential, they may be combined in a variety of ways. However, the most crucial roles for the success of the team, once it is formed, are those of the team leader and the facilitator. The team leader is responsible for the content—the work done by the team. The facilitator is responsible for ensuring that the process affecting the work of the team is the best for the stage and situation the team is in.[21]

The need for a trained facilitator needs to be considered in situations such as these:

- The team has been meeting for some time and is incapable of resolving conflicting issues
- A new member has been added, thus upsetting established relationships
- A key contributor has been lost to the group
- There are other factors, such as lack of sufficient resources, the threat of project cancellation, or a major change in requirements, with the potential of disrupting the smooth functioning of the team

Supplementing the team with on-call experts can often compensate for a shortfall in either the number of members or members' competencies. Selected members must willingly share their expertise, listen attentively, abide by the team's ground rules, and support all team decisions.

It is helpful to select a team member to serve as a timekeeper until the team has become more adept at self-monitoring its use of time. The role of timekeeper is often rotated, giving consideration to whether the selected member has a full role to play in the deliberations at a particular meeting.

Some team missions require very formal documentation, and a scribe or notetaker may be needed. This role can be distracting for a member whose full attention is needed on the topics under discussion. For this reason, an assistant, not a regular member of the team, is sometimes assigned to take the minutes and publish them. Care should be taken not to select a team member for this role solely on the basis of that team member's gender or position in the organization. Another function that should be assigned early in the development of a team is the responsibility of booking a meeting room, sending the invites, and ensuring supplies are at hand in the meeting room.

All team members must adhere to expected standards of quality, responsibility, ethics, and confidentiality (see "ASQ Code of Ethics," Chapter 1). It is imperative that the most competent individuals available are selected for each role. See Table 4.2 for the attributes of good role performance.

Very frequently, a team must function in parallel with day-to-day assigned work and with the members not relieved of responsibility for the regularly assigned work. This, of course, places a burden and stress on the team members. The day-to-day work and the work of the team must both be conducted effectively.

Table 4.2 Team roles, responsibilities, and performance attributes.

Role name	Responsibility	Definition	Attributes of good role performance
Champion	Advocate	The person initiating a concept or idea for change/improvement	• Is dedicated to seeing it implemented • Holds absolute belief it is the right thing to do • Has perseverance and stamina
Sponsor	Backer, risk taker	The person who supports a team's plans, activities, and outcomes	• Believes in the concept/idea • Has sound business acumen • Is willing to take risk and responsibility for outcomes • Has authority to approve needed resources • Will be listened to by upper management
Team leader	Change agent, chair, head	A person who: • Staffs the team or provides input for staffing requirements • Strives to bring about change/improvement through the team's outcomes • Is entrusted by followers to lead them • Has the authority for and directs the efforts of the team • Participates as a team member • Coaches team members in developing or enhancing necessary competencies • Communicates with management about the team's progress and needs • Handles the logistics of team meetings • Takes responsibility for team records	• Is committed to the team's mission and objectives • Has experience in planning, organizing, staffing, controlling, and directing • Is capable of creating and maintaining channels that enable members to do their work • Is capable of gaining the respect of team members; serves as a role model • Is firm, fair, and factual in dealing with a team of diverse individuals • Facilitates discussion without dominating • Actively listens • Empowers team members to the extent possible within the organization's culture • Supports all team members equally • Respects each team member's individuality
Facilitator	Helper, trainer, adviser, coach	A person who: • Observes the team's processes and team members' interactions and suggests process changes to facilitate positive movement toward the team's goals and objectives • Intervenes if discussion develops into multiple conversations • Intervenes to skillfully prevent an individual from dominating the discussion or to engage an overlooked individual in the discussion • Assists the team leader in bringing discussions to a close • May provide training in team building, conflict management, and so forth	• Is trained in facilitating skills • Is respected by team members • Is tactful • Knows when and when not to intervene • Deals with the team's process, not content • Respects the team leader and does not override his or her responsibility • Respects confidential information shared by individuals or the team as a whole • Will not accept facilitator role if expected to report to management information that is proprietary to the team • Will abide by the ASQ Code of Ethics

Continued

Table 4.2 *Continued.*

Role name	Responsibility	Definition	Attributes of good role performance
Timekeeper	Gatekeeper, monitor	A person designated by the team to watch the use of allocated time and remind the team members when their time objective may be in jeopardy	• Is capable of assisting the team leader in keeping the team meeting within the predetermined time limitations • Is sufficiently assertive to intervene in discussions when the time allocation is in jeopardy • Is capable of participating as a member while still serving as a timekeeper
Scribe	Recorder, note taker	A person designated by the team to record critical data from team meetings. Formal "minutes" of the meetings may be published and distributed to interested parties.	• Is capable of capturing on paper or electronically the main points and decisions made in a team meeting and providing a complete, accurate, and legible document (or formal minutes) for the team's records • Is sufficiently assertive to intervene in discussions to clarify a point or decision in order to record it accurately • Is capable of participating as a member while still serving as a scribe
Team members	Participants, subject matter experts	The persons selected to work together to bring about a change/improvement, achieving this in a created environment of mutual respect, sharing of expertise, cooperation, and support	• Are willing to commit to the purpose of the team • Are able to express ideas, opinions, and suggestions in a nonthreatening manner • Are capable of listening attentively to other team members • Are receptive to new ideas and suggestions • Are even-tempered and able to handle stress and cope with problems openly • Are competent in one or more fields of expertise needed by the team • Have favorable performance records • Are willing to function as team members and forfeit "star" status

Source: R. T. Westcott, *The Certified Manager of Quality/Organizational Excellence Handbook*, 3rd ed. (Milwaukee, WI: ASQ Quality Press, 2006), 75–76.

The inability to be in two places at once calls for innovative time management, conflict resolution, and negotiation skills.[22]

TEAM CONFLICT

> Identify common group challenges, including groupthink, members with hidden and/or competing agendas, intentional distractions, and other disruptive behaviors. Describe ways of resolving these issues and keeping team members on task. (Understand)
>
> **Body of Knowledge I.D.5**

Team members are most productive in an environment in which others are responsive and friendly, encourage contributions, and promote a sense of worth. Patrick Lencioni identified some problems that teams experience in his book *The Five Dysfunctions of a Team: A Leadership Fable*.[23] The five "dysfunctions" are as follows:

1. Absence of trust
2. Fear of conflict
3. Lack of commitment
4. Avoidance of accountability
5. Inattention to results

Current expert opinion on team building holds that team members should each assume the responsibility for identifying anything wrong with the team's collaboration and take steps to improve the team's performance. When some team members fail to trust others on the team, it is the responsibility of the team members themselves to increase their trust. Rather than expect the team leader or sponsor to observe conflict and resolve it, the team members should openly confront conflict and resolve it themselves as quickly as possible. When one or more members of the team seem to lack commitment, fail to accept accountability for their responsibility, or are not fully concerned with the team's results, the team members themselves are responsible for identifying and correcting these behaviors. The team members may need to enlist the support of some outside resource, such as the company's human resources department or a consultant, but the responsibility for improving the team's performance rests on the team members.

Peter Scholtes, one of the authors of *The Team Handbook* , spelled out 10 problems that frequently occur within teams and are typical of the types of situations for which team members, leaders, and facilitators must be prepared. Following is Scholtes's list, along with recommended actions:[24]

Problem 1. Floundering or difficulty in starting or ending an activity. *Solution:* Redirect team to the project plan and written statement of purpose.

Problem 2. Team members attempt to influence the team process based on their position of authority in the organization. *Solution:* Talk to the members off-line; clarify the impact of their organizational role and the need for consensus. Ask for cooperation and patience.

Problem 3. Participants who talk too much. *Solution:* Structure the meeting so that everyone is encouraged to participate (e.g., have members write down their opinions, then discuss them in the meeting one person at a time).

Problem 4. Participants who rarely speak. *Solution:* Practice gatekeeping by using phrases such as, "John, what's your view on this?" or divide tasks into individual assignments and have all members report.

Problem 5. Unquestioned acceptance of opinions as facts, or participants making opinions sound like facts. *Solution:* Do not be afraid to ask whether something is an opinion or a fact. Ask for supporting data.

Problem 6. Rushing to get to a solution before the problem-solving process is worked through. *Solution:* Remind the group of the cost of jumping to conclusions.

Problem 7. Attempting to explain other members' motives. *Solution:* Ask the other person to clarify.

Problem 8. Ignoring or ridiculing another's values or statements made. *Solution:* Emphasize the need for listening and understanding. Support the discounted person.

Problem 9. Digression/tangents creating unfocused conversations. *Solution:* Remind members of the written agenda and time estimates. Continually direct the conversation back on track. Remind the team of its mission and the norms established at the first meeting.

Problem 10. Conflict involving personal matters. *Solution:* Request that these types of conflict be taken off-line. Reinforce ground rules.

Groupthink is another issue that is quite common in teams, especially if team members want to avoid conflict and just get along. Groupthink occurs when most of the team members support an idea or decision that hasn't been fully explored, or when some team members won't voice their disagreement. Several actions may help reduce groupthink:[25]

- Brainstorming alternatives before selecting an approach
- Encouraging members to express their concerns
- Ensuring that ample time is given to surface, examine, and comprehend all ideas and suggestions
- Developing rules for examining each alternative
- Appointing an "objector" to challenge proposed actions

Hidden and/or competing agendas are another team problem, especially with cross-functional teams, where there may be allegiance of team members to elevate their own department's goals above the team's goals. The team leader needs to be cognizant of competing agendas, goals, and priorities—and bring the team back to the team's project goals and the team's ground rules—to ensure these conflicts are resolved.

Solutions to conflicts should be in the best interest of the team. Team members should be nonjudgmental, listening to team discussions and new ideas. Group feelings should be verbalized by periodically surfacing undercurrents or by giving feedback.

One important skill needed in working with teams is the ability to provide constructive feedback during and/or at the end of a meeting. Feedback is an important vehicle to help the team mature. This feedback can be provided by the facilitator or by team members.

There are two types of feedback: motivational and coaching. *Motivational feedback* must be constructive, that is, specific, sincere, clear, timely, and descriptive of what actually occurred in the meeting. *Coaching or corrective feedback* specifically states the improvements that need to be made. Scholtes provides the following guidelines for providing constructive feedback:[26]

- Be specific
- Make observations, not conclusions
- Share ideas or information, not advice
- Speak for yourself
- Restrict feedback to known things
- Avoid using labels
- Do not exaggerate
- Phrase the issue as a statement, not a question

Having a team complete a self-evaluation at the end of each meeting (or occasionally) can be useful in helping the team members further develop their team skills and take more responsibility for team progress. Team members can be asked to write down how well the team is doing on each of the norms (for example, on a scale of 1–5) and to list any additional norms they believe need to be added. A group discussion of the information can then result in revised norms and specific actions the team will take in the future to improve.

Chapter 5
Training and Evaluation

Describe the various elements of training, including linking the training to organizational goals, identifying training needs, adapting information to meet adult learning styles, and using coaching and peer training methods. Use various tools to measure the effectiveness of the training, including post-training feedback, end-of-course tests, and individual and department performance improvements measures. (Understand)

Body of Knowledge I.E

LINK TRAINING TO ORGANIZATIONAL GOALS

Like all other programs undertaken by an organization, mandatory training should be conducted only to satisfy a business need. The starting point for all training should be linking the training to organizational goals. Training may provide employees with the skills and knowledge necessary to perform their jobs better, and it may prepare the employees to be capable of taking on more responsibility and performing more-important tasks. The primary aim of all training is to satisfy the business objectives of the organization, so it is imperative that those goals be clearly identified and that the training be linked to achieving them.

Not all training is mandatory. Often, organizations provide self-selected optional training to allow employees to improve their general or discipline competencies. Even this optional training should satisfy a clearly stated objective, such as raising the workforce morale or enhancing employees' professional development.

Joseph Juran and Frank Gryna suggested the following elements to consider when ensuring alignment of training to the organization's objectives:[1]

- The quality problems and challenges faced by the organization

- The knowledge and skills needed to solve these problems and meet these challenges
- The knowledge and skills actually possessed by the jobholders
- The training facilities and processes already in existence
- The prevailing climate for training in the organization, based on the record of past programs
- What needs to be done differently to achieve the desired quality

NEEDS ASSESSMENT

Once the business purpose for performing training has been identified, the next step is to determine which skills and business knowledge the persons receiving the training should have as the result of the training. This constitutes a training needs assessment. The needs assessment produces a list of the knowledge that the trainees need to know and the skills they need to be able to perform in sufficient detail such that the people developing the training can provide the appropriate amount of detail and content in the training materials. A training needs assessment may be conducted employing any or several of the following sources:

- Accidents and scrap
- Assessment centers
- Assimilation of new employees
- Business changes
- Changes in procedures
- Customer returns/calls
- Employee grievances/complaints
- Employee interviews needs assessment questionnaire
- Employee opinion/climate surveys
- Employment/skills tests
- Exit interviews
- Focus groups
- Job redesign
- Needs analysis
- New equipment/software
- Observations
- Performance appraisal results
- Promotions and terminations

- Reorganization
- Technology changes
- Quality and process improvement
- Unique business circumstance, such as merger, operations ramp-up, and so on

ADAPT INFORMATION TO MEET ADULT LEARNING STYLES

The training provided must be adapted to the individual trainees. People learn in different ways, and the training provided to team members must accommodate the unique learning style of each trainee. While nearly all adults can learn using a variety of methods, most people learn best in one style or another. Anthony Gregorc developed a model that classifies adult learning styles as *concrete sequential*, *concrete random*, *abstract sequential*, or *abstract random*. Neal Fleming developed a model that divides adult trainees into *visual*, *auditory*, *reading/writing*, or *kinesthetic* learners. What is important to understand about adult learning styles is that adult learners are not the same. Whenever possible, training should be customized to the intended audience; when it is, it will be more effective.[2]

Consider an adult learner whose preferences are indicated in the following table and the sort of training that would be most effective in each case:

Preferred style	**Suggested methods**
Visual	Visual cues, facial expressions, and utilization of maps, graphics, and pictures
Auditory	Verbal instructions, talking, and discussions
Kinesthetic (tactile)	Physical activities and hands-on experiences
Cognitive	
Systems perspective	Show the "big picture," how the pieces fit into a larger system
Logical steps	Provide a plan with practical steps that clearly lead to the desired outcome
Experimental	Give learners an opportunity to try the concepts out to determine if they work
Impact	Demonstrate how the concept will result in significant and desirable results

SELECT THE TRAINING DELIVERY METHOD

Training delivery methods are divided into two major categories: on-the-job training (OJT) and off-the-job training. Table 5.1 compares when each category should be selected. On-the-job training involves having the trainer coach or guide the trainee while the trainee is actually performing a work-related job. OJT involves an expert coaching the trainee to do a specific job when the trainee can apply what is learned to his or her job immediately. Off-the-job training involves

Table 5.1 Job training selection criteria.

Selection factors	Consider on-the-job training when . . .	Consider off-the-job training when . . .
Task frequency	Key tasks occur on a regular basis	Key tasks do not occur on a regular basis
Skill mastery	Skills can be mastered only over time with practice	Skills can be acquired rapidly with little practice
Subject matter/content	Content does not change frequently	Content requires frequent revisions
Numbers of prospective trainees	Few trainees are to be trained at the same time	Many employees have the same training needs, and there are cost savings in training a group
Training facility	Required equipment and/or other resources are not available on site	Required equipment and/or other resources can be brought into a classroom
Work environment	The work environment is conducive to learning	The work environment is not appropriate or comfortable for learning
Instructor availability	Qualified instructors are not available on site but master performers are	Qualified instructors are available
Accuracy requirements	Actual job requirements are best experienced firsthand	Actual job requirements can be accurately simulated in a classroom environment
Target audience level	Potential trainees have diverse backgrounds and experience levels	Potential trainees have similar backgrounds and experience levels
Target audience motivation	Learners are well motivated and can work on their own with limited supervision	Learners are not sufficiently motivated to work on their own
Time requirements	Time to complete training is not a critical factor	Time to complete training is critical

Source: The ASTD Training and Development Handbook (New York: McGraw-Hill, 1996).

taking the trainee away from his or her normal job for a short period in order to provide training that the trainee can apply upon returning to his or her normal duties. Organizations often prefer on-the job training to off-the-job training.

On-the-job training may be conducted by an expert who is engaged specifically to provide the OJT training or by a fellow employee (or peer) who provides the OJT when the need for it arises. In either case, the instructor should be an expert who thoroughly understands the job to be performed, possesses the skills necessary to do the job, and has access to all of the information necessary to successfully perform the job.

On-the-job training is training usually conducted at the workstation when the trainer is physically collocated with the person being trained, or at the normal place of work. On-the-job training is typically done one-on-one,[3] and it is best for developing motor tasks, such as

- procedures for installing software,
- conducting specific part or product inspections, and
- procedures for performing routine troubleshooting.

Off-the-job training, which takes place away from the actual work site, may be more preferable for knowledge-based tasks that require some degree of problem solving and decision making, such as

- continuous improvement tools,
- communication skills, and
- data analysis.

There certainly are many cases where training plans would utilize both off-the-job and on-the-job training. Training can start off-the-job in a classroom setting learning the concepts and then move to practicing or doing what was learned in the on-the-job setting. Another example would be learning general concepts as a group in a classroom setting and then receiving training on-the-job for the job-specific skills by a more experienced person with the same job.

When the objective of the training is understood and the individuals who are to be trained have been identified, a selection of the best method of delivering the training can be made. Five training delivery methods are listed. All five of these methods are now available as both face-to-face instruction and virtually over the internet. One important consideration in selecting one of these methods is how long it will take for the trainee to learn what is needed. Everyone is busy today, so training must not take people away from their normal duties and their assigned work more often or for longer periods than necessary.

Workbooks and self-study materials are available on the internet, from professional trainers, or from media outlets on most topics the process analyst and other employees will need. Since hard-copy workbooks must be prepared in advance of the training, they are usually not interactive. Online training is often interactive, employing simulations, quizzes, exercises, and games.

Lectures from highly qualified instructors who possess both the knowledge of the subject and the skill to present it in an interesting manner are still a common means for delivering training. Lectures can be interactive if the instructor is capable of engaging the trainees in dialogue, but normally are not—lectures, like workbooks, are usually prepared before the training session so they are normally not interactive. Many courses can be provided by trainers who deliver their training online over the internet or an organization's intranet, and with contemporary software tools they can still be interactive. Most corporate trainers are required to be certified by the organization or by professional organizations.

Job aids are a very popular means of delivering training. They can include avatars and "smart applications" that are available on the trainees' computers or handheld devices, or they can be printed (sometimes laminated) cards that are

easy for the employee to carry and access. When these are prepared before the training session, they are not interactive, but today many job aids are interactive.

Video training is a powerful means for delivering training. Live lectures and training sessions can be recorded and played back when the trainee needs them, and lectures can be interspersed with videos to stimulate discussions and facilitate learning. Normally they are not interactive, but they can be used to stimulate interactive dialogue between trainees and instructors.

Computer-based training utilizes preprogrammed lectures, interesting videos, and cartoon videos to present the training. However, with modern technology, they can also be interactive. Many excellent training programs have been developed and are available on a variety of topics in subjects that process analysts and employees will need to learn. Trainees located anywhere in the world can "attend" a virtual learning session that includes workbooks, lectures, job aids, and video training, as well as interactive discussions.

There are important considerations in selecting a training method. Once training needs have been identified and the objectives are in place, it is time to translate those training concepts into practice. Decisions on where and how the training is to be delivered need to happen. When selecting a delivery method, the following must be considered:

- Audience makeup
- Organizational culture
- Financial issues
- Administrative issues
- Instructor competencies
- Safety issues

Figure 5.1 outlines a checklist of important questions to consider when determining an appropriate delivery system for training.

EVALUATE TRAINING EFFECTIVENESS

Departmental and Training Performance Improvement Measures

Evaluation is essential in determining whether the training program meets the objectives of the training plan. Evaluation includes these elements:[4]

1. Verification of the design (for example, subject content and delivery methods)
2. Applicability of facilities, equipment and tools, and media to be used
3. Qualifications of the trainer
4. Selection of the participants
5. Measures to be used to assess training effectiveness (validation)
6. Measures to be used to assess outcomes resulting from training (validation)

- Training content
  - Abstract or concrete?
  - Technical or nontechnical?
  - Didactic or experiential?
  - Mandated or required (for example, by a regulatory body, or management in support of a strategic objective)?
- Learning constraints
  - Short or long time for learning mastery?
  - Short or long time to apply content?
- Training audience
  - Size—individual learners or groups?
  - Geographic dispersion—one location or multiple locations?
  - Education level—basic or advanced?
  - Training experience on a topic—new or refresher?
  - Internal employees or external personnel (for example, customers and suppliers)?
  - Low or high experience?
  - Low or high motivation?
- Instructor competence/train-the-trainer requirements (if applicable)
  - Professional or nonprofessional training capability?
  - Internal employee or external consultant?
- Training facilities
  - Ad hoc or dedicated training facilities?
  - On site or external?
  - Media/equipment available or required?
- Organizational preferences and capabilities
  - Self-directed or instructor led?
  - Traditional modes or technology driven?
- Budget practices for training expenditures
  - Departmental funding or companywide coverage?
  - Individually funded or budgeted line items?
- Evaluation provisions
  - Outputs (for example, new/enhanced skills, improved productivity)?
  - Outcomes (for example, improved customer satisfaction, increased profits, return on training investment)?

Figure 5.1 Considerations for selecting a training system.

Source: ASQ's Foundations in Quality Self-Directed Learning Series, Certified Quality Manager, Module 7 (Milwaukee, WI: ASQ Quality Press, 2001), 7–26.

Technical training effectiveness can be greatly enhanced by four key considerations:

1. Appropriate preparation of the training facilities
2. Appropriate timing of the training relative to when performance is required
3. Appropriate sequence of training relative to skills mastery
4. Appropriate feedback indicating performance difficulties and progress

Table 5.2 describes five levels for evaluating training. Donald Kirkpatrick is credited with defining the first four levels (reaction, learning, behavior, and results) for evaluating training.[5] Dana Robinson and James Robinson expanded level three to distinguish between type A (are participants applying the skills and behavior as taught?) and type B (are participants applying nonobservable skills—for example, mental skills or learning—to the job?) learning.[6] Level 5 in Table 5.2 is a perspective addressed by Russ Westcott.[7]

In Figure 5.2, a matrix comparing each level of evaluation to value of information, power to show results, frequency of use, and difficulty of assessment is shown. The five levels represent a hierarchy with evaluation progressing from lowest to highest. The first four levels provide individual performance improvement measures, while the fifth level provides a departmental or

Table 5.2 Levels of training evaluation.

No.	Level	Questions	Comments
1	Reaction	Were the participants pleased with the training?	The typical "smile sheets" collected at the end of a program, session, or module.
2	Learning	Did the participants learn what was intended for them to learn?	Were the training objectives met? Typically determined from some kind of test.
3	Behavior	Did participants change their behavior on the basis of what was taught?	Typically determined from an assessment or how learned behaviors are applied on the job.
4	Results	Was there a positive effect on the organization resulting from participants' changed behavior?	Typically measured from pretraining versus post-training analysis of the organization's outcomes. Usually a "quantity" type measure (increased production, lower rejects, number of time periods without a customer complaint, and so on).
5	ROTI	Was there a measurable net dollar payback for the organization resulting from participants' application of learned behavior?	Return on training investment (ROTI) is based on the dollar value added by the investment in the training.

Source: R. T. Westcott, *The Certified Manager of Quality/Organizational Excellence Handbook*, 3rd ed. (Milwaukee, WI: ASQ Quality Press, 2006), 564.

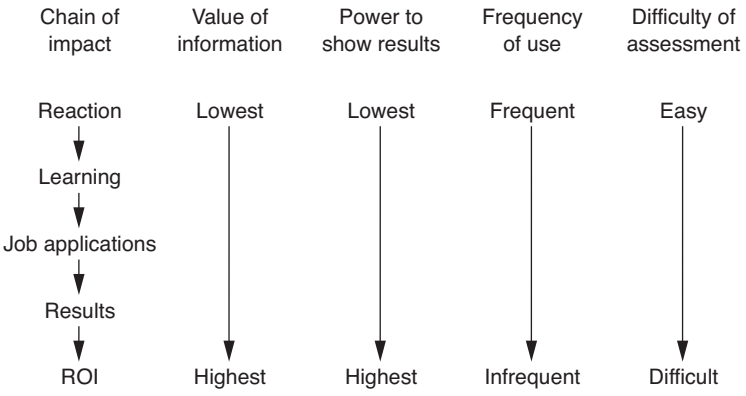


Figure 5.2 Characteristics of evaluation levels.

Source: R. T. Westcott, *The Certified Manager of Quality/Organizational Excellence Handbook*, 3rd ed. (Milwaukee, WI: ASQ Quality Press, 2006), 564.

organizational performance improvement measure to evaluate training effectiveness. Descriptions of the levels are listed below.

1. The reaction level provides the lowest-value information and results and is frequently and easily used.
2. The learning level is used to obtain a more in-depth assessment of whether specific training objectives were met.
3. The behavior (job applications) level assesses whether the training is applied back on the job, usually after some time has passed.
4. The results level measures the quantitative difference between the outcomes of the work units affected prior to their people receiving training (the baseline) and the outcomes some time after the training ended. The objectives for training measured could be decrease in scrap rate, increase in number of savings accounts opened, increased classroom attendance, elimination of medication errors in a hospital, and so on.
5. The ROI level offers the highest-value information and results, is not used as frequently, and is more difficult to assess. Level 5 is based on placing dollar values on the baseline, the results, and the improvement, then determining the value received for the dollars spent. When expressed as a ratio, a $3 return for every $1 spent is a useful minimum ROI. Quality training programs that score high at all levels are likely to be very successful.

Two formulas can be used to evaluate at level 5: the *benefits-to-cost ratio* (BCR) and the *return on training investment* (ROTI).

$$\text{BCR} = \frac{\text{Program benefits}}{\text{Program costs}}$$

$$\text{ROTI} = \frac{\text{Net program benefits (total benefits} - \text{costs)}}{\text{Program costs}}$$

A rule of thumb is that if ROTI is less than $3 (or a ratio of 3:1), meaning $3 of benefits are obtained from every $1 spent, then training should not be considered (unless mandated).

LINK TO ORGANIZATIONAL AND INDIVIDUAL PERFORMANCE MEASURES

Whenever training is provided, it should be followed by an evaluation that compares the results of the training to the objectives of the training, if this is permitted. Some countries prohibit individual training evaluations, including the European Work Councils. As stated earlier, the training objectives against which the effectiveness of the training are measured should be linked to business objectives. The training should also be linked to the measures used to assess organizational and individual performance. For example, if the objective of the training is to increase safety on the shop floor, those employees and teams who are responsible for shop floor safety should be given the training they need, and then after the training their implementation of safety tools and activities—which should always be assessed—can be used as a measure of how successful the training was.

In this world of global competition between world-class quality organizations, a competent and empowered workforce could be the differentiating factor for success. It is important to use the results of training effectiveness as feedback. The feedback may show failures or ineffectiveness. As in the PDCA cycle (explained in Chapter 6), use the feedback for continuous improvement to improve the quality training program. The ineffectiveness or failure is likely to be linked to one or more of the following causes:

- Cultural resistance by line managers
- Doubt as to the usefulness of the training, which occurs when
  - no linkage exists with the strategic plans of the organization,
  - no apparent connection is evident between the behaviors to be learned and their application on the job,
  - no projected goals are established for post-training improvement, and
  - the question of "What's in it for me?" is inadequately addressed for participants and their supervisors.

Lack of participation (involvement) by line managers could cause the following issues:

- Technique versus problem orientation
- Inadequacies of leaders
- Mixing of levels of participants
- Lack of application during the course
- Language that is too complex
- Lack of participation by the training function

- Inadequate training delivery or lack of trainer competency
- Operational and logistical deficiencies[8]

A successful quality training program will provide the workforce with the skills necessary to carry out additional responsibilities, grant access to information for better decision making, and, ultimately, lead to empowerment. An empowered workforce results in better responsiveness to customers, increased business performance, and a better quality of work life.

TOOLS FOR ASSESSING TRAINING EFFECTIVENESS

There are many post-training feedback surveys used to assess the training effectiveness. In a research study, Baba Deros and colleagues evaluated the areas of participants' perceptions with respect to the following:[9]

- the overall training program;
- teaching materials, delivery, and tools; and
- facilitators.

These elements should be assessed for participants' perceptions with respect to the overall training program:

- Achievement of workshop/training course objectives
- Usefulness of workshop/training course
- Positive effects from workshop/training course
- Relevance of workshop/training course to work
- Appropriateness of workshop/training course duration
- Importance of workshop/training course to work
- Overall training program

Assess these elements for participants' perceptions on training materials, delivery, and tools:

- Notes for workshop/training course are clear
- Notes for workshop/training course are easily understood
- Notes for workshop/training course contain adequate information
- Adequate exercises are provided in workshop/training course
- Effective exercises are provided in workshop/training course
- Audiovisual aid provided is satisfactory
- Understand overall participants' perceptions on training materials, delivery, and tools

The elements should be assessed for participants' perceptions on facilitators:

- Facilitator is well-prepared

- Facilitator knows the material he or she is presenting
- Facilitator provides real examples
- Facilitator presentation is clear
- Facilitator presentation is easy to understand
- Facilitator involves participants during discussions
- Facilitator involves participants in training activity
- Facilitator presentation is effective
- Facilitator presentation helps me to learn
- Facilitator receives high overall perceptions from participants

In addition to perception surveys from the participants, end-of-course tests can also be administered to assess the participants' knowledge of the skills attained during training.

The researchers in the previously mentioned study also assessed the following before and after training:

- Knowledge of the practices of the skills
- Level of understanding of the skills
- Level of practice of the skills

Part II

Quality Tools and Process Improvement Techniques

Chapter 6

Process Improvement Concepts and Approaches

Define and explain elements of Plan–Do–Check–Act (PDCA), activities, incremental and breakthrough improvement, and DMAIC phases (define, measure, analyze, improve, control). (Apply)

Body of Knowledge II.A

PLAN–DO–CHECK–ACT (PDCA)

The most well-known methodology for continuous improvement, *plan–do–check–act* (PDCA), was developed by Walter Shewhart. W. Edwards Deming adapted the cycle to *plan–do–study–act* (PDSA), also known as the *Deming wheel*, emphasizing the role of learning in improvement.

PDCA is a model for continual process improvement. By developing a measurable action plan, decision making based on facts can happen, putting the plan into action. As Figure 6.1 shows, the cycle is endless. The cycle must be continued to see resulting improvements.

As depicted in Figure 6.1, there are four steps of the PDCA/PDSA cycle:

Plan. Recognize the opportunity for improvement and gather the data or do the research to answer, "What are the key targets the team expects this project to achieve?" Once a problem is identified, the situation needs to be observed and data gathered to give a better definition of the problem. When the problem is defined, root cause analysis (discussed further in Chapter 21) takes place, which also occurs in this step of the PDCA cycle. A popular and very effective tool for root cause analysis is the *five why's* tool. By asking the question "Why?" at least five times, a series of causes and effects results. This domino effect should end with the root cause. After the root cause has been identified, a countermeasure needs to be created and planned out. Know what the criteria are so progress can be measured—how will the team know if it was worth it? Or, how will the team know if it is working? Data need to be gathered to determine whether the plan will work.

Do. Communicate the plan and implement according to the plan. As Paul Palmes says in his audiocast on the PDCA cycle, "If you change horses in midstream . . . people drown."[1] Communication is important. Everyone affected

Figure 6.1 The PDCA/PDSA cycle.

by the implementation of the countermeasure needs to be involved. If possible, the proposed solution should be done on a small scale first, with as much data being collected as possible while noting the conditions that occur as the change is being implemented.

Check. Check according to the plan just as the team implements according to the plan (in the *do* cycle). The team analyzes the information collected from the *do* phase. Did the action produce the desired results? Were new problems created?

Act. A decision is made on whether it is feasible to adopt the change. If the change is adopted, the team uses the PDCA cycle as an automatic improvement cycle and looks for more opportunities for improvement. Sometimes, as a result of the *check* phase, it is decided the plan should be altered, and the PDCA cycle starts over again. Other possible actions include abandoning the idea, amplifying or reducing the scope, and then, always, beginning the PDCA cycle over again.

KAIZEN

Kaizen is a combination of two Japanese words (*kai* + *zen*) meaning continuous improvement. Kaizen is a process-oriented system and encompasses the whole organization, with the key to success being management's demonstration of complete support. Some of the goals of kaizen include the following:

- Continuous improvement
- Elimination of waste
- Just-in-time (JIT) manufacturing
- Standardized work
- Total quality control

The kaizen philosophy works with the principle of having a strong respect for the people. Improving the quality of the workforce impacts the quality of the

product and/or service. When there is a focus on improvement in all aspects of the workplace, problems are not looked at as mistakes but as opportunities. When a workforce embraces kaizen, they participate in

- training on problem-solving and quality tools,
- doing the problem solving,
- implementing improvements,
- receiving recognition for their successes, and
- a suggestion program (which costs little to nothing to implement).

In Masaaki Imai's book, *Kaizen: The Key to Japan's Success*,[1] he relates the kaizen approach to the PDCA cycle, as shown in Figure 6.2.

The Toyota production system is well-known for its kaizen approach to productivity improvement, with the main goal of eliminating waste.

Kaizen events, also called *kaizen blitzes*, are typically five-day, highly intensive events with a structured approach. These events focus on process improvement that may also result in the development of a new or revised work standard. Kaizen blitzes involve a team of workers that may be targeting eliminating waste, improving the work environment, reducing cycle time, reducing costs, or setup time reduction (single-minute exchange of dies [SMED], explained more in Chapter 8).

The goal of kaizen events is to create a sense of urgency and generate enthusiasm for rapid results. Because of the immediacy, resources need to be in place and readily available for use.

The kaizen event follows the Plan–Do–Check–Act cycle, including the following steps:[2]

PLAN:

1. Identify need: Determine the purpose of the kaizen.
2. Form kaizen team: Typically six to eight team members.
3. Develop kaizen objectives: To document the scope of the project. The objectives should be SMART (Specific, Measurable, Achievable, Realistic, and Time-based).

Plan	What?	Definition of problem Analysis of problem
	Why?	Identification of causes
	How?	Planning countermeasures
Do		Implementation
Check		Confirmation of the result
Act		Standardization

Figure 6.2 Kaizen and the PDCA cycle.

4. Collect current state baseline data: Either from measure phase or from additional data as needed.
5. Develop schedule and kaizen event agenda: Typically, one week or less.

DO:

6. Hold kaizen event using DMAIC.

   Sample kaizen event agenda:

   - Review kaizen event agenda
   - Review kaizen objectives and approach
   - Develop kaizen event ground rules with team
   - Present baseline measure and background info
   - Hold event:
     - Define: Problem (derived from objectives), agree on scope for the event
     - Measure: Review measure baseline collected
     - Analyze: Identify root causes, wastes, and inefficiencies
     - Improve: Create action item list and improvement recommendations
     - Control: Create standard operating procedures to document and sustain improvements. Prepare summary report and present to sponsor.
   - Identify and assign action items
   - Document findings and results
   - Discuss next steps and close meeting
7. Implement: Implement recommendations, fine-tune, and train.

CHECK/ACT:

8. Summarize: Summarize results.

   Kaizen summary report items:

   - Team members
   - Project scope
   - Project goals
   - Before kaizen description
   - Pictures (with captions)
   - Key kaizen breakthroughs
   - After kaizen description

- Results
- Summary
- Lessons learned
- Kaizen report card with follow-up date

9. Control: If targets are met, standardize the process. If targets are not met, or the process is not stabilized, restart the kaizen event PDCA cycle.

INCREMENTAL AND BREAKTHROUGH IMPROVEMENT

> *Quality programs that focus on continuous improvement are vital in providing incremental improvement of processes, products, and services in an existing technological paradigm. These programs view quality as being measurable in some quantitative way. Breakthrough improvement that leads to development of new paradigms requires thinking of quality in a different way.*[3]

The plan–do–check/study–act cycle and kaizen strategy typically focus on *incremental improvement* on a continuous basis. By taking one step at a time, process improvement is achieved on a gradual basis, as opposed to 100% improvement upon completion of the first process improvement event. Although this strategy is being implemented on processes and subprocesses throughout the organization, the output of one improvement event is the input to another new process improvement event, and businesses often lose patience because of the slow pace of progress.

Incremental improvement initiatives alone do not allow a business to keep up with the rapid pace of change in the technological arena, as well as keep up with customer demands and competition. The Six Sigma philosophy and reengineering are two approaches to achieving breakthrough improvement. *Breakthrough improvement* is a method of solving chronic problems that results from the effective execution of a strategy designed to reach the next level of quality. Such change often requires a paradigm shift within the organization.

When initiating a method of improvement, the primary goal is to control variation. After reviewing the data, special cause problems and common cause problems are determined by using control charts (see Chapter 14). Once a state of controlled variation is reached, higher levels of quality are achieved by eliminating chronic problems. At this point, to achieve breakthrough improvement, organizations should focus on reducing variation in those areas most critical to meeting customers' requirements. The Six Sigma philosophy translates to the organizational belief that it is possible to produce totally defect-free products or services.

Reengineering is an extreme action for breakthrough improvement, unlike the gradual improvement of processes resulting from incremental changes. When an organization undergoes reengineering, they are seeking drastic improvement results, which often means a paradigm shift has to happen within the organization.

With a total reengineering of an entire organization, its present structure and how the current work processes produce and deliver its products or services may not be a consideration. With a completely new approach, the organization

may ignore the current status and start with a fresh, new tactic. Unfortunately, companies have used this tactic in desperation to cut costs by drastically reducing the number of employees. This, obviously, is a very unfavorable approach, and rather than reengineer the entire company all at once, process reengineering has become a more constructive method.

In process reengineering, a team will map out the structure and functions of a process to identify and purge the non-value-added activities, reducing waste and costs accordingly. This results in the development of a new and less costly process that performs the same functions.

Another aspect to reengineering is using creativity and innovation to help a business keep up with the rapid pace of change in the technological arena, as well as keeping up with customer demands and competition. Breakthrough improvement needs insight. To develop radical or paradigm-shifting products and services, incremental improvement must be combined with creativity and innovation. Some useful tools can help promote creativity:

- *Lateral thinking.* A process that includes recognizing patterns, becoming imaginative with the old ideas, and creating new ones
- *Imaginary brainstorming.* Breaks traditional thinking patterns
- *Knowledge mapping.* A process of visual thinking
- *Picture association.* Using pictures to generate new perspectives
- *Morphological box.* Used to develop the anatomy of a solution

Define, Measure, Analyze, Improve, Control Phases

Six Sigma is a quality management philosophy and methodology that focuses on reducing variation, measuring defects (per million output/opportunities), and improving the quality of products, processes, and services. The concept of Six Sigma was developed in the early 1980s at Motorola Corporation and became popularized in the late 1990s by General Electric Corporation and their former CEO, Jack Welch.

The DMAIC approach is the Six Sigma methodology that stands for the five phases of the Define, Measure, Analyze, Improve, and Control method. Figure 6.3 shows the activities within each DMAIC phase. These activities may vary by reference but are generally performed for each project. Each phase and the activities will be described next.

Define Phase

The purpose of the Define phase is to delineate the business problem and scope the project and process to be improved. The activities and most commonly used tools in the Define phase are shown in Table 6.1. The following steps can be applied to meet the objectives of the Define phase:

1. Create project charter, plan, and stakeholder analysis

   In this activity, the project team works with the project sponsor and champion to define the problem to be improved and the goals and scope of the project. The scope of the process, with the high-level steps that are part of the process and project, are also identified.

Phase	Step
Define	1. Create project charter, plan and stakeholder analysis 2. Perform initial VOC (voice of the customer) and identify critical to satisfaction (CTS) criteria 3. Select team and launch project
Measure	4. Define the current process and VOP (voice of the process) performance 5. Define detailed VOC 6. Validate measurement system
Analyze	7. Develop cause-and-effect relationships 8. Determine and validate root causes 9. Develop process capability
Improve	10. Design future state with costs and benefits 11. Establish performance targets and project scorecard 12. Gain approval, train, and pilot
Control	13. Implement improvement recommendations and manage change 14. Incorporate process control plans and scorecard 15. Implement continuous improvement cycle, plan, do, check, act (PDCA)

Figure 6.3 DMAIC phases and activities.

Source: Reprinted from S. Furterer and D. Wood, *ASQ Certified Manager of Quality/Organizational Excellence Handbook*, 2021.[4]

Table 6.1 Define phase activities and common tools.

No.	Activities	Tools
1	Create project charter, plan, and stakeholder analysis	• Project charter • SIPOC (suppliers, inputs, process, outputs, customers) • Stakeholder analysis • Communication plan • Change plan
2	Perform initial voice of the customer (VOC) and identify critical to satisfaction (CTS)	CTS summary
3	Select team and launch the project	• RACI (responsibilities) matrix • Rules of engagement • IFR (items for resolution) • Project plan

Source: S. Furterer, "Lean-Six Sigma Course Materials," University of Dayton, 2018.

2. Perform initial voice of the customer (VOC) and identify CTS/CTQ

The initial voice of the customer (VOC) is derived based on interviews and qualitative data collection from the stakeholders of the process. A stakeholder analysis is performed to identify the roles, concerns, and engagement of the stakeholders impacted by the

process to be improved. This helps to develop the initial Critical to Satisfaction (CTS)/Critical to Quality (CTQ) criteria.

3. Select team and launch project
   The stakeholder helps to identify the team members, who will represent each stakeholder group, to work through the DMAIC process.

Measure Phase

The purpose of the Measure phase is to understand and document the current state of the processes to be improved, collect the detailed voice of the customer information, baseline the current state, and validate the measurement system. The activities and most commonly used tools in the Measure phase are shown in Table 6.2. The activities performed during the Measure phase include the following:

4. Define the current process and VOP (voice of the process) performance
   In this step, the current process is mapped using a process map and/or value stream map. Additionally, a data collection plan is defined that identifies the data to be collected to understand the CTS. The data are then collected to understand the voice of the process, which helps us to understand the current performance of the process.

5. Define detailed VOC (voice of the customer)
   Additional and more detailed VOC information will be collected in the Measure phase, using qualitative methods, such as interviews or focus groups, and quantitative surveys to assess stakeholder satisfaction.

Table 6.2 Measure phase activities and common tools.

Measure Phase		
No.	**Activities**	**Tools**
1	Define the current process and VOP performance	• Process map, value stream map • Data collection plan with operational definitions • Metrics with baseline • Pareto chart • VOP matrix • Benchmarking • Check sheets • Histograms
2	Define the detailed VOC	• Surveys, interviews, focus groups, affinity diagrams
3	Validate the measurement system	• Measurement system validation

Source: S. Furterer, "Lean-Six Sigma Course Materials," University of Dayton, 2018.

6. Validate measurement system

   The measurement system is assessed to ensure that the system that is used to collect and measure data is accurate and represents the process, Gage R&R (Repeatability and Reproducibility) study and attribute agreement analysis tool are used to assess the repeatability and reproducibility of the measurement system, the first for variable measures, and the second for attribute measures. This helps ensure that operators who are measuring the metrics are doing so consistently and accurately.

Analyze Phase

The purpose of the Analyze phase is to analyze the data collected related to the voice of the customer and the voice of the process to identify the root causes of the process problems and to develop the capability of the process. The activities and most commonly used tools in the Analyze phase are shown in Table 6.3. The activities performed and tools applied during the Analyze phase include the following:

7. Develop cause-and-effect relationships

   Root cause analysis is performed to identify the input and process factors that impact the process. Cause-and-effect diagrams, why–why diagrams, and failure mode and effects analysis (FMEA) are used to develop the cause-and-effect relationships to identify the critical few causes that contribute to the process problems.

8. Determine and validate root causes

   If necessary, additional data are collected to validate the root causes. To determine and validate root causes, the Six Sigma team can perform a process analysis coupled with waste elimination. A process analysis consists of the following steps:

   1. Document the process (using process maps from the Measure phase)
   2. Identify non-value-added activities and waste

Table 6.3 Analyze phase activities and common tools.

Analyze Phase		
No.	**Activities**	**Tools**
7	Develop cause-and-effect relationships	• Cause-and-effect diagrams • Cause-and-effect matrix • Why–why diagram
8	Determine and validate root causes	• Process analysis, histograms and graphical analysis (covered in Measure), waste analysis, value analysis, 5S tool, FMEA, basic statistics (covered in Measure)
9	Develop process capability	• DPPM/DPMO, process capability

Source: S. Furterer, "Lean-Six Sigma Course Materials," University of Dayton, 2018.

3. Consider eliminating non-value-added activities and waste
4. Identify and validate (collect more data if necessary) root causes of non-value-added activities and waste
5. Begin generating improvement opportunities

9. Develop process capability

   Process capability analysis is performed to assess whether the current processes are capable of meeting the required specifications of the process.

Improve Phase

The purpose of the Improve phase is to identify improvement recommendations, design the future state, implement pilot projects, train, and document the new processes. The activities and most commonly used tools in the Improve phase are shown in Table 6.4. The activities performed and tools applied during the Improve phase are the following:

10. Design future state with costs and benefits

    During this activity, the improvement ideas to improve the process are generated. Action plans specifying how to implement the improvements are developed. The improvement ideas are prioritized and organized into ideas that can be implemented in the short term, within three to six months, and long-term items, which will take more time to implement.

Table 6.4 Improve phase activities and common tools.

Improve Phase		
No.	**Activities**	**Tools**
10	Design future state process and improvements	• Quality function deployment • Recommendations for improvement • Action plan • Cost/benefit analysis • Future state process map • Future state value stream map • Appreciative inquiry • Affinity diagram • Relationship diagram • Opportunity map • Strategies and strengths matrix
11	Establish performance targets and project scorecard	• Dashboards/scorecards • Revised VOP matrix
12	Gain approval, train, and pilot	• Training plan and materials • Procedures • Policies • RACI (Responsible, Approve, Consult, Inform)

Source: S. Furterer, "Lean-Six Sigma Course Materials," University of Dayton, 2018.

11. Establish performance targets and project scorecard
    The performance targets and project scorecard are developed to assess whether the improvements implemented had a positive impact on the processes.

12. Gain approval, train, and pilot
    The improvement ideas are piloted on a smaller basis, perhaps in one department or one area of the company, to ensure that they work as planned. Approval to implement the ideas are obtained from the project sponsor and/or steering committee. The improvements are then rolled out to the organization more broadly. Any appropriate and necessary training to ensure that operators and staff can properly perform the process is performed.

Control Phase

The purpose of the Control phase is to measure the results of the pilot projects and manage the change on a broader scale, report scorecard data and the control plan, identify replication opportunities, and develop future plans for improvement. The activities and most commonly used tools in the Control phase are shown in Table 6.5. The activities performed and tools applied during the Control phase are the following:

13. Implement improvement recommendations and manage change
    The improvements are rolled out to the organization more broadly than the initial pilot activities. Change management techniques should be applied to manage the process change within the organization.

14. Incorporate process control plans and scorecard
    Process control plans are developed in the Control phase to ensure that the new process changes are maintained. The control

Table 6.5 Control phase activities and common tools.

Control Phase		
No.	**Activities**	**Tools**
13	Implement improvement recommendations and manage change	• Hypothesis testing
14	Incorporate process control plans and dashboards	• Dashboards • Basic statistics, graphical analysis, sampling, mistake proofing, FMEA (Failure Mode and Effects Analysis), control plan, process capability, DPPM (Defective Parts Per Million)/DPMO (Defective Parts Per Million Opportunities) • Statistical process control • Standard work
15	Implement continuous improvement cycle; plan–do–check–act (PDCA)	• Prioritization matrices • Process map repository

Source: S. Furterer, "Lean-Six Sigma Course Materials," University of Dayton, 2018.

plans and dashboards or scorecards are used to measure the change and maintain the gains achieved.

15. Implement continuous improvement cycle, plan–do–check–act (PDCA)

    Additional improvements are implemented using the PDCA cycle for continuous improvement within the process.

Thomas Pyzdek's graphic, shown in Figure 6.4, shows the key questions that should be asked and answered in each phase of the DMAIC methodology.

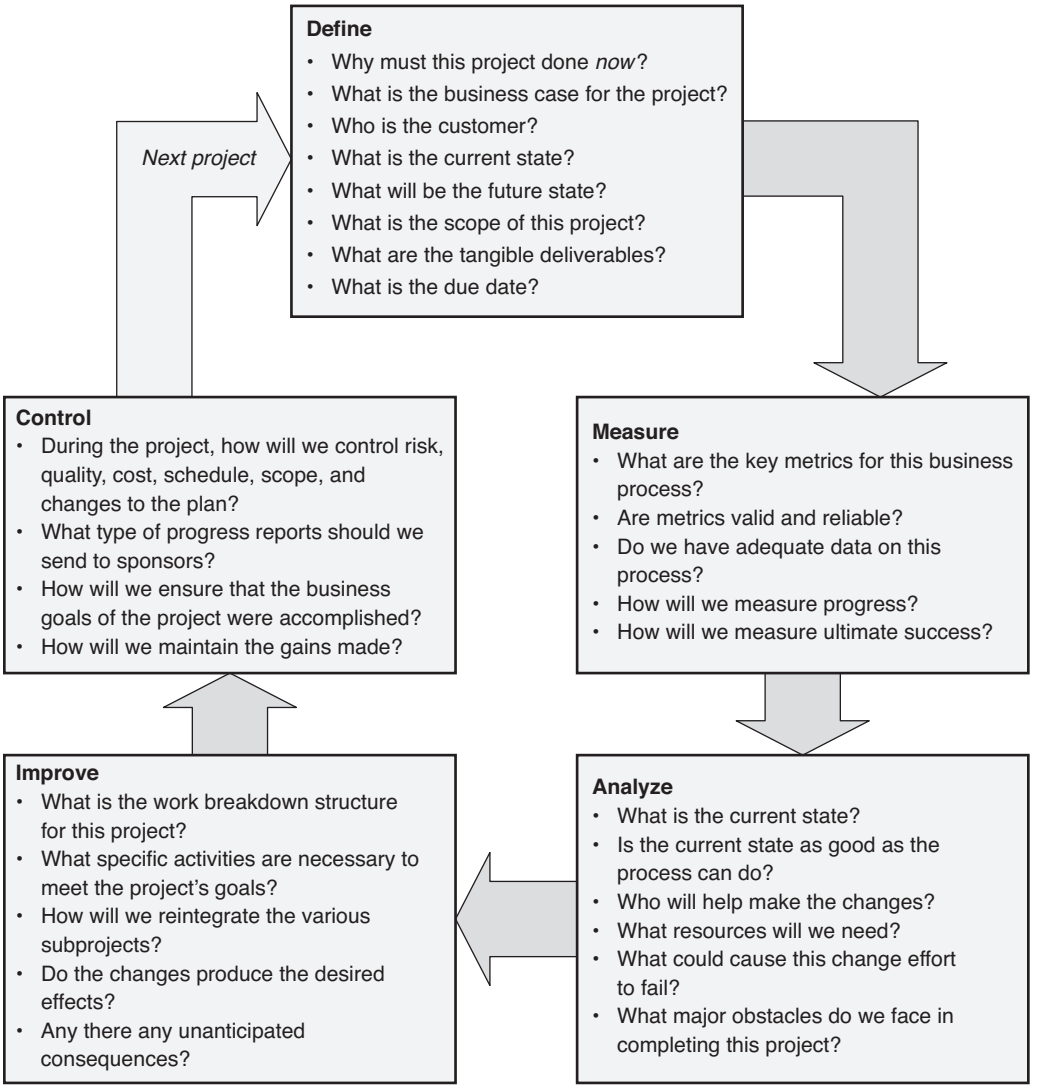


Figure 6.4 DMAIC cycle.

Source: Copyright © 2003 by Thomas Pyzdek, all rights reserved. Reproduction permitted providing copyright notice remains intact. For more information, visit http://www/pyzdek.com. Also see DMAIC versus DMADV. Search this website for more information on DMAIC and DMADV.

Chapter 7
Basic Quality Tools

Select, construct, apply, and interpret the seven basic quality tools: (1) cause and effect diagrams, (2) flowcharts (process maps), (3) check sheets, (4) Pareto charts, (5) scatter diagrams, (6) run charts and control charts, and (7) histograms. (Evaluate)

Body of Knowledge II.A

The *seven basic quality tools* are scientific tools used in analyzing and improving process performance. These classic quality tools are also referred to as the *seven basic tools*. They are primarily a graphical means for process problem analysis through the examination of data.

Figure 7.1 shows that some of the basic quality tools are

- *quantitative:* used for organizing and communicating numerical data, or
- *nonquantitative:* used to process useful information for decision making

With a team in place ready to collect useful data, the next step is for the team to know how to select and apply the tools designed to manage the data. In some instances, just one tool can be used for problem identification, problem solving, process improvement, or process management. In many cases it takes various combinations of the seven basic quality tools, depending on the nature of the problem or objective.

CAUSE-AND-EFFECT DIAGRAM

The *cause-and-effect diagram* is used to generate a list of possible root causes of a problem. It is also known as the *Ishikawa diagram*, after its developer, Kaoru Ishikawa, or the *fishbone diagram* due to its distinctive shape. Once a team has identified a problem, the diagram is used to divide root causes into broad categories. Results of further brainstorming of those root causes can be sorted into the identified categories.

Quantitative	Nonquantitative
• Check sheets • Pareto charts • Scatter diagrams • Run and control charts • Histograms	• Cause-and-effect diagrams • Flowcharts or process maps

Figure 7.1 The seven basic quality tools.

Categories typical for the manufacturing environment are known as the four Ms:

- Manpower
- Machinery
- Methods
- Materials

Sometimes *measurement* or *environment* will be added (Figure 7.2). For service processes, the categories often used are:

- Measurement
- Materials
- People
- Environment
- Method (could include policies and procedures)
- Information systems

The cause-and-effect diagram provides a way of organizing the large number of subcategories generated from the brainstorming session. Figure 7.3 illustrates a completed cause-and-effect diagram.

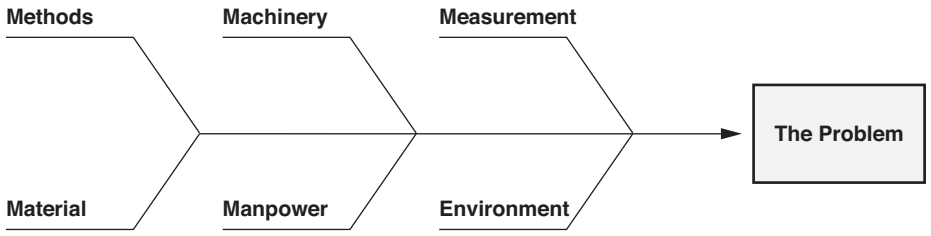


Figure 7.2 Cause-and-effect diagram for a manufacturing problem.

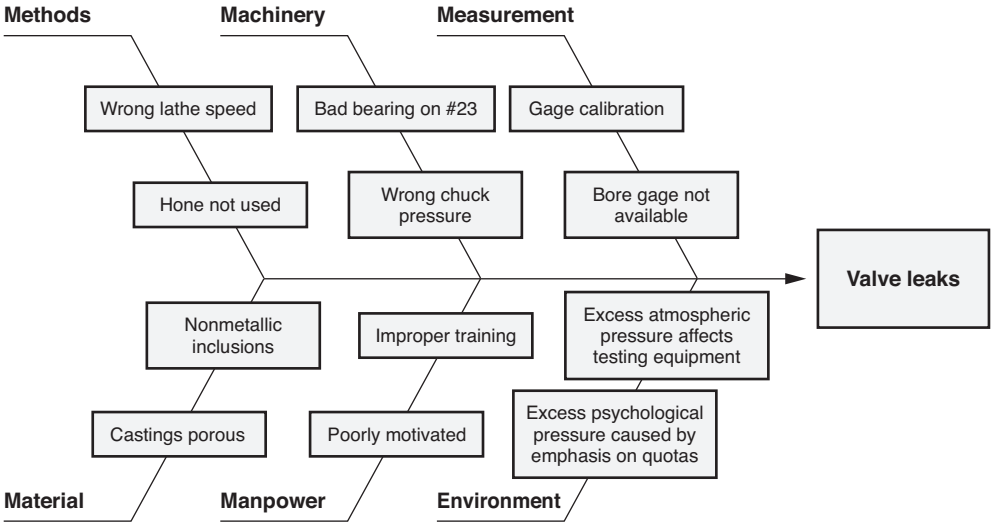


Figure 7.3 Completed cause-and-effect diagram for a manufacturing problem.

Figure 7.4 shows a cause-and-effect diagram for a financial services mortgage loan origination process. The effect is for delays in the loan origination process. The causes were brainstormed with the process improvement team members, who were subject matter experts in the consumer loan origination process at the bank.

The next step in the root cause analysis is to collect data to determine which of the causes are most likely to be acting on the problem being studied.

FLOWCHARTS (PROCESS MAPS)

For a team to work on process improvement, they first need to make sure they have a good understanding of how the process works. A flowchart (also known as a *process map*) is a basic quality tool that provides graphical representation of the sequential steps in a process. A process map is a graphical display of steps, events, and operations that constitute a process. A process map helps us to document, understand, and gain agreement on a process. The process map can be used to document the current "as is" process or a future state, or "to be" process, to designate the process after it is implemented or improved. A process is a sequence of activities with the purpose of getting work done. A typical process map uses rectangles to represent an activity or task, diamonds to represent decisions, and ovals or circles to represent connectors to either activities on the same page or another page. Flow usually flows from left to right, and top to bottom.

Process maps help process owners understand how work is accomplished, how all processes transform inputs into outputs, how small processes combine to form bigger processes, and how processes are both connected and interdependent. Process maps also help process owners see how their work affects others and how other roles affect their work, how even small improvements make a difference, and that process improvements require communication and teamwork.

This section on the process architecture map is derived from the systems engineering book by S. L. Furterer.[1] A special tool, developed by the author,

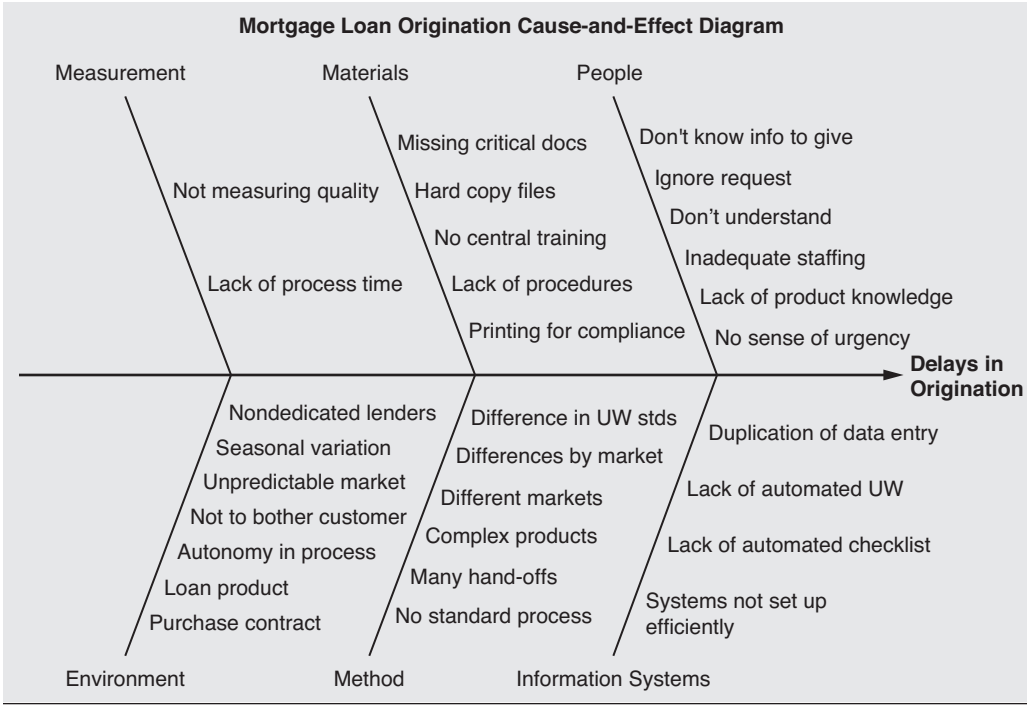


Figure 7.4 Cause-and-effect diagram for a financial services process.
Source: Sandra L. Furterer.

combines both a process map and a process architecture and is called a process architecture map (PAM).[2] The process architecture provides the key elements or information used within a process or system. The traditional process map shows the sequence of activities performed by "actors" or roles within a system. To accurately define a PAM, we must first define a process. A process is a sequence of activities that are performed in coordination to achieve some intended result. A process is also described as a set of activities involved in transforming inputs into outputs. Processes typically cross traditional organizational boundaries or departments.[3] The activities jointly realize a course of action. Each process is enacted by a single organization, but it may interact with processes performed by other organizations, systems, or subsystems.

The PAM has three primary purposes: communication, knowledge capture, and analysis. In using a PAM for communication, we want to convey a rigorous understanding of the process and the ability to manage change. In knowledge gathering, we are interested in understanding the associations of processes and activities. Finally, in analysis we want to be able to study the process for optimization and transformation purposes.

The steps to develop the process scenarios are as follows:

1. Identify the processes that will be mapped, creating a process map list. Define the boundaries of the processes to be mapped based on the value chain or SIPOC.

2. From the processes to be mapped and a stakeholder analysis, identify the roles that perform the processes. Identify representatives who perform these roles to take part in the process map development.
3. Identify the major activities within the process and the sequence of activities performed or to be performed within the process. Identify the process steps and uncover complexities using brainstorming and storyboarding techniques. Brainstorming is a useful tool to have the participants generate ideas in a free-form manner, without evaluating the ideas prematurely. Storyboarding is a way to develop different stories of how the system will be used, while generating what the process looks like from a user perspective.
4. Arrange the steps in time sequence and differentiate operations by the particular symbols chosen to represent activities, decisions, connectors, and start and end points.
5. Identify who (the actor) performs each activity. Do not use names of people; use roles.
6. Identify the documents or information used for each activity.
7. Identify the system, technology, or method used in each activity.
8. Create a process architecture map of each process.
9. For a more detailed process architecture, you may identify potential risks to the process and the control mechanisms. You may then add additional knowledge that is helpful to perform the process.
10. Always observe the actual process as it is performed, if possible, and revise your process map.

For the PAM specifically, we use the following conventions:

1. **Swim lanes**, located down the left side of the diagram, are used in a PAM to represent the different elements related to the process, including
   - the activities or tasks of the process in sequential order;
   - the functional roles or actors of the activities taking place in that part of the flow (decisions or delays do not need a role designated);
   - information or documents, forms, or printed reports used in the activity;
   - technology, equipment, information systems, or methods related to the activities. The methods could include indicating a completely automated activity, a completely manual activity, or a combination of a human activity augmented by automation; and
   - knowledge that is important for training purposes, such as a link to the detailed procedure or work instructions, notes on the process, metrics to be measured, and so on.
   - Knowledge can relate to any rows above the knowledge column.

Note that there are three rows of activities, three corresponding rows of roles, information, and technology.

2. **Start** and **end points** in the process flow, designated by an oval.
3. **Activities**. A series of activities that make up a process.
4. **Decisions** must have at least two arrows exiting, and lines should be labeled with the appropriate condition.
5. **Connectors** are oval symbols that connect the sequence or flow between shapes. Connectors are circles that can denote flow on the existing page of the process map or connect to another page. For an on-page connector, the number in the circle starts with the page number, and numbers after the period indicate the sequential order of the ovals used on that page. For an off-page connector, the first number denotes the page number where the flow continues, and the number after the dot is the sequential order of the off-page connectors. Connectors are used to minimize the number of arrows crossing the page and causing confusion for the reader.
6. **Delay** (D symbol) is used to represent any delay in the process where work is stalled or dependent on a given time frame. Indicate the amount of time and unit of time when using this symbol, if known (e.g., 10 minutes or 4 hours).

Some tips for creating process maps:

- Use roles on process map; avoid names
- Flow is from top to bottom, left to right
- Connect all symbols, either to the first start oval, the last end oval, or a sequential symbol
- Never (or rarely) cross arrows
- Share process maps with other process analysts developing connected subsystems and processes
- Control documents: include the process name, date of origination or revision, and version number
- Use the wall and flip chart paper or whiteboards to map out the process with the people involved in the process
- Validate steps/activities/data outside of the meeting
- Do not be afraid to start over
- Do not get stuck on the detail—get stuck on the flow and value
- Walk through the actual existing process, if there is one
- Numbering conventions are recommended
- The activities are inherently referred to by the numbering using the row (1, 2, and 3) and then the column numbers (1 through 9)

The PAM is used as the foundational tool to document the current process, perform a lean analysis, identify improvement opportunities, and document the future process after improvements are implemented. Process maps are great tools used to train process owners on the process as well. The process map can be used to generate customer requirements, information systems requirements, and develop an information model such as a class diagram. The PAM template allows the creation of a cover page that summarizes the high-level process steps from the SIPOC or value stream map to provide the connection to the system view of where this process fits within the entire system. A system here is referring to the set of processes that interconnect to achieve a work system. The cover page also provides an inventory of the process architecture roles or process stakeholders, information, and technology.

A brief description of the symbols shown in Figure 7.5 and used in the PAM follows.

- The rectangle is used to describe an activity or task of the process.
- A diamond represents a decision made in the process. The questions in the decision should be designed to ask a Yes or No question. If more paths are desired, additional yes/no questions can be asked.
- The Start/End oval is used to identify where the process starts and ends.
- The circle connector is used to connect symbols where the arrows may cross the page and make the process map difficult to read. It can be used to connect to other symbols on the page and to other pages.

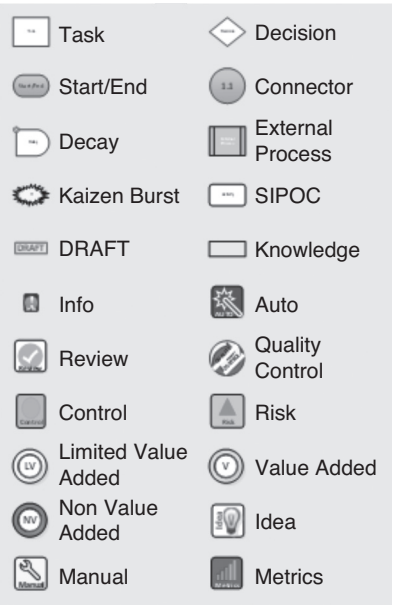


Figure 7.5 Process architecture map icons or symbols.

Source: Sandra L. Furterer.

- The *D* is used to denote a wait or delay in the process.
- The external process can be used to connect the process to a process map that is external, separate, but related to this process map.
- The kaizen burst identifies an idea generated while process mapping.
- The SIPOC activity is used on the cover page for a SIPOC process step.
- The DRAFT symbol can be used to identify that the process map is a draft and must be reviewed further before it is finalized for use.
- The Knowledge symbol is used to add additional knowledge text to the knowledge swim lane.
- The Info icon is placed in the square on the knowledge swim lane to identify that text providing additional knowledge will be placed on the swim lane.
- The additional symbols are used within the knowledge lane to designate other important actions or information:
  - auto—an automated process
  - review—a review step
  - quality control—an inspection or quality control step
  - control—a control mechanism embedded in a process activity
  - risk—identifying an activity that has inherent risk, and where a control may be incorporated
- The value-added, Limited-value-added, and Non-value-added activity icons (green check mark, yellow triangle, and red *x* within a circle) identify the value of the activity to the customer of the process.
- As the process analyst is working with the customers to develop the process maps, if ideas for improvement arise, they can be noted in the knowledge swim lane and identified with an idea light bulb symbol.
- If a task is fully manual, identify that it is a manual task; where there is further opportunity to automate the task, it can be marked in the knowledge swim lane with a manual activity symbol.
- If there are metrics that are collected at certain points in the process, the metrics icon can be shown in the knowledge swim lane, and the metric titles can be entered beneath the symbol.

An example of a completed process architecture map is shown in Figure 7.6 for the arrival and triage process in an emergency department.

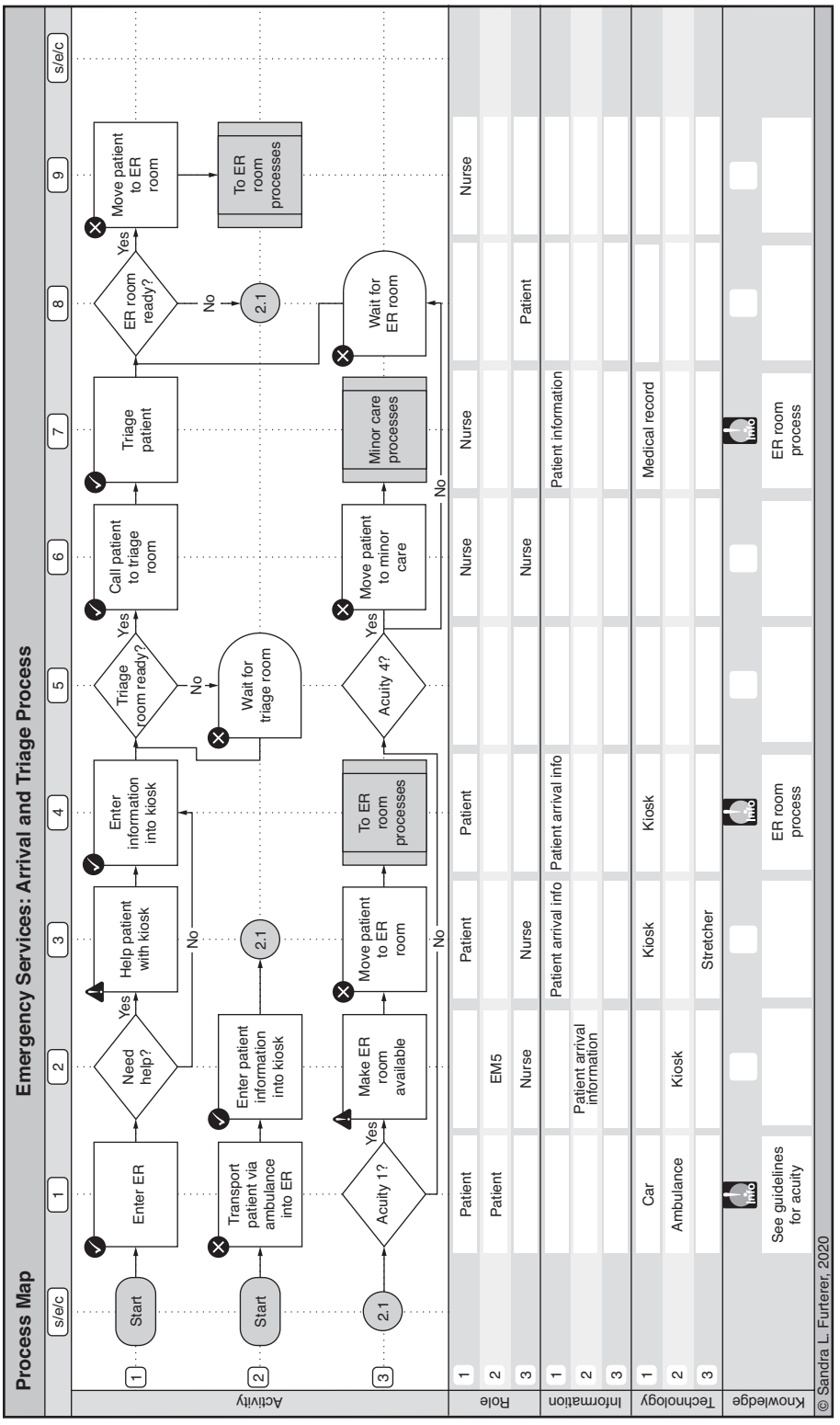


Figure 7.6 Sample process architecture map of emergency services—arrival and triage process.

Source: Sandra L. Furterer.

CHECK SHEETS

The check sheet is a quality tool that is used in processes where there is a significant human element. A *check sheet* (sometimes called a *tally sheet*) is a structured form that is custom designed by the user to enable data to be quickly and easily recorded for analysis. Generally, check sheets are used to gather data on the frequency or patterns of particular events, problems, defects, and so on. Check sheets must be designed to gather the specific information needed. For instance, depending on the problem-solving effort, organizing the data by machines versus shifts or versus suppliers can show different trends.

Figure 7.7 shows defects observed by a quality inspector or technician who inspected a batch of finished products. The check sheet in this case shows the following:

- The fact (not opinion) that incomplete lenses are not a big problem
- Groupings to be investigated:
  a. Why are most cracked covers black?
  b. Why are all the fogged lenses green?
- Rows and columns can be easily totaled to obtain useful subtotals

As depicted in Figure 7.8, time-related check sheets show multiple examples of the variety of trends that can be investigated. Two observations worth noting in this hotel housekeeping check sheet are the following:

- "*TV Guide* missing" category shows a trend worth investigating.
- Something amiss appears to have happened on July 8 and should be investigated.

In some cases, recording the location of defects is necessary to provide a more visually oriented data collection device. This type of check sheet is called a *measles chart* or a *defect concentration diagram.* For example, if inspecting a vehicle's paint finish, a diagram of the vehicle's body would be useful for marking where any defects are located. Clusters will then indicate the biggest problem areas.

Line 12 Dec. 4, 2013	Lens color		
	Red	Green	Black
Cracked cover	II	I	IIIIII
Fogged		IIII	
Pitted	IIII	III	IIIII
Incomplete	I		I

Figure 7.7 Defects table example.

Source: D. W. Benbow, A. K. Elshennawy, and H. F. Walker, *The Certified Quality Technician Handbook* (Milwaukee, WI: ASQ Quality Press, 2003), 12.

Deficiencies noted July 5–11, 2013	5	6	7	8	9	10	11
Towels incorrectly stacked				IIIII			
Soap or shampoo missing	IIIIIIII	IIIIIII		IIIII			
TV Guide missing		II	III	IIIII	IIIIIII	IIIIIIIII	I
Mint missing from pillow	I		I	IIIII		I	
Toilet paper not folded into V			I	IIIII			

Figure 7.8 Time-related check sheet example.

Source: D. W. Benbow, A. K. Elshennawy, and H. F. Walker, *The Certified Quality Technician Handbook* (Milwaukee, WI: ASQ Quality Press, 2003), 12.

PARETO CHARTS

Pareto charts are based on the *Pareto principle*, which suggests that most effects are the result of relatively few causes. Vilfredo Pareto, a nineteenth-century Italian economist, noted that 80% of the wealth in Italy was held by 20% of the population. This observation was later defined by Joseph Juran in 1950 as the Pareto principle.

Pareto principle—The suggestion that most effects are the result of relatively few causes, that is, 80% of effects come from 20% of the possible causes (e.g., machines, raw materials, operators).

Pareto chart—A basic tool used to graphically rank causes from most significant to least significant. It utilizes a vertical bar graph in which bar height reflects the relative importance of causes.

Because the Pareto chart displays the category bars in descending order of length, from longest to shortest, it gives a clear visual representation of their relative contribution to the total effect.

Using the data from Figure 7.8, the Pareto diagram in Figure 7.9 shows that the problem-solving team working on reducing deficiencies should put their main efforts into preventing missing *TV Guides*. If the team were to focus their attention on finding a resolution to the towels being incorrectly stacked, it would only solve about 7.6% of occurrences. The right side of Figure 7.9 includes another feature, cumulative percentage.

Although in Figure 7.9 "*TV Guide* missing" appears to be the biggest contributor to the overall problem, the most frequent is not always the most important. It is also important to do a similar analysis based on costs (or severity for impacts to the goals of the business or customer satisfaction) as not all problems have equal financial impact. In this case, one would assume "*TV Guide* missing" does have a high financial impact compared to the other causes.

Sometimes when collecting data, a team may find that there are a large number of causes but only a few occurrences of each. In those cases, it may be necessary to do some creative grouping to obtain a single cause that can amount to a "big hitter."

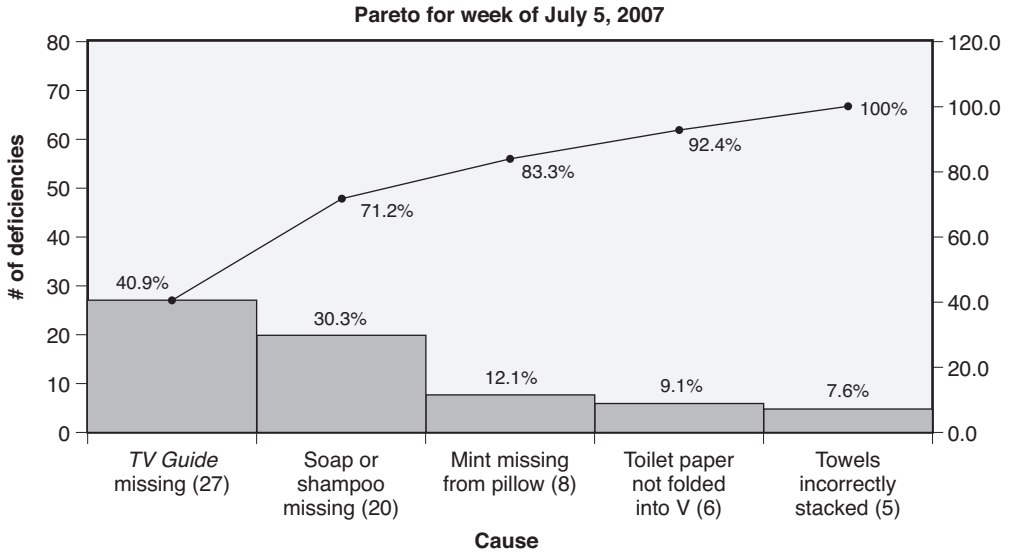


Figure 7.9 Pareto diagram example.

SCATTER DIAGRAM

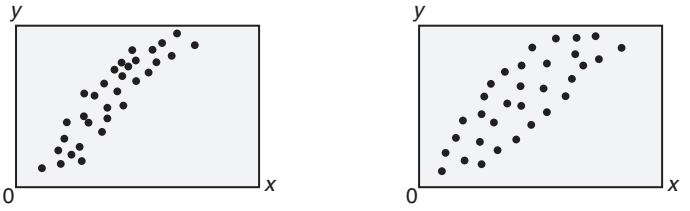
A *scatter diagram* is a basic tool that graphically portrays the possible relationship between two variables or process characteristics. Two sets of data are plotted on a graph. The scatter diagram can help analyze data when a problem-solving team is working to determine the root cause of a problem but has several causes proposed.

If the diagram shows there is a correlation between two variables, it does not necessarily mean a direct cause-and-effect relationship exists. If it appears that the *y*-axis variable can be predicted based on the value of the variable, then there is correlation. A regression line can be drawn through the points to better gauge the strength of the correlation. The closer the point pattern is to the regression line, the greater the correlation (which ranges from –1.0 to +1.0).

When determining if two variables are related, measurements for the independent variable (horizontal or *x*-axis) are plotted against the dependent variable (vertical or *y*-axis). The resulting pattern of points is then checked to see if a relationship is obvious.

If the data points fall along a single, straight line (left side of Figure 7.10 and Figure 7.11), there is a high degree of correlation. In Figure 7.10, the slope of the plot is upward, and so it has a positive correlation. On the right side of Figure 7.11, the scatter diagram shows a lower degree of positive correlation, indicating the existence of other sources of variation in the process.

A numeric value called the *correlation coefficient* (*r*) can be calculated to further define the degree of correlation. If the data points fall exactly on a straight line with the right end tipped upward (left side of Figure 7.10), $r = +1$ and so has a high degree of positive correlation. If the data points fall exactly on a straight line that tips down on the right end (left side of Figure 7.11), $r = -1$ and so has a high degree of negative correlation. The value of *r* is always between –1 and +1 inclusive: $-1 \leq r \leq +1$.

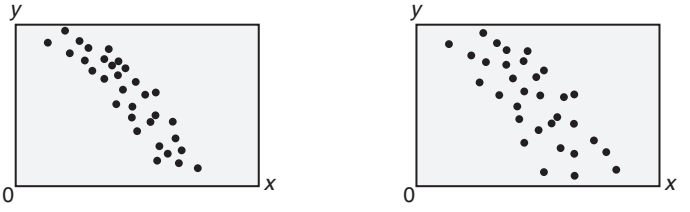


Positive correlation
An increase in *y* may depend on an increase in *x*

Possible positive correlation
If *x* is increased, *y* may increase somewhat

Figure 7.10 Scatter diagrams depicting high degree and low degree of positive correlation.

Source: Adapted from D. W. Benbow, R. W. Berger, A. K. Elshennawy, and H. F. Walker, *The Certified Quality Engineer Handbook* (Milwaukee, WI: ASQ Quality Press, 2002), 281.



Negative correlation
A decrease in *y* may depend on an increase in *x*

Possible negative correlation
As *x* is increased, *y* may decrease somewhat

Figure 7.11 Scatter diagrams depicting high degree and low degree of negative correlation.

Source: Adapted from D. W. Benbow, R. W. Berger, A. K. Elshennawy, and H. F. Walker, *The Certified Quality Engineer Handbook* (Milwaukee, WI: ASQ Quality Press, 2002), 281.

If the correlation coefficient (r) has a value near zero, it indicates no correlation. See Figure 7.12.

There are three points to consider:

- There may be some relationships that are nonlinear.
- The scales of graphs may be arbitrarily expanded or compressed on either axis and, therefore, a visual reading of the slope will not indicate the strength of the correlation.
- A direct and strong correlation does not specify a cause-and-effect relationship.

Run Charts

A *run chart* is a chart that tracks a quality characteristic over time. The run chart graphs the data in the time order that the data were collected. Other terms for a run chart are a *time series chart* and a *trend chart*. A run chart helps to identify trends, fluctuations over time, and unusual events.

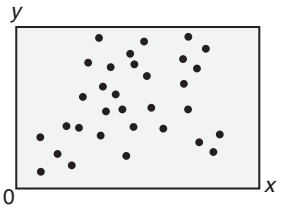


Figure 7.12 Scatter diagram depicting no correlation.

Source: Adapted from D. W. Benbow, R. W. Berger, A. K. Elshennawy, and H. F. Walker, *The Certified Quality Engineer Handbook* (Milwaukee, WI: ASQ Quality Press, 2002), 281.

The basic steps involved in constructing a run chart are as follows:[4]

1. Construct a horizontal (x) axis line and a vertical (y) axis line. The horizontal axis represents time, and the vertical axis represents the values of measurement or the frequency at which an event occurs.
2. Collect data for an appropriate number of time periods, in accordance with your data collection strategy.
3. Plot a point for each time a measurement is taken.
4. Connect the points with a line.

Keeping in mind the process, interpret the chart. Possible signals that the process has significantly changed are the following:

- Six points in a row that steadily increase or decrease
- Nine points in a row that are on the same side of the average
- Other patterns such as significant shifts in levels, cyclical patterns, and bunching of data points

An example of a run chart that graphs the triage time of an emergency department during the day is shown in Figure 7.13.

Control Charts

Control charts are run charts with control limits that help to identify whether a process is stable and in control. The most widely used control charts were introduced by Walter Shewhart in the 1920s and are called Shewhart charts. They include variable control charts, where the variable is a quality characteristic of a continuous variable. There are $\bar{x}$ and R charts, $\bar{x}$ and s charts, and individual and moving range charts. The $\bar{X}$ chart graphs the average of a subgroup sample from the process over time. The range chart graphs the range of the subgroup over time. The $\bar{X}$ chart graphs the central tendency or average of the sample, while the R chart graphs the variability of the subgroup sample over time. The control limits typically are set at plus or minus three standard deviations from the mean

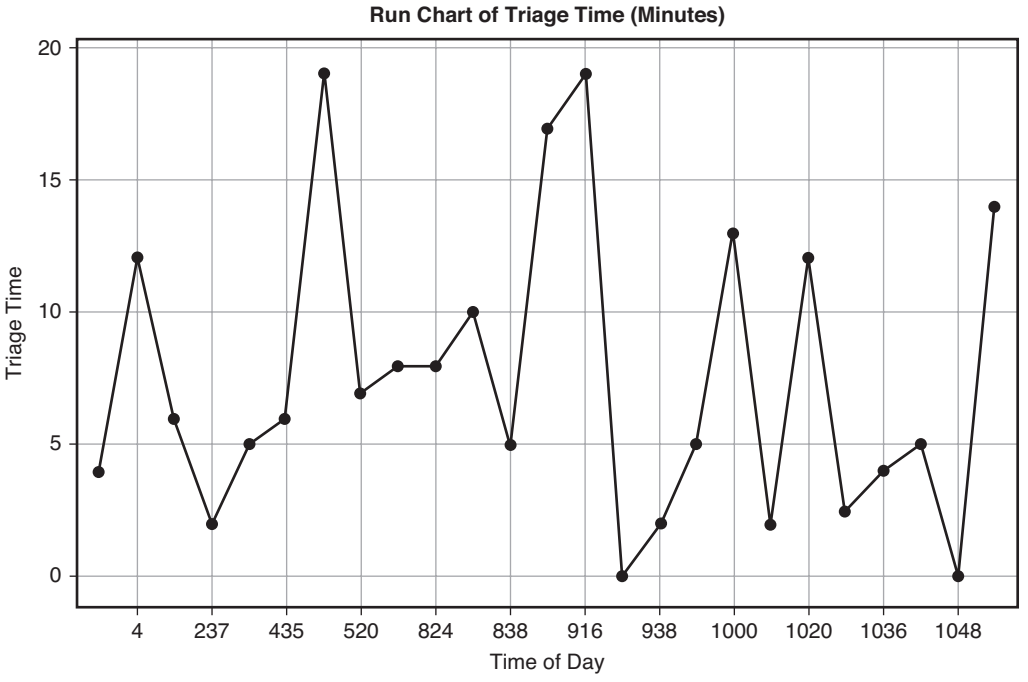


Figure 7.13 Example of a run chart for triage time in an emergency department.
Source: Sandra L. Furterer.

for the $\bar{X}$ chart, and three standard deviations from the average range on the R chart or standard deviation of the s chart. When only random variation exists, where there are no identifiable nonrandom trends or points that fall outside of the control limits, the process is considered to be in control. There are also attribute control charts, and p, np, c and u charts, that graph the percentage of defective units, number of defective units, defects, and defects per unit, respectively.

The control charts will be discussed further and in more detail in Chapter 14.

HISTOGRAMS

The *histogram* is the tool most commonly used to provide a graphical picture of the frequency distribution of large amounts of data. It also is used to show how often each different value occurs in a set of data. The data are shown as a series of rectangles of equal width but varying height. With a minimum of 50 data points, histograms can be used in these situations:

- Determining if the data are numerical
- Wanting to see the shape of the data's distribution; this is important when determining whether the output of a process has a normal distribution
- Analyzing whether a process can meet a customer's requirements

- Analyzing what the output from a supplier's process looks like
- Determining whether a process change has occurred from one time period to another
- Determining whether the outputs of two or more processes are different
- Required to communicate the distribution of data quickly and easily to others

Utilizing a minimum of 50 consecutive points, the worksheet in Figure 7.14 can help you construct a histogram.

Histogram Worksheet

Process: _____ Calculated by: _____

Data dates: _____ Date: _____

Step 1. Number of bars

Find how many bars there should be for the amount of data you have. This is a ballpark estimate. At the end, you may have one more or less.

# Data points	# of bars (*B*)	
50	7	
	8	
	9	
100	10	*B* = _____
	11	
150	12	
	13	
200	14	

Step 2. Width of bars

Total range of the data = *R* = Largest value – Smallest value

= _____ – _____ = _____

Width of each bar = *W* = *R* / *B*

= _____ / _____ = _____

Adjust for convenience. *W* must not have more decimal places than the data.

W = _____

Step 3. Find the edges of the bars

Choose a convenient number, L1, to be the lower edge of the first bar. This number can be lower than any of the data values. The lower edge of the second bar will be *W* more than L1. Keep adding *W* to find the lower edge of each bar.

L1	L2	L3	L4	L5	L6	L7	L8	L9	L10	L11	L12	L13	L14
__	__	__	__	__	__	__	__	__	__	__	__	__	__

Figure 7.14 Histogram worksheet.

Source: Adapted from http://www.asq.org/learn-about-quality/data-collection-analysis-tools/overview/histogram-worksheet.html.

The histogram worksheet helps determine the number of bars, the range of numbers that go into each bar, and the labels for the bar edges. After calculating *W* in step 2 of the worksheet, judgment is used to adjust it to a convenient number. For example, 0.9 can be rounded to an even 1.0. The value for *W* must not have more decimal places than the numbers being graphed.

As shown in Figure 7.15, for 100 data points and a range of scores from 300 to 800, the histogram will have 10 bars, each with a width of 50, the first bar starting with 300 and the last bar starting with 750. The resulting histogram is shown in Figure 7.16.

Histogram worksheet example using 100 students' math SAT scores (data is fabricated) ranging from 300 to 800:

SAT score	Tally of 100 student scores	Frequency
300–349	||||| ||	7
350–399	||||| ||||| |||	13
400–449	||||| ||||| |||||		16
450–499	||||| ||||| ||||| ||||	19
500–549	||||| ||||| ||||| |||||	20
550–599	||||| ||||| |||	13
600–649	||||| |||	8
650–699	||	2
700–749			1
750–800			1

Step 1: For 100 data points,
# of bars *B* = 10

Step 2: The range (*R*) = 800 – 300 = 500

The width of each bar

$W = R/B$

$W = 500/10 = 50$

Step 3: L1 = 300

L2 = 350

.
.
.

L10 = 750

Figure 7.15 Tally and frequency distribution.

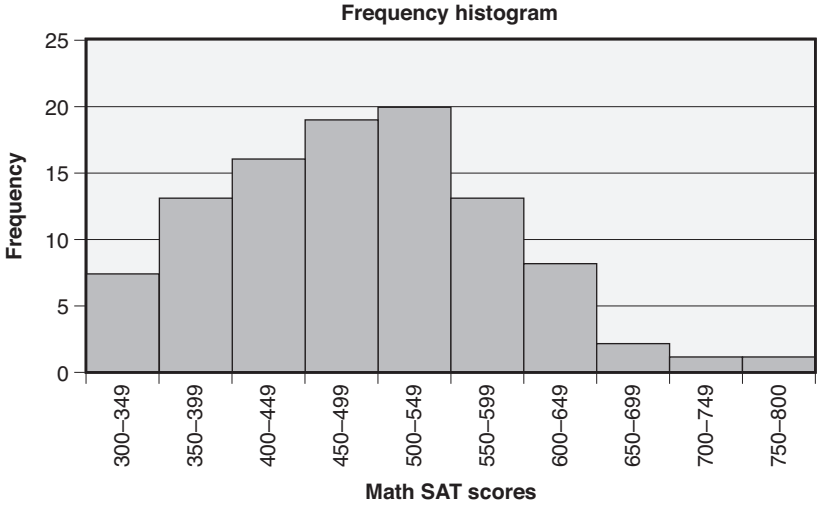


Figure 7.16 Histogram of student SAT scores.

Chapter 8

Process Improvement Techniques

LEAN

> Identify and apply lean concepts and tools, including set-up reduction (SUR), pull (including just-in-time [JIT] and kanban), 5S, continuous flow manufacturing (CFM), value-added analysis, value stream mapping, theory of constraints (TOC), poka-yoke, and total productive/predictive maintenance (TPM) to reduce waste in areas of cost, Inventory, labor, and distance. (Apply)
>
> **Body of Knowledge II.C.1**

The *lean approach*, or *lean thinking*, is "A focus on reducing cycle time and waste using a number of different techniques and tools, for example, value stream mapping, and identifying and eliminating monuments and non-value-added steps. Lean and agile are often used interchangeably."[1] Lean practices use both incremental and breakthrough improvement approaches to eliminate waste and variation, making organizations more competitive, agile, and responsive to markets. As noted in George Alukal's article "Create a Lean, Mean Machine," "Waste of resources has direct impact on cost, quality, and delivery. . . . The elimination of waste results in higher customer satisfaction, profitability, throughput, and efficiency."[2]

Setup Reduction (SUR)

The goal of *setup reduction* is to provide a rapid and efficient way of converting a manufacturing process from running the current product to running the next product. This method is also referred to as *quick changeover, single-minute exchange of die* (SMED), or *rapid exchange of tooling and dies* (RETAD). The time that is lost in production from machine setups can be greatly reduced by applying the SUR method. The concept is that all changeovers (and startups) can and should take less than 10 minutes.

There are seven basic steps to reducing changeover time using the SMED system:

1. *Observe* the current methodology.
2. Separate the internal and external activities. *Internal* activities are those that can only be performed while the process is stopped, whereas *external* activities can be done while the last batch is being produced or once the next batch has started, for example, gathering the required tools for the job *before* the machine stops.
3. Convert (where possible) internal activities into external ones (preheating of tools is a good example of this).
4. Streamline the remaining internal activities by simplifying them. Focus on fixings—Shigeo Shingo rightly observed that it is only the last turn of a bolt that tightens it; the rest is just movement.
5. Streamline the external activities so that they are of a similar scale to the internal ones.
6. Document the new procedure and actions that are yet to be completed.
7. Do it all again: for each iteration of the process, a 45% improvement in setup times should be expected, so it may take several iterations to cross the 10-minute line.[3]

The SMED concept is credited to Shigeo Shingo, one of the main contributors to the consolidation of the Toyota production system, along with Taiichi Ohno.[4]

Pull (including just-in-time and kanban)

The pull system (Figure 8.1) ensures that the product is provided to each customer on time in the amount needed. It pulls the product demanded or ordered by the customer starting at the end of the production process and working backward. Just-in-time and kanban techniques are used to achieve the pull system.

Just-in-Time (JIT)

This lean methodology is an inventory strategy that provides for the delivery of material or product at the exact time and place where the material or product will be used. When this material requirements planning system is implemented, there is a reduction of in-process inventory and its related costs (such as warehouse space), which in turn can dramatically increase the return on investment, quality, and efficiency of an organization.

By implementing JIT, buffer stock is eliminated or reduced, and new stock is ordered when stock reaches the reorder level (facilitated by the use of kanban cards/signals).

Kanban

This tool takes its name from the Japanese word meaning *sign* or *card*. Although kanban is related to just-in-time (JIT), it is in fact the means through which JIT is managed to form a "pull" system. This is done with kanban cards. Kanban cards are visible signs that tell what is needed, when it is needed, and how much is needed. A kanban card signals when to refill goods removed from a stocking location or when a subassembly has been used. After a certain quantity is used, the kanban card is returned upstream to the supplying process, thereby signaling replenishment.

You need kanban cards to have a pull system. Visible cards let you control inventory so you have the correct amount of product (i.e., no more, no less) ready to ship when your customer needs product (not before or after). There are many types of kanban systems and sundry complicated pull systems, but the concept is straightforward.

Think of kanban as a tool for managers to control the flow of product in a manufacturing operation. It is only as good as those who design it, so you need to be sure the people who design your kanban system use and understand it.[5]

5S

This tool is used with other lean concepts as the first step in clearing things out that are not necessary to create a clean and orderly workspace. Maintaining cleanliness and efficiency allows waste and errors to be exposed. In Table 8.1 a brief description of each 5S term is provided along with the actual Japanese word from which 5S originated.

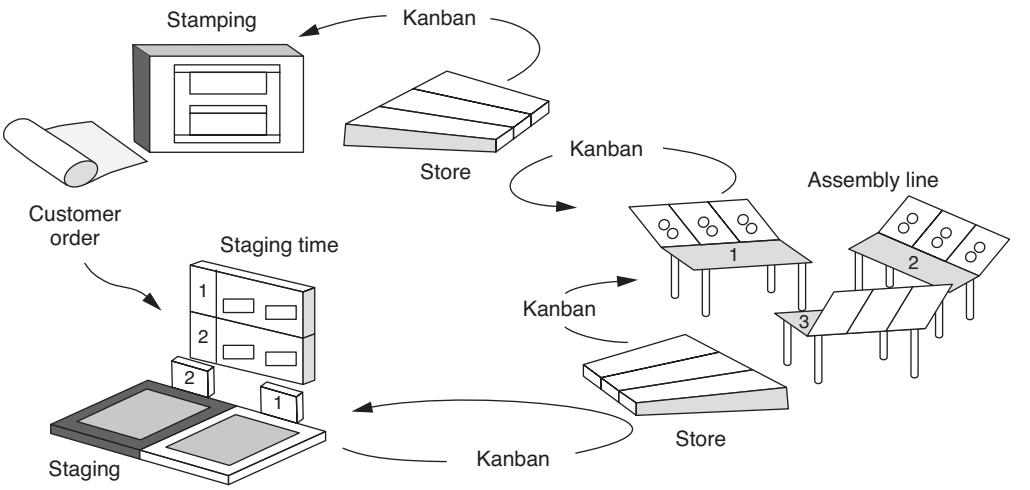


Figure 8.1 Pull system.

Source: Adapted from T. J. Shuker, "The Leap to Lean," in *54th Annual Quality Congress Proceedings* (Indianapolis, IN: Lean Concepts, 2000), 109.

Table 8.1 5S terms and descriptions.

5S English term	5S Japanese term	Brief description
Sort	Seiri	Separate needed tools, parts, and instructions from unneeded materials, removing the latter
Set in order	Seiton	Arrange and identify parts and tools for ease of use. Where will they best meet their functional purpose?
Shine	Seiso	Clean up the workplace, eliminating the root causes of waste, dirt, and damage
Standardize	Seiketsu	Develop and maintain agreed-upon conditions to keep everything clean and organized
Sustain	Shitsuke	Apply discipline in following procedures

Note: These are adopted descriptions and English terms adapted from and not literally translated from the original 5S Japanese terms.

By implementing 5S, the workforce is empowered to control their work environment and consequently promote awareness of the 5S concept and principles of improvement.

Continuous Flow Manufacturing

This lean methodology is also known as *one-piece flow*, meaning product moves through the manufacturing process one unit at a time. This is in contrast to batch processing, which produces batches of multiples of the same item and then sends the product through the process batch by batch.

As each processing step is completed, the unit is then pulled downstream by the next step in the process (see Figure 8.2). The worker does not have to deal with waiting (as you would with batch processing), transporting products, and storing inventory.

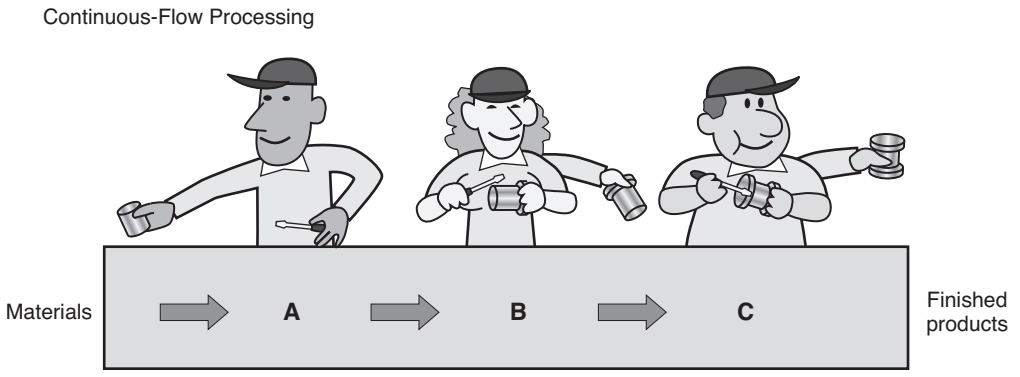


Figure 8.2 Continuous flow.

Source: Adapted from T. J. Shuker, "The Leap to Lean," in *54th Annual Quality Congress Proceedings* (Indianapolis, IN: Lean Concepts, 2000): 108.

For continuous flow to make sense, you need to understand takt time, standardized work, and pull system. Henry Ford used continuous flow when he "pulled" cars along an assembly line as workers performed one operation or did one job at a time. Since Ford's Model T assembly line, the idea of continuous flow has embraced increasingly sophisticated and novel manufacturing concepts. Today, products with dozens of colors and hundreds of options must flow continuously, just-in-time, without waste or stagnation (*muda*).

Think of takt time as a metronome that fixes the tempo at which work is done. Takt time measures the pace of production, like an orchestra conductor's baton, making sure everyone is on the beat and the process is smooth and continuous. If the pace is disrupted, continuous flow is lost, and corrections must be made.[6]

Takt time is the available production time divided by the rate of customer demand. Operating to takt time sets the ideal production pace to customer demand:[7]

$$\frac{\text{Daily available work time}}{\text{Parts required per day}} = \frac{\text{Time}}{\text{Volume}} = \text{Takt time}$$

Standardized work is documented and agreed-upon work instructions that express the best-known methods and work sequence for each manufacturing or assembly process.[8]

Value-Added Analysis[9]

The value analysis (VA) is a technique to distinguish the activities in the process as being value added, of limited value, or non-value added. The value analysis can be performed for manufacturing or service processes that are part of the system.

The definitions follow:

- Value-added activities: Activities that the customer would pay for, that add value for the customer
- Limited-value-added activities: Activities that the customer would not want to pay for but are required because of regulatory, financial reporting, or documentation purposes, or because of the way the process is currently designed
- Non-value-added activities: Activities that the customer would not want to pay for, or do not add value for the customer

To calculate the percentage of value-added activities:

100% X (Number of value-added activities /

Number of total activities [value added + limited value added + non-valued added])

You can calculate the percentage of value-added time as

100% X (Total time spent in value-added activities /

Total time for process [value-added time + limited-value-added time + non-value-added time])

Typically, percentage of value-added time is about 1% to 5% (non-value-added time and limited-value-added time = 95% to 99%)

Steps for the value analysis:

1. Identify the activities (from the process maps)
2. Identify each activity as value added, limited value added, or non-value added
3. Calculate either the percentage of value-added activities or the percentage of value-added time as a baseline
4. Attempt to eliminate, combine, or change each activity that is non-value added or limited value added

For the process architecture map (PAM) used to develop process maps discussed in Chapter 7, the symbols shown are used while entering the activity information to identify the type of activity as value added, limited value added, non-value added, or not defined yet, as shown in Figure 8.3.

Consider the following focus areas for optimizing the process:[10]

- Labor-intensive processes—can they be reduced, eliminated, combined?
- Delays—can they be eliminated?
- Review or approval cycles—are all reviews and approvals necessary and value added?
- Decisions—are they necessary?

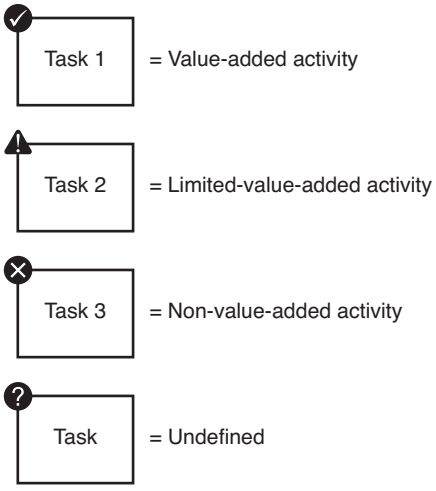


Figure 8.3 Symbols on process architecture map (PAM) for value analysis.

Source: Sandra L. Furterer.

- Rework—why is it necessary?
- Paperwork—is all of the documentation necessary? Try to limit the number of ways you handle and store it.
- Duplications—across the same or multiple organizations
- Omissions—what is slipping through the cracks, causing customer dissatisfaction?
- Activities that require accessing multiple information systems
- Travel—look at the layout requiring the travel
- Storing and retrieving information—is it necessary, do we need that many copies?
- Inspections—are they necessary?
- Is the sequence of activities, or flow, logical?
- Is standardization, training, and documentation lacking?
- Look at inputs to processes—are they all necessary?
- Look at data and information used—are they all necessary?
- What are the outputs of processes? Are they all necessary?
- Can you combine tasks?
- Is the responsible person at too high or low of a level?
- Optimize the processes by incorporating the improvements identified in the value analysis

Some other optimization tools are beyond the scope of this text:

- Simulation—simulate changes in the process flow
- Design of experiments—to identify factors that contribute to the most variability in the processes
- Linear regression modeling
- Lean-Six Sigma
- Statistical analysis and process capability analysis
- Statistical process control
- Work sampling
- Job design
- Operations research methods

An example of a lean analysis with the value analysis plus a waste analysis for the emergency department arrival and triage process (from Chapter 7) is shown in Figure 8.4.

Lean Analysis Emergency Services: Arrival and Triage Process-1

#	Activity	Value Analysis	Trans-portation	Over-Production	Motion	Defects	Delay	Inventory	Processing	People	Root Cause(s)
1	Enter ER	✓									
2	Help patient with kiosk	!							⊗		
3	Enter information into kiosk	✓									
4	Call patient to triage room	✓									
5	Triage patient	✓									
6	Move patient to ER room	⊗	⊗								
7	Transport patient via ambulance into ER	⊗	⊗								
8	Enter patient information into kiosk	✓									
9	Wait for triage room	⊗					⊗				
10	Make ER room available	!							⊗		
11	Move patient to ER room	⊗	⊗								
12	Move patient to minor care	⊗	⊗								
13	Wait for ER room	⊗					⊗				
14											
15											
16											
17											
18											
19											
20											
21											
22											
23											
24											
25											
26											
27											

Figure 8.4 Sample lean analysis with value analysis and waste analysis for the emergency department arrival and triage process.

Source: Sandra L. Furterer.

Value Stream Mapping

This section describes the primary actions required to bring a product from concept to placing the product in the hands of the end user.[11] *Value stream mapping* is charting the sequence of movements of information, materials, and production activities in the value stream (all activities involving the designing, ordering, producing, and delivering of products and services to the organization's customers). An advantage to this is that a "before action is taken" value stream map depicts the current state of the organization and enables identification of how value is created and where waste occurs. Plus, employees see the whole value stream rather than just the one part in which they are involved. This improves understanding and communications and facilitates waste elimination. A *value stream map* (VSM) is used to identify areas for improvement. At the macro level, a VSM identifies waste along the value stream and helps strengthen supplier and customer partnerships and alliances. At the micro level, a VSM identifies waste—non-value-added activities—and identifies opportunities that can be addressed with a kaizen blitz. Figures 8.5 and 8.6 are value stream map examples (macro level and micro level, respectively).[12]

Theory of Constraints (TOC)

The theory of constraints was developed by Eliyahu Goldratt, initially in his book, *The Goal*[13] and then in his book, *What Is This Thing Called Theory of Constraints and How Should It Be Implemented?*[14] *The Goal* is written as a novel and describes the

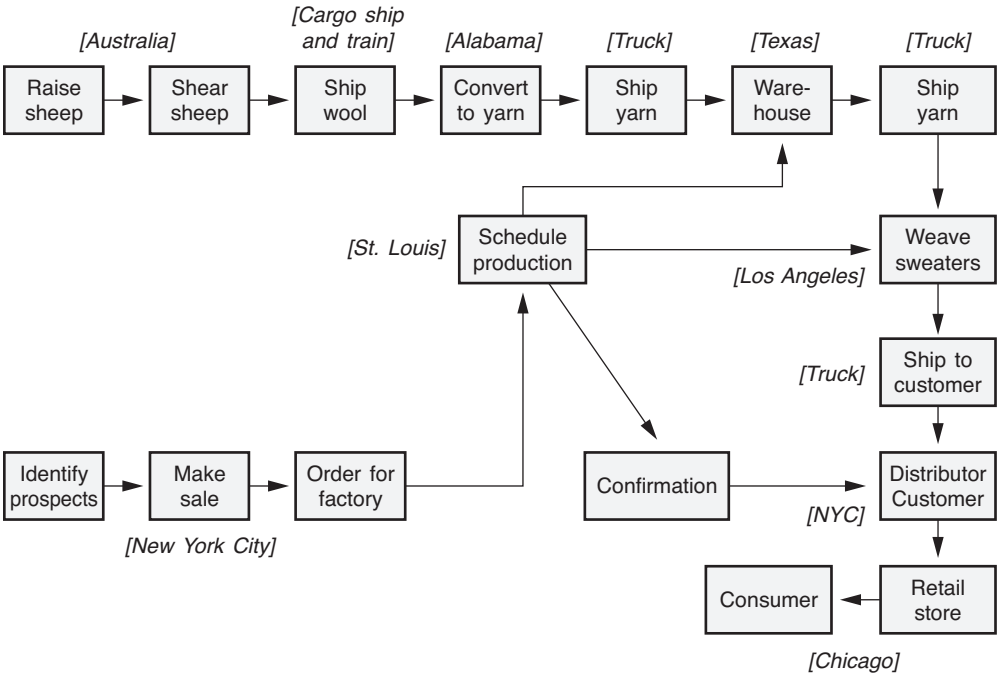


Figure 8.5 Value stream map example—macro level (partial).

Source: R. T. Westcott, *The Certified Manager of Quality/Organizational Excellence Handbook*, 3rd ed. (Milwaukee, WI: ASQ Quality Press, 2006), 391.

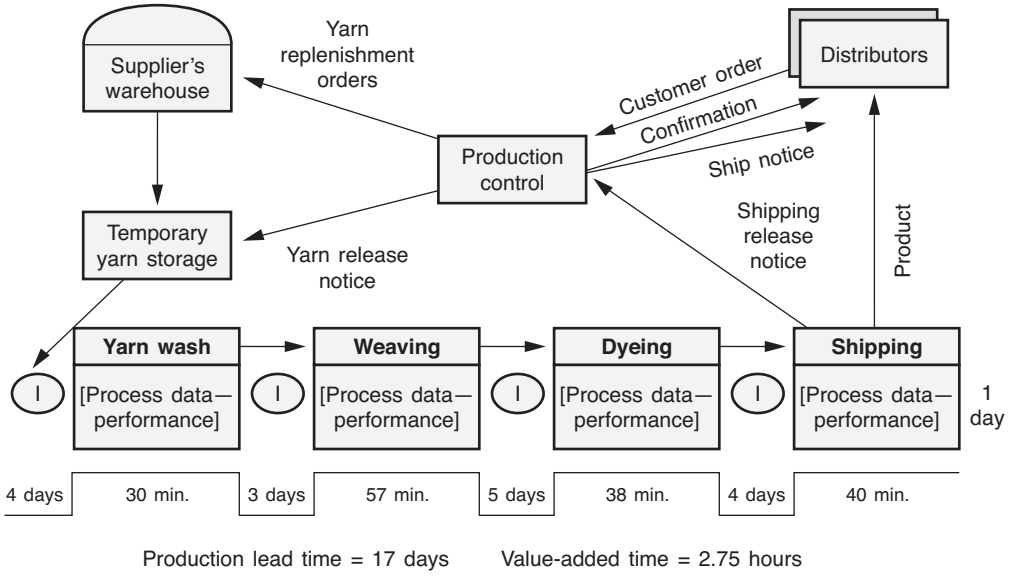


Figure 8.6 Value stream map example—plant level (partial).

journey of Alex, the plant's manager, to applying the theory of constraints. The second book describes in more detail the concepts and how to apply them. The five steps of focusing of the TOC method are the following:

1. Identify the systems constraints: The system constraints should be identified and prioritized according to their impact on the system's goal.
2. Decide how to exploit the system's constraints: Identify how to manage the system's resources to allow the constraints to be improved.
3. Subordinate everything else to the previous decision: Identify ways to reduce the limiting impact of the constraints, which many times are policies, such as marketing, purchasing, production, and so on.
4. Elevate the system's constraints: Elevate the constraint to continually improve it.
5. If in the previous steps a constraint has been broken, go back to step one, but don't allow inertia to cause a system constraint.

TOC advocates using cause and effect to understand the causes of constraints and reduce or eliminate them.

To implement TOC, Goldratt recommends the follow method:

1. How to Become a Jonah: In *The Goal*, Jonah was a catalyst for change, using the Socratic method for Alex, the plant manager, to find his own problems and be guided to improvement.
2. The devastating impact of the organization's psychology: Everyone in the organization must define a common way to make change happen.
3. Reaching the initial consensus and the initial step: All functions should buy in before any significant change occurs.
4. How to reach the top: Work sideways through the organization to convince others of the value of TOC, then work up the organization, through each successive layer of management.
5. What about existing new projects? Integrating the other philosophies, such as JIT, TQM, and SPC (Statistical Process Control), by understanding and aligning the goals of each management philosophy with TOC.

The TOC states that there are three ways to increase money making: (1) increase throughput, (2) decrease inventory, and (3) decrease operating expense. You must understand the relationship of these three avenues together within the concept of the different management philosophies. For additional information on TOC, see the references in the endnotes.

Poka-Yoke

This tool also takes its name from a Japanese term that means to mistake-proof a process by building safeguards into the system that avoid or immediately

find errors. It comes from *poka*, which means "error," and *yokeru*, meaning "to avoid."[15]

Poka-yoke devices can provide defect prevention for an entire process. These mechanisms can give warning or control, or can even shut down an operation:

- *When a defect is about to occur, a* warning *buzzer or light can be activated in order to alert workers. This is similar to the "lights on" warning buzzer that sounds in most automobiles when the driver leaves a vehicle with the engine off and lights on. Hopefully, the driver will notice the warning and correct the mistake (turn off the lights) before a defect (dead battery) occurs. The driver may elect to ignore the warning, pointing out the fact that warnings, while good, are not always the most effective poka-yoke devices that can be deployed.*
- *Probably the most effective mistake-proofing is achieved through* control *of operations. By deploying poka-yoke devices throughout a process in order to prevent errors, defects will not occur. For example, lights that are automatically turned off by a timer in the car when the engine is off are controlled in order to prevent a defect (dead battery). Good poka-yoke devices can even prevent intentional errors. This factor is especially important in the area of computer and automatic teller machine security.*
- *Another function that can be performed by poka-yoke devices is* shutdown. *When an error is detected, an operation can be shut down, preventing defects from occurring. Missing screws in chassis assemblies are a common manufacturing headache.*

  Workers can be told to make sure that all screws are installed. Banners and quality signs can be hung; however, missing screws will still be a problem. Poka-yoke can come to the rescue!

  One way to prevent the missing screw problem is to install a counter on the power screwdriver used to put in the chassis screws. The counter will register the number of installations performed on each unit. When the required number of screws has been installed, a switch in the conveyer assembly can be closed, allowing the chassis to move to the next work position. The conveyor is "shut down" until all the screws have been put in.[16]

In all cases, whether your goal is detecting or preventing defects, defects are caused by errors. Mistakes can be classified into four categories:

- *Information errors.* Misread or misinterpreted information
- *Misalignment.* Parts misaligned or machine is mistimed
- *Omission or commission.* Material or part is added or parts are omitted
- *Selection errors.* Wrong part, wrong orientation, or wrong operation

To implement poka-yoke, the workforce needs to be involved to determine where human errors can occur. After determining the source for each potential error, a poka-yoke method or mechanism can be devised for prevention. If there is no method to prevent the error, then a method to lessen the potential for occurrence of that error should be devised.

Total Productive/Predictive Maintenance (TPM)

Total productive (*predictive*) *maintenance* (TPM) aims to reduce loss due to equipment-related wastes, including the following:

- Downtime (due to inefficient setup or work stoppages)
- Speed losses
- Defective product (needing rework or repair)
- Constant adjustments
- Machine breakdowns

TPM allows the worker to not only run the machine or equipment but to proactively maintain it. The machine operator can maintain the machinery with proper routine care, minor repairs, and routine maintenance. With the operators being responsible for and more involved in the machinery's operation, they understand the equipment better and are motivated to take better care, leading to less abuse and accidental damage. Cooperation among the operators and maintenance workers in performing maintenance inspections and preventive maintenance activities is critical to fully achieving implementation of TPM. "The aim of TPM is to attain the 'four zeros,' that is, zero defects, zero downtime, zero accidents, and zero waste."[17]

Alukal says that cutting out the following eight types of waste (called *muda* in Japanese) is the major objective of lean implementation.

1. *Overproduction*. Making more, earlier, or faster than required by the next process.
2. *Inventory waste*. Any supply in excess of a one-piece flow (make one batch and move one batch) through the manufacturing process, whether it is raw materials, work in process, or finished goods.
3. *Defective product*. Product requiring inspection, sorting, scrapping, downgrading, replacement, or repair.
4. *Overprocessing*. Extra effort that adds no value to the product (or service) from the customer's point of view.
5. *Waiting*. Idle time waiting for such things as manpower, materials, machinery, measurement, or information.
6. *Underutilized people*. Not fully using people's mental and creative skills and experience.*
7. *Motion*. Any movement of people, tooling, and equipment that does not add value to the product or service.
8. *Transportation waste*. Transporting parts or materials around the plant.[18]

*The traditional definition for the major objectives of lean implementation describes seven types of waste. Alukal adds the additional waste of people who are underutilized.

There are a number of lean tools and techniques, and the selection of which to use greatly depends on the root causes of variation and waste.

Refer to Figure 8.4 for an example of the identification of the wastes from the process architecture map (PAM).

SIX SIGMA

> Identify key Six Sigma concepts including variation reduction, voice of the customer (VOC), belt levels (yellow, green, black, master black), and their roles and responsibilities. (Understand)
>
> **Body of Knowledge II.C.2**

Six Sigma is a methodology that provides businesses with the tools to improve the capability of their business processes. From Benbow and Kubiak's *The Certified Six Sigma Black Belt Handbook*, "Six Sigma is a fact-based, data-driven philosophy of quality improvement that values defect prevention over defect detection. It drives customer satisfaction and bottom-line results by reducing variation and waste, thereby promoting a competitive advantage. It applies anywhere variation and waste exist, and every employee should be involved."[19]

Motorola first developed Six Sigma in the mid-1980s as a set of tools and strategies for process improvement; when Jack Welch adopted it as General Electric's business strategy in 1995, the Six Sigma philosophy became well-known. The most basic and simplest idea behind Six Sigma is that if you can measure how many "defects" you have in a process, you can systematically figure out how to eliminate them and get as close to "zero defects" as possible. The Six Sigma approach is a quality philosophy that embodies a collection of techniques and tools for use in reducing variation and advocates a program of improvement that focuses on strong leadership tools and an emphasis on bottom-line financial results. Although Six Sigma was originally designed for the manufacturing sector, it became a recognized quality strategy throughout many sectors of industry. The International Organization for Standardization (ISO) came out with a new standard in 2011 defining the Six Sigma methodology. Titled ISO 13053-1:2011, *Quantitative Methods in Process Improvement—Six Sigma*, it is a two-part standard: *Part 1: DMAIC Methodology*, and *Part 2: Tools and Techniques*. Both parts pertain to all sectors and organizations.

The word *sigma* (σ) is actually a statistical term that measures how far a process deviates from perfection; it is the *standard deviation* of a given process. The quantity of units processed divided into the number of defects actually occurring, multiplied by one million, results in defects per million:

$$\frac{\#\,Defects}{\#\,Units\ produced} \times 10^6$$

The term *defects per million opportunities* (DPMO) is used to determine a sigma level based on the number of DPMO:

D = number of defects

U = number of units sampled or produced during the time period

O = number of opportunities for a defect to occur (ways to have defects)

Calculate the DPMO:

$$DMPO = \frac{D}{(U \times O)} \times 10^6$$

With the added statistical tolerance of a 1.5 sigma shift in the mean, a Six Sigma process can be achieved for processes that produce no more than 3.4 defective parts per million opportunities. See Table 8.2.

An example of DPMO calculation for a payroll paycheck process is given. There are three opportunities for a defect to occur, O = 3:[20]

NUMBER OF OPPORTUNITIES

- Timesheet process
- Data entry of payroll data
- Computer application

Number of units = 300 paychecks per pay period

Number of defects = 3 defects per payroll batch (on average)

$$DPMO = \frac{3}{(300 \times 3)} \times 10^6 = 3,333.33$$

Using a conversion table, as shown in Table 8.2, the sigma level is about 4.2.

When an organization decreases the amount of variation occurring, the process sigma level will increase.

The Certified Six Sigma Black Belt Handbook offers the definitions of Six Sigma as a philosophy, a set of tools, and a methodology.[21]

Table 8.2 Defects per million opportunities (DPMO) at various process sigma levels.

Process sigma level		Defects per million opportunities
1 sigma	=	690,000 DPMO
2 sigma	=	308,000 DPMO
3 sigma	=	66,800 DPMO
4 sigma	=	6,210 DPMO
5 sigma	=	230 DPMO
6 sigma	=	3.4 DPMO

Dr. W. Edwards Deming, the quality guru, incorporated the basic understanding of statistical theory and variation into his system of profound knowledge. Variation occurs in all processes, and excessive variation can cause defects and inconsistency in processes. Statistical tools help us to quantify and analyze variation and the factors that contribute to it. Tools such as design of experiments, analysis of variance (ANOVA), regression, and correlation analyses all help to identify factors that contribute to the variability of processes.

Peter Scholtes provided some interesting observations related to variation:[22]

- They do not see trends that are occurring in a process.
- They see trends when there are none.
- They do not know when expectations are realistic, or not.
- The do not understand past performance, so they can't predict future performance.
- They do not know the difference between prediction, forecasting, and guesswork.
- They give others credit or blame when those people are simply either lucky or unlucky, which usually occurs because people tend to attribute everything to human effort, heroics, frailty, error, or deliberate sabotage, no matter what the systemic cause.
- They are less likely to distinguish between fact and opinion.

Understanding the mean and standard deviation, and the factors that contribute to these statistics of a process, helps us to improve the process through the application of Six Sigma methods and tools. Statistical knowledge of the metrics to measure a process helps us to predict performance in the process. For example, if we have a stable process in a hospital's emergency department, we are able to predict how long, on average, or within plus or minus one, two, or three standard deviations, a patient is likely to spend in the emergency department.

Six Sigma Philosophy

Six Sigma as a philosophy views all work as processes. Every process can be defined, measured, analyzed, improved, and controlled (DMAIC). Using the formula $y = f(x)$, key process drivers can be identified. With a process input (x) being a causal factor, the process output (y) can be measured (y is a function of x).

x's are variables that will have the greatest impact on y. If y is customer satisfaction, then x will be key influences to customer satisfaction, be they inputs (i.e., from customers or suppliers) or process variables (i.e., materials, methods, environment, machine issues, and so on). If an organization controls the inputs to the process, (x), the outputs, or process performance (y) can be controlled. It is important that all x's be identified in order to determine which of those inputs are controllable. Figure 8.7 shows a system where, with proper data collection and analysis, feedback is part of the process for improvement to the inputs to produce high-quality outputs.

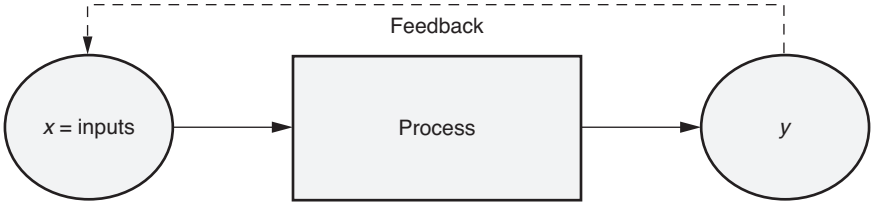


Figure 8.7 *y* is a function of *x*.

Table 8.3 Traditional and Lean–Six Sigma (LSS) thinking in an organization.

From traditional thinking	To LSS principles and thinking
Problem driven	Customer driven
Reacting to dissatisfaction	Preventing dissatisfaction
Results at any cost-oriented thinking	Cross-functional, process-oriented thinking, and discipline
Used to waste and rework	Eliminate waste to improve processes and throughput
Fixing blame	Fixing the problems
People management	System management, reducing variation, process measurement, standardization
Reward firefighting and crisis management	Reward team effort and improvement
Measure cost and productivity	Measure throughput, customer satisfaction, processes, quality
Authoritative	Empowerment, accountability

Source: Sandra L. Furterer.

Table 8.3 illustrates the traditional thinking in an organization with respect to quality of products and services, versus an organization where the culture change happens to embrace quality practices.[23]

An explanation of each thinking is shown next.

PROBLEM-DRIVEN VERSUS CUSTOMER-DRIVEN

- Problem-driven: Focused on each problem as they arise, drop projects and process improvement efforts to fix unrelated problems
- Customer-driven: Focused on customers' needs and how we can improve our processes to provide seamless service that meets their needs; this includes both external and internal customers

REACTING TO DISSATISFACTION VERSUS PREVENTING DISSATISFACTION

- Reacting to dissatisfaction: Reacting to the loudest complaints when they occur
- Preventing dissatisfaction: Mistake-proofing and improving processes to prevent problems and customer dissatisfaction

RESULTS AT ANY COST-ORIENTED THINKING VERSUS CROSS-FUNCTIONAL, PROCESS-ORIENTED THINKING AND DISCIPLINE

- Results at any cost-oriented thinking: Thinking that quality requires higher costs, more QC reviews, and that compliance testing and audits can prevent problems
- Cross-functional, process-oriented thinking and discipline: More efficient and reliable processes can be delivered defect-free, focusing on process improvement, customer satisfaction, and on the entire process, instead of departmental silos

USED TO WASTE AND REWORK VERSUS ELIMINATING WASTE TO IMPROVE PROCESSES AND THROUGHPUT

- Used to waste and rework: Allowing inefficient activities, redundant data entry, mistakes, and poor quality to exist and languish in our processes (that rework is OK, as long as the defects are fixed); designing processes based on compliance and regulatory requirements only, versus customers' needs and requirements
- Eliminating waste to improve processes and throughput: Focus on how long it takes to get through the end-to-end process the first time defect-free (throughput), with a focus on eliminating waste activities that do not add customer value

FIXING BLAME VERSUS FIXING THE PROBLEMS

- Fixing blame: Blaming people in the process for mistakes, instead of the multiple factors that impact process quality, timeliness, and service, such as the way work is organized, the order that activities are performed in, information systems and lack of automation, forms and information flow, lack of clear process design, lack of metrics, and lack of accountability
- Fixing the problems: Focus on process improvement and transformation to identify the problems, root causes of those problems, and designing the processes with the needs of the customers as a major focus

PEOPLE MANAGEMENT VERSUS SYSTEM MANAGEMENT

- People management: Thinking that it just takes better people management or organizational structure, not process design and focus on root causes and factors that impact quality
- System management, reducing variation, process measurement and management, standardization: Understanding the entire process, the hand-offs, inefficiencies, and root causes that impede customer satisfaction, measuring the process so that we know when we improve, or when we are "out of control"; distinction of "random" (many factors that cause small variation; normal in a stable process) versus "special" causes (sporadic, extreme factors that lead to unstable processes)

REWARD FIREFIGHTING AND CRISIS MANAGEMENT VERSUS REWARD TEAM EFFORT AND IMPROVEMENT

- Reward firefighting and crisis management: When there is a problem that could have been prevented with good process and practice, we reward the effort it takes to fix the problem (double-posting errors), instead of preventing the problem and designing a quality process in the first place
- Reward team effort and improvement: Focus on process transformation teams to work together with process owners and subject matter experts to improve processes and eliminate root causes forever

MEASURE COST AND PRODUCTIVITY VERSUS MEASURE THROUGHPUT, CUSTOMER SATISFACTION, PROCESSES, AND QUALITY

- Measure cost and productivity: Measure cost of a process, and how many full-time equivalents (FTEs) it takes to perform the process, without focus on measuring customer satisfaction and quality
- Measure throughput, customer satisfaction, processes, and quality: Understanding how our processes work, documenting the processes for common understanding, improvement, and training. Incorporating metrics focused on throughput, customer satisfaction (service), and quality.

AUTHORITATIVE VERSUS EMPOWERMENT

- Authoritative: Telling people what to do and how to do it
- Empowerment: Leveraging process owners and subject matter experts to improve their processes and measuring the processes and holding people accountable to perform the process in the best practice manner

Define	Measure	Analyze	Improve	Control
• Project charter • Stakeholder analysis • SIPOC • Process map (high level) • Communication plan • Change plan • Project plan • Responsibilities matrix • Items for resolution (IFR) • Ground rules	• Process map • Critical to quality characteristics • Data collection plan with operational definitions • Pareto chart • Measurement system analysis • Metrics with baseline • Benchmarking • Check sheets • Histograms • Surveys, interviews, focus groups, affinity diagrams • Descriptive statistics	• Cause-and-effect diagrams • Cause-and-effect matrix • Why–why diagram • Process analysis, histograms and graphical analysis, waste analysis, value analysis, FMEA • Statistical analysis • ANOVA • DPPM/DPMO, process capability	• Quality function deployment • Recommendations for improvement • Action plan • Cost/benefit analysis • Future state process map • Affinity diagram • Dashboards/ scorecards • Training plan and materials • Procedures • Policies	• Hypothesis testing • Dashboards • Statistical analysis • Graphical analysis • Sampling • Mistake proofing • FMEA • Control plan • Process capability • DPPM/DPMO • Statistical process control • Standard work • Prioritization matrices

Figure 8.8 Six Sigma tools by DMAIC phase.

Source: Sandra L. Furterer.

Engagement with quality tools and Lean-Six Sigma can help to change the culture in an organization from one that acts in the traditional thinking (left side of Table 8.3) to the Lean-Six Sigma thinking on the right side of Table 8.3.

Six Sigma Tools

There are many tools that are part of the Lean-Six Sigma (LSS) tool kit, which are selected based on the problem to be solved. Figure 8.8 shows the most common tools applied within each LSS DMAIC phase.[24]

Six Sigma Methodology

Six Sigma organizations actually utilize two project methodologies, each with five phases: DMAIC (define, measure, analyze, improve, control) and DMADV (define, measure, analyze, design, verify). Both are measurement-based strategies that focus on process improvement and reducing variation.[25]

Used to improve existing business processes, DMAIC is a rigorous and robust method that is the most widely adopted and recognized. A Six Sigma team member working on an improvement project will follow the five steps of DMAIC, utilizing the tools necessary. See Chapter 6 for more information on the DMAIC methodology.

Where DMAIC is used on existing processes needing incremental improvement, the DMADV methodology is mostly used on DFSS (Design for Six Sigma) projects for a new design or—in some cases when the process, product, or service has proven incapable of meeting customer requirements—a redesign.

Businesses with successful implementation of Six Sigma programs delineate roles and responsibilities for the various people involved in project activities. Six Sigma roles and responsibilities are defined within a hierarchy or ranking order in organizations that have implemented a Six Sigma program (see Table 8.4).

Depending on an organization's vision and deployment of Six Sigma, implementations and roles may vary, but every project must have organizational support. Six Sigma executives and champions set the direction for selecting and deploying projects. They ensure, at a high level, that projects succeed. The executives and champions, sometimes with the assistance of a Master Black Belt (smaller companies may sometimes use consultants for the Master Black Belt role), use a selection process that makes sure project goals are tied to the organizational goals to add value and are appropriate with the organizational plan.

At the project level, there are Black Belts and Green Belts (larger organizations will sometimes have Yellow Belts and White Belts as well). These are the people conducting projects and implementing improvements. Many corporations have instituted a certification program for these roles that verifies skills for the appropriate belt level.

The Green Belt and Black Belt roles tend to be the most common and used consistently to lead Six Sigma projects. While the Black Belt role usually functions in a full-time quality position, the Green Belts have other responsibilities and roles within the company. Traditionally, the Black Belts run the improvement projects and are supported by the Green Belts, who may have roles as engineers,

Table 8.4 Six Sigma roles and responsibilities.

Roles	Responsibilities
Executive leadership	Provide overall alignment by establishing the strategic focus of the Six Sigma program within the context of the organization's culture and vision.
Champions	Translate the company's vision, mission, goals, and metrics into an organizational deployment plan and identify individual projects. Identify resources and remove roadblocks.
Master Black Belt	Trains and coaches Black Belts and Green Belts. Functions more at the Six Sigma program level by developing key metrics and the strategic direction. Acts as an organization's Six Sigma technologist and internal consultant.
Black Belt	Leads problem-solving projects. Trains and coaches project teams.
Green Belt	Assists with data collection and analysis for Black Belt projects. Leads Green Belt projects or teams.
Yellow Belt	Participates as a project team member. Reviews process improvements that support the project.
White Belt	Can work on local problem-solving teams that support overall projects but may not be part of a Six Sigma project team. Understands basic Six Sigma concepts from an awareness perspective.

data analysts, technicians, or assemblers. Typically, Six Sigma organizations will require that the leaders who are responsible for a business area, such as a department or area supervisor, be trained and often certified as Green Belts. Often, analysts such as the Certified Quality Process Analyst would assist the Green Belt while training and working toward the Green Belt certification. It is expected at the Green Belt level that the individual would have a basic understanding of statistics. By collecting data and doing the analysis, he or she can do problem solving and root cause analysis to solve quality problems. The training that Green Belts receive allows them to use Six Sigma tools and methodology and, with the supervision of a Black Belt, they can lead small projects, usually within their own department or specific business area.

Six Sigma can be successful when these things happen:

- Management must lead the improvement efforts and foster an environment that supports Six Sigma initiatives as a business strategy
- Every employee must focus on customer satisfaction
- Teams are assigned well-defined projects
- Provide champions as leaders of the Six Sigma improvement process to remove roadblocks for the Six Sigma improvement teams
- Provide experts who are designated as Black Belts for guidance and coaching
- Value and use the collected data
- View defects as opportunities
- Provide statistical training at all levels, ensuring each employee a minimum of Six Sigma Green Belt status

Six Sigma can achieve improvements in quality and cost reduction quickly and on an incremental, continuous basis to achieve breakthrough levels of process quality.

Voice of the Customer (VOC)

The voice of the customer (VOC) is a term used to describe collecting and listening to the needs or voice of the customer. There are quantitative and qualitative ways to collect the VOC from the customers of the process, as follows:[26]

- Surveys—a properly designed questionnaire, which can provide Likert scale quantification of survey results or open-ended qualitative responses
- Focus groups—3 to 12 individuals assembled to explore specific topics and questions
- Face-to-face interviews—individual interviews of 30 to 60 minutes to gather information on processes and ideas for improvement
- Satisfaction/complaint cards—used to collect overall satisfaction and/or complaints

  - Dissatisfaction sources—complaints, rework, customer re-visit
  - Competitive shopper—shopping a competitor by purchasing their products

Here are some tips on listening to the customer:

- Do not use your own instincts as research data (you are not the customer)
- See the world from the customer's side
- The higher you are in the organization, the more out of touch you are
- Get customers to talk; 90–96% of unhappy customers will not complain
- Do research to retain customers
- Determine how satisfied customers are
- Conduct research on customer expectations
- Develop a customer profile
- Share the results of customer research studies

Surveys have many advantages:

- Conducting a survey is an efficient way of collecting information from a large number of respondents
- Statistical techniques can be used to determine validity, reliability, and statistical significance
- A wide range of information can be collected
- They are relatively easy to administer
- There is an economy in data collection due to the focus provided by standardized questions

Surveys can also have disadvantages:

- Surveys depend on subjects' motivation, honesty, memory, and ability to respond
- Subjects may have forgotten their reasons
- They may not be motivated to give accurate answers
- Structured surveys, particularly those with closed questions, may have low validity
- Errors due to nonresponse may exist
- Survey question answer choices could lead to vague data sets, based on personal abstract notion concerning "strength of choice"

BENCHMARKING

> Define and describe this technique and how it can be used to support best practices. (Understand)
>
> **Body of Knowledge II.B.3**

A carpenter might make a mark on his workbench so he can easily and efficiently cut every table to the exact length. In business, *benchmarks* are standards against which performance can be measured. Benchmarks are commonly used by companies to achieve quality performance. In theory, benchmarks are those standards that the organization strives to achieve. They are identified from many possible sources:

- Customer specifications
- Customer expectations
- The competition's product performance
- The best in the company's own or a related industry
- The best in the world

Benchmarking can be informal (when an individual or a team observes and copies the work that an outstanding individual or team is doing) or formal. *Formal benchmarking* is a term that normally refers to emulating the *best practices in the industry* or even the *best practices in the world*.

Formal benchmarking consists of following these steps:

1. Obtain a commitment to change the organization's business practices
2. Determine which processes the company needs to improve
3. Identify the best practices
4. Form a benchmarking partnership with a firm that displays the best practices
5. Study the benchmarking partner's operations and products for best measures and practices
6. Create benchmarks that are measures of outstanding performance
7. Compare current practices with the benchmark partner's practices
8. Develop a plan to change the firm's operational practices to achieve the benchmark standards

Obtain a Commitment to Change the Organization's Business Practices

Upper management must endorse the policy to employ benchmarking to drive change in the organization. This commitment must not be sought or rendered lightly. Significant changes will often be necessary, and the resistance to change old practices is very strong in most firms.

Obtaining a commitment from upper management is a good start toward making benchmarking an effective driver of change in the organization, but it is not sufficient. Employees and leaders at all levels who participate in the processes that need to be improved must be invited to contribute to planning and implementing the necessary changes, or the benchmarking initiative will almost certainly fail.

Determine Which Processes the Company Needs to Improve

Means for determining which processes need to be improved consist of identifying waste (*muda*) and determining which business processes created the waste. Techniques for identifying waste are described in the lean section in this chapter. Internal weaknesses in the company and threats as determined in a strengths–weaknesses–opportunities–threats (SWOT) analysis are good candidates for benchmarking.

W. Edwards Deming warned that unless the company possesses deep understanding of its own processes, benchmarking (copying) processes that have been successful in other companies will not produce significant improvement. It is unlikely that a company will select an appropriate benchmarking partner unless its own processes to be benchmarked are fully understood.

Identify the Best Practices

Determining which companies and agencies possess the processes with the best practices requires some research. Professional societies and trade organizations frequently publish a list of those companies that practice best-in-class processes in a particular industry. The Malcolm Baldrige National Quality award is granted each year to organizations in various categories that have demonstrated that they possess best quality practices, and the Baldrige award winners have agreed in advance to serve as benchmark partners for organizations seeking support for their own quality improvement programs. Winners of other national and international award programs are also nearly always proud of their accomplishments and accordingly are available to provide information about their processes. The marketing department of most large firms includes some individuals or teams who are tasked with continuous scanning of the competitive marketplace to identify companies and agencies that are likely to pose a threat in the future to the parent organization. These internal competitive intelligence experts can be consulted or even tasked to locate competitors who possess processes that exhibit the best practices in a given industry.

It is not always essential to find benchmarking practices from within a company's own industry. One large aerospace company was having trouble implementing statistical process control in its space-qualified component

manufacturing process. A team of manufacturing and industrial engineers from the aerospace firm partnered with a large cookie manufacturer in the same city and were able to model the cookie manufacturer's implementation of Statistical Process Control for its own operation.

Benchmarking against best in class may not be possible in the following scenarios:[27]

- The best in the world is not known
- There is no related process available
- The best in class is inaccessible due to geography or expense
- The best in class is not willing to partner

Form a Benchmarking Partnership

There are two considerations in selecting a benchmarking partner. First, the benchmarking partner should be best in class with respect to the processes that need to be improved. There is little point in performing a benchmarking activity if the benchmarking partner is not significantly better at something than the company seeking to improve. Second, the benchmarking partner must want to provide information that can be used to develop measures of outstanding performance. Again, there is little value in performing a benchmarking activity if the necessary information cannot be obtained.

The best benchmarking partners are companies that believe it is in their own best interest to share information about their practices and business processes. Most companies are reluctant to share information about their operations with other firms, particularly competitors. Accordingly, in order to form a benchmarking partnership, it may be necessary to seek companies and organizations in different industries. Regardless of which industry a company is in, the benchmarking partner should feel that there is some value to itself in sharing information with a benchmarking partner. Some companies believe that to share information about themselves is a method for improving their public image and increasing sales. There is great public image and marketing value to a company in winning the Baldrige award, and a condition of applying for that award is to agree to make information about your processes available to other companies.

Quid quo pro is a term that describes giving something of value to get something of value—offering a benchmarking partner something that they value is an excellent way to encourage them to share information about their practices. Some companies will accept monetary payments in exchange for information about their processes, but most will not. If one of a company's business processes is already recognized as best in class, this company would have no difficulty in forming a partnership with another company whose processes are also best in class in a quid quo pro exchange for information about each other's best-in-class processes.

Study the Benchmarking Partner's Operations and Products

This step consists of collecting and analyzing information and data on the performance of the benchmark leader. Visiting the benchmark leader is always

desirable. Source information may be obtained from internet searches; books and trade journals; professional associations; corporate annual reports and other financial documents; and consulting firms that specialize in collecting, collating, and presenting benchmark information for a fee. Caution should be exercised whenever benchmark information is collected and analyzed since the data any company presents about itself are bound to be biased and will always be presented in as favorable a light as possible.

Create Benchmark Measures

There are many sorts of comparisons that benchmarking can highlight. These include organizational, process, performance, and project benchmarks.

Organizational benchmarking compares the overall strategic activities of the benchmark leader with another company. How the benchmark leader sets and accomplishes goals, integrates all the aspects of its business, satisfies or delights its customers, and drives its financial successes are examples of questions one would ask to understand how this best-in-class firm operates.

Process benchmarking compares a specific business process performed by the leading firm to processes the other firm's desire to improve. Enterprise resource planning (ERP), strategic project management, customer relationship management (CRM), and employee retention are examples of specific best-in-class processes that a company who is striving to improve its business might seek to understand.

Performance benchmarking enables managers to compare their own company's products and services to those recognized as the best in class. Price, technical quality, customer service, packaging, bundling, speed, reliability, and attractiveness are examples of factors performance benchmarking compares.

Project benchmarking consists of comparing a best-in-class project with other projects. Of all the types of benchmarking, this is perhaps the easiest to execute since it allows comparison to be made with organizations that are not direct competitors. While the objectives and even the practices between two projects are different, they will share many of the same elements. Projects share the common constraints of time, cost, resources, and performance. Before a new project is begun, benchmarking can stimulate the selection and application of better techniques and tools for planning, scheduling, monitoring, and controlling the project. Many companies insist on a *postmortem*, a formal meeting following the completion of each major project, to surface lessons learned during the execution of the project. These lessons learned can lead to benchmarks that can be used to stimulate improvements in subsequent projects.

Compare Current Practices with the Partner's

One of the main reasons benchmarking projects fail is that the company neglects to establish specific plans for closing the gap between current practices and the benchmark leader's practices. To avoid this pitfall, it is mandatory that specific gaps be identified.

Develop a Plan to Change Operational Practices

When gaps exist between the firm's current practices and the benchmark leader's practices, a plan to close those gaps must be developed and implemented. This plan must address overcoming the inevitable resistance to change that will surface. Employees and even managers who have performed a job in the same way for a long time—sometimes decades—always find it difficult to change what they do. The benchmarking activity will not have impact if it does not result in an action plan to improve current processes.

RISK MANAGEMENT

> Recognize the types of risk that can occur throughout the organization, such as scheduling, shipping/receiving, financials, operations and supply chain, employee and user safety, and regulatory compliance changes. Describe risk control and mitigation methods: avoidance, reduction, prevention, segregation, and transfer. (Understand)
>
> **Body of Knowledge II.B.**

The purpose of risk management is to reduce potential risks to an acceptable level before they occur, throughout the life of a product or service. We will use the term *system* to describe a product or service and the related processes for design, development, testing, deployment, and retirement.

Risk management is defined as an

> *[o]rganized, analytic process to identify what might cause harm or loss (identify risks); to assess and quantify the identified risks; and to develop and, if needed, implement an appropriate approach to prevent or handle causes of risk that could result in significant harm or loss.*[28]

Risk is defined as

> *[a] measure of the potential inability to achieve overall program objectives within defined cost, schedule, and technical constraints and has two components:*
>
> 1. *The probability (or likelihood) of failing to achieve a particular outcome and*
> 2. *The consequences (or impact) of failing to achieve that outcome.*[29]

The risk management process includes the following activities:

- Risk planning: The risk planning step develops a strategy for identifying, analyzing, handling, and monitoring risks. The strategy should include both a process and the way that it will be implemented,

and the risks will be documented and traced throughout the phases of the product or service life cycle.

- Risk identification: The risk identification step entails brainstorming and identifying potential risks that could impact the successful completion of the mission. If an existing similar product or service exists, collecting data on warranty claims and customer complaints can be an excellent way to identify potential risks for the new or revised system.
- Risk analysis: The risk analysis assesses the contributing causes, outcomes, and impacts of the risk events.
- Risk handling: The team, during the risk handling activity, develops risk handling approaches for each risk to investigate whether the risk likelihood or consequence can be reduced.
- Risk monitoring: Risk monitoring is the active monitoring throughout the life cycle to monitor and reassess the risks as more knowledge is acquired.

Components of the risk management tools include risk assessment, risk handling approach, risk prioritization, and the risk cube. Each tool will be discussed next.

Risk Assessment

The risk assessment tool includes the generation of the potential risk events that could occur related to the system, at this point in time.

- The risk event is the potential risk that can occur related to the system
- The contributing causes are those causes that contribute to the risk event possibly occurring
- The outcomes are the potential results if the risk event was to occur
- The impact is the effect on the system if the risk event should occur

An easy way to generate the risk assessment is to write a sentence including the terms:

> "As a result of <contributing causes>, <risk event> may occur, causing <outcomes>, which can be expressed as <impact>."[30]

Here's an example for an emergency department process: As a result of <only one nurse being scheduled for triage, even in patient volume surges, resource scheduling not based on patient volumes>, <patient volume surges cause backup in triage >, causing <patients to leave without being seen by a healthcare provider>, which can be expressed as <an impact on a patient's health and hospital loses revenue>.

Risk Types

The types of risk are specific to the organization, their environment, and the product, service, or system that they provide. Some possible types of risk could include the following:

- Scheduling risks: Risks of scheduling the production of a product, managing all of the factors inherent in a production process; scheduling resources for an information technology project
- Shipping/receiving: Risks of shipping a product or receiving raw materials from suppliers, such as product defects, obsolescence, damage to the product, or using an ineffective acceptance sampling plan
- Financials: Risks related to tracking financials, use of appropriate accounting techniques, getting appropriate data for financial measures, risk of fraud
- Operations: Risks related to operations, risk of cybersecurity breeches in a bank
- Supply chain: Disruptions in the supply chain due to supplier issues, shipping delays, resource shortages, or pandemics
- Employee: Risk of people having the training and skills to perform their work; user errors
- User safety: Risk of spread of disease during a global pandemic; safety of employees with machinery
- Regulatory compliance and changes: Risk of ineffective monitoring of regulatory changes; not appropriately documenting regulatory compliance changes

An effective way to identify risk types is to follow your value chain activities and identify potential risks related to the activities within the processes.

Risk Handling Approach

Risk handling is the process that identifies and selects options to manage the identified risks to an acceptable level during the systems project. Risk handling options include acceptance (assumption), avoidance, control (mitigation), transfer, research, and monitor.[31,32]

In the CQPA body of knowledge, segregation, or removing the risk from normal operations (e.g., removing defective products from the production process) is listed as a risk control and mitigation method. The other risk handling options listed are explored and applied before a segregation approach. The segregation approach would be one that is performed if the risks are not appropriately prevented or mitigated.

Risk handling options[33,34]

This section provides each of the most common risk handling options with an example of each.

1. Acceptance (assumption): Assumption accepts the risks and takes no action at this time. It is typically assumed that the risk is rated low, or it would take an inordinate amount of resources to reduce the risk to an acceptable level.

Here is an example of an acceptance or assumption risk handling approach for the emergency department (ED):

The risk is that a bus drops patients from the senior living center for those who need emergency care, causing a brief surge in patient arrivals. It would be assumed that this will occur, and since it is of minor impact it is just accepted.

2. Avoidance: In the avoidance handling approach, action is taken to eliminate the risk to reduce the likelihood of the risk to 5% and/or eliminate the negative consequence to the system.

This is an example of an avoidance risk handling approach for the ED:

The risk is delays in giving reports from the ED to inpatient nurses, which causes a delay in getting patients admitted to the inpatient floors. To avoid the risk, define accountability, priority, and measure, and provide technology to ensure report is given.

3. Control (mitigate) or reduction: In the control or mitigation handling approach, activities are performed to reduce the likelihood and/or the consequence to an acceptable level. It does not completely eliminate the risk, as avoidance does.

Here is an example of a control (mitigate) risk handling approach for the ED:

The risk is that patient volume surges cause a backup in triage. The team would create a surge staffing plan to control or mitigate this risk.

4. Transfer: In the transfer handling approach, the risk event or impact is shifted away from the program. The risk could be transferred between stakeholders or within a system itself. This approach does not change the likelihood or the impact of the risk.

This is an example of the transfer risk handling approach for the ED:

The risk event is that patients are not registered before they are ready to be discharged. To transfer the risk, align registration resources to ED volumes to transfer responsibility to the registration department.

5. Research: The research handling approach includes collecting additional information before a decision is made to reduce the risk.

Here is an example of a research risk handling approach for the ED:

The risk is that a new regulation requires reporting of ED surges. Research the requirements of the new regulation and assess the impact on resources.

6. Monitor

The monitor handling approach is to take no immediate action but monitor for changes related to the risk.

Following is an example of the monitor risk handling approach for our ED:

The risk is of a hurricane occurring during hurricane season. The weather will be monitored, as there may not be much else that can be done to mitigate weather conditions.

Risk Prioritization

Within the risk prioritization tool, the team assesses the risk event likelihood and the consequences. The risk likelihood is the probability that the risk will occur, typically assessed on a scale of 1 to 5, as shown in Table 8.5. Level 1 is not likely that the risk will occur. Level 2 represents a low likelihood that the risk will occur. Level 3 is that the risk is likely to occur. Level 4 is that the risk is highly likely to occur, and the level 5 is a near certainty that the risk will occur.

Risk Cube

The risk cube is a matrix that maps each risk aligned to its risk likelihood and the consequences of the risks. This provides a simple graphical view of where to focus the risks, based on the color coding of the risk cube: red is for high risk—these risks should be closely monitored and continually re-assessed; yellow is for medium risk—these risks should be monitored and re-assessed periodically; and green is for low risk—occasional monitoring and re-assessment should be applied for these risk events.

The consequences represent the magnitude of the impact of the risk. It is also typically assessed on a scale of 1 to 5. The impact or consequences are typically assessed related to the technical aspects, the system project schedule and/or the cost of the program. The impact matrix can be found in Table 8.6.

Once the risk likelihood and consequences are assessed, the risk cube is used to display the risks (by risk event number) on the space in the cube based on the intersection of the risk likelihood level and the impact number. The risk cube does a nice job of visually showing which risks are most important to incorporate a satisfactory risk handling approach if needed to reduce the risk likelihood or impact.

The risk assessment for the emergency department is shown in Table 8.7. The risk handling approach is shown in Table 8.8. The Risk Prioritization is shown in Table 8.9, and the Risk Cube is shown in Figure 8.9 for the Emergency Department. These represent examples risks and are not a comprehensive list of all of the risks for the Emergency Department.

Table 8.5 Risk likelihood.

What is the likelihood the risk will happen?		
No.	**Level**	**Your approach and processes . . .**
1	Not likely	. . . will effectively avoid or mitigate this risk based on standard practice
2	Low likelihood	. . . have usually mitigated this type of risk with minimal oversight in similar cases
3	Likely	. . . may mitigate this risk, but workarounds will be required
4	Highly likely	. . . cannot mitigate this risk, but a different approach might
5	Near certainty	. . . cannot mitigate this type of risk; no known processes or workarounds are available.

Source: Richard Sugarman, "University of Dayton ENM 505 Course Materials," University of Dayton, 2015.

Table 8.6 Magnitude of impact or risk consequences.

Given the risk is realized, what would be the magnitude of the impact?			
Level	**Technical**	**Schedule**	**Cost**
1	Minimal or no impact	Minimal or no impact	Minimal or no impact
2	Minor performance shortfall; same approach retained	Additional activities required, able to meet key dates	Budget increase or unit production cost increase < 1%
3	Moderate performance shortfall, but workarounds available	Minor schedule slip, will miss needed dates	Budget increase or unit production cost increase < 5%
4	Unacceptable, but workarounds available	Project critical path affected	Budget increase or unit production cost increase < 10%
5	Unacceptable; no alternatives exist	Cannot achieve key project milestones	Budget increase or unit production cost increase > 10%

Source: Richard Sugarman, "University of Dayton ENM 505 Course Materials," University of Dayton, 2015.

Table 8.7 Risk assessment.

Risk no.	Risk event	Contributing causes	Outcomes	Impact
1	Patient volume surges cause backup in triage	Only one nurse being scheduled for triage, even in patient volume surges; resource scheduling not based on patient volumes	Patients leave without being seen by a healthcare provider	Impacts patient's health and hospital loses revenue
2	Patient waiting room becomes full	No clinical visibility to waiting room; no one "owns" patients in waiting room	Patients leave without being seen by a healthcare provider	Impacts patients' health
3	Patients not registered before ready to be discharged	Not enough registration staff is scheduled; patient volume surges	Patient is delayed for discharge	Impacts length of stay, patient satisfaction, and patient care
4	Delays in transporting patients to exams or inpatient floors	Admitting patients in batches; transport priorities not aligned to ED; transporters not trained in telemetry transports	Delay in patient care	Impacts length of stay, patient satisfaction, and patient care

Continued

Table 8.7 *Continued.*

Risk no.	Risk event	Contributing causes	Outcomes	Impact
5	Delays in admitting patients to inpatient floors or units	Staffing schedules not aligned between ED and inpatient floors/units; lengthy admission process	Delay in patient care	Impacts length of stay, patient satisfaction, and patient care
6	Delays in giving reports from ED to inpatient nurses	Not a priority with inpatient nurses; no technology to contact nurses	Delay in patient care	Impacts length of stay, patient satisfaction, and patient care
7	A brief patient surge of arrivals is experienced	A bus drops patients from the senior living center for emergency care	Delay in patient care	Patients must wait longer than desired, and other patients may leave without treatment
8	A new regulation requires reporting of ED surges	A new regulation is passed in the county	Reporting is provided by the ED	Additional resources may be needed for the reporting
9	Risk of a hurricane during hurricane season	Climate change causing more hurricanes	Emergency hurricane procedures will need to be enacted	Emergency department operations may be disrupted

Source: Sandra L. Furterer.

Table 8.8 Risk handling approach.

Risk no.	Risk event	Risk handling type	Risk handling description
1	Patient volume surges cause backup in triage	Mitigation	Create surge staffing plan
2	Patient waiting room becomes full	Mitigation	Provide alerts for volume in waiting room
3	Patients not registered before ready to be discharged	Transfer	Align registration resources to ED volumes
4	Delays in transporting patients to exams or inpatient floors	Mitigation	Change process to reduce batch processing of admissions

Continued

Table 8.8 *Continued.*

Risk no.	Risk event	Risk handling type	Risk handling description
5	Delays in admitting patients to inpatient floors or units	Mitigation	Align staffing between ED and inpatient floors/units to historical ED demand
6	Delays in giving reports from ED to inpatient nurses	Avoidance	Define accountability and priority, and provide appropriate technology
7	A brief patient surge of arrivals is experienced	Assumption	Accept the risk since it is of minimal impact
8	A new regulation requires reporting of ED surges	Research	Research the requirements of the new regulation and assess the impact on resources
9	Risk of a hurricane during hurricane season	Monitor	Monitor weather conditions during hurricane season

Source: Sandra L. Furterer.

Table 8.9 Risk prioritization.

Risk no.	Risk event	Risk likelihood	Risk impact
1	Patient volume surges cause backup in triage	4	5
2	Patient waiting room becomes full	3	4
3	Patients not registered before ready to be discharged	1	1
4	Delays in transporting patients to exams or inpatient floors	2	2
5	Delays in admitting patients to inpatient floors or units	4	3
6	Delays in giving reports from ED to inpatient nurses	4	2
7	A brief patient surge of arrivals is experienced	1	2
8	A new regulation requires reporting of ED surges	1	1
9	Risk of a hurricane during hurricane season	1	5

Source: Sandra L. Furterer.

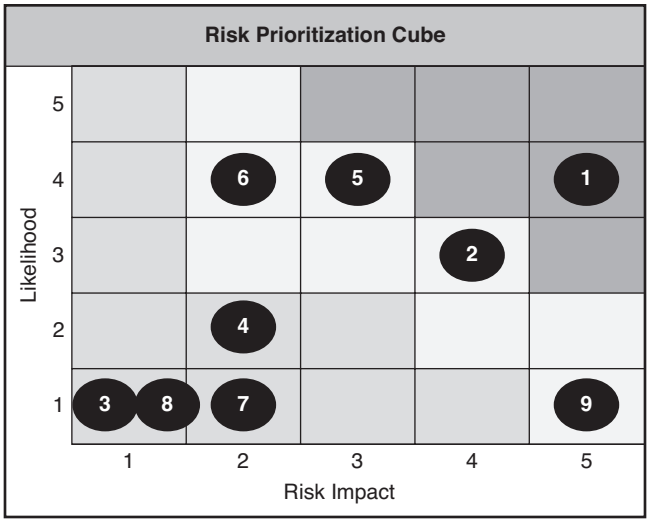


Figure 8.9 Risk cube for emergency department.

Source: Sandra L. Furterer.

Risk-Based Thinking and Prevention

In the ISO 9001:2015 standard, section 0.3.3 and clause A.4, Risk-Based Thinking, encourage risk-based thinking applied to planning and implementing quality management system (QMS) processes and will determine the level of documented information. A key purpose of a QMS is to act as a preventive tool.

According to this standard, "Organizations can decide whether or not to develop a more extensive risk management methodology than is required by this International Standard, e.g. through the application of other guidance or standards."[35] The organization is responsible for determining the level of application of risk-based thinking and the actions to address risk. Controls are incorporated in a proactive way before problems occur.

BUSINESS PROCESS MANAGEMENT (BPM)

> Define and describe this continuous process improvement practice, including the business process lifecycle phases (Design, Modeling, Execution, Monitoring, and Optimization). (Understand)
>
> **Body of Knowledge II.B.5**

In Figure 8.10, we see three bodies of knowledge—quality, productivity, and information technology—that have evolved into what is today known as business process management (BPM). The quality body of knowledge started with statistical

process control in the 1920s. The statistical concepts along with the principles of quality gurus Dr. W. Edwards Deming, Joseph Juran, Philip Crosby, Armand Feigenbaum, and others evolved into total quality management, which became popular in the 1980s. At about the same time, business process reengineering grew in popularity. The principles and tools evolved into Six Sigma. Six Sigma began at Motorola with Mikel Harry and Richard Schroeder. It was popularized at General Electric when Jack Welch was the CEO. He was a great advocate of Six Sigma. Six Sigma uses the DMAIC method and a large variety of quality problem-solving tools, including statistics. The value of Six Sigma is in the very structured approach, the focus on defects and variation, and then also the mentoring and certifications of Black Belts and Green Belts.[36]

The productivity body of knowledge, started in the early 1900s with the Ford production system, and evolved into just-in-time and the Toyota production system, which then evolved into lean. Lean and Six Sigma integrated and synthesized the principles, tools, and methodology combining to form LSS.

In the Information Technology body of knowledge, we began in the 1970s with MRP (materials requirements planning) and MRP II (manufacturing

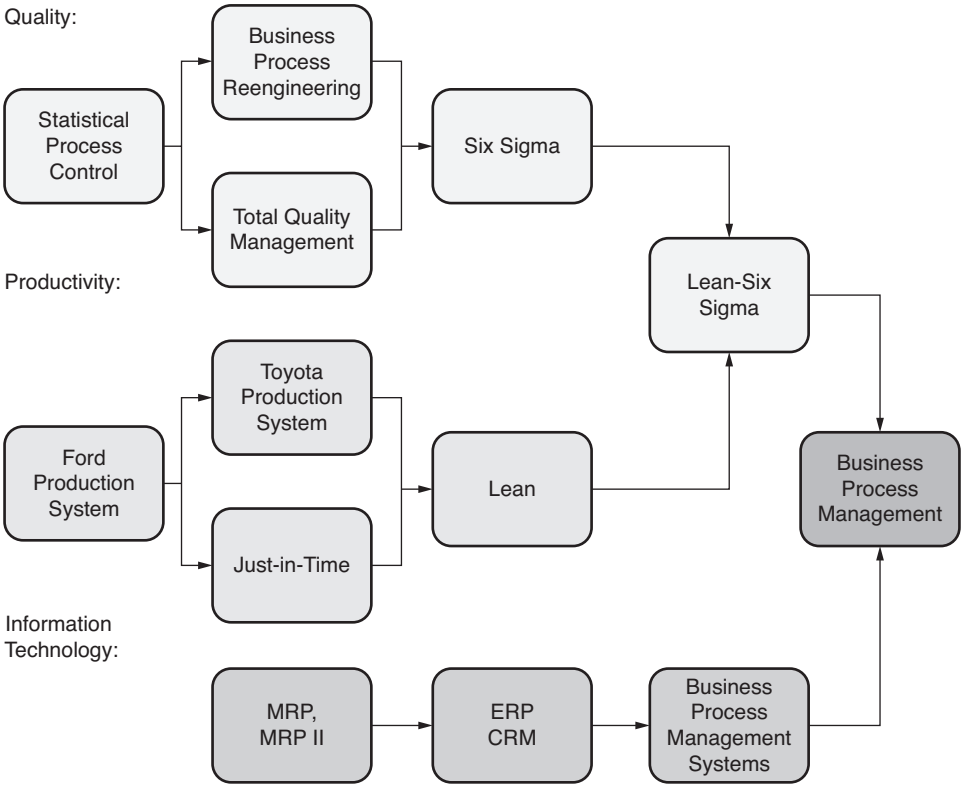


Figure 8.10 The evolution to business process management.

Source: Sandra L. Furterer.

resource planning), which evolved into ERP (enterprise resource planning), and CRM (customer relationship management). BPMS (business process management systems) technology supported business process management, where the principles of Lean-Six Sigma formed the basis for the principles and improvement tools of BPM.

Business process management (BPM) is a disciplined approach to *analyze*, *identify*, *design*, *execute*, *document*, *measure*, *monitor*, *improve*, and *control* both automated and nonautomated business processes to achieve consistent, *targeted results aligned* with an organization's *strategic goals*. BPM is thereby the method by which an enterprise's "Quality" program (e.g., TQM) is carried out. There are several essential factors that will help to ensure that an organization can embrace BPM and leverage the value of BPM.

- BPM enables the alignment of the business strategy, the core value chains, and business processes.
- It is important to align the process goals to the business processes with organizational strategy.
- Executive sponsorship/governance is critical to ensuring change happens. Like any organization-wide change effort, top management support is critical. Setting up a governance structure guides and manages the organization with respect to BPM goals and initiatives.
- Process ownership is critical when improving cross-functional processes that span many departments.
- Institution practices include how BPM is practiced in the organization.
- It is important to incorporate technology of the business processes to enable and optimize these processes.
- Complex problems exist in the cross-organizational nature of business processes, and the impact must be assessed and optimization of the processes must be performed from a cross-functional perspective to avoid sub-optimization of processes.
- The BPM concepts, tools, and training should be continuously adapted and enhanced to improve business processes.
- And finally, alignment of employee bonuses and rewards to business process performance looks very different from a functionally/departmentally managed organization, versus a process-oriented organization.

There are three main goals of BPM:

1. To improve the products and services of the organization through a structured approach to performance improvement that centers on systematic design and management of a company's business processes
2. To transform the culture to support BPM implementation

3. To gain business capabilities by transforming to an organization that has IT-enabled business process changes

Business Process Management Principles

There are several important principles of BPM:

- Processes are assets.

  Processes should create value for customers. Processes are responsible for the end-to-end work of delivering value to the customer. Customers can be internal and external. Different organizations have different objectives and different core processes. The organization acts very differently when processes are treated as an asset. BPM practices ensure that the processes are documented, kept up to date, and are accessible to the organization to leverage and improve.

- Processes should be managed and continuously improved.

  A managed process produces consistent value to customers and has the foundation for the process to be improved. Processes should be measured, documented, monitored, controlled, and analyzed.

- Information technology (IT) is an essential enabler.

  Business processes are the focus for improvement, and IT is the key enabling tool. IT provides information (real-time process information) to monitor and control processes.

BPM Life Cycle

The BPM life cycle for designing, assessing, documenting, measuring, executing, and monitoring processes is shown in Figure 8.11.

Phase 1: Design

The purpose of process design is the formal definition of the goals, deliverables, and organization of the activity and rules needed to produce a product, service, or outcome.

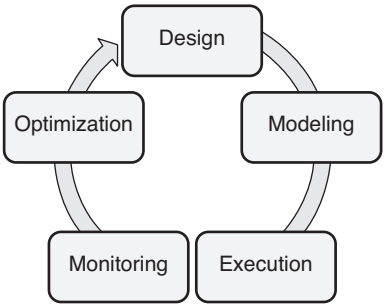


Figure 8.11 BPM life cycle phases.

Source: Sandra L. Furterer.

Process design can be performed at two levels:

- Cross-functional process
- Business function workflow

The cross-functional process is a set of activities that cross departments in an organization. It is usually broader in scope, more complex, and potentially more strategic to the organization. The cross-functional process is a *combination of all the activities and support needed to produce and deliver an objective, outcome, product, or service—regardless of where the activity is performed. Activities are shown in the context of their relationship with one another, to provide a picture of sequence and flow.*[37]

A workflow, as defined by the Association of Business Process Management Professionals in the body of knowledge, is a set of activities performed within a department. A ***workflow*** *is the aggregation of activity within a single Business Unit. Activity will be a combination of work from one or more processes. Organization of this work will be around efficiency. Modeling will show this work as a flow that describes each activity's relationship with all the others performed in the Business Unit.*[38]

This definition varies somewhat from the one used in BPM systems, where it is defined as the flow of work through the system to get the work accomplished, which almost by the nature of the automation can easily connect disparate processes across departments. However, for this material we will use the concept that workflow versus process provides an important distinction to differentiate activities within a single department and those that cross department boundaries.

The important concept to glean from this discussion is the system of processes, from Deming's theory of systems. Small processes that exist within departments or business units connect and form larger, cross-functional processes, which cross departments or business units. It is important to focus not only on the goals and efficiencies of the individual departments but on the entire stream or system of the processes when optimizing processes.

In this phase, processes are assessed if they exist and are designed if they do not exist. It is important to define the process design requirements based on the voice of the customer. Quality function deployment, discussed in Chapter 17, can be used to ensure alignment and prioritization between the customer requirements and the process requirements.

It is important to purposefully design the organization's processes. We find that many processes were never truly "designed" for efficiency and to meet the strategic goals of the organization. Many processes just grew with the company and met the need at the time but never were designed for optimization and to ensure that they meet the customers' goals. Most processes are less efficient than they could be if they were properly designed. When processes are designed, the focus should be on the sets of activities, their sequences, the interaction of the activities with the people that perform the activities, the supporting technology and information systems that they use, and any data, information, tools, and equipment that is used as well. Metrics and control mechanisms should be incorporated into the processes to ensure that the goals of the processes are met, along with the customers' needs, and to ensure that the processes are continually improved.

It is important to understand how the process is performed today. Starting from a blank sheet of paper or whiteboard, and then designing an ideal process without regard to the challenges in the current process will tend to create either infeasible designs or ones that are not cost-effective. So, before the organization starts to design or redesign the process, process modeling should be used to understand the current state of the processes.

Following are some best practices in process design:

- **Design around value-added activities:** It is important to understand what provides value to the customer within the process. Understanding which activities provide value to the process is important to enhance the value of these activities, and reduce or eliminate activities that do not add value to the process.
- **Perform work where it makes most sense:** This design principle is important, because too often the processes move back and forth between departments, due to either politics or where a process "grew up" in an organization. It is important for the people who have the tools, knowledge, and skills to perform the process, regardless of organization structure.
- **Create a single point of contact for the customer:** This design principle will put the customer first when designing the process. Too often, especially large companies assume that a customer can navigate the maze of organizations when trying to solve a problem. To them, they shouldn't need to know the distinction between the channels and the organization that supports them. If the customer has a problem and seeks help via the web, versus the phone, we should not be sending them to a completely different organization to solve their problem, and too often companies do. The customer ends up confused and perhaps with a different solution, depending on the channel that they come into our company through. When the author was working in healthcare, one of the IT folks believed it was just part of doing business in a hospital, that the patient should need a patient advocate to maneuver the maze of departments in a hospital when being provided care. This type of thinking should be abolished as organizations design their processes for the care and ease of the customer.
- **Reduce handoffs:** Many of these design principles are interconnected. If work is performed where it makes the most sense, the number of hand-offs between the steps of the process may potentially be reduced. Hand-offs many times are where the process gets stuck. The next upstream process may not realize that the work is ready to move to the next step of the process, so the work sits and waits. Focusing on the hand-offs can vastly streamline the process and reduce total cycle time.
- **Reduce batch sizes:** Reducing the size of the batches can help the work flow through the process more quickly and reduce the inventory and wait time that builds up between process steps. Continuous flow and reducing the batch size is a critical tenet of lean thinking.

- **Put access to information where it is needed the most:** With integrated systems and BPM systems, it should be easier to provide information where it is needed most to ensure the quality and timeliness of the process.
- **Capture information once and share it with everyone:** Along with giving access to information where it is most needed, quality information should be shared with all of the process stakeholders, including, as appropriate, customers and suppliers. Web-based patient charts and electronic medical information systems are attempts to share patient information with the patient and all other appropriate medical providers. This is quickly changing healthcare processes for the better. Online financial and banking information is another technology that is providing information when and where it is needed.
- **Redesign the process before considering automation:** Automating inefficient processes increases costs by requiring technology to adopt inefficiencies. This design principle encourages eliminating unnecessary activities before automating the process. Again, BPM systems enable quickly changing processes and business rules that manage the processes.
- **Design for desired performance metrics:** As the saying goes, you get what you measure. It is important to select the critical process metrics carefully to encourage the desired process performance.
- **Standardize processes:** This design principle encourages standardizing the process so that everyone performing the optimized process is performing it in the same manner.
- **Consider co-located networked teams and outsourcing:** This design principle incorporates co-locating teams that perform a cross-functional process; also consider whether the process can be outsourced to a vendor.

Phase 2: Modeling

In the business process modeling phase, the process models are developed for the organization. Furterer provides four main meta or conceptual models included in her strategic business process architecture (SBPA). The meta models describe the elements of an organization that can be used to model the organization and the relationships between the elements of the models. The four main meta models are[39]

1. strategic models, which include the elements of the strategic plans, including an organization's strategies, goals, objectives, and initiatives, as well as other elements that help to define the strategies in an organization;
2. value chain and process models, which help to describe the operational processes of the organization;

3. leadership and workforce models, which describe how leaders govern, lead, and manage the workforce; and
4. information and application models, which describe the conceptual information and information system applications that support the business's capabilities.

The value chain and process meta model (Figure 8.12) will guide the modeling of the processes in the organization. Starting from the value chain activities, describing the high-level value-added and support activities, these provide a system view of the organization's operational processes. The business function decomposition provides an inventory of all of the functions that can be used to guide the design and documentation of the business processes via process maps, or the process architecture map (PAM), discussed earlier.

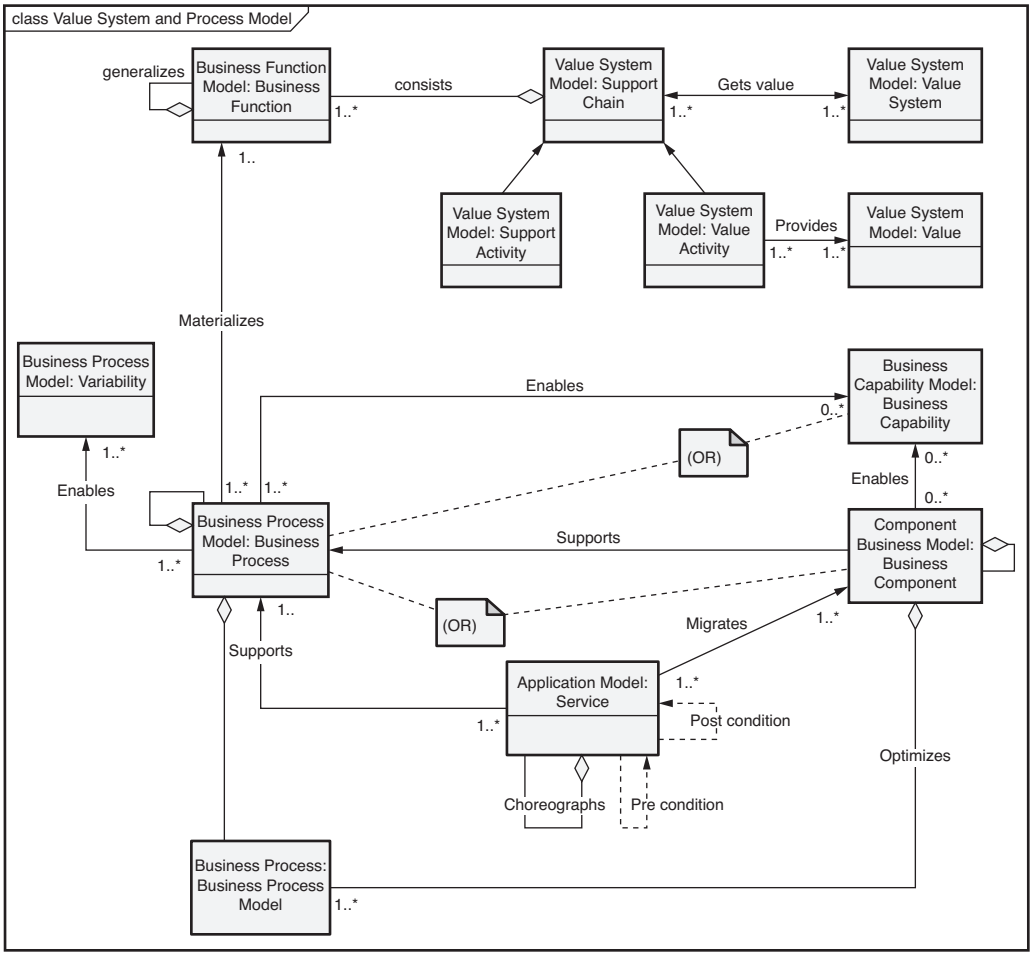


Figure 8.12 Value chain and process meta model.

Source: Sandra L. Furterer.

Phase 3: Execution

In the execution phase, the processes that were designed and modeled are implemented.

Listed are eight aspects of good solutions:[40]

- Involves "change" not "train": The revisions to the new process should involve significant change and improvement, not just training people how to do the process better; training should be a given.
- Take the root cause out of the process: It is important to have identified the root causes within the process analysis phase and ensure that the process design fixes the root causes.
- Cost-effective: The new solution should be cost-effective.
- Innovative "upstream" fix: For cross-functional processes, the entire process should be optimized.
- Employs poka-yoke (mistake-proofing): Poka-yoke, a Japanese term for mistake-proofing, should be designed into the process so that the problems are prevented, not fixed after they occur.
- Involves the customer/customer requirements: Ensure that the process design meets the customers' requirements.
- Allows you to meet your performance target: Ensure that the process design allows the performance targets to be met.

These six elements help to ensure we are designing a lasting solution:

1. Review the data gathered (process map, data and graphical analysis, etc.) in both the process modeling and process analysis phases.
2. Study the verified root causes identified in the process analysis phase.
3. Look for changes in the process that will eliminate the root causes.
4. Use process knowledge but also look for other similar processes, both inside and outside your organization.
5. Talk with many people—including customers and subject matter experts—to get creative ideas.
6. Look at processes in other industries—benchmarking similar processes—even in other industries to consider innovative ideas that others have made work in their processes.

There are three main goals of organizational or process change:

- Change the way people think and behave in an organization—a new mindset; this begins with a person at an individual level and is why training and project work is vital.
- Change the norms—standards, models, or patterns—that guide behavior.

- Change the organization's systems or processes—all work is a process, and improvement requires change at the process and system level; this cannot happen until people's behavior and norms change.

What is process transformation?

- Process transformation is the fundamental rethinking of a process—the goal is innovation and the creative application of new business approaches, techniques, and technology.
- Process transformation is cross-functional.
- Change agents must understand the culture, resistance to change, and limitations to change to make change happen.
- Process transformation can be applied at any level in a business as long as it is related to the radical rethinking of how the business area should work—including its markets and products.

By definition, improvement makes whatever you have better. It does not rethink it—it improves it. So, if you are looking for ways to do the same things faster, for lower cost, or with improved quality, you are doing the same things. At some point, however, the industry will have evolved. Technology will have moved beyond your ability to simply improve what you have. Your competition will have better ways, and the market will require new approaches. For these reasons, transformation should be regarded as a strategic move. It is a long-term commitment to the business and to its ability to compete in the global market. It is also a commitment to modernize, upgrade, and rethink how the business should work in the future.

Phase 4: Monitoring

In the monitoring phase, process performance management can be used to ensure that the processes maintain the gains and are performed as designed, or improvements are identified as well.

Process performance management is

> the measurement of specific operational characteristics as defined by key performance indicators (KPIs), standards, labor contracts, the finance department, industry best practices, ISO, and others.[41]

These factors affect the ability to measure processes:

- Level of flexibility in accessing data from multiple applications
- Process understanding
- Agreement in what to measure and how to measure it
- Ability of IT to build flexible performance measurement applications
- Reporting presentation and data drill-down
- Acceptance of performance measurement by those who will be measured

Process performance management involves both an understanding of what to measure and how to measure it. Process managers must measure processes and define metrics to understand how the process is performing to help focus process optimization.

Some examples of measuring operational performance are the following:

- Quality: Defects, exceptions, waste, problems, opportunities, compliance to standards and regulatory/legal, first run yield
- Timeliness: Process time, delay time, takt time, throughput time
- Cost: Cost of processes, scrap, savings
- Customer satisfaction/experience: Satisfaction; interaction, errors, requirements, complaints, experience
- Capacity: Transaction volume
- Flow: Backlog, constraints, bottlenecks

Characteristics of effective measurement:

- Alignment: Alignment with corporate strategies and objectives
- Accountability: Metrics owner defines, monitors, and controls
- Predictive: Predict process performance
- Actionable: Timely, actionable data, so can intervene in the process
- Few in number: Select high-value information
- Easy to understand: Straightforward, connected to action
- Balanced and linked: Metrics are balanced and aligned
- Transformative: Metrics support transformational change
- Standardized: Standard metrics
- Context-driven: Within the process, gauge performance over time
- Reinforced: Attach compensation or incentives
- Relevant: Reviewed and refreshed metrics

There are several measurement success factors, including:

- Measurement skills sets exist and are used
- Measurement roles and responsibilities are clear and communicated
- The organizational structure supports the measurement system
- There is empowerment with accountability to transform processes based on results
- Process performance results are tied to compensation and incentives

Phase 5: Optimization[42]

The purpose of the optimization phase is to optimize the process by streamlining the process, removing inefficiencies, and ensuring that the process goals of the stakeholders are met. There are many optimization tools for optimizing a process.

Process simulation: Simulation tools can be applied to enable process modeling. This provides the ability to test potential process solutions and propose these solutions prior to actual implementation of the process changes.

Optimization modeling: A number of operations research optimization tools can be applied:

- Linear programs
- Network models
- Queuing models
- Markov chains
- Heuristics
- Inventory and production planning applications
- Transportation, assignment models, and logistics applications
- Integer programming

It is important to pilot improvements and test that they work. There should be an assessment of the process performance against the process metrics using the appropriate statistical inferential tests.

Continuous improvement through a plan–do–check–act cycle is an important part of the optimize phase. Process improvements should continue throughout the life cycle of the process, including continual improvement of technology to support the processes.

Part VI

Appendices

Appendix A

Body Of Knowledge for the ASQ Certified Quality Process Analyst (CQPA)—2020

Included in this Body of Knowledge (BoK) are explanations (subtext) and cognitive levels for each topic or subtopic in the test. These details will be used by the Examination Development Committee as guidelines for writing test questions and are designed to help candidates prepare for the exam by identifying specific content within each topic that can be tested. Except where specified, the subtext is not intended to limit the subject or be all-inclusive of what might be covered in an exam but is intended to clarify how topics are related to the role of the Certified Quality Process Analyst (CQPA). The descriptor in parentheses at the end of each subtext entry refers to the highest cognitive level at which the topic will be tested. A complete description of cognitive levels is provided at the end of this document.

I. Quality Concepts and Team Dynamics (20 Questions)

A. Professional Conduct and Ethics

Identify and apply behaviors that are aligned with the ASQ Code of Ethics. (Apply)

B. Quality Concepts

1. Quality

Describe how using quality techniques to improve processes, products, and services can benefit all parts of an organization. Describe what quality means to various stakeholders (e.g., employees, organization, customers, suppliers, community) and how each can benefit from quality. (Understand)

2. Quality planning

Define a quality plan, describe its purpose for the organization as a whole, and know who has responsibility for contributing to its development. (Understand)

3. Quality standards, requirements, and specifications

Define and distinguish between national or international standards, customer requirements, and product or process specifications. (Understand)

4. Quality documentation

   Identify and describe common elements of various document control systems, including configuration management. Describe the relationship between quality manuals, procedures, and work instructions. (Understand)

5. Cost of quality (COQ)

   Define and describe the four cost of quality categories: prevention, appraisal, internal failure, and external failure. (Understand)

C. Quality Audits

1. Audit types

   Define and distinguish between basic audit types, including internal and external audits; product, process, and systems audits; and first-, second-, and third-party audits. (Understand)

2. Audit components

   Identify various elements of the audit process, including audit purpose and scope, the standard to audit against, audit planning (preparation) and performance, opening and closing meetings, final audit report, and verification of corrective actions. (Understand)

3. Audit roles and responsibilities

   Identify and describe the roles and responsibilities of key audit participants: lead auditor, audit team member, client, and auditee. (Understand)

D. Team Dynamics

1. Types of teams

   Distinguish between various types of teams: process improvement teams, workgroups/workcells, self-managed teams, temporary/ad hoc project teams, and cross-functional teams. (Analyze)

2. Team development

   Identify various elements in team building, such as inviting team members to share information about themselves during the initial meeting, using ice-breaker activities to enhance team membership, and developing a common vision and agreement on team objectives. (Apply)

3. Team stages

   Describe the classic stages of team evolution: forming, storming, norming, performing, and adjourning. (Understand)

4. Team roles and responsibilities

   Describe the roles and responsibilities of various team stakeholders: sponsor, champion, facilitator, team leader, and team member. (Understand)

5. Team conflict

   Identify common group challenges, including groupthink, members with hidden and/or competing agendas, intentional distractions, and other disruptive behaviors. Describe ways of resolving these issues and keeping team members on task. (Understand)

E. Training and Evaluation

Describe various elements of training, including linking the training to organizational goals, identifying training needs, adapting information to meet adult learning styles, and using coaching and peer training methods. Describe various tools to measure the effectiveness of the training, including post-training feedback, end-of-course tests, and individual and department performance improvement measures. (Understand)

II. Quality Tools and Process Improvement Techniques (26 Questions)

A. Process Improvement Concepts and Approaches

Define and explain elements of Plan-Do-Check-Act (PDCA), kaizen activities, incremental and breakthrough improvement, and DMAIC phases (define, measure, analyze, improve, control). (Apply)

B. Basic Quality Tools

Select, construct, apply, and interpret the seven basic quality tools: (1) cause and effect diagrams, (2) flowcharts (process maps), (3) check sheets, (4) Pareto charts, (5) scatter diagrams, (6) run charts and control charts, and (7) histograms. (Evaluate)

C. Process Improvement Techniques

1. Lean

   Identify and apply lean concepts and tools, including set-up reduction (SUR), pull (including just-in-time (JIT) and kanban), 5S, continuous flow manufacturing (CFM), value-added analysis, value stream mapping, theory of constraints (TOC), poka-yoke, and total productive/predictive maintenance (TPM) to reduce waste in areas of cost, inventory, labor, and distance. (Apply)

2. Six Sigma

   Identify key Six Sigma concepts, including variation reduction, voice of the customer (VOC), belt levels (yellow, green, black, master black), and their roles and responsibilities. (Understand)

3. Benchmarking

   Define and describe this technique and how it can be used to support best practices. (Understand)

4. Risk management

   Recognize the types of risk that can occur throughout the organization, such as scheduling, shipping/receiving, financials, operations and supply chain, employee and user safety, and regulatory compliance and changes. Describe risk control and mitigation methods: avoidance, reduction, prevention, segregation, and transfer. (Understand)

5. Business process management (BPM)

   Define and describe this continuous process improvement practice, including the business process life cycle phases (Design, Modeling, Execution, Monitoring, and Optimization). (Understand)

D. Management and Planning Tools

1. Quality management tools

   Select and apply affinity diagrams, tree diagrams, process decision program charts, matrix diagrams, interrelationship digraphs, prioritization matrices, and activity network diagrams. (Apply)

2. Project management tools

   Select and interpret scheduling and monitoring tools, such as Gantt charts, program evaluation and review technique (PERT), and critical path method (CPM). (Apply)

III. Data Analysis (33 Questions)

A. Basic Concepts

1. Basic statistics

   Define, calculate, and interpret measures of central tendency (mean, median, mode) and measures of dispersion (standard deviation, range, variance). (Analyze)

2. Basic distributions

   Define and explain frequency distributions (normal, binomial, Poisson, and Weibull) and the characteristics of skewed and bimodal distributions. (Understand)

3. Probability concepts

   Describe and use probability concepts: independent and mutually exclusive events, combinations, permutations, additive and multiplicative rules, and conditional probability. Perform basic probability calculations. (Apply)

4. Reliability concepts

   Define basic reliability concepts: mean time to failure (MTTF), mean time between failures (MTBF), mean time between maintenance (MTBM), and mean time to repair (MTTR). Identify elements of the bathtub curve model and how they are used to predict failure patterns. (Remember)

B. Data Types, Collection, and Integrity

1. Measurement scales

   Define and use nominal, ordinal, interval, and ratio measurement scales. (Apply)

2. Data types

   Identify, define, and classify data in terms of continuous (variables) and discrete (attributes or counts). Determine when it is appropriate to convert attributes data to variables measures. (Apply)

3. Data collection and analysis

   Identify and describe the advantages of collecting and analyzing real-time data. (Understand)

4. Data integrity

   Recognize methods that verify data validity and reliability from source through data analysis using various techniques such as auditing trails, vendor qualification, error detection software, training for record management etc., to prevent and detect data integrity issues. (Apply)

5. Data plotting

   Identify the advantages and limitations of using this method to analyze data visually. (Understand)

C. Sampling

1. Sampling methods

   Define and distinguish between various sampling methods, such as random, sequential, stratified, systemic/fixed sampling, rational subgroup sampling, and attributes and variables sampling. (Understand)

2. Acceptance sampling

   Identify and define sampling characteristics, such as lot size, sample size, acceptance number, and operating characteristic (OC) curve. Identify when to use the probability approach to acceptance sampling. (Understand)

D. Measurement System Analysis

Define and distinguish between accuracy, precision, repeatability and reproducibility (gage R&R) studies, bias, and linearity. (Apply)

E. Statistical Process Control (SPC)

1. Fundamental concepts

   Distinguish between control limits and specification limits, and between process stability and process capability. (Apply)

2. Rational subgroups

   Explain and apply the principles of rational subgroups. (Apply)

3. Control charts for attributes data

   Identify, select, and interpret control charts (p, np, c, and u) for data that is measured in terms of discrete attributes or discrete counts. (Analyze)

4. Control charts for variables data

   Identify, select, and interpret control charts ($\bar{X}$–*R*, $\bar{X}$–*s*, and XmR) for data that is measured on a continuous scale. (Analyze)

5. Common and special cause variation

   Interpret various control chart patterns (runs, hugging, trends) to determine process control, and use SPC rules to distinguish between common cause and special cause variation. (Analyze)

6. Process capability measures

   Describe the conditions that must be met in order to measure capability. Calculate C_p, C_{pk}, P_p, and P_{pk} measures and interpret their results. (Analyze)

F. Advanced Statistical Analysis

1. Regression and correlation models

   Describe how these models are used for estimation and prediction. (Apply)

2. Hypothesis testing

   Calculate confidence intervals using *t-tests* and the *z-statistic* and determine whether the result is significant. (Analyze)

3. Design of experiments (DOE)

   Define and explain basic DOE terms: response, factors, levels, treatment, interaction effects, randomization, error, and blocking. (Understand)

4. Taguchi concepts and methods

   Identify and describe Taguchi concepts: quality loss function, robustness, controllable and uncontrollable factors, and signal to noise ratio. (Understand)

5. Analysis of variance (ANOVA)

   Define key elements of ANOVAs and how the results can be used. (Understand)

IV. Customer-Supplier Relations (13 Questions)

A. Internal and External Customers and Suppliers

Define and distinguish between internal and external customers and suppliers. Describe their impact on products, services, and processes, and identify strategies for working with them to make improvements. (Apply)

B. Customer Satisfaction Methods

Describe the different types of tools used to gather customer feedback: surveys, focus groups, complaint forms, and warranty analysis. Explain key elements of quality function deployment (QFD) for understanding and translating the voice of the customer. (Understand)

C. Product and Process Approval Systems

Describe how validation and qualification methods, including beta testing, first-article, in-process, and final inspection are used to approve new or updated products, processes, and services. (Understand)

D. Supplier Management

1. Supplier selection

Describe and outline criteria for selecting, approving, and classifying suppliers, including internal rating programs and external certification standard requirements, including environmental/social responsibility. (Understand)

2. Supplier performance

Describe supplier performance in terms of measures such as quality (e.g., defect rates, functional performance), price, delivery speed, delivery reliability, level of service, and technical support. (Understand)

E. Material Identification, Status, and Traceability

Describe the importance of identifying material by lot, batch, source, and conformance status, including impact for recalls. Describe key requirements for preserving the identity of a product and its origin. Use various methods to segregate nonconforming material and process it according to procedures. (Apply)

V. Corrective and Preventive Action (CAPA) (8 Questions)

A. Corrective Action

Demonstrate key elements of the corrective action process: identify the problem, contain the problem, determine the root causes, propose solutions to eliminate and prevent their recurrence, verify that the solutions are implemented, and confirm their effectiveness. (Apply)

B. Preventive Action

Demonstrate key elements of a preventive action process: track data trends and patterns, use failure mode and effects analysis (FMEA), review product and process monitoring reports, and study the process to identify potential failures, defects, or deficiencies. Improve the process by developing error/mistake-proofing methods and procedural changes, verify that the changes are made, and confirm their effectiveness. (Apply)

LEVELS OF COGNITION BASED ON BLOOM'S TAXONOMY – REVISED (2001)

In addition to **content** specifics, the subtext for each topic in this BOK also indicates the intended **complexity level** of the test questions for that topic. These levels are based on "Levels of Cognition" (from Bloom's Taxonomy Revised, 2001) and are presented below in rank order, from least complex to most complex.

Remember

Recall or recognize terms, definitions, facts, ideas, materials, patterns, sequences, methods, principles, etc.

Understand

Read and understand descriptions, communications, reports, tables, diagrams, directions, regulations, etc.

Apply

Know when and how to use ideas, procedures, methods, formulas, principles, theories, etc.

Analyze

Break down information into its constituent parts and recognize their relationship to one another and how they are organized; identify sublevel factors or salient data from a complex scenario.

Evaluate

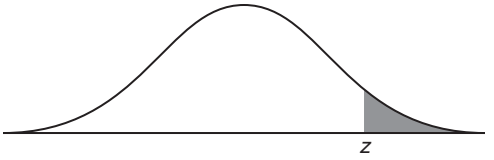
Make judgments about the value of proposed ideas, solutions, etc., by comparing the proposal to specific criteria or standards.

Create

Put parts or elements together in such a way as to reveal a pattern or structure not clearly there before; identify which data or information from a complex set is appropriate to examine further or from which supported conclusions can be drawn.

Appendix B

Areas under Standard Normal Curve



z	Area	z	Area	z	Area	z	Area	z	Area	z	Area	z	Area
0.00	0.5000	0.50	0.3085	1.00	0.1587	1.50	0.0668	2.00	0.0228	2.50	0.0062	3.00	1.35E-03
0.01	0.4960	0.51	0.3050	1.01	0.1562	1.51	0.0655	2.01	0.0222	2.51	0.0060	3.01	1.31E-03
0.02	0.4920	0.52	0.3015	1.02	0.1539	1.52	0.0643	2.02	0.0217	2.52	0.0059	3.02	1.26E-03
0.03	0.4880	0.53	0.2981	1.03	0.1515	1.53	0.0630	2.03	0.0212	2.53	0.0057	3.03	1.22E-03
0.04	0.4840	0.54	0.2946	1.04	0.1492	1.54	0.0618	2.04	0.0207	2.54	0.0055	3.04	1.18E-03
0.05	0.4801	0.55	0.2912	1.05	0.1469	1.55	0.0606	2.05	0.0202	2.55	0.0054	3.05	1.14E-03
0.06	0.4761	0.56	0.2877	1.06	0.1446	1.56	0.0594	2.06	0.0197	2.56	0.0052	3.06	1.11E-03
0.07	0.4721	0.57	0.2843	1.07	0.1423	1.57	0.0582	2.07	0.0192	2.57	0.0051	3.07	1.07E-03
0.08	0.4681	0.58	0.2810	1.08	0.1401	1.58	0.0571	2.08	0.0188	2.58	0.0049	3.08	1.04E-03
0.09	0.4641	0.59	0.2776	1.09	0.1379	1.59	0.0559	2.09	0.0183	2.59	0.0048	3.09	1.00E-03
0.10	0.4602	0.60	0.2743	1.10	0.1357	1.60	0.0548	2.10	0.0179	2.60	0.0047	3.10	9.68E-04
0.11	0.4562	0.61	0.2709	1.11	0.1335	1.61	0.0537	2.11	0.0174	2.61	0.0045	3.11	9.36E-04
0.12	0.4522	0.62	0.2676	1.12	0.1314	1.62	0.0526	2.12	0.0170	2.62	0.0044	3.12	9.04E-04
0.13	0.4483	0.63	0.2643	1.13	0.1292	1.63	0.0516	2.13	0.0166	2.63	0.0043	3.13	8.74E-04
0.14	0.4443	0.64	0.2611	1.14	0.1271	1.64	0.0505	2.14	0.0162	2.64	0.0041	3.14	8.45E-04
0.15	0.4404	0.65	0.2578	1.15	0.1251	1.65	0.0495	2.15	0.0158	2.65	0.0040	3.15	8.16E-04
0.16	0.4364	0.66	0.2546	1.16	0.1230	1.66	0.0485	2.16	0.0154	2.66	0.0039	3.16	7.89E-04
0.17	0.4325	0.67	0.2514	1.17	0.1210	1.67	0.0475	2.17	0.0150	2.67	0.0038	3.17	7.62E-04
0.18	0.4286	0.68	0.2483	1.18	0.1190	1.68	0.0465	2.18	0.0146	2.68	0.0037	3.18	7.36E-04
0.19	0.4247	0.69	0.2451	1.19	0.1170	1.69	0.0455	2.19	0.0143	2.69	0.0036	3.19	7.11E-04
0.20	0.4207	0.70	0.2420	1.20	0.1151	1.70	0.0446	2.20	0.0139	2.70	0.0035	3.20	6.87E-04
0.21	0.4168	0.71	0.2389	1.21	0.1131	1.71	0.0436	2.21	0.0136	2.71	0.0034	3.21	6.64E-04
0.22	0.4129	0.72	0.2358	1.22	0.1112	1.72	0.0427	2.22	0.0132	2.72	0.0033	3.22	6.41E-04

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z	Area	z	Area	z	Area	z	Area	z	Area	z	Area	z	Area
0.23	0.4090	0.73	0.2327	1.23	0.1093	1.73	0.0418	2.23	0.0129	2.73	0.0032	3.23	6.19E-04
0.24	0.4052	0.74	0.2296	1.24	0.1075	1.74	0.0409	2.24	0.0125	2.74	0.0031	3.24	5.98E-04
0.25	0.4013	0.75	0.2266	1.25	0.1056	1.75	0.0401	2.25	0.0122	2.75	0.0030	3.25	5.77E-04
0.26	0.3974	0.76	0.2236	1.26	0.1038	1.76	0.0392	2.26	0.0119	2.76	0.0029	3.26	5.57E-04
0.27	0.3936	0.77	0.2206	1.27	0.1020	1.77	0.0384	2.27	0.0116	2.77	0.0028	3.27	5.38E-04
0.28	0.3897	0.78	0.2177	1.28	0.1003	1.78	0.0375	2.28	0.0113	2.78	0.0027	3.28	5.19E-04
0.29	0.3859	0.79	0.2148	1.29	0.0985	1.79	0.0367	2.29	0.0110	2.79	0.0026	3.29	5.01E-04
0.30	0.3821	0.80	0.2119	1.30	0.0968	1.80	0.0359	2.30	0.0107	2.80	0.0026	3.30	4.83E-04
0.31	0.3783	0.81	0.2090	1.31	0.0951	1.81	0.0351	2.31	0.0104	2.81	0.0025	3.31	4.67E-04
0.32	0.3745	0.82	0.2061	1.32	0.0934	1.82	0.0344	2.32	0.0102	2.82	0.0024	3.32	4.50E-04
0.33	0.3707	0.83	0.2033	1.33	0.0918	1.83	0.0336	2.33	0.0099	2.83	0.0023	3.33	4.34E-04
0.34	0.3669	0.84	0.2005	1.34	0.0901	1.84	0.0329	2.34	0.0096	2.84	0.0023	3.34	4.19E-04
0.35	0.3632	0.85	0.1977	1.35	0.0885	1.85	0.0322	2.35	0.0094	2.85	0.0022	3.35	4.04E-04
0.36	0.3594	0.86	0.1949	1.36	0.0869	1.86	0.0314	2.36	0.0091	2.86	0.0021	3.36	3.90E-04
0.37	0.3557	0.87	0.1922	1.37	0.0853	1.87	0.0307	2.37	0.0089	2.87	0.0021	3.37	3.76E-04
0.38	0.3520	0.88	0.1894	1.38	0.0838	1.88	0.0301	2.38	0.0087	2.88	0.0020	3.38	3.62E-04
0.39	0.3483	0.89	0.1867	1.39	0.0823	1.89	0.0294	2.39	0.0084	2.89	0.0019	3.39	3.50E-04
0.40	0.3446	0.90	0.1841	1.40	0.0808	1.90	0.0287	2.40	0.0082	2.90	0.0019	3.40	3.37E-04
0.41	0.3409	0.91	0.1814	1.41	0.0793	1.91	0.0281	2.41	0.0080	2.91	0.0018	3.41	3.25E-04
0.42	0.3372	0.92	0.1788	1.42	0.0778	1.92	0.0274	2.42	0.0078	2.92	0.0018	3.42	3.13E-04
0.43	0.3336	0.93	0.1762	1.43	0.0764	1.93	0.0268	2.43	0.0075	2.93	0.0017	3.43	3.02E-04
0.44	0.3300	0.94	0.1736	1.44	0.0749	1.94	0.0262	2.44	0.0073	2.94	0.0016	3.44	2.91E-04
0.45	0.3264	0.95	0.1711	1.45	0.0735	1.95	0.0256	2.45	0.0071	2.95	0.0016	3.45	2.80E-04
0.46	0.3228	0.96	0.1685	1.46	0.0721	1.96	0.0250	2.46	0.0069	2.96	0.0015	3.46	2.70E-04
0.47	0.3192	0.97	0.1660	1.47	0.0708	1.97	0.0244	2.47	0.0068	2.97	0.0015	3.47	2.60E-04
0.48	0.3156	0.98	0.1635	1.48	0.0694	1.98	0.0239	2.48	0.0066	2.98	0.0014	3.48	2.51E-04
0.49	0.3121	0.99	0.1611	1.49	0.0681	1.99	0.0233	2.49	0.0064	2.99	0.0014	3.49	2.42E-04

Appendix C

Control Limit Formulas

VARIABLES CHARTS

$\bar{x}$ and R chart: Averages chart: $\bar{\bar{x}} \pm A_2\bar{R}$ Range chart: LCL = $D_3\bar{R}$ UCL = $D_4\bar{R}$

$\bar{x}$ and s chart: Averages chart: $\bar{\bar{x}} \pm A_3\bar{s}$ Std. dev. chart: LCL = $B_3\bar{s}$ UCL = $B_4\bar{s}$

Individuals and moving range chart (two-value moving window):

Individuals chart: $\bar{x} \pm 2.66\bar{R}$ Moving range: UCL = $3.267\bar{R}$

Moving average and moving range (two-value moving window):

Moving average: $\bar{\bar{x}} \pm 1.88\bar{R}$ Moving range: UCL = $3.267\bar{R}$

ATTRIBUTES CHARTS

p chart : $\bar{p} \pm 3\sqrt{\dfrac{\bar{p}(1-\bar{p})}{n}}$

np chart : $n\bar{p} \pm 3\sqrt{n\bar{p}(1-\bar{p})}$

c chart : $\bar{c} \pm 3\sqrt{\bar{c}}$

u chart : $\bar{u} \pm 3\sqrt{\dfrac{\bar{u}}{n}}$

Appendix D

Factors for Control Charts

	Chart for averages			Chart for standard deviations					
Obs	Factors for control limits			Factors for central line		Factors for control limits			
n	A	A_2	A_3	c_4	$1/c_4$	B_3	B_4	B_5	B_6
2	2.121	1.881	2.659	0.7979	1.2533	0	3.267	0	2.606
3	1.732	1.023	1.954	0.8862	1.1284	0	2.568	0	2.276
4	1.500	0.729	1.628	0.9213	1.0854	0	2.266	0	2.088
5	1.342	0.577	1.427	0.9400	1.0638	0	2.089	0	1.964
6	1.225	0.483	1.287	0.9515	1.0509	0.030	1.970	0.029	1.874
7	1.134	0.419	1.182	0.9594	1.0424	0.118	1.882	0.113	1.806
8	1.061	0.373	1.099	0.9650	1.0362	0.185	1.815	0.179	1.751
9	1.000	0.337	1.032	0.9693	1.0317	0.239	1.761	0.232	1.707
10	0.949	0.308	0.975	0.9727	1.0281	0.284	1.716	0.276	1.669
11	0.905	0.285	0.927	0.9754	1.0253	0.321	1.679	0.313	1.637
12	0.866	0.266	0.886	0.9776	1.0230	0.354	1.646	0.346	1.610
13	0.832	0.249	0.850	0.9794	1.0210	0.382	1.618	0.374	1.585
14	0.802	0.235	0.817	0.9810	1.0194	0.406	1.594	0.399	1.563
15	0.775	0.223	0.789	0.9823	1.0180	0.428	1.572	0.421	1.544
16	0.750	0.212	0.763	0.9835	1.0168	0.448	1.552	0.440	1.526
17	0.728	0.203	0.739	0.9845	1.0157	0.466	1.534	0.458	1.511
18	0.707	0.194	0.718	0.9854	1.0148	0.482	1.518	0.475	1.496
19	0.688	0.187	0.698	0.9862	1.0140	0.497	1.503	0.490	1.483
20	0.671	0.180	0.680	0.9869	1.0132	0.510	1.490	0.504	1.470
21	0.655	0.173	0.663	0.9876	1.0126	0.523	1.477	0.516	1.459
22	0.640	0.167	0.647	0.9882	1.0120	0.534	1.466	0.528	1.448
23	0.626	0.162	0.633	0.9887	1.0114	0.545	1.455	0.539	1.438
24	0.612	0.157	0.619	0.9892	1.0109	0.555	1.445	0.549	1.429
25	0.600	0.153	0.606	0.9896	1.0105	0.565	1.435	0.559	1.420

Continued

Continued

	Chart for ranges						
Obs	Factors for central line			Factors for control limits			
n	d_2	$1/d_2$	d_3	D_1	D_2	D_3	D_4
2	1.128	0.8865	0.853	0	3.686	0	3.267
3	1.693	0.5907	0.888	0	4.358	0	2.575
4	2.059	0.4857	0.880	0	4.698	0	2.282
5	2.326	0.4299	0.864	0	4.918	0	2.114
6	2.534	0.3946	0.848	0	5.079	0	2.004
7	2.704	0.3698	0.833	0.205	5.204	0.076	1.924
8	2.847	0.3512	0.820	0.388	5.307	0.136	1.864
9	2.970	0.3367	0.808	0.547	5.394	0.184	1.816
10	3.078	0.3249	0.797	0.686	5.469	0.223	1.777
11	3.173	0.3152	0.787	0.811	5.535	0.256	1.744
12	3.258	0.3069	0.778	0.923	5.594	0.283	1.717
13	3.336	0.2998	0.770				
14	3.407	0.2935	0.763				
15	3.472	0.2880	0.756				
16	3.532	0.2831	0.750				
17	3.588	0.2787	0.744				
18	3.640	0.2747	0.739				
19	3.689	0.2711	0.733				
20	3.735	0.2677	0.729				
21	3.778	0.2647	0.724				
22	3.819	0.2618	0.720				
23	3.858	0.2592	0.716				
24	3.895	0.2567	0.712				
25	3.931	0.2544	0.708				

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Glossary

A

Ac—See *acceptance number*.

acceptable process level (APL)—The process level that forms the outer boundary of the zone of acceptable processes. (A process located at the APL will have only a *probability of rejection* designated *a* when the plotted statistical measure is compared to the acceptance control limits.)

Note: In the case of two-sided tolerances, upper and lower acceptable process levels will be designated UAPL and LAPL, respectively. (These need not be symmetrical around the standard level.)

acceptance (control chart or acceptance control chart usage)—A decision that the *process* is operating in a satisfactory manner with respect to the *statistical measure* being plotted.

acceptance control chart—A *control chart* intended primarily to evaluate whether or not the plotted measure can be expected to satisfy specified *tolerances*.

acceptance control limit (ACL)—*Control limits* for an *acceptance control chart* that permit some assignable shift in process level based on specified requirements, provided within-*subgroup* variability is in a *state of statistical control*.

acceptance number (Ac)—The largest number of *nonconformities* or nonconforming items found in the *sample* by *acceptance sampling inspection by attributes* that permit the acceptance of the lot as given in the *acceptance sampling plan*.

acceptance quality limit (AQL)—The AQL is the *quality* level that is the worst tolerable product average when a continuing series of lots is submitted for *acceptance sampling*.

Note 1: This concept only applies when an *acceptance sampling scheme* with rules for switching and for discontinuation is used.

Note 2: Although individual lots with quality as bad as the acceptance quality limit can be accepted with fairly high probability, the designation of an acceptance quality limit does not suggest that this is a desirable quality level.

Note 3: *Acceptance sampling schemes* found in standards, with their rules for switching and for discontinuation of sampling inspection, are designed to

encourage suppliers to have process averages consistently better than the acceptance quality limit. If suppliers fail to do so, there is a high probability of being switched from *normal inspection* to *tightened inspection*, where *lot* acceptance becomes more difficult. Once on tightened inspection, unless corrective action is taken to improve product quality, it is very likely that the rule requiring discontinuance of sampling inspection will be invoked.

Note 4: The use of the abbreviation AQL to mean acceptable quality level is no longer recommended since modern thinking is that no fraction defective is really acceptable. Using "acceptance quality limit" rather than "acceptable quality level" indicates a technical value where acceptance occurs.

acceptance sampling—A sampling after which decisions are made to accept or not to accept a *lot*, or other grouping of products, materials, or services, based on sample results.

acceptance sampling inspection—An acceptance *inspection* where the acceptability is determined by sampling *inspection*.

acceptance sampling inspection by attributes—An *acceptance sampling inspection* whereby the presence or absence of specified *characteristics* of each item in a sample is observed to statistically establish the acceptability of a *lot* or *process*.

acceptance sampling inspection by variables—An *acceptance sampling inspection* in which the acceptability of a *process* is determined statistically from measurements on specified quality *characteristics* of each item in a *sample* from a *lot*.

Note: Lots taken from an acceptable process are assumed to be acceptable.

acceptance sampling inspection system—A collection of *acceptance sampling plans* or *acceptance sampling schemes* together with criteria by which appropriate plans or schemes may be chosen.

acceptance sampling plan—A plan that states the *sample size(s)* to be used and the associated criteria for *lot* acceptance.

acceptance sampling procedure—The operational requirements and/or instructions related to the use of a particular *acceptance sampling plan*.

Note: This covers the planned method of selection, withdrawal, and preparation of *sample(s)* from a *lot* to yield knowledge of the *characteristic(s)* of the lot.

acceptance sampling scheme—The combination of *acceptance sampling plans* with *switching rules* for changing from one plan to another.

acceptance sampling system—A collection of sampling schemes.

accessibility—A measure of the relative ease of admission to the various areas of an item for the purpose of operation or maintenance.

accreditation—Certification, by a duly recognized body, of the facilities, capability, objectivity, competence, and integrity of an agency, service, or operational group or individual to provide the specific service or operation needed. For

example, the Exemplar Global (U.S.) accredits those organizations that register companies to the ISO 9000 series standards.

accuracy—The closeness of agreement between a test result or measurement result and the true value.

ACL—See *acceptance control limit*.

ACSI—The American Customer Satisfaction Index is an economic indicator, a cross-industry measure of the satisfaction of U.S. customers with the quality of the goods and services available to them—both those goods and services produced within the United States and those provided as imports from foreign firms that have substantial market shares or dollar sales.

action limits—The *control chart control limits* (for a process *in a state of statistical control*) beyond which there is a very high probability that a value is not due to chance. When a measured value lies beyond an action limit, appropriate corrective action should be taken on the process.

Example: Typical action limits for an $\bar{x}$ *chart* are $\pm 3\hat{\sigma}$ (three *standard deviations*).

action plan—The detailed plan to implement the actions needed to achieve strategic goals and objectives (similar to, but not as comprehensive as a project plan).

active listening—Paying attention solely to what others are saying (for example, rather than what you think of what they are saying or what you want to say back to them).

activity network diagram (AND)—See *arrow diagram*.

ADDIE—An instructional design model (analysis, design, development, implementation, and evaluation).

ad hoc team—See *temporary team*.

adult learning principles—Key principles about how adults learn that impact how education and training of adults should be designed.

affinity diagram—A management and planning tool used to organize ideas into natural groupings in a way that stimulates new, creative ideas. Also known as the KJ method.

agile approach—See *lean approach/lean thinking*.

AIAG—Automotive Industry Action Group.

alias—An *effect* that is completely confounded with another effect due to the nature of the designed experiment. Aliases are the results of *confounding*, which may or may not be deliberate.

α (alpha)—(1) The maximum probability, or risk, of making a *type I error* when dealing with the *significance level* of a test; (2) The *probability* or risk of incorrectly deciding that a shift in the process mean has occurred when the process is

unchanged when referring to α in general or as the *p-value* obtained in a test; (3) α_i is usually designated as producer's risk.

alpha testing—In-house tests conducted on prototypes to ensure that the product is meeting requirements under controlled conditions. Usually done in the development stage.

alternative hypothesis, H_1—A hypothesis that is accepted if the *null hypothesis* (H_0) is disproved.

Example: Consider the null hypothesis that the statistical model for a *population* is a *normal distribution*. The alternative hypothesis to this null hypothesis is that the statistical model of the population is not a normal distribution.

Note 1: The alternative hypothesis is a statement that contradicts the null hypothesis. The corresponding test statistic is used to decide between the null and alternative hypotheses.

Note 2: The alternative hypothesis can be denoted H_1 or H_A with no clear preference as long as the symbolism parallels the null hypothesis notation.

analogies—A technique used to generate new ideas by translating concepts from one application to another.

analysis of covariance (ANCOVA)—A technique for estimating and testing the effects of treatments when one or more *concomitant variables* influence the *response variable*.

Note: Analysis of covariance can be viewed as a combination of *regression analysis* and *analysis of variance*.

analysis of variance (ANOVA)—A technique for determining if there are statistically significant differences between group means by analyzing group *variances*. An ANOVA is an analysis technique that evaluates the importance of several factors of a set of data by subdividing the variation into component parts. An analysis of variance table generally contains columns for:

- Source
- *Degrees of freedom*
- Sum of squares
- Mean square
- *F*-ratio or *F-test* statistic
- *p-value*
- Expected mean square

The basic assumptions are that the *effects* from the sources of *variation* are additive, and that the e*xperimental errors* are independent, normally distributed, and have equal *variances*. ANOVA tests the *hypothesis* that the within-group variation is homogeneous and does not vary from group to group. The *null hypothesis* is that the group means are equal to each other. The

alternative hypothesis is that at least one of the group means is different from the others.

analytical thinking—Breaking down a problem or situation into discrete parts to understand how each part contributes to the whole.

ANCOVA—See *analysis of covariance*.

andon board—A visual device (usually lights) displaying status alerts that can easily be seen by those who should respond.

ANOVA—See *analysis of variance*.

AOQ—See *average outgoing quality*.

AOQL—See *average outgoing quality limit*.

APL—See *acceptable process level*.

AQL—See *acceptance quality limit*.

arithmetic average—See *arithmetic mean*.

arithmetic mean—A calculation or estimation of the center of a set of values. It is the sum of the values divided by the number in the sum:

$$\overline{x} = \frac{1}{n}\sum_{i=1}^{n} x_i$$

where $\overline{x}$ is the arithmetic mean.

The average of a set of n observed values is the sum of the observed values divided by n:

$$\overline{x} = \frac{x_1 + x_2 + \ldots + x_n}{n}$$

See also *sample mean* and *population mean*.

ARL (average run length)—See *average run length*.

arrow diagram—A management and planning tool used to develop the best possible schedule and appropriate controls to accomplish the schedule; the critical path method (CPM) and the program evaluation review technique (PERT) make use of arrow diagrams.

AS9100—An international quality management standard for the aeronautics industry embracing the ISO 9001 standard.

ASME—American Society of Mechanical Engineers.

ASN—See *average sample number*.

ASQ—American Society for Quality, a society of individual and organizational members dedicated to the ongoing development, advancement, and promotion of quality concepts, principles, and technologies.

assessment—An estimate or determination of the significance, importance, or value of something.

assignable cause—A specifically identified factor that contributes to *variation* and is feasible to detect and identify. Eliminating assignable causes so that the points plotted on a *control chart* remain within the *control limits* helps achieve a *state of statistical control*.

Note: Although assignable cause is sometimes considered synonymous with *special cause*, a special cause is assignable only when it is specifically identified. See also *special cause*.

ASTD—American Society for Training and Development.

ASTM—American Society for Testing and Materials.

ATF—Bureau of Alcohol, Tobacco, Firearms and Explosives.

ATI—See *average total inspection*.

attribute—A countable or categorized quality *characteristic* that is *qualitative* rather than *quantitative* in nature. Attribute data come from *discrete*, *nominal*, or *ordinal scales*. Examples of attribute data are irregularities or flaws in a sample and results of pass/fail tests.

attributes control chart—A *Shewhart control chart*, where the measure plotted represents countable or categorized data.

attributes data—"Does/does not exist" data. The control charts based on attribute data include fraction defective chart, number of affected units chart, count chart, count-per-unit chart, quality score chart, and demerit chart.

attributes, inspection by—See *inspection by attributes*.

audit—A planned, independent, and documented assessment to determine whether agreed-on requirements are being met.

auditee—The individual or organization being audited.

auditor—An individual or organization carrying out an audit.

audit team—The group of trained individuals conducting an audit under the direction of a team leader, relevant to a particular product, process, service, contract, or project.

autocorrelation—The internal *correlation* between members of a series of observations ordered in time.

Note: Autocorrelation can lead to misinterpretation of *runs* and trends in *control charts*.

autonomation—Use of specially equipped automated machines capable of detecting a defect in a single part, stopping the process, and signaling for assistance. See also *jidoka*.

availability—(1) The ability of a product to be in a state to perform its designated function under stated conditions at a given time. Availability can be expressed by the ratio

$$\frac{\text{uptime}}{\text{total time}}$$

(2) A measure of the degree to which an item is in the operable and committable state at the start of the mission when the mission is called for at an unknown (random) time.

average—The *arithmetic mean*.

average outgoing quality (AOQ)—The expected average quality level of outgoing product for a given value of incoming product quality.

Note: Unless otherwise specified, the AOQ is calculated over all accepted *lots* plus all nonaccepted lots after the latter have been 100% inspected and the nonconforming items replaced by conforming items. An approximation often used is AOQ equals incoming *process* quality multiplied by the *probability of acceptance*. This formula is exact for accept-zero plans and overestimates other plans.

average outgoing quality limit (AOQL)—The maximum *average outgoing quality* over all possible values of incoming product quality level for a given *acceptance sampling plan*, and rectification of all nonaccepted *lots* unless specified otherwise.

average run length (ARL)—The expected number of samples (or *subgroups*) plotted on a *control chart* up to and including the decision point that a *special cause* is present. The choice of ARL is a compromise between taking action when the process has not changed (ARL too small) or not taking action when a special cause is present (ARL too large).

average sample number (ASN)—The average number of sample *units* per *lot* used for making decisions (acceptance or nonacceptance).

average total inspection (ATI)—The average number of items inspected per lot, including *100% inspection* of items in nonaccepted *lots*.

Note: Applicable when the procedure calls for 100% inspection of nonaccepted lots.

B

balanced design—A design where all *treatment* combinations have the same number of observations. If *replication* in a design exists, it would be balanced only if the replication was consistent across all the treatment combinations. In other words, the number of replicates of each treatment combination is the same.

balanced incomplete block design—An *incomplete block design* in which each *block* contains the same number (k) of different *levels* from the (l) *levels* of the principal *factor* arranged so that every pair of *levels* occurs in the same number (l) of *blocks* from the b *blocks*.

Note: This design implies that every *level* of the principal *factor* appears the same number of times in the experiment.

balanced scorecard—Translates an organization's mission and strategy into a comprehensive set of performance measures to provide a basis for strategic measurement and management, typically using four balanced views: financial, customers, internal business processes, and learning and growth.

batch—A definite quantity of product accumulated under conditions considered uniform, or accumulated from a common source. This term is sometimes synonymous with *lot*.

batch processing—Running large batches of a single product through the process at one time, resulting in queues awaiting next steps in the process.

bathtub curve—Also called life history curve or Weibull curve. A graphic demonstration of the relationship of failures over the life of a product versus the probable failure rate. Includes three phases: early or infant failure (break-in), a stable rate during normal use, and wear-out.

behavioral theories—Motivational theories, notably those of Abraham Maslow, Frederick Herzberg, Douglas McGregor, and William Ouchi.

benchmarking—An improvement process in which a company measures its performance against that of best-in-class companies (or others who are good performers), determines how those companies achieved their performance levels, and uses the information to improve its own performance. The areas that can be benchmarked include strategies, operations, processes, and procedures.

β (beta)—(1) The maximum *probability*, or risk, of making a *type II error*. See comment on α (*alpha*); (2) The probability or risk of incorrectly deciding that a shift in the *process mean* has not occurred when the process has changed; (3) β is usually designated as *consumer's risk*. See *power curve*.

beta testing—The final test before the product is released to the commercial market. Beta testers are existing customers.

bias—Inaccuracy in a *measurement system* that occurs when the *mean* of the measurement result is consistently or systematically different than its *true value*.

bimodal—A probability distribution having two distinct statistical modes.

binomial confidence interval (one sample)—To construct $100(1-\alpha)\%$ *confidence intervals* on the parameter p of a binomial distribution, if n is large and $p \le 0.1$. For instance,

$$\hat{p} - z_{\alpha/2}\sqrt{\frac{\hat{p}(1-\hat{p})}{n}} \le p \le \hat{p} + z_{\alpha/2}\sqrt{\frac{\hat{p}(1-\hat{p})}{n}}$$

where the unbiased point estimator of p is

$$\hat{p} = x / n.$$

If n is small, then tables of the *binomial distribution* should be used to establish the confidence interval on p. If n is large but p is small, then the Poisson approximation to the binomial is useful in constructing confidence intervals.

binomial confidence interval (two sample)—If there are two binomial parameters of interest, p_1 and p_2, then an approximate $100(1-\alpha)\%$ *confidence interval on the difference is*

$$\hat{p}_1 - \hat{p}_2 - z_{\alpha/2}\sqrt{\frac{\hat{p}_1(1-\hat{p}_1)}{n_1} + \frac{\hat{p}_2(1-\hat{p}_2)}{n_2}} \le p_1 - p_2 \le \hat{p}_1 - \hat{p}_2 + z_{\alpha/2}\sqrt{\frac{\hat{p}_1(1-\hat{p}_1)}{n_1} + \frac{\hat{p}_2(1-\hat{p}_2)}{n_2}}$$

where

$$\hat{p}_1 = x_1/n_1 \text{ and } \hat{p}_2 = x_2/n_2.$$

binomial distribution—A two-parameter discrete distribution involving the *mean* (μ) and the *variance* (σ^2) of the variable x with *probability* p where p is a constant, $0 \le p \le 1$, and sample size n. Mean = np and variance = $np(1-p)$.

blemish—An *imperfection* that causes awareness but does not impair function or usage.

block—A collection of *experimental units* more homogeneous than the full set of experimental units. Blocks are usually selected to allow for *special causes*, in addition to those introduced as *factors* to be studied. These special causes may be avoidable within blocks, thus providing a more homogeneous experimental subspace.

block diagram—A diagram that shows the operation, interrelationships, and interdependencies of components in a system. Boxes, or blocks (hence the name), represent the components; connecting lines between the blocks represent interfaces. There are two types of block diagrams: a functional block diagram, which shows a system's subsystems and lower-level products, their interrelationships, and interfaces with other systems; and a reliability block diagram, which is similar to the functional block diagram except that it is modified to emphasize those aspects influencing reliability.

block effect—An *effect* resulting from a *block* in an *experimental design*. Existence of a block effect generally means that the method of blocking was appropriate.

blocking—The method of including *blocks* in an experiment in order to broaden the applicability of the conclusions or to minimize the impact of selected *assignable causes*. The randomization of the experiment is restricted and occurs within blocks.

body language—The expression of thoughts and emotions through movement or positioning of the body.

Box–Behnken design—A type of *response surface design* constructed by judicious combination of 2^k *factorial designs* with *balanced incomplete block designs*. It is

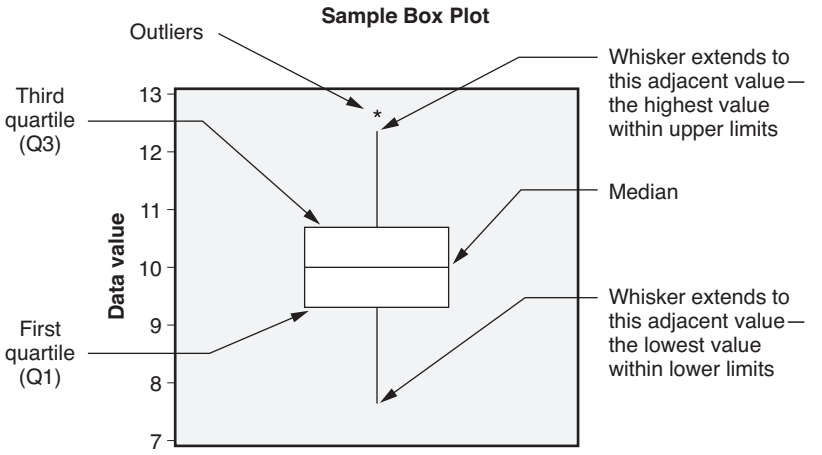
most useful when it is difficult to have more than three *levels* of a *factor* in an experiment or when trying to avoid extreme combinations of *factor levels*.

box plot—Box plots, which are also called box-and-whisker plots, are particularly useful for showing the distributional characteristics of data. A box plot consists of a box, whiskers, and *outliers*. A line is drawn across the box at the *median*. By default, the bottom of the box is at the *first quartile* (Q1) and the top is at the *third quartile* (Q3) value. The whiskers are the lines that extend from the top and bottom of the box to the adjacent values. The adjacent values are the lowest and highest observations that are still inside the region defined by the following limits:

$$\text{Lower limit: } Q1 - 1.5\,(Q3 - Q1)$$

$$\text{Upper limit: } Q3 + 1.5\,(Q3 - Q1)$$

Outliers are points outside of the lower and upper limits, and usually are plotted with asterisks (*).



BPR—Business process reengineering. See *reengineering*.

brainstorming—A problem-solving tool that teams use to generate as many ideas as possible related to a particular subject. Team members begin by offering all their ideas; the ideas are not discussed or reviewed until after the brainstorming session.

breakthrough—A method of solving chronic problems that results from the effective execution of a strategy designed to reach the next level of quality. Such change often requires a paradigm shift within the organization.

burn-in—The operation of an item under stress to stabilize its characteristics.

business partnering—The creation of cooperative business alliances between constituencies within an organization or between an organization and its customers or suppliers. Partnering occurs through a pooling of resources in a trusting atmosphere focused on continuous, mutual improvement. See also *customer–supplier partnership*.

business processes—Processes that focus on what the organization does as a business and how it goes about doing it. A business has functional processes (generating output within a single department) and cross-functional processes (generating output across several functions or departments).

business process management (BPM)—A disciplined approach to *analyze*, *identify*, *design*, *execute*, *document*, *measure*, *monitor*, *improve*, and *control* both automated and nonautomated business processes to achieve consistent, *targeted results aligned* with an organization's *strategic goals*.

C

***c* (count)**—The number of *events* (often *nonconformities*) of a given classification occurring in a *sample* of fixed size. A *nonconforming unit* may have more than one nonconformity.

Example: *Blemishes* per 100 meters of rubber hose. Counts are *attribute* data. See *c-chart*.

CAB—Corrective Action Board.

capability—(1) The performance of a *process* demonstrated to be in a *state of statistical control*. See *process capability* and *process performance*. (2) A measure of the ability of an item to achieve mission objectives given the conditions during the mission.

capability index—See *process capability index*.

capability ratio (C_p)—Is equal to the specification tolerance width divided by the process capability.

cascading training—Training implemented in an organization from the top down, where each level acts as trainers to those below.

case study—A prepared scenario (story) that, when studied and discussed, serves to illuminate the learning points of a course of study.

cause—A cause is an identified reason for the presence of a symptom, *defect*, or problem. See *effect* and *cause-and-effect diagram*.

cause-and-effect diagram—A tool for analyzing process variables. It is also referred to as the Ishikawa diagram, because Kaoru Ishikawa developed it, or the fishbone diagram, because the complete diagram resembles a fish skeleton. The diagram illustrates the main causes and sub-causes leading to an effect (symptom). The cause-and-effect diagram is one of the seven basic tools of quality.

CBT—Computer-based training. Training delivered via computer software.

***c*-chart (count chart)**—An *attributes control chart* that uses *c* (*count*) or number of *events* as the plotted values where the opportunity for occurrence is fixed. Events, often *nonconformities*, of a particular type form the count. The fixed opportunity relates to samples of constant size or a fixed amount of material.

Examples include flaws in each 100 square meters of fabric, errors in each 100 invoices, or number of absentees per month:

$$\text{Central line: } \bar{c}$$

$$\text{Control limits: } \bar{c} \pm 3\sqrt{\bar{c}}$$

where $\bar{c}$ is the *arithmetic mean* of the number of events.

Note: If the *lower control limit* calculates ≤ 0, there is no lower control limit. See also *u chart*, a count chart where the opportunity for occurrence is variable.

cell—A layout of workstations and/or various machines for different operations (usually in a U shape) in which multitasking operators proceed with a part from machine to machine to perform a series of sequential steps to produce a whole product or major subassembly.

cellular team—The cross-trained individuals who work within a cell.

center line—See *central line*.

central line—A line on a *control chart* representing the long-term *average* or a standard value of the *statistical measure* plotted. The central line calculation for each type of *control chart* is given under the specific control chart term; that is, for the *individuals control chart*, the central line is $\bar{x}$.

certification—The receipt of a document from an authorized source stating that a device, process, or operator has been certified to a known standard.

chain acceptance sampling inspection—An *acceptance sampling inspection* in which the criteria for acceptance of the current *lot* are governed by the sampling results of that *lot* and those of a specified number of the preceding consecutive lots.

chain reaction—A series of interacting events described by W. Edwards Deming: improve quality > decrease costs > improve productivity > increase market share with better quality and lower price > stay in business, provide jobs, and provide more jobs.

chaku–chaku—(Japanese) Meaning load–load in a cell layout, where a part is taken from one machine and loaded into the next.

champion—An individual who has accountability and responsibility for many processes or who is involved in making strategic-level decisions for the organization. The champion ensures ongoing dedication of project resources and monitors strategic alignment (also referred to as a sponsor).

chance cause—See *random cause*.

chance variation—See *random cause*.

change agent—The person who takes the lead in transforming a company into a quality organization by providing guidance during the planning phase, facilitating implementation, and supporting those who pioneer the changes.

change management—The strategies, processes, and practices involved in creating and managing change.

changeover—Changing a machine or process from one type of product or operation to another.

characteristic—A distinguishing feature or inherent property of a product, *process*, or system related to a requirement. A property that helps to differentiate between items of a given *sample* or *population*. The differentiation may be either *quantitative* (by *variable*) or *qualitative* (by *attribute*).

charter—A documented statement officially initiating the formation of a committee, team, project, or other effort in which a clearly stated purpose and approval is conferred.

checklist—A tool for organizing and ensuring that all important steps or actions in an operation have been taken. Checklists contain items that are important or relevant to an issue or situation. Checklists should not be confused with check sheets and data sheets.

checkout—Tests or observations of an item to determine its condition or status.

check sheet—A simple data-recording device. The check sheet is custom designed for the particular use, allowing ease in interpreting the results. The check sheet is one of the seven basic tools of quality. Check sheets should not be confused with data sheets and checklists.

χ^2 (chi-square) distribution—A positively skewed distribution that varies with the *degrees of freedom* with a minimum value of zero.

χ^2 (chi-square) statistic—A value obtained from the χ^2 *distribution* at a given percentage point and a given *degree of freedom*.

χ^2 (chi-square) test—A *statistic* used in testing a *hypothesis* concerning the discrepancy between *observed* and expected results.

chronic problem—A long-standing adverse situation that can be remedied by changing the status quo. For example, actions such as revising an unrealistic manufacturing process or addressing customer defections can change the status quo and remedy the situation.

clearance number—As associated with a *continuous sampling plan*, the number of successively inspected units of product that must be found acceptable during the *100% inspection* sequence before action to change the amount of inspection can be taken. The clearance number is often designated as *i*.

coaching—A continual improvement technique by which people receive one-to-one learning through demonstration and practice and that is characterized by immediate feedback and correction.

code of conduct—The expected behavior that has been mutually developed and agreed on by a team.

code of ethics—A guide for ethical behavior of the members of ASQ and those individuals who hold certification in its various divisions.

coefficient of determination (R^2)—A measure of the part of the *variance* for one *variable* that can be explained by its linear relationship with another variable (or variables). The coefficient of determination is the square of the correlation between the observed y values and the fitted y values, and is also the fraction of the variation in y that is explained by the fitted equation. It is a percentage between zero and 100, with higher values indicating a stronger degree of the combined linear relationship of several predictor variables $x_1, x_2, \ldots x_p$ to the *response variable Y*. See also *regression analysis*.

coefficient of variation (CV)—This measures relative dispersion. It is the *standard deviation* divided by the *mean* and is commonly reported as a percentage.

comment cards—Printed cards or slips of paper used to solicit and collect comments from users of a service or product.

commercial/industrial market—Refers to business market customers who are described by variables such as location, NAICS code, buyer industry, technological sophistication, purchasing process, size, ownership, and financial strength.

common cause—See *random cause*.

common causes of variation—Causes that are inherent in any process all the time. A process that has only common causes of variation is said to be stable or predictable or in control. Also called chance causes.

competence—Refers to a person's ability to learn and perform a particular activity. Competence consists of knowledge, experience, skills, aptitude, and attitude components (KESAA factors).

competency-based training—A training methodology that focuses on building mastery of a predetermined segment or module before moving on to the next.

complaint handling—The process and practices involved in receiving and resolving complaints from customers.

complete block—A *block* that accommodates a complete set of *treatment* combinations.

completely randomized design—A design in which the *treatments* are assigned at random to the full set of *experimental units*. No *blocks* are involved in a *completely randomized design*.

completely randomized factorial design—A *factorial design* in which all the *treatments* are assigned at random to the full set of *experimental units*. See *completely randomized design*.

compliance—An affirmative indication or judgment that the supplier of a product or service has met the requirements of the relevant specifications, contract, or regulation; also, the state of meeting the requirements.

computer-based instruction—Any instruction delivered via a computer.

concomitant variable—A *variable* or *factor* that cannot be accounted for in the data analysis or design of an experiment but whose *effect* on the results should be

accounted for. For example, the *experimental units* may differ in the amount of some chemical constituent present in each unit, which can be measured, but not adjusted. See *analysis of covariance*.

confidence coefficient (1—α)—See *confidence level*.

confidence interval—A confidence interval is an estimate of the interval between two *statistics* that includes the *true value* of the *parameter* with some probability. This probability is called the *confidence level* of the estimate. Confidence levels typically used are 90%, 95%, and 99%. The interval either contains the parameter or it does not. See *z-confidence interval*, *t-confidence interval*.

confidence level (confidence coefficient [1 − α])—(1) The *probability* that the *confidence interval* described by a set of *confidence limits* actually includes the population parameter; (2) The probability that an interval about a sample *statistic* actually includes the population parameter.

confidence limits—The endpoints of the interval about the sample *statistic* that is believed, with a specified *confidence level*, to include the population parameter. See *confidence interval*.

configuration management (CM)—A discipline and a system to control changes that are made to hardware, software, firmware, and documentation throughout a system's life cycle.

conflict resolution—A process for resolving disagreements in a manner acceptable to all parties.

conformance—An affirmative indication or judgment that a product or service has met the requirements of a relevant specification, contract, or regulation.

confounding—Indistinguishably combining an *effect* with other effects or *blocks*. When done deliberately, higher-order effects are systematically *aliased* so as to allow estimation of lower-order effects. Sometimes confounding results are from inadvertent changes to a design during the running of an experiment, or poor planning of the design. This can diminish or even invalidate the effectiveness of the experiment.

consensus—Finding a proposal acceptable enough that all team members can support the decision and no member opposes it.

consistency—See *precision*.

consultative—A decision-making approach in which a person talks to others and considers their input before making a decision.

consumer market customers—End users of a product or service.

consumer's risk (β)—The *probability of acceptance* when the quality level has a value stated by the *acceptance sampling plan* as unsatisfactory.

Note 1: Such acceptance is a *type II error*.

Note 2: Consumer's risk is usually designated as β (*beta*).

continual process improvement—Includes the actions taken throughout an organization to increase the effectiveness and efficiency of activities and processes in order to provide added benefits to the customer and

organization. It is considered a subset of total quality management and operates according to the premise that organizations can always make improvements. Continual improvement can also be equated with reducing process variation.

continuous distribution—A distribution where data are from a *continuous scale*. Examples of continuous scales include the *normal*, *t*, and *F* distributions.

continuous quality improvement (CQI)—A philosophy and actions for repeatedly improving an organization's capabilities and processes with the objective of customer satisfaction.

continuous sampling plan—An *acceptance sampling inspection* applicable to a continuous-flow process, which involves acceptance or nonacceptance on an item-by-item basis and uses alternative periods of *100% inspection* and sampling, depending on the quality of the observed process output.

continuous scale—A scale with a continuum of possible values.

Note: A continuous scale can be transformed into a *discrete scale* by grouping values, but this leads to some loss of information.

contrast—Linear function of the *response values* for which the sum of the coefficients is zero with not all coefficients equal to zero. Questions of logical interest from an experiment may be expressed as contrasts with carefully selected coefficients.

contrast analysis—A technique for estimating the *parameters* of a *model* and making *hypothesis* tests on preselected linear combinations of the *treatments* or *contrasts*.

control chart—A chart that plots a *statistical measure* of a series of *samples* in a particular order to steer the *process* regarding that measure and to control and reduce variation.

Note 1: The order is usually time- or sample number order–based.

Note 2: The control chart operates most effectively when the measure is a process *characteristic* correlated with an ultimate product or service characteristic.

control chart, acceptance—See *acceptance control chart*.

control chart, standard given—A *control chart* whose *control limits* are based on adopted standard values applicable to the *statistical measures* plotted on the chart.

Note 1: Standard values are adopted at any time for computing the control limits to be used as criteria for action in the immediate future or until additional evidence indicates need for revision.

Note 2: This type of control chart is used to discover whether *observed values* differ from standard values by an amount greater than chance. An example of this use is to establish and verify an *internal reference material*.

Note 3: The subscript zero is used for standard chart parameters, that is, $\bar{x}_0$, $\bar{y}_0$, R_0.

control chart factor—A factor, usually varying with *sample size*, that converts specified statistics or parameters into *control limits* or a *central line* value.

Note: Common control chart factors for *Shewhart control charts* are d_2, A_2, D_3, and D_4. See $\bar{x}$ *chart* and *range*.

control factor—In *robust parameter design*, a *control factor* is a *predictor variable* that is controlled as part of the standard experimental conditions. In general, inference is made on control factors while *noise factors* are allowed to vary to broaden the conclusions.

control limit—A line on a *control chart* used for judging the stability of a *process*.

Note 1: Control limits provide statistically determined boundaries for the *deviations* from the *central line* of the statistic plotted on a *Shewhart control chart* due to *random causes* alone.

Note 2: Control limits (with the exception of the *acceptance control chart*) are based on actual process data, not on *specification limits*.

Note 3: Other than points outside of *control limits*, out-of-control criteria can include *runs*, trends, cycles, periodicity, and unusual patterns within the control limits.

Note 4: The control limit calculation for each type of control chart is given under the specific control chart term, that is, for the *individuals control chart* under calculation of its control limits.

control plan—(1) A document describing the system elements to be applied to control *variation* of *processes*, products, and services in order to minimize deviation from their preferred values; (2) A document, or documents, that may include the characteristics for quality of a product or service, measurements, and methods of control.

corrective action—Action taken to eliminate the root cause(s) and symptom(s) of an existing deviation or nonconformity to prevent recurrence.

correlation—Correlation measures the linear association between two variables. It is commonly measured by the *correlation coefficient r*. See also *regression*.

correlation coefficient (*r*)—A number between –1 and 1 that indicates the degree of linear relationship between two sets of numbers:

$$r = \frac{s_{xy}}{s_x s_y} = \frac{n\Sigma xy - \Sigma y}{\sqrt{\left[n\Sigma x^2 - (\Sigma x)^2 - (\Sigma y)^2\right]}}$$

where s_x is the *standard deviation* of x, s_y is *standard deviation* of y, and s_{xy} is the *covariance* of x and y.

Correlation coefficients of –1 and +1 represent perfect linear agreement between two variables; $r = 0$ implies no linear relationship at all. If r is positive, y increases as x increases. In other words, if a *linear regression equation* were fit, the *linear regression coefficient* would be positive. If r is negative, y decreases as

x increases. In other words, if a linear regression equation were fit, the linear regression coefficient would be negative.

cost of quality (COQ)—The total costs incurred relating to the quality of a product or service. There are four categories of quality costs: internal failure costs (costs associated with defects found before delivery of the product or service), external failure costs (costs associated with defects found during or after product or service delivery), appraisal costs (costs incurred to determine the degree of conformance to quality requirements), and prevention costs (costs incurred to keep failure and appraisal costs to a minimum).

covariance—This measures the relationship between pairs of observations from two variables. It is the sum of the products of *deviations* of pairs of variables in a random *sample* from their sample means divided by the number in the sum minus one.

$$\text{Sample covariance} = \frac{1}{n-1}\sum_{i=1}^{n}(x_i - \bar{x})(y_i - \bar{y}),$$

where $\bar{x}$ is the sample *mean* for the first sample and $\bar{y}$ is the sample mean for the second sample.

Note: Using $n - 1$ provides an unbiased estimator of the *population* covariance. When the covariance is standardized to cover a range of values from –1 to 1, it is more commonly known as the *correlation coefficient*.

C_p (process capability index)—An index describing *process capability* in relation to specified *tolerance* of a *characteristic* divided by a measure of the length of the *reference interval* for a process in a *state of statistical control*:

$$C_p = \frac{U - L}{6\sigma}$$

where *U* is upper specification limit, *L* is lower *specification limit*, and 6σ is the process capability.

See also P_p, a similar term, except that the *process* may not be in a *state of statistical control*.

C_{pk} (minimum process capability index)—An index that represents the smaller of C_{pkU} (*upper process capability index*) and C_{pkL} (*lower process capability index*).

C_{pkL} (lower process capability index, CPL)—An index describing *process capability* in relation to the lower *specification limit*:

$$C_{pk_L} = \frac{\mu - L}{3\sigma}$$

where σ = process average, *L* = lower specification limit, and 3σ = half of the *process capability*.

C_{pkU} (upper process capability index; CPU)—An index describing *process capability* in relation to the upper *specification limit*:

$$C_{pk_U} = \frac{U - \mu}{3\sigma}$$

where μ = process average, U = upper specification limit, and 3σ = half of the *process capability*.

CPM—See *critical path method*.

C_{pm} (process capability index of the mean)—An index that takes into account the location of the mean, defined as

$$C_{pm} = \frac{(U - L)/2}{3\sqrt{\sigma^2 + (\mu - T)^2}}$$

where U = upper *specification limit*, L = lower specification limit, σ = *standard deviation*, μ = expected value, and T = *target value*.

CQPA—Certified Quality Process Analyst.

critical path—Refers to the sequence of tasks that takes the longest time and determines a project's completion date.

critical path method (CPM)—An activity-oriented project management tool that uses arrow-diagramming techniques to demonstrate both the time and cost required to complete a project. It provides one time estimate—normal time—and allows for computing the critical path.

critical thinking—The careful analysis, evaluation, reasoning (both deductive and inductive), clear thinking, and systems thinking leading to effective decisions.

crossed design—A design where all the *factors* are crossed with each other. See *crossed factor*.

crossed factor—Two *factors* are crossed if every *level* of one factor occurs with every level of the other in an experiment.

cross-functional team—A group consisting of members from more than one department or work unit that is organized to accomplish a project.

CSR—Customer service representative.

cumulative frequency distribution—The sum of the frequencies accumulated up to the upper boundary of a class in a distribution.

cumulative sum chart (CUSUM chart)—The CUSUM *control chart* calculates the cumulative sum of *deviations* from *target* to detect shifts in the level of the measurement. The CUSUM chart can be graphical or numerical. In the graphical form, a V-mask indicates action: whenever the CUSUM trace moves outside the V-mask, take control action. The numerical (or electronic) form

computes CUSUM from a selected bias away from target value and has a fixed *action limit*. Additional tests for abnormal patterns are not required.

curtailed inspection—An *acceptance sampling procedure* that contains a provision for stopping inspection when it becomes apparent that adequate data have been collected for a decision.

curvature—The departure from a straight-line relationship between the *response variable* and *predictor variable*. Curvature has meaning with *quantitative* predictor variables, but not with *categorical* (nominal) or *qualitative* (ordinal) predictor variables. Detection of curvature requires more than two *levels* of the *factors* and is often done using *center points*.

customer—Recipient of a product or service provided by a supplier. See *external customer* and *internal customer*.

customer delight—The result achieved when customer requirements are exceeded in unexpected ways the customer finds valuable.

customer loyalty/retention—The result of an organization's plans, processes, practices, and efforts designed to deliver their services or products in ways that create retained and committed customers.

customer-oriented organization—An organization whose mission, purpose, and actions are dedicated to serving and satisfying its customers.

customer relationship management (CRM)—An organization's knowledge of its customers' unique requirements and expectations, and use of that knowledge to develop a closer and more profitable link to business processes and strategies.

customer satisfaction—The result of delivering a product or service that meets customer requirements, needs, and expectations.

customer segmentation—The process of differentiating customers based on one or more dimensions for the purpose of developing a marketing strategy to address specific segments.

customer service—The activities of dealing with customer questions; also sometimes the department that takes customer orders or provides post-delivery services.

customer–supplier partnership—A long-term relationship between a buyer and supplier characterized by teamwork and mutual confidence. The supplier is considered an extension of the buyer's organization. The partnership is based on several commitments. The buyer provides long-term contracts and uses fewer suppliers. The supplier implements quality assurance processes so that incoming inspection can be minimized. The supplier also helps the buyer reduce costs and improve product and process designs.

customer value—The market-perceived quality adjusted for the relative price of a product.

CUSUM chart—See *cumulative sum chart*.

CV—See *coefficient of variation*.

CWQC—Companywide quality control.

cycle time—Refers to the time that it takes to complete a process from beginning to end.

cycle time reduction—To reduce the time that it takes, from start to finish, to complete a particular process.

D

D—The smallest shift in *process* level that it is desired to detect, stated in terms of original units.

data integrity—Refers to the completeness, consistency, and accuracy of data. Complete, consistent, and accurate data should be attributable, legible, contemporaneously recorded, original or a true copy, and accurate (ALCOA). Data integrity is critical throughout the CGMP data life cycle, including in the creation, modification, processing, maintenance, archival, retrieval, transmission, and disposition of data after the record's retention period ends. System design and controls should enable easy detection of errors, omissions, and aberrant results throughout the data's life cycle.

data pedigree—Documentation of the origins and history of a data set, including its technical meaning, background on the process that produced it, the original collection of samples, measurement processes used, and the subsequent handling of the data, including any modifications or deletions made, through the present.

data reliability—The consistency of the data over time, across data types and across different operators measuring the data.

data validity—The extent to which the scores from a measure represent the variable they are intended to.

debugging—A process to detect and remedy inadequacies.

decision matrix—A matrix used by teams to evaluate problems or possible solutions. For example, after a matrix is drawn to evaluate possible solutions, the team lists them in the far-left vertical column. Next, the team selects criteria to rate the possible solutions, writing them across the top row. Then, each possible solution is rated on a scale of 1 to 5 for each criterion and the rating is recorded in the corresponding grid. Finally, the ratings of all the criteria for each possible solution are added to determine its total score. The total score is then used to help decide which solution deserves the most attention.

defect—The nonfulfillment of a requirement related to an intended or specified use.

Note: The distinction between the concepts *defect* and *nonconformity* is important as it has legal connotations, particularly those associated with product liability issues. Consequently, the term *defect* should be used with extreme caution.

defective (defective unit)—A *unit* with one or more *defects*.

defining relation—Used for *fractional factorial designs*. It consists of *generators* that can be used to determine which *effects* are *aliased* with each other.

degrees of freedom (ν, df)—In general, the number of independent comparisons available to estimate a specific *parameter* that allows entry to certain statistical tables.

δ (delta lowercase)—The smallest shift in *process* level that it is desired to detect, stated in terms of the number of *standard deviations* from the *average*. It is given by

$$(\delta = D/\sigma)$$

where D is the size of the shift it is desired to detect and σ is the standard deviation.

Deming cycle—See *plan–do–check–act cycle*.

Deming Prize—Award given annually to organizations that, according to the award guidelines, have successfully applied companywide quality control based on statistical quality control and will keep up with it in the future. Although the award is named in honor of W. Edwards Deming, its criteria are not specifically related to Deming's teachings. There are three separate divisions for the award: the Deming Application Prize, the Deming Prize for Individuals, and the Deming Prize for Overseas Companies. The award process is overseen by the Deming Prize Committee of the Union of Japanese Scientists and Engineers in Tokyo.

demographics—Variables among buyers in the consumer market, which include geographic location, age, sex, marital status, family size, social class, education, nationality, occupation, and income.

demonstrated—That which has been measured by the use of objective evidence gathered under specified conditions.

dependability—A measure of the degree to which an item is operable and capable of performing its required function at any (random) time during a specified mission profile, given item availability at the start of the mission.

dependent variable—See *response variable*.

deployment—Term used in strategic planning to describe the process of cascading goals, objectives, and plans throughout an organization.

derating—(1) Using an item in such a way that applied stresses are below rated values, or (2) the lowering of the rating of an item in one stress field to allow an increase in rating in another stress field.

design for manufacturing (DFM)—The design of a product for ease in manufacturing. Also, design for assembly (DFA) is used.

design for Six Sigma (DFSS)—The aim is to produce a robust design that is consistent with applicable manufacturing processes and assures a fully capable process that will produce quality products.

design generator—See *generator*.

design of experiments (DOE, DOX)—The arrangement in which an experimental program is to be conducted, including the selection of *factor* combinations and their *levels*.

Note: The purpose of designing an experiment is to provide the most efficient and economical methods of reaching valid and relevant conclusions from the experiment. The selection of the design is a function of many considerations, such as the type of questions to be answered, the applicability of the conclusions, the homogeneity of *experimental units*, the *randomization* scheme, and the cost to run the experiment. A properly designed experiment will permit simple interpretation of valid results.

design resolution—See *resolution*.

design review—Documented, comprehensive, and systematic examination of a design to evaluate its capability to fulfill the requirements for quality.

design space—In design of experiments, the multidimensional region of possible *treatment* combinations formed by the selected *factors* and their *levels*.

desired quality—Refers to the additional features and benefits a customer discovers when using a product or service that lead to increased customer satisfaction. If missing, a customer may become dissatisfied.

deviation—The difference between a measurement (measurement usage) and its stated value or intended level.

deviation control—Deviation control involves *process* control, where the primary interest is detecting small shifts in the *mean*. Typical *control charts* used for this purpose are *CUSUM*, *EWMA*, and *Shewhart control charts* with *runs* rules. This type of control is appropriate in advanced stages of a quality improvement process. See also *threshold control*.

discrete distribution—A *probability distribution* where data are from a *discrete scale*. Examples of *discrete distributions* are the *binomial* and *Poisson* distributions. *Attribute* data involve discrete distributions.

discrete scale—A scale with only a set or sequence of distinct values. Examples: Defects per unit, events in a given time period, types of defects, number of orders on a truck.

discrimination—See *resolution*.

dispersion—A term synonymous with *variation*.

dispersion effect—The influence of a single *factor* on the *variance* of the *response variable*.

dissatisfiers—Those features or functions that the customer or employee has come to expect, and, if they were no longer present, would result in dissatisfaction.

distance learning—Learning where student(s) and instructor(s) are not colocated, often carried out through electronic means.

distribution—Depicts the amount of potential variation in outputs of a process; it is usually described in terms of its shape, average, and standard deviation.

DMAIC—A methodology used in the Six Sigma approach: define, measure, analyze, improve, control.

documentation control (DC)—A system used to track and store electronic documents and/or paper documents.

DOE—See *design of experiments*.

dot plot—A plot of a *frequency distribution* where the values are plotted on the *x*-axis. The *y*-axis is a count. Each time a value occurs, the point is plotted according to the count for the value.

double sampling—A multiple *acceptance sampling inspection* in which at most two *samples* are taken.

Note: The decisions are made according to defined rules.

downsizing—The planned reduction in workforce due to economics, competition, merger, sale, restructuring, or reengineering.

duplication—See *repeated measures*.

durability—A measure of useful life (a special case of reliability).

E

effect—(1) The result of taking an action; the expected or predicted impact when an action is to be taken or is proposed. An effect is the symptom, *defect*, or problem. See *cause* and *cause-and effect diagram*. (2) (design of experiments usage) A relationship between a *factor*(s) and a *response variable*(s). Specific types include *main effect*, *dispersion effect*, or *interaction effect*.

eighty–twenty (80–20) rule—A term referring to the Pareto principle, which suggests that most effects come from relatively few causes; that is, 80% of the effects come from 20% of the possible causes.

element—See *unit*.

employee involvement—A practice within an organization whereby employees regularly participate in making decisions on how their work areas operate, including making suggestions for improvement, planning, objectives setting, and monitoring performance.

empowerment—A condition whereby employees have the authority to make decisions and take action in their work areas, within stated bounds, without prior approval. For example, an operator can stop a production process upon detecting a problem, or a customer service representative can send out a replacement product if a customer calls with a problem.

end users—External customers who purchase products/services for their own use.

environmental analysis/scanning—Identifying and monitoring factors from both inside and outside the organization that may impact the long-term viability of the organization.

EPA—Environmental Protection Agency.

event—An occurrence of some *attribute* or outcome. In the quality field, events are often *nonconformities*.

evolutionary operation (EVOP)—A sequential form of experimentation conducted in production facilities during regular production. The range of variation of the *factor* levels is usually quite small in order to avoid extreme changes, so it often requires considerable *replication* and time. It is most useful when it would be difficult to do standard experimentation techniques like *factorial design*.

EVOP—See *evolutionary operation*.

EWMA—See *exponentially weighted moving average*.

EWMA chart—See *exponentially weighted moving average chart*.

excited quality—The additional benefit a customer receives when a product or service goes beyond basic expectations. Excited quality wows the customer and distinguishes the provider from the competition. If missing, the customer will still be satisfied.

executive education—Usually refers to the education (and training) provided to top management.

expected quality—Also known as basic quality, the minimum benefit or value a customer expects to receive from a product or service.

experiment space—See *design space*.

experimental design—See *design of experiments*.

experimental error—The variation in the *response variable* beyond that accounted for by the *factors*, *blocks*, or other assignable sources in the conduct of an experiment.

experimental plan—The assignment of *treatments* to an *experimental unit*, and the time order in which the *treatments* are to be applied.

experimental run—A single performance of an experiment for a specific set of *treatment* combinations.

experimental unit—The smallest entity receiving a particular *treatment*, subsequently yielding a value of the *response variable*.

experimentation—See *design of experiments*.

explanatory variable—See *predictor variable*.

exploratory data analysis (EDA)—Exploratory data analysis isolates patterns and features of the data and reveals these forcefully to the analyst.

exponential distribution—A continuous distribution where data are more likely to occur below the average than above it. Typically used to describe the break-in portion of the bathtub curve.

exponentially weighted moving average (EWMA)—A *moving average* that is not greatly influenced when a small or large value enters the calculation:

$$w_t = \lambda x_i + (1-\lambda) w_{t-1}$$

where w_t is the exponentially weighted moving average (EWMA) at the present time t, λ (*lambda*) is a defined or experimentally determined weighting factor, x_i is the observed value at time t, and w_{t-1} is the EWMA at the immediately preceding time interval.

exponentially weighted moving average chart (EWMA chart)—A *control chart* where each new result is averaged with the previous *average* value using an experimentally determined weighting factor, λ. Usually only the averages are plotted and the *range* is omitted. The action *signal* is a single point out of limits. The advantage of the EWMA chart compared to the *MA chart* is that the average does not jump when an extreme value leaves the moving average. The weighting factor λ can be determined by an effective time period. Additional tests are not appropriate because of the high correlation between successive averages.

$$\text{Control limits} : \bar{\bar{X}}_0 \pm 3\sigma_{w_t}$$

$$\text{Center line} : \bar{\bar{X}}_0$$

external audit—An audit performed by independent and impartial auditors who are not members of the audit team.

external customer—A person or organization who receives a product, a service, or information but is not part of the organization supplying it. See also *internal customer*.

F

$F_{v1, v2}$—*F-test* statistic. See *F-test*.

facilitator—An individual who is responsible for creating favorable conditions that will enable a team to reach its purpose or achieve its goals by bringing together the necessary tools, information, and resources to get the job done. A facilitator addresses the processes a team uses to achieve its purpose.

factor—A *predictor variable* that is varied with the intent of assessing its *effect* on a *response variable*.

factor level—See *level*.

factorial design—An *experimental design* consisting of all possible *treatments* formed from two or more *factors*, each studied at two or more *levels*. When

all combinations are run, the *interaction effects* as well as *main effects* can be estimated. See also 2^k *factorial design*.

failure—The event, or inoperable state, in which an item or part of an item does not, or would not, perform as previously specified.

failure, dependent—Failure that is caused by the failure of an associated item(s). Not independent.

failure, independent—Failure that occurs without being caused by the failure of any other item. Not dependent.

failure, random—Failure whose occurrence is predictable only in a probabilistic or statistical sense. This applies to all distributions.

failure analysis—Subsequent to a failure, the logical systematic examination of an item, its construction, application, and documentation to identify the failure mode and determine the failure mechanism and its basic course.

failure mechanism—The physical, chemical, electrical, thermal, or other process that results in failure.

failure mode—The consequence of the mechanism through which the failure occurs, such as short, open, fracture, excessive wear.

failure mode analysis (FMA)—A procedure to determine which malfunction symptoms appear immediately before or after a failure of a critical parameter in a system. After all the possible causes are listed for each symptom, the product is designed to eliminate the problems.

failure mode and effects analysis (FMEA)—A procedure in which each potential failure mode in every subitem of an item is analyzed to determine its effect on other subitems and on the required function of the item. Typically, two types of FMEAs are used: DFMEA (design) and PFMEA (process).

failure rate—The total number of failures within an item population divided by the total number of life units expended by that population during a particular measurement interval under stated conditions.

FDA—Food and Drug Administration.

***F* distribution**—A *continuous distribution* that is a useful reference for assessing the ratio of independent *variances*. See *variance, tests for*.

feedback—The response to information received in interpersonal communication (written or oral); it may be based on fact or feeling and helps the party who is receiving the information judge how well he or she is being understood by the other party. Generally, feedback is information about a process or performance and is used to make decisions that are directed toward improving or adjusting the process or performance as necessary.

feedback loops—Pertains to open-loop and closed-loop feedback. Open-loop feedback focuses on how to detect or measure problems in the inputs and how to plan for contingencies. Closed-loop feedback focuses on how to measure the outputs and how to determine the control points where adjustment can be made.

filters—Relative to human-to-human communication, those perceptions (based on culture, language, demographics, experience, and so on) that affect how a message is transmitted by the sender and how a message is interpreted by the receiver.

finding—A conclusion of importance based on observation(s) and/or research. Example: An audit finding.

first-article testing—Tests a production process to demonstrate process capability and that tooling meets the quality standard.

fishbone diagram—See *cause-and-effect diagram*.

fitness for use—A term used to indicate that a product or service fits the customer's defined purpose for that product or service.

five S's—Five practices for maintaining a clean and efficient workplace (Japanese).

five why's—A repetitive questioning technique for probing deeper to surface the root cause of a problem.

fixed factor—A *factor* that only has a limited number of *levels* that are of interest. In general, inference is not made to other levels of fixed factors not included in the experiment. For example, if a manufacturing environment has three milling machines to be used in the experiment. See also *random factor.*

fixed model—A *model* that contains only *fixed factors*.

flowchart—A graphical representation of the steps in a process. Flowcharts are drawn to better understand processes. The flowchart is one of the seven basic tools of quality.

focus group—A qualitative discussion group consisting of 8 to 10 participants, invited from a segment of the customer base to discuss an existing or planned product or service, led by a facilitator working from predetermined questions (focus groups may also be used to gather information in a context other than customers).

fourteen (14) points—W. Edwards Deming's 14 management practices to help organizations increase their quality and productivity:

1. Create constancy of purpose for improving products and services
2. Adopt a new philosophy
3. Cease dependence on inspection to achieve quality
4. End the practice of awarding business on price alone; instead, minimize total cost by working with a single supplier
5. Improve constantly and forever every process for planning, production, and service
6. Institute training on the job
7. Adopt and institute leadership
8. Drive out fear

9. Break down barriers between staff areas
10. Eliminate slogans, exhortations, and targets for the workforce
11. Eliminate numerical quotas for the workforce and numerical goals for management
12. Remove barriers that rob people of pride of workmanship and eliminate the annual rating or merit system
13. Institute a vigorous program of education and self-improvement for everyone
14. Put everybody in the company to work to accomplish the transformation

fractional factorial design—An *experimental design* consisting of a subset (fraction) of the *factorial design*. Typically, the fraction is a simple proportion of the full set of possible *treatment* combinations. For example, half-fractions, quarter-fractions, and so forth, are common. While fractional factorial designs require fewer runs, some degree of *confounding* occurs.

frequency—The number of occurrences or *observed values* in a specified class, *sample*, or *population*.

frequency distribution—A set of all the various values that individual observations may have and the *frequency* of their occurrence in the *sample* or *population*. See *cumulative frequency distribution*.

***F*-test**—A statistical test that uses the *F distribution*. It is most often used when dealing with a *hypothesis* related to the ratio of independent *variances*:

$$F = \frac{s_L^2}{s_s^2}$$

where s_L^2 is the larger variance and s_S^2 is the smaller variance. See *analysis of variance*.

fully nested design—See *nested design*.

G

***g* chart**—An *attributes control chart* based on a shifted *geometric distribution* for the number of occurrences of a given *event* per *unit* of *process* output. The *g* chart is for the total number of events:

$$\text{Center line (CL): } \overline{t}$$

$$\text{Upper control limit (UCL): } \overline{t} + k\sqrt{n\left(\frac{\overline{t}}{n} - \alpha\right)\left(\frac{\overline{t}}{n} - \alpha + 1\right)}$$

$$\text{Lower control limit (LCL): } \overline{t} - k\sqrt{n\left(\frac{\overline{t}}{n} - \alpha\right)\left(\frac{\overline{t}}{n} - \alpha + 1\right)}$$

where a is the known minimum possible number of events, n is the *sample size*, k is the σ multiplier (for example, 3σ), and $\bar{t}$ is the average total number of events per *subgroup*. The calculation for $\bar{t}$ is

$$\bar{t} = \frac{t_1 + t_2 + \ldots + t_r}{r}$$

where $t_1 + t_2 + \ldots + t_r$ is the total number of events occurring in each subgroup and r is the number of subgroups. (Note that r is not the correlation coefficient r used elsewhere in this glossary.) The g chart is commonly used in healthcare and hospital settings. See h *chart* for the average number of events chart.

gage R&R study—A type of *measurement system analysis* done to evaluate the performance of a test method or *measurement system*. Such a study quantifies the capabilities and limitations of a measurement instrument, often estimating its *repeatability* and *reproducibility*. It typically involves multiple operators measuring a series of items or multiple times.

Gantt chart—A type of bar chart used in process/project planning and control to display planned work and finished work in relation to time. Also called a milestone chart when interim checkpoints are added.

gap analysis—A technique that compares a company's existing state to its desired state (as expressed by its long-term plans) to help determine what needs to be done to remove or minimize the gap.

gatekeeping—The role of an individual (often a facilitator) in a group meeting in helping ensure effective interpersonal interactions (for example, someone's ideas are not ignored due to the team moving on to the next topic too quickly).

Gaussian distribution—See *normal distribution*.

generator—In *design of experiments*, a generator is used to determine the level of *confounding* and the pattern of *aliases* in a *fractional factorial design*.

geometric distribution—A case of the *negative binomial distribution* where $c = 1$ (c is the integer parameter). The geometric distribution is a *discrete distribution*.

goal—A statement of general intent, aim, or desire; it is the point toward which management directs its efforts and resources; goals are usually nonquantitative.

Graeco-Latin square design—An extension of a *Latin square design* that involves four *factors* in which the combination of the *level* of any one of them with the *levels* of the other three appears once and only once.

groupthink—Occurs when most or all team members coalesce in supporting an idea or decision that hasn't been fully explored, or when some members secretly disagree but go along with the other members in apparent support.

H

***h* chart**—An *attributes control chart* based on a shifted *geometric distribution* for the number of occurrences of a given *event* per unit of *process* output. The *h* chart is for the *average* number of events:

$$\text{Center line (CL): } \overline{t}$$

$$\text{Upper control limit (UCL): } \frac{\overline{t}}{n} + \frac{k}{\sqrt{n}}\sqrt{n\left(\frac{\overline{t}}{n} - \alpha\right)\left(\frac{\overline{t}}{n} - \alpha + 1\right)}$$

$$\text{Lower control limit (LCL): } \frac{\overline{t}}{n} - \frac{k}{\sqrt{n}}\sqrt{n\left(\frac{\overline{t}}{n} - \alpha\right)\left(\frac{\overline{t}}{n} - \alpha + 1\right)}$$

where a is the known minimum possible number of events, n is the *sample size*, k is the σ multiplier (for example, 3σ), and $\overline{t}$ is the average total number of events per *subgroup*. The calculation for $\overline{t}$ is

$$\overline{t} = \frac{t_1 + t_2 + \ldots + t_r}{r}$$

where $t_1 + t_2 + \ldots + t_r$ is the total number of events occurring in each subgroup and r is the number of subgroups. (Note that r is not the correlation coefficient r used elsewhere in this glossary.) The *h* chart is commonly used in healthcare and hospital settings. See g *chart* for the total number of events chart.

H_0—See *null hypothesis*.

H_1—See *alternative hypothesis*.

H_A—See *alternative hypothesis*.

hierarchical design—See *nested design*.

histogram—A plot of a *frequency distribution* in the form of rectangles (cells) whose bases are equal to the class interval and whose areas are proportional to the frequencies. The pictorial nature of the histogram lets people see patterns that are difficult to see in a simple table of numbers. The histogram is one of the seven basic tools of quality.

hoshin kanri, hoshin planning—Japanese-based strategic planning/policy deployment process that involves consensus at all levels as plans are cascaded throughout the organization, resulting in actionable plans and continual monitoring and measurement.

Hotelling's T^2—See T^2.

house of quality—A diagram (named for its house-shaped appearance) that clarifies the relationship between customer needs and product features. It helps correlate market or customer requirements and analysis of competitive products with higher-level technical and product characteristics and makes it possible to bring several factors into a single figure. Also known as quality function deployment (QFD).

hypothesis—A statement about a *population* to be tested. See *null hypothesis*, *alternative hypothesis*, and *hypothesis testing*.

hypothesis testing—A statistical *hypothesis* is a conjecture about a *population parameter*. There are two statistical hypotheses for each situation—the *null hypothesis* (H_0) and the *alternative hypothesis* (H_1). The null hypothesis proposes that there is no difference between the population of the sample and the specified population; the alternative hypothesis proposes that there is a difference between the sample and the specified population. See *moving average*.

I

i—See *moving average*.

***I* chart (individuals control chart)**—See *individuals control chart*.

imprecision—A measure of *precision* computed as a *standard deviation* of the test or measurement results. Less precision is reflected by a larger standard deviation.

incomplete block—A *block* that accommodates only a subset of *treatment* combinations. See *balanced incomplete block design*.

incomplete block design—A design in which the *design space* is subdivided into *blocks* in which there are insufficient *experimental units* available to run a complete *replicate* of the experiment.

in-control process—A condition where the existence of *special causes* is no longer indicated by a *Shewhart control chart*. It indicates (within limits) a predictable and *stable process*, but it does not indicate that only *random causes* remain; nor does it imply that the distribution of the remaining values is normal Gaussian.

independent variable—See *predictor variable*.

indicators—Predetermined measures used to measure how well an organization is meeting its customers' needs and its operational and financial performance objectives. Such indicators can be either leading or lagging indicators. Indicators are also devices used to measure lengths or flow.

indifference quality level—The quality level that, in an *acceptance sampling plan*, corresponds to a *probability of acceptance* of 0.5 when a continuing series of *lots* is considered.

indifference zone—The region containing quality levels between the *acceptance quality limit* and the *limiting quality level*.

indirect customers—Customers who do not receive process output directly but are affected if the process output is incorrect or late.

individual development—A process that may include education and training, but also includes many additional interventions and experiences to enable an individual to grow and mature both intellectually as well as emotionally.

individuals control chart (*x* chart; *I* chart)—A *variables control chart* with individual values plotted in the form of a *Shewhart control chart* for individuals and *subgroup* size $n = 1$.

Note 1: The x chart is widely used in the chemical industry because of cost of testing, test turnaround time, and the time interval between independent samples.

Note 2: This chart is usually accompanied by a *moving range chart*, commonly with $n = 2$.

Note 3: An individual chart sacrifices the advantages of averaging subgroups (and the assumptions of the *normal distribution* central limit theorem) to minimize *random variation*:

$$\text{Center line(CL)} : \bar{x} (x_0 \text{ if standard given})$$

$$\text{Control limits} : \bar{x} \pm E_2 \, \bar{M}\bar{R} \text{ or } \bar{x} \pm E_3 \bar{s} \text{ (if standard given, } x_0 \pm 3s_0)$$

where $\bar{x}$ is the average of the individual variables

$$\bar{x} = \frac{x_1 + x_2 + \ldots + x_n}{n}$$

where R is the range, $\bar{s}$ is average sample standard deviation, x_0 is the standard value for the average, and σ_0 is the standard value for the population standard deviation. (Use the formula with $\bar{M}\bar{R}$ when the sample size is small, and the formula with $\bar{s}$ when the sample is larger, generally > 10 to 12.)

inherent process variation—The variation in a *process* when the process is operating in a *state of statistical control*.

inherent R and M value—A measure of reliability or maintainability that includes only the effects of an item design and its application and assumes an ideal operation and support environment.

input—Material, product, or service that is obtained from an upstream internal provider or an external supplier and is used to produce an output.

input variable—A variable that can contribute to the variation in a *process*.

inspection—Measuring, examining, testing, and gauging one or more characteristics of a product or service and comparing the results with specified requirements to determine whether conformity is achieved for each characteristic.

inspection, 100 percent—See *100 percent inspection*.

inspection, attributes—See *inspection by attributes*.

inspection, curtailed—See *curtailed inspection*.

inspection, normal—See *normal inspection*.

inspection, rectifying—See *rectifying inspection*.

inspection, reduced—See *reduced inspection*.

inspection, tightened—See *tightened inspection*.

inspection, variables—See *inspection by variables*.

inspection by attributes—An *inspection* noting the presence, or absence, of the *characteristic*(s) in each of the items in the group under consideration and counting how many items do, or do not, possess the *characteristic*(s), or how many such events occur in the *item*, group, or opportunity space.

Note: When *inspection* is performed by simply noting whether the item is nonconforming or not, the inspection is termed inspection for *nonconforming* items. When inspection is performed by noting the number of nonconformities on each *unit*, the inspection is termed inspection for number of nonconformities.

inspection by variables—An *inspection* measuring the magnitude(s) of the *characteristic*(s) of an item.

inspection level—An index of the relative amount of *inspection* of an *acceptance sampling scheme* chosen in advance and relating the *sample size* to the *lot* size.

Note 1: A lower/higher inspection level can be selected if experience shows that a less or more discriminating *operating characteristic curve* will be appropriate.

Note 2: The term should not be confused with severity of sampling, which concerns *switching rules* that operate automatically.

inspection lot—A collection of similar units or a specific quantity of similar material offered for inspection and subject to a decision with respect to acceptance.

interaction effect—The *effect* for which the apparent influence of one *factor* on the *response variable* depends on one or more other factors. Existence of an *interaction effect* means that the factors cannot be changed independently of each other.

interaction plot—The plot providing the *average* responses at the combinations of *levels* of two distinct *factors*.

interactive multimedia—A term encompassing technology that allows the presentation of facts and images with physical interaction by the viewer, for example, taking a simulated certification exam on a computer, or training embedded in transaction processing software.

intercept—See *regression analysis*.

intermediate customers—Distributors, dealers, or brokers who make products and services available to the end user by repairing, repackaging, reselling, or creating finished goods from components or subassemblies.

internal audit—An audit performed by impartial members of the organization being audited.

internal customer—The recipient (person or department) of another person's or department's output (product, service, or information) within an organization. See also *external customer*.

internal reference material—A reference material that is not traceable to a national body but is stable (within stated time and storage conditions), homogeneous, and appropriately characterized.

interrelationship digraph—A management and planning tool that displays the relationship between factors in a complex situation. It identifies meaningful categories from a mass of ideas and is useful when relationships are difficult to determine.

intervention—An action taken by a leader or a facilitator to support the effective functioning of a team or work group.

inventory, active—The group of items assigned an operational status.

inventory, inactive—The group of items being held in reserve for possible future assignment to an operational status.

Ishikawa diagram—See *cause-and-effect diagram*.

isolated lot—A unique *lot*, or one separated from the sequence of *lots* in which it was produced or collected.

isolated sequence of lots—A group of *lots* produced in succession but not forming part of a large sequence or produced by a continuing *process*.

item—A nonspecific term used to denote any product, including systems, materials, parts, subassemblies, sets, accessories, and so on (*Source*: MIL-STD-280).

J

jidoka—Japanese method of autonomous control involving the adding of intelligent features to machines to start or stop operations as control parameters are reached, and to signal operators when necessary.

job aid—Any device, document, or other media that can be provided to a worker to aid in correctly performing tasks (for example, laminated setup instruction card hanging on machine, photos of product at different stages of assembly, or a metric conversion table).

job description—A narrative explanation of the work, responsibilities, and basic requirements of a job.

job enrichment—Increasing the worker's responsibilities and authority in work to be done.

job specification—A list of the important functional and quality attributes (knowledge, skills, aptitudes, and personal characteristics) needed to succeed in the job.

joint planning meeting—A meeting involving representatives of a key customer and the sales and service team for that account to determine how better to meet the customer's requirements and expectations.

Juran's trilogy—See *quality trilogy*.

just-in-time (JIT) manufacturing—An optimal material requirement planning system for a manufacturing process in which there is little or no manufacturing material inventory on hand at the manufacturing site and little or no incoming inspection.

just-in-time training—Providing job training coincidental with, or immediately prior to, an employee's assignment to a new or expanded job.

K

kaikaku—A Japanese term that means a breakthrough improvement in eliminating waste.

kaizen—A Japanese term that means gradual, unending improvement by doing little things better and setting and achieving increasingly higher standards. The term was made famous by Masaaki Imai in his book *Kaizen: The Key to Japan's Competitive Success*.

kaizen blitz/event—An intense, short time frame (typically three to five consecutive days), team approach to employ the concepts and techniques of continual improvement (for example, to reduce cycle time or increase throughput).

kanban—A system inspired by Taiichi Ohno's (Toyota) visit to a US supermarket. The system signals the need to replenish stock or materials or to produce more of an item (also called a pull approach).

Kano model—A representation of the three levels of customer satisfaction defined as dissatisfaction, neutrality, and delight. Named after Noriaki Kano.

kurtosis—A measure of peakedness or flattening of a distribution near its center in comparison to the *normal distribution*.

L

L—See *lower specification limit*.

λ (lambda)—The weighting factor in *EWMA* calculations where $0 < \lambda \leq 1$.

lateral thinking—A process that includes recognizing patterns, becoming unencumbered with old ideas, and creating new ones.

Latin square design—A design involving three *factors* in which the combination of the *levels* of any one of them with the levels of the other two appears once and only once. It is often used to reduce the impact of two blocking factors by balancing out their contributions. A basic assumption is that these block factors do not interact with the factor of interest or with each other. This design is particularly useful when the assumptions are valid for minimizing the amount of experimentation. See *Graeco-Latin square design*.

LCALI—A process for operating a listening-post system for capturing and using formerly unavailable customer data. LCALI stands for listen, capture, analyze, learn, and improve.

LCL—See *lower control limit*.

leader—An individual recognized by others as the person to lead an effort. One cannot be a leader without one or more followers. The term is often used interchangeably with "manager." A leader may or may not hold an officially designated management-type position.

leadership—An essential part of a quality improvement effort. Organization leaders must establish a vision, communicate that vision to those in the organization, and provide the tools, knowledge, and motivation necessary to accomplish the vision.

lean approach/lean thinking—A focus on reducing cycle time and waste using a number of different techniques and tools, for example, value stream mapping, and identifying and eliminating monuments and non-value-added steps. "Lean" and "agile" are often used interchangeably.

lean manufacturing—Applying the lean approach to improving manufacturing operations.

learner-controlled instruction—When a learner works without an instructor, at an individual pace, building mastery of a task. Computer-based training is a form of LCI. Also called self-directed learning.

learning curve—The time it takes to achieve mastery of a task or body of knowledge.

learning organization—An organization that has as a policy to continue to learn and improve its products, services, processes, and outcomes.

least squares, method of—A technique of estimating a *parameter* that minimizes the sum of the difference squared, where the difference is between the *observed value* and the predicted value (*residual*) derived from the *model*.

Note: *Experimental errors* associated with individual observations are assumed to be independent. The usual *analysis of variance*, *regression analysis*, and *analysis of covariance* are all based on the method of least squares.

lesson plan—A detailed plan created to guide an instructor in delivering training and/or education.

level—A potential setting, value, or assignment of a *factor* or the value of the *predictor variable*.

level of significance—See *significance level*.

life cycle—A product life cycle is the total time frame from product concept to the end of its intended use; a project life cycle is typically divided into five stages: concept, planning, design, implementation, evaluation, and closeout.

life units—A measure of duration applicable to the item, for example, operating hours, cycles, distance, rounds fired, attempts to operate.

limiting quality level (LQL)—The quality *level* that, for the purposes of *acceptance sampling inspection*, is the limit of an unsatisfactory process average when a continuing series of *lots* is considered.

Note: The LQL is sometimes referred to as the *rejectable quality level* (RQL), *unacceptable quality level* (UQL), or limiting quality (LQ), but limiting quality level is the preferred term.

linear regression—The mathematical application of the concept of a scatter diagram where the correlation is actually a cause-and-effect relationship.

linear regression coefficients—The values associated with each *predictor variable* in a *linear regression equation*. They tell how the *response variable* changes with each unit increase in the *predictor variable*. See *regression analysis*.

linear regression equation—A function that indicates the linear relationship between a set of *predictor variables* and a *response variable*. See *regression analysis*.

linearity (general sense)—The degree to which a pair of variables follows a straight-line relationship. Linearity can be measured by the *correlation coefficient*.

linearity (measurement system sense)—The difference in *bias* through the range of measurement. A measurement system that has good *linearity* will have a constant bias no matter the magnitude of measurement. If one views the relation between the observed measurement result on the *y*-axis and the *true value* on the *x*-axis, an ideal *measurement system* would have a line of slope equal to 1.

line balancing—A method of proportionately distributing workloads within the value stream to meet takt time.

line graph budget—A graphic representation of the planned and/or actual expenditures of a project's budget throughout the performance of the project life cycle.

lognormal distribution—If log x is normally distributed, it is a lognormal distribution. See *normal distribution*.

lot—A definite part of a population constituted under essentially the same conditions as the *population* with respect to the sampling purpose.

Note: The sampling purpose may, for example, be to determine lot acceptability or to estimate the mean value of a particular *characteristic*.

lot-by-lot—The *inspection* of a product submitted in a series of *lots*.

lot quality—A *statistical measure* of quality of the product from a given *lot*. These measures may relate to the occurrence of *events* or to physical measurements. For the purposes of this glossary, the most commonly used measure of lot quality is likely to be the percentage or proportion of *nonconforming units* in a *lot*.

lot size (N)—The number of items in a *lot*.

lot tolerance percent defective (LTPD)—When the percentage of *nonconforming units* is expressed as a percent defective, this may be referred to as the *lot tolerance percent defective* (LTPD).

lower control limit (LCL)—The *control chart* control limit that defines the lower control boundary.

lower specification limit (lower tolerance limit, L)—The *specification* or *tolerance limit* that defines the lower limiting value.

LQL—See *limiting quality level*.

LRPL—See *rejectable process level*.

LTPD—See note under *limiting quality level*.

M

MA chart—See *moving average chart*.

main effect—The influence of a single *factor* on the *mean* of a *response variable*.

main effects plot—A plot giving the *average* responses at the various *levels* of individual *factors*.

maintainability—The measure of the ability of an item to be retained or restored to specified condition when maintenance is performed by personnel having specified skill levels, using prescribed procedures and resources, at each prescribed level of maintenance and repair.

maintenance—All actions necessary for retaining an item in or restoring it to a specified condition.

maintenance, corrective—All actions performed, as a result of failure, to restore an item to a specified condition. Corrective maintenance can include any or all of the following steps: localization, isolation, disassembly, interchange, reassembly, alignment, and checkout.

maintenance, preventive—All actions performed in an attempt to retain an item in a specified condition by providing systematic inspection, detection, and prevention of incipient failures.

maintenance action rate—The reciprocal of the mean time between maintenance actions = 1/MTBMA.

maintenance time constraint (*t*)—The maintenance time that is usually prescribed as a requirement of the mission.

Malcolm Baldrige National Quality Award (MBNQA)—An award established by Congress in 1987 to raise awareness of quality management and to recognize U.S. companies that have implemented successful quality management systems. Criteria for Performance Excellence are published each year. Three awards may be given annually in each of five categories: manufacturing businesses, service businesses, small businesses, education institutions, and healthcare organizations. The award is named after the late Secretary of Commerce Malcolm Baldrige, a proponent of quality management. The US Commerce Department's National Institute of Standards and Technology manages the award, and ASQ administers it. The major emphasis in determining success is achieving results.

market-perceived quality—The customer's opinion of your products or services as compared to those of your competitors.

materials review board (MRB)—A quality control committee or team, usually employed in manufacturing or other materials-processing installations, that has the responsibility and authority to deal with items or materials that do not conform to fitness-for-use specifications. An equivalent, the error review board, is sometimes used in software development.

matrix chart/diagram—A management and planning tool that shows the relationships between various groups of data; it yields information about the relationships and the importance of task/method elements of the subjects.

mean—See *arithmetic mean*.

mean maintenance downtime (MDT)—Includes supply time, logistics time, administrative delays, active maintenance time, and so on.

mean maintenance time—The measure of item maintainability taking into account maintenance policy. The sum of preventive and corrective maintenance times, divided by the sum of scheduled and unscheduled maintenance events, during a stated period of time.

mean time between failures (MTBF)—A basic measure of reliability for repairable items: the mean number of life units during which all parts of the item perform within their specified limits, during a particular measurement interval, under stated conditions.

mean time between maintenance (MTBM)—A measure of reliability, taking into account maintenance policy: the total number of life units expended by a given time, divided by the total number of maintenance events (scheduled and unscheduled) due to that item.

mean time between maintenance actions (MTBMA)—A measure of the system reliability parameter related to demand for maintenance manpower: the total number of system life units, divided by the total number of maintenance actions (preventive and corrective) during a stated period of time.

mean time to failure (MTTF)—A basic measure of system reliability for non-repairable items: the total number of life units of an item, divided by the total number of failures within that population during a particular measurement interval, under stated conditions.

mean time to repair (MTTR)—A basic measure of maintainability: the sum of corrective maintenance times at any specific level of repair, divided by the total number of failures within an item repaired at that level during a particular interval, under stated conditions.

means, tests for—Testing for *means* includes computing a *confidence interval* and hypothesis testing by comparing means to a *population* mean (known or unknown) or to other *sample* means. Which test to use is determined by whether s is known, whether the test involves one or two samples, and other factors.

If s is known, the *z-confidence interval* and *z-test* apply. If s is unknown, the *t-confidence interval* and *t-test* apply.

measurement system—Everything that can introduce variability into the measurement *process*, such as equipment, operator, sampling methods, and accuracy.

measurement systems analysis (MSA)—A statistical analysis of a *measurement system* to determine the variability, *bias*, *precision*, and *accuracy* of the measurement system(s). Such studies may also include the limit of detection, selectivity, *linearity*, and other *characteristics* of the system in order to determine the suitability of the measurement system for its intended purpose.

median—The value for which half the *data* are larger and half are smaller. The median provides an estimator that is insensitive to very extreme values in a data set, whereas the *average* is affected by extreme values.

Note: For an odd number of units, the median is the middle measurement; for an even number of units, the median is the average of the two middle measurements.

mentor—A person who voluntarily assumes a role of trusted advisor and teacher to another person. The mentor may or may not be the mentored person's organizational superior or even in the same organization. Usually, the only reward the mentor receives is self-gratification in having helped someone else.

meta-analysis—The use of statistical methods to combine the results of multiple studies into a single conclusion.

method of least squares—See *least squares, method of*.

M_i—See *moving average*.

midrange—(Highest value + lowest value)/2.

mind mapping—A technique for creating a visual representation of a multitude of issues or concerns by forming a map of the interrelated ideas.

mission profile—A time-phased description of the events and environments an item experiences from initiation to completion of a specified mission, to include the criteria of mission success or critical failures.

mission statement—An explanation of purpose or reasons for existing as an organization; it provides the focus for the organization and defines its scope of business.

mistake-proofing—The use of *process* or design features to prevent manufacture of nonconforming product. See *poka-yoke*.

mixed model—A model where some *factors* are fixed, but other *factors* are random. See *fixed factors* and *random factors*.

mixed variables and attribute sampling—The *inspection* of a sample by *attributes*, in addition to *inspection by variables* already made of a previous *sample* from the *lot*, before a decision as to acceptability or rejectability of the lot can be made.

mixture design—A design constructed to handle the situation in which the *predictor variables* are constrained to sum to a fixed quantity, such as proportions of ingredients that make up a formulation or blend.

mode—The most frequent value of a *variable*.

model—The description relating a *response variable* to *predictor variable*(s) and including attendant assumptions.

model I analysis of variance (fixed model)—An analysis of variance in which the *levels* of all *factors* are fixed rather than random selections over the range of versions to be studied for those factors.

model II analysis of variance (random model)—An analysis of variance in which the *levels* of all *factors* are assumed to be selected at random over the range of versions to be studied for those factors.

moving average—Let x_1, x_2, . . . denote individual observations. The moving average of span w at time i is

$$M_i = \frac{x_i + x_{i-1} + \ldots + x_{i-w+1}}{w}$$

At time period i, the oldest observation in the moving average set is dropped and the newest one added to the set.

The variance, V, of the moving average M_i is

$$V(M_i) = \frac{1}{w^2} \sum_{j=1-w+1}^{i} V(x_i) = \frac{1}{w^2} \sum_{J=i-w+1}^{i} \sigma^2 = \frac{\sigma^2}{w}$$

moving average chart (MA chart)—A *variables control chart* where the simple unweighted *moving average* of the last w observations is plotted and provides a convenient substitute for the $\bar{x}$ *chart*. A fixed number of samples, w, is required for averaging, but the choice of the interval for w may be difficult to optimize. The control *signal* is a single point out of limits. Additional tests are not appropriate because of the high correlation introduced between successive averages that share several common values. The MA chart is sensitive to trends and is sometimes used in conjunction with *individuals charts* and/or *MR charts*. It is, however, probably less effective than either the *CUSUM* or *exponentially weighted moving average* (EWMA) chart for this purpose.

Note 1: This chart is particularly useful when only one observation per *subgroup* is available. Examples are process characteristics such as temperature, pressure, and time.

Note 2: This chart has the disadvantage of an unweighted carryover effect lasting w points.

$$\text{Each plotted point} : M_i = \frac{x_i + x_{i-1} + \ldots + x_{i-w+1}}{w}$$

where M_i is the moving range of span w at time i. At time period i, the oldest observation in the moving average set is dropped and the newest one is added to the set. For time periods where $i < w$, the average of the observations for periods 1, 2 . . . i is plotted. Example (where $w = 4$):

Observation, *i*	x_i	M_i
1	9.45	9.45
2	7.99	8.72
3	9.29	8.91
4	11.66	9.5975
5	12.16	10.275

$$\text{Central line: } \overline{x}$$

$$\text{Control limits: } \overline{x} \pm \frac{3\sigma}{\sqrt{w}}$$

where $\overline{x}$ is the average of the individual variables

$$\overline{x} = \frac{x_1 + x_2 + \ldots + x_n}{n}$$

where $\overline{n}$ is the total number of samples, σ the standard deviation, and w is the moving range span.

moving range chart (MR chart)—A *control chart* that plots the absolute difference between the current and previous value. It often accompanies an *individual's chart* or *moving average chart*.

Note: The current observation replaces the oldest of the latest $n + 1$ observations.

$$\text{Central line: } \overline{R}$$

$$\text{Control limits: UCL} = D_4\overline{R}$$

$$\text{LCL} = D_3\overline{R}$$

where D_4 and D_3 are *control chart factors*.

MRB—See *material review board*.

***MR* chart**—See *moving range chart*.

MSA—See *measurement systems analysis*.

μ (mu)—See *population mean*.

muda—(Japanese) An activity that consumes resources but creates no value; seven categories are correction, processing, inventory, waiting, overproduction, internal transport, and motion (waste).

multilevel continuous sampling—A continuous *acceptance sampling inspection* of consecutively produced items where two or more sampling inspection rates are either alternated with *100% inspection* or with each other, depending on the quality of the observed *process* output.

multimodal—A *probability distribution* having more than one mode. See *bimodal* and *trimodal*.

multiple acceptance sampling inspection—An *acceptance sampling inspection* in which, after each *sample* has been inspected, a decision is made based on defined decision rules to accept, not accept, or take another *sample*.

Note: For most multiple sampling plans, the largest number of samples that can be taken is specified, with an accept or not accept decision being forced at that point.

multiple linear regression—See *regression analysis*.

multivariate control chart—A variables *control chart* that allows plotting of more than one variable. These charts make use of the T^2 *statistic* to combine information from the *dispersion* and *mean* of several variables.

multivoting—A decision-making tool that enables a group to sort through a long list of ideas to identify priorities.

mystery shopper—A person who pretends to be a regular shopper in order to get an unencumbered view of how a company's service process works.

N

n—See *sample size*.

N—See *lot size*.

natural process limits—See *reference interval*.

natural team—A work group having responsibility for a particular process.

negative binomial distribution—A two-parameter, *discrete distribution*.

negotiation—A process where individuals or groups work together to achieve common goals under an agreement that assures that each party's values and priorities be addressed to reach a win-win result.

nested design—A design in which the second *factor* is nested within *levels* of the first factor, and each succeeding factor is nested within levels of the previous factor.

nested factor—A *factor* (A) is nested within another factor (B) if the *levels* of A are different for every level of B. See *crossed factor*.

next operation as customer—Concept that the organization has service/product providers and service/product receivers, or internal customers.

noise factor—In *robust parameter design*, a noise factor is a *predictor variable* that is hard to control or is not desired to control as part of the standard experimental conditions. In general, it is not desired to make inference on noise factors, but they are included in an experiment to broaden the conclusions regarding *control factors*.

nominal scale—A scale with unordered, labeled categories, or a scale ordered by convention. Examples: type of defect, breed of dog, complaint category.

Note: It is possible to count by category, but not order or measure.

nonconforming unit—A *unit* with one or more *nonconformities*.

nonconformity—The result of nonfulfillment of a specified requirement. See also *blemish*, *defect*, and *imperfection*.

nondestructive testing and evaluation (NDT)—Testing and evaluation methods that do not damage or destroy the product being tested.

non-value-added—Refers to tasks or activities that can be eliminated with no deterioration in product or service functionality, performance, or quality in the eyes of the customer.

normal distribution (Gaussian distribution)—A *continuous*, symmetrical *frequency distribution* that produces a bell-shaped curve. The location *parameter* (*x*-axis) is the *mean*, μ. The scale parameter, σ, is the *standard deviation* of the normal distribution. When measurements have a normal distribution, 68.26% of the values lie within plus or minus one standard deviation of the mean ($\mu \pm 1\sigma$), 95.44% lie within plus or minus two standard deviations of the mean ($\mu \pm 2\sigma$), while 99.73% lie within plus or minus three standard deviations of the mean ($\mu \pm 3\sigma$). The probability function is

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

where

$$-\infty < x < \infty \text{ and with parameters } -\infty < \mu < \infty \text{ and } \sigma > 0.$$

normal inspection—The inspection that is used when there is no reason to think that the quality level achieved by the *process* differs from a specified level. See *tightened inspection* and *reduced inspection*.

normal probability plot—See *probability plot*.

norms—Behavioral expectations, mutually agreed-on rules of conduct, protocols to be followed, social practice.

***np* (number of affected or categorized units)**—The total number of *units* in a *sample* in which an *event* of a given classification occurs. A unit (area of opportunity) is counted only once, even if several events of the same classification are encountered.

Note: In the quality field, the classification generally is number of *nonconforming units*.

***np* chart (number of categorized units control chart)**—An *attributes control chart* for number of *events* per unit where the opportunity is variable. (The *np* chart is for the number of nonconforming whereas the *p chart* is for the proportion nonconforming.)

Note: Events of a particular type, for example, number of absentees or number of sales leads, form the count. In the quality field, events are often expressed

as *nonconformities*, and the variable opportunity relates to *subgroups* of variable size or variable amounts of material. If a standard is given:

$$\text{Central line: } np$$

$$\text{Control limits: } np \pm 3\sqrt{np(1-p)}$$

where np is the standard value of the events per unit, and p is the standard value of the fraction nonconforming.

If no standard is given:

$$\text{Central line: } \overline{np}$$

$$\text{Control limits: } \overline{np} \pm 3\sqrt{\overline{np}(1-\overline{p})}$$

where $\overline{np}$ is the average value of the events per unit and $\overline{p}$ is the average value of the fraction nonconforming.

null hypothesis, H_0—The *hypothesis* in *tests of significance* that there is no difference (null) between the *population* of the *sample* and the specified population (or between the populations associated with each sample). The null hypothesis can never be proved true, but it can be shown (with specified risks or error) to be untrue, that is, a difference exists between the populations. If it is not disproved, one assumes there is no adequate reason to doubt it is true, and the null hypothesis is accepted. If the null hypothesis is shown to be untrue, then the *alternative hypothesis* is accepted. Example: In a random sample of independent random variables with the same *normal distribution* with unknown *mean* and unknown *standard deviation*, a typical null hypothesis for the mean, μ, is that the mean is less than or equal to a given value, μ_0. The hypothesis is written as $H_0 = \mu \leq \mu_0$.

O

objective—A quantitative statement of future expectations and an indication of when the expectations should be achieved; it flows from goals and clarifies what people must accomplish.

objective evidence—Verifiable qualitative or quantitative observations, information, records, or statements of fact pertaining to the quality of an item or service or to the existence and implementation of a quality system element.

objective setting—See *SMART WAY*.

observation—An item or incidence of objective evidence found during an audit.

observational unit—The smallest entity on which a *response variable* is measured. It may or may not be the same as the *experimental unit*.

observed value—The particular value of a *characteristic* determined as a result of a test or measurement.

OC curve—See *operating characteristic curve*.

off-the-job training—Training that takes place away from the actual work site.

ogive—A type of graph that represents the cumulative frequencies for the classes in a *frequency distribution*.

100% inspection—Inspection of selected characteristics of every item under consideration.

1 – α—See *confidence level*.

1 – β—The power of testing a hypothesis is 1 − β. It is the probability of correctly rejecting the null hypothesis, H_0.

one-tailed test—A *hypothesis* test that involves only one of the tails of a distribution. Example: We wish to reject the *null hypothesis* H_0 only if the true *mean* is larger than μ_0.

$$H_0: \mu = \mu_0$$

$$H_1: \mu < \mu_0$$

A one-tailed test is either right-tailed or left-tailed, depending on the direction of the inequality of the *alternative hypothesis*.

one-to-one marketing—The concept of knowing customers' unique requirements and expectations and marketing to these. See also *customer relationship management*.

on-the-job training (OJT)—Training usually conducted at the workstation, typically done one on one.

operable—The state of being able to perform the intended function.

operating characteristic curve (OC curve)—A curve showing the relationship between the *probability* of acceptance of product and the incoming quality level for a given *acceptance sampling plan*.

Note: Several terms in this glossary need to be referenced for better understanding of operating characteristic curves: *a*, *b*, *acceptance quality level*, *consumer's risk*, *indifference quality level*, *indifference zone*, *limiting quality level*, *probability of acceptance*, *probability of nonacceptance*, and *producer's risk*.

ordinal scale—A scale with ordered, labeled categories.

Note 1: There is sometimes a blurred line between ordinal and *discrete scales*. When subjective opinion ratings such as excellent, very good, neutral, poor, and very poor are coded (as numbers 1–5), the apparent effect is conversion from an ordinal to a discrete scale. Such numbers should not be treated as ordinary numbers, however, because the distance between 1 and 2 may not be the same as between 2 and 3, or 3 and 4, and so forth. On the other hand, some categories that are ordered objectively according to magnitude, such as the

Richter scale, which ranges from zero to 8 according to the amount of energy released, could be related to a discrete scale as well.

Note 2: Sometimes *nominal scales* are ordered by convention. An example is the blood groups A, B, and O, which are always stated in this order. The same is the case if different categories are denoted by single letters; they are then ordered by convention, according to the alphabet.

organization culture—Refers to the collective beliefs, values, attitudes, manners, customs, behaviors, and artifacts unique to an organization.

original inspection—The *inspection* of a *lot*, or other amount, not previously inspected.

Note: This is in contrast, for example, to inspection of a *lot* that has previously been designated as not acceptable and is submitted again for inspection after having been further sorted, reprocessed, and so on.

orthogonal contrasts—A set of *contrasts* whose coefficients satisfy the condition that, if multiplied in corresponding pairs, the sum of the products equals zero. See *contrast analysis*.

orthogonal design—A design in which all pairs of *factors* at particular *levels* appear together an equal number of times. Examples include a wide variety of special designs such as a *Latin square*, *completely randomized factorial design*, and *fractional factorial design*. Statistical analysis of the results for *orthogonal designs* is relatively simple because each *main effect* and *interaction effect* can be evaluated independently.

OSHA—Occupational Safety and Health Administration.

outlier—An extremely high or an extremely low data value compared to the rest of the data values. Great caution must be used when trying to identify an outlier.

out-of-control process—A *process* operating with the presence of *special causes*. See *in-control process*.

out of spec—A term used to indicate that a unit does not meet a given specification.

output—The deliverables resulting from a process, a project, a quality initiative, an improvement, and so on. Outputs include data, information, documents, decisions, and tangible products. Outputs are generated both from the planning and management of the activity and the delivered product, service, or program. Output is also the item, document, or material delivered by an internal provider (supplier) to an internal receiver (customer).

output variable—The variable representing the outcome of the *process*.

outsourcing—A strategy and an action to relieve an organization of processes and tasks in order to reduce costs, improve quality, reduce cycle time (for example, by parallel processing), reduce the need for specialized skills, and increase efficiency.

P

p—The ratio of the number of *units* in which at least one *event* of a given classification occurs to the total number of units. A unit is counted only once even if several events of the same classification are encountered within it. *p* can also be expressed as a percentage.

P—See *probability*.

$p_{.95}$, $p_{.50}$, $p_{.10}$, $p_{.05}$—The submitted quality in terms of the proportion of variant units for which the *probability of acceptance* is 0.95, 0.50, 0.10, 0.05 for a given *sampling plan*.

p_1—The percent of *nonconforming* individual items occurring when the *process* is located at the *acceptable process level (APL)*.

p_2—The percent of *nonconforming* individual items occurring when the *process* is located at the *rejectable process level (RPL)*.

P_a—See *probability of acceptance*.

panels—Groups of customers recruited by an organization to provide ad hoc feedback on performance or product development ideas.

paradigm—The standards, rules, attitudes, mores, and so on, that influence the way an organization lives and behaves.

parameter—A constant or coefficient describing some *characteristic* of a *population*. Examples: *standard deviation* and *mean*.

Pareto chart—A basic tool used to graphically rank causes from most significant to least significant. It utilizes a vertical bar graph in which the bar height reflects the frequency or impact of causes.

partially nested design—A *nested design* in which several *factors* may be *crossed*, as in *factorial experiments*, and other factors are nested within the crossed combinations.

participative management—A style of managing whereby the manager tends to work from theory Y assumptions about people, involving the workers in decisions made. See *theory Y*.

partnership/alliance—A strategy leading to a relationship with suppliers or customers aimed at reducing costs of ownership, maintenance of minimum stocks, just-in-time deliveries, joint participation in design, exchange of information on materials and technologies, new production methods, quality improvement strategies, and the exploitation of market synergy.

parts per million (PPM or ppm)— The number of units of mass of a contaminant per million units of total mass. One ppm is equivalent to the absolute fractional amount multiplied by one million.

part-to-part variation—The variability of the data due to measurement items rather than the *measurement system*. This *variation* is typically estimated from the measurement items used in a study, but could be estimated from a *representative sample* of product.

***p* chart**—See *proportion chart*.

Pearson's correlation coefficient—See *correlation coefficient*.

percentile—The division of the data set into 100 equal groups.

performance appraisal/evaluation—A formal method of measuring employees' progress against performance standards and providing feedback to them.

performance plan—A performance management tool that describes desired performance and provides a way to assess performance objectively.

PERT—See *program evaluation and review technique*.

pilot run—A trial production run consisting of various production tests conducted to ensure that the product is being built to specification.

Plackett–Burman design—An *experimental design* used where there are many *factors* to study. It only studies the *main effects* and is primarily used as a *screening design* before applying other types of designs. In general, Plackett–Burman designs are two-level, but three-, five-, and seven-level designs are available. They allow for efficient estimation of the main effects but assume that interactions can initially be ignored.

plan–do–check–act (PDCA) cycle—A four-step process for quality improvement. In the first step (plan), a plan to effect improvement is developed. In the second step (do), the plan is carried out, preferably on a small scale. In the third step (check), the effects of the plan are observed. As part of the last step (act), the results are studied to determine what was learned and what can be predicted. The plan–do–check–act cycle is sometimes referred to as the Shewhart cycle, because Walter A. Shewhart discussed the concept in his book *Statistical Method from the Viewpoint of Quality Control*, and as the Deming cycle because W. Edwards Deming introduced the concept in Japan. The Japanese subsequently called it the Deming cycle. Sometimes referred to as plan–do–study–act (PDSA).

plan–do–study–act (PDSA) cycle—A variation of the plan–do–check–act (PDSA) cycle.

PMI—Project Management Institute (www.pmi.org).

Poisson distribution—The Poisson distribution describes occurrences of isolated events in a continuum of time or space. It is a one-parameter, *discrete distribution* depending only on the *mean*.

poka-yoke—(Japanese) A term that means to mistake-proof a process by building safeguards into the system that avoid or immediately find errors. It comes from poka, which means *error,* and yokeru, which means *to avoid*.

pooled standard deviation—A *standard deviation* value resulting from some combination of individual standard deviation values. It is most often used when individual standard deviation values are similar in magnitude and can be denoted by *sp*. See *t-test (two sample).*

population—(1) The entire set (totality) of *units*, quantity of material, or observations under consideration. A population may be real and finite, real

and infinite, or completely hypothetical. See *sample*. (2) A group of people, objects, observations, or measurements about which one wishes to draw conclusions.

population covariance—See *covariance*.

population mean (μ)—The true *mean* of the *population*, represented by μ *(mu)*. The *sample mean*, $\bar{x}$, is a common estimator of the population mean.

population standard deviation—See *standard deviation*.

population variance—See *variance*.

power—The equivalent to 1 minus the *probability* of a *type II error (1 − β)*. A higher power is associated with a higher probability of finding a statistically significant difference. Lack of power usually occurs with smaller sample sizes.

power curve—The curve showing the relationship between the *probability (1 − β)* of rejecting the *hypothesis* that a sample belongs to a given *population* with a given *characteristic(s)* and the actual population value of that characteristic(s).

Note: If β, the probability of accepting the hypothesis, is used instead of *(1 − β)*, the curve is called an *operating characteristic (OC) curve*.

P_p (process performance index)—An index describing *process performance* in relation to specified *tolerance*:

$$P_p = \frac{U - L}{6s}$$

s is used for *standard deviation* instead of σ since both *random* and *special causes* may be present.

Note: A *state of statistical control* is not required.

P_{pk} (minimum process performance index)—The smaller of *upper process performance index* and *lower process performance index*.

P_{pkL} (lower process performance index or PPL)—An index describing *process performance* in relation to the *lower specification limit*. For a symmetrical normal distribution:

$$P_{pk_L} = \frac{\bar{x} - L}{3s}$$

where *s* is defined under P_p.

P_{pkU} (upper process performance index or PPU)—An index describing *process performance* in relation to the *upper specification limit*. For a symmetrical *normal distribution*:

$$P_{pk_U} = \frac{U - \bar{x}}{3s}$$

where *s* is defined under P_p.

PPL—See P_{pkL}.

PPU—See P_{pkU}.

P_r—See *probability of rejection*.

precision—The closeness of agreement between randomly selected individual measurements or test results. See *repeatability* and *reproducibility*.

precision-to-tolerance ratio (PTR)—A measure of the *capability* of the *measurement system*. It can be calculated by

$$\text{PTR} = \frac{5.15 \times \hat{\sigma}_{ms}}{\text{USL} - \text{LSL}}$$

where $\hat{\sigma}_{ms}$ is the estimated *standard deviation* of the total measurement system variability. In general, reducing the PTR will yield an improved measurement system.

predicted—That which is expected at some future date, postulated on analysis of past experience and tests.

predicted value—The prediction of future observations based on the formulated *model*.

prediction interval—Similar to a *confidence interval*, it is an interval based on the *predicted value* that is likely to contain the values of future observations. It will be wider than the confidence interval because it contains bounds on individual observations rather than a bound on the *mean* of a group of observations.

predictor variable—A *variable* that can contribute to the explanation of the outcome of an experiment.

prevention versus detection—A term used to contrast two types of quality activities. Prevention refers to those activities designed to prevent nonconformances in products and services. Detection refers to those activities designed to detect nonconformances already in products and services. Another phrase used to describe this distinction is "designing-in quality versus inspecting-in quality".

preventive action—Action taken to eliminate the potential causes of a nonconformity, defect, or other undesirable situation in order to prevent occurrence.

primary customer—The individual or group who directly receives the output of a process.

priorities matrix—A tool used to choose between several options that have many useful benefits, but where not all of them are of equal value.

probability (*P*)—The chance of an *event* occurring.

probability distribution—A function that completely describes the probabilities with which specific values occur. The values may be from a *discrete scale* or a *continuous scale*.

probability of acceptance (P_a)—The *probability* that when using a given *acceptance sampling plan*, a *lot* will be accepted when the *lot* or *process* is of a specific quality level.

probability of nonacceptance—See *probability of rejection*.

probability of rejection (P_r)—The probability that when using a given *acceptance sampling plan*, a *lot* will not be accepted when *the lot* or *process* is of a specified quality level.

probability plot—The plot of ranked data versus the *sample* cumulative frequency on a special vertical scale. The special scale is chosen (that is, normal, lognormal, and so on) so that the *cumulative distribution* is a straight line.

problem solving—A rational process for identifying, describing, analyzing, and resolving situations in which something has gone wrong without explanation.

process—An activity or group of activities that takes an input, adds value to it, and provides an output to an internal or external customer; a planned and repetitive sequence of steps by which a defined product or service is delivered. A process can be graphically represented using a *flowchart*.

process analysis—Defining and quantifying the process capability from data derived from mapping and measuring the work performed by the process.

process audit—An audit of a process.

process average—See *sample mean* or *population mean*.

process capability—The calculated inherent variability of a *characteristic* of a product. It represents the best performance of the *process* over a period of stable operations. Process capability is expressed as $6\hat{\sigma}$, where $\hat{\sigma}$ is the *sample standard deviation* (short-term component of variation) of the process under a *state of statistical control*.

process capability index—A single-number assessment of ability to meet *specification limits* on the quality *characteristic*(s) of interest. The indices compare the variability of the characteristic to the specification limits. Three basic process capability indices are C_p, C_{pk}, and C_{pm}.

Note: Since there are many different types and variations of process capability indices, details are given under the symbol for the specific type of index.

process control—*Process* management that is focused on fulfilling process requirements. Process control is the methodology for keeping a process within boundaries and minimizing the variation of a process.

process decision program chart (PDPC)—A management and planning tool that identifies all events that can go wrong and the appropriate countermeasures for these events. It graphically represents all sequences that lead to a desirable effect.

process improvement—The act of changing a process to reduce variability and cycle time and make the process more effective, efficient, and productive.

process improvement team (PIT)—A natural work group or cross-functional team whose responsibility is to achieve needed improvements in existing processes. The life span of the team is based on the completion of the team purpose and specific goals.

process management—The collection of practices used to implement and improve process effectiveness; it focuses on holding the gains achieved through process improvement and assuring process integrity.

process mapping—The flowcharting of a work process in detail, including key measurements.

process owner—The manager or leader who is responsible for ensuring that the total process is effective and efficient.

process performance—The statistical measure of the outcome of a *characteristic* from a *process* that may *not* have been demonstrated to be in a *state of statistical control*.

Note: Use this measure cautiously since it may contain a component of variability from *special causes* of unpredictable value. It differs from *process capability* because a state of statistical control is not required.

process performance index—A single-number assessment of ability to meet *specification limits* on the quality *characteristic*(s) of interest. The indices compare the variability of the characteristic to the specification limits. Three basic process capability indices are P_p, P_{pk}, and P_{pm}.

Note: Since there are many different types and variations of process capability indices, details are given under the symbol for the specific type of index.

process quality—A statistical measure of the quality of product from a given *process*. The measure may be an *attribute (qualitative)* or a *variable (quantitative)*. A common measure of process quality is the fraction or proportion of nonconforming units in the process.

process quality audit—An analysis of elements of a process and appraisal of completeness, correctness of conditions, and probable effectiveness.

process-to-tolerance ratio—See *precision to tolerance ratio.*

process variable—See *variable*.

producer's risk (α)—The *probability* of nonacceptance when the quality level has a value stated by the *acceptance sampling plan* as acceptable.

Note 1: Such nonacceptance is a *type I error.*

Note 2: Producer's risk is usually designated as α.

Note 3: *Quality level* could relate to fraction nonconforming and be *acceptable* to *AQL*.

Note 4: Interpretation of the producer's risk requires knowledge of the stated quality level.

product audit—Audit of a product.

production part approval process (PPAP)—In the automotive industry, PPAP is used to show that suppliers have met all the engineering requirements based on a sample of parts produced from a production run made with production tooling, processes, and cycle times.

product/service liability—The obligation of a company to make restitution for loss related to personal injury, property damage, or other harm caused by its product or service.

product quality audit—A quantitative assessment of conformance to required product characteristics.

product warranty—The organization's stated policy that it will replace, repair, or reimburse a customer for a defective product, providing the product defect occurs under certain conditions and within a stated period of time.

professional development plan—An individual development tool for an employee. Working together, the employee and his/her supervisor create a plan that matches the individual's career needs and aspirations with organizational demands.

program evaluation and review technique (PERT)—An event-oriented project management planning and measurement technique that utilizes an arrow diagram to identify all major project events and demonstrates the amount of time (critical path) needed to complete a project. It provides three time estimates: optimistic, most likely, and pessimistic.

project—A temporary endeavor undertaken to create a unique project, service, or result.

project constraints—Projects are constrained by schedule, budget, and project scope.

project life cycle—Refers to five sequential phases of project management: concept, planning, design, implementation, and evaluation.

project management (PM)—The application of knowledge, skills, tools, and techniques to project activities to meet project requirements throughout a project's life cycle.

project management body of knowledge (PMBoK)—An inclusive term that describes the sum of knowledge within the profession of project management. The complete project management body of knowledge includes proven, traditional practices that are widely applied and innovative practices that are emerging in the project management profession. A guide to the PMBoK is maintained and periodically updated by the Project Management Institute (PMI).

project plan—All the documents that comprise the details of why the project is to be initiated, what the project is to accomplish, when and where it is to be implemented, who will have responsibility, how the implementation will be carried out, how much it will cost, what resources are required, and how the project's progress and results will be measured.

project team—A designated group of people working together to produce a planned project's outputs and outcome.

proportion chart (*p* chart or percent categorized units control chart)—An *attributes control chart* for number of *units* of a given classification per total number of units in the *sample* expressed as either a proportion or percentage.

Note 1: The classification often takes the form of *nonconforming units*.

Note 2: The *p* chart applies particularly when the sample size is variable.

Note 3: If the *upper control limit* (UCL) calculates ≥ 1, there is no UCL; if the *lower control limit* (LCL) calculates ≤ 0, there is no LCL.

a. When the fraction nonconforming is known, or is a specified standard value:

$$\text{Central line} : p$$

$$\text{Control limits} : p \pm 3\sqrt{\frac{p(1-p)}{n}}$$

where p is known fraction nonconforming (or standard value).

$$\text{Plotted value} : \hat{p}$$

where $\hat{p}$ is the *sample* fraction nonconforming:

$$\hat{p} = \text{D}/n$$

where D is the number of product units that are nonconforming and n is the sample size.

b. When the fraction nonconforming is not known:

$$\text{Central line} : \overline{p}$$

$$\text{Control limits} : \overline{p} \pm 3\sqrt{\frac{\overline{p}(1-\overline{p})}{n}}$$

where $\overline{p}$ is the *average* value of the fraction of the classification (often average percent nonconforming), and n is the total number of units. These limits are considered trial limits.

c. For variable sample size:

$$\text{Central line} : \overline{p}$$

$$\text{Control limits} : \overline{p} \pm 3\sqrt{\frac{\overline{p}(1-\overline{p})}{n_i}}$$

where n_i is varying sample size.

$$\text{Plotted value} : \hat{p}$$

where $\hat{p}$ is the *sample* fraction nonconforming:

$$\hat{p} = D_i/n$$

where D_i is the number of nonconforming units in sample *i*, and *n* is the sample size.

proportions, tests for—Tests for proportions include the *binomial distribution*. See *binomial confidence interval*, and *z-test (two proportions)*. The *standard deviation* for proportions is given by

$$s = \sqrt{\frac{p(1-p)}{n}}$$

where *p* is the *population* proportion and *n* is the *sample* size.

psychographic customer characteristics—Variables among buyers in the consumer market that address lifestyle issues and include consumer interests, activities, and opinions.

PTR—See *precision-to-tolerance ratio*.

pull system—See *kanban*.

***p*-value**—The *probability* of observing the *test statistic* value or any other value at least as unfavorable to the *null hypothesis*.

Q

QPA—Quality process analyst.

qualitative data—See *attributes data*.

quality—A subjective term for which each person has his or her own definition. In technical usage, quality can have two meanings: (1) the characteristics of a product or service that bear on its ability to satisfy stated or implied needs, and (2) a product or service free of deficiencies.

quality assessment—The process of identifying business practices, attitudes, and activities that are enhancing or inhibiting the achievement of quality improvement in an organization.

quality assurance/quality control (QA/QC)—Two terms that have many interpretations because of the multiple definitions for the words "assurance" and "control." For example, assurance can mean the act of giving confidence, the state of being certain, or the act of making certain; control can mean an evaluation to indicate needed corrective responses, the act of guiding, or the state of a process in which the variability is attributable to a constant system of chance causes. (For a detailed discussion on the multiple definitions, see ANSI/ISO/ASQC A35342 *Statistics—Vocabulary and symbols—Statistical quality control*.) One definition of quality assurance is all the planned and systematic activities implemented within the quality system that can be

demonstrated to provide confidence that a product or service will fulfill requirements for quality. One definition for quality control is the operational techniques and activities used to fulfill requirements for quality. Often, however, quality assurance and quality control are used interchangeably, referring to the actions performed to ensure the quality of a product, service, or process.

quality characteristics—The unique characteristics of products and of services by which customers evaluate their perception of quality.

quality circles—Quality improvement or self-improvement study groups composed of a small number of employees—10 or fewer—and their supervisor, who meet regularly with an aim to improve a process.

quality council—The group driving the quality improvement effort and usually having oversight responsibility for the implementation and maintenance of the quality management system, operating in parallel with the normal operation of the business. Sometimes called *quality steering committee*.

quality engineering—The analysis of a manufacturing system at all stages to maximize the quality of the process itself and the products it produces.

quality function—The entire spectrum of activities through which an organization achieves its quality goals and objectives, no matter where these activities are performed.

quality function deployment (QFD)—A multifaceted matrix in which customer requirements are translated into appropriate technical requirements for each stage of product development and production. The QFD process is often referred to as listening to the voice of the customer. See also *house of quality*.

quality improvement—Actions taken throughout the organization to increase the effectiveness and efficiency of activities and processes in order to provide added benefits to both the organization and its customers.

quality level agreement (QLA)—Internal service/product providers assist their internal customers in clearly delineating the level of service/product quality required in quantitatively measurable terms. A QLA may contain specifications for accuracy, timeliness, quality/usability, product life, service availability, or responsiveness to needs.

quality management—Coordinated activities to direct and control an organization with regard to *quality*. Such activities generally include establishment of the quality policy, quality objectives, quality planning, *quality control*, *quality assurance*, and quality improvement.

quality management system—The organizational structure, processes, procedures, and resources needed to implement, maintain, and continually improve quality management.

quality planning—The activity of establishing quality objectives and quality requirements.

quality trilogy—A three-pronged approach to managing for quality. The three legs are quality planning (developing the products and processes required to meet customer needs), quality control (meeting product and process goals), and quality improvement (achieving unprecedented levels of performance). Attributed to Joseph M. Juran.

quantitative data—See *variable (control chart usage)*.

questionnaires—See *survey*.

queue processing—Processing in batches (contrast with continuous flow processing).

queue time—Wait time of product awaiting next step in process.

R

r—See *correlation coefficient*.

R—See *range*.

***R* chart**—See *range chart*.

R^2—See *coefficient of determination*.

R^2_{adj}—R^2 *(coefficient of determination)* adjusted for *degrees of freedom*:

$$R^2_{adj} = 1 = \frac{\text{Sum of squares error}/(n-p)}{\text{Sum of squares total}/(n-1)}$$

where p is the number of coefficients fit in the *regression* equation.

$\bar{R}$ **(pronounced r-bar)**—The *average* range calculated from the set of *subgroup* ranges under consideration. See *range*.

RACI—A structure that ensures that every component of the project's scope of work is assigned to a person/team and that each person/team is *responsible*, *accountable*, *consulting*, or *informing* for the assigned task.

RAM—See *responsibility assignment matrix*.

random cause—The source of *process* variation that is inherent in a process over time. Also called *common cause* or *chance cause*.

Note: In a process subject only to random cause variation, the variation is predictable within statistically established limits.

random factor—A *factor* that uses *levels* that are selected at random from a large or infinite number of possibilities. In general, inference is made to other levels of the same factor. See also *fixed factor*.

randomization—The process used to assign *treatments* to *experimental units* so that each experimental unit has an equal chance of being assigned a particular *treatment*. Randomization validates the assumptions made in statistical analysis and prevents unknown biases from impacting the conclusions.

randomized block design—An *experimental design* consisting of *b blocks* with *t treatments* assigned via *randomization* to the *experimental units* within each block. This is a method for controlling the variability of experimental units. For the *completely randomized design*, no stratification of the experimental units is made. In the randomized block design, the treatments are randomly allotted within each block, that is, the randomization is restricted.

randomized block factorial design—A *factorial design* run in a *randomized block design* where each *block* includes a complete set of factorial combinations.

random model—A *model* that contains only random *factors*.

random sampling—Sampling where a *sample* of *n* sampling *units* is taken from a *population* in such a way that each of the possible combinations of *n* sampling units has a particular probability of being taken.

random variation—Variation from *random causes*.

range (*R*)—A measure of *dispersion*, which is the absolute difference between the highest and lowest *value* in a given *subgroup*:

$$R = \text{Highest observed value} - \text{Lowest observed value}$$

range chart (*R* chart)—A *variables control chart* that plots the range of a *subgroup* to detect shifts in the subgroup range. See *range (R)*.

$$\text{Central line: } \bar{R}$$
$$\text{Upper control limit: } D_4\bar{R}$$
$$\text{Lower control limit: } D_3\bar{R}$$

where $\bar{R}$ is the average range; D_3 and D_4 are factors from Appendix D.

Note: A range chart is used when the sample size is small; if the sample is larger (generally > 10 to 12), the *s* chart should be used.

rational subgroup—A *subgroup* wherein the variation is presumed to be only from *random causes*.

Re—See *rejection number*.

record—Document or electronic medium that furnishes objective evidence of activities performed or results achieved. Example: A filled-in form is a *record*.

rectifying inspection—An inspection of all, or a specified number of, items in a *lot* or other amount previously rejected on *acceptance sampling* inspection, as a consequence of which all *nonconforming items* are removed or replaced.

reduced inspection—An *inspection* less severe than *normal inspection*, to which the latter is switched when inspection results of a predetermined number of *lots* indicate that the quality level achieved by the *process* is better than that specified.

redundancy—The existence of more than one means for accomplishing a given function. Each means of accomplishing the function need not necessarily be identical.

redundancy, active—That redundancy wherein all redundant items are operating simultaneously.

redundancy, standby—That redundancy wherein an alternative means of performing the function is not operating until it is activated upon failure of the primary means of performing the function.

reengineering—Completely redesigning or restructuring a whole organization, an organizational component, or a complete process. It is a "start all over again from the beginning" approach, sometimes called a breakthrough. In terms of improvement approaches, reengineering is contrasted with incremental improvement (kaizen).

reference interval—The interval bounded by the 99.865% distribution fractile, $X_{99.865\%}$, and the 0.135% distribution fractile, $X_{0.135\%}$, expressed by the difference $X_{99.865\%} - X_{0.135\%}$.

Note 1: This term is used only as an arbitrary, but standardized, basis for defining the *process performance index*, P_p, and *process capability index*, C_p.

Note 2: For a *normal distribution*, the reference interval may be expressed in terms of *standard* deviations as 6σ, or $6s$ when estimated from a sample.

Note 3: For a nonnormal distribution, the reference interval may be estimated by appropriate probability scales or from the sample kurtosis and sample skewness.

Note 4: The conditions prevailing must always be stated as *process capability* conditions (a *state of statistical control* required) or *process performance* conditions (a state of statistical control not required).

regression—See *regression analysis*.

regression analysis—A technique that uses *predictor variable*(s) to predict the *variation* in a *response variable*. Regression analysis uses the method of *least squares* to determine the values of the *linear regression coefficients* and the corresponding *model*. It is particularly pertinent when the predictor variables are *continuous* and emphasis is on creating a predictive model. When some of the predictor variables are *discrete*, *analysis of variance* or *analysis of covariance* is likely a more appropriate method. This resulting model can then test the resulting predictions for statistical significance against an appropriate *null hypothesis* model. The model also gives some sense of the degree of *linearity* present in the data. When only one predictor variable is used, regression analysis is often referred to as *simple linear regression*. A simple linear regression model commonly uses a *linear regression equation* expressed as $Y = b_0 + b_1x + e$, where Y is the response, x is the value of the predictor variable, b_0 and b_1 are the linear regression coefficients, and e is the random error term. b_0 is often called the *intercept*, and b_1 is often called the *slope*.

When multiple predictor variables are used, regression is referred to as *multiple linear regression*. For example, a multiple linear regression model with three predictor variables commonly uses a linear regression equation expressed as $Y = b_0 + b_1x_1 + b_2x_2 + b_3x_3 + e$, where Y is the response; x_1, x_2, and x_3 are the values of the predictor variables; b_0, b_1, b_2, and b_3 are the linear regression coefficients; and e is the random error term. The random error terms in regression analysis are often assumed to be normally distributed with a constant *variance*. These assumptions can be readily checked through *residual analysis* or *residual plots*. See *regression coefficients, tests for*.

regression coefficients, tests for—A test of the individual *linear regression coefficients* to determine their significance in the *model*. These tests assume that the *response variable* is normally distributed for a fixed level of the *predictor variable*, the variability of the response variable is the same regardless of the value of the predictor variable, and that the predictor variable can be measured without error. See *regression analysis*.

reject—(acceptance sampling usage) To decide that a *batch*, *lot*, or quantity of product, material, or service has not been shown to satisfy the requirement criteria based on the information obtained from the *sample*(s).

Note: In *acceptance sampling*, the words "to reject" generally are used to mean to not accept, without direct implication of product usability. Lots that are rejected may be scrapped, sorted (with or without *nonconforming units* being replaced), reworked, reevaluated against more-specific usability criteria, held for additional information, and so on. Because the common language usage "reject" often results in an inference of unsafe or unusable product, it is recommended that the words "not accept" be used instead.

rejectable process level (RPL)—The *process* level that forms the inner boundary of the rejectable process zone.

Note: In the case of two-sided *tolerances*, upper and lower rejectable process levels will be designated URPL and LRPL, respectively. (These need not be symmetrical around the standard level.)

rejectable process zone—See *rejectable process level*.

rejectable quality level (RQL)—See *limiting quality level (LQL)*.

rejection number (Re)—The smallest number of *nonconformities* or *nonconforming units* found in the *sample* by *acceptance sampling by attributes* that requires the *lot* to be not accepted, as given in the *acceptance sampling plan*.

relative frequency—The number of occurrences or *observed values* in a specified class divided by the total number of occurrences or observed values.

reliability—In measurement systems analysis, refers to the ability of an instrument to produce the same results over repeated administration—to measure consistently. In reliability engineering, it is the probability of a product performing its intended function under stated conditions for a given period of time. For redundant items, this is equivalent to the definition of mission reliability. See also *mean time between failures*.

reliability, mission—The ability of an item to perform its required functions for the duration of a specified *mission profile*.

remedy—Something that eliminates or counteracts a problem cause; a solution.

repair—Action taken on a nonconforming product so that it will fulfill the intended usage requirements, although it may not conform to the originally specified requirements. See *maintenance, corrective*.

repeatability—*Precision* under conditions where independent measurement results are obtained with the same method on identical measurement items by the same operator using the same equipment within a short period of time.

repeated measures—The measurement of a *response variable* more than once under similar conditions. Repeated measures allow one to determine the inherent variability in the *measurement system*. Also known as *duplication* or repetition.

replicate—A single repetition of the experiment. See also *replication*.

replication—Performance of an experiment more than once for a given set of *predictor variables*. Each of the repetitions of the experiment is called a *replicate*. Replication differs from *repeated measures* in that it is a repeat of the entire experiment for a given set of *predictor variables*, not just a repeat of measurements on the same experiment.

Note: Replication increases the precision of the estimates of the *effects* in an experiment. It is more effective when all elements contributing to the *experimental error* are included. In some cases, replication may be limited to *repeated measures* under essentially the same conditions. In other cases, replication may be deliberately different, though similar, in order to make the results more general.

representative sample—A *sample* that by itself or as part of a sampling system or protocol exhibits *characteristics* and properties of the *population* sampled.

reproducibility—*Precision* under conditions where independent measurement results are obtained with the same method on identical measurement items with different operators using different equipment.

resample—An analysis of an additional *sample* from a *lot*. Resampling not included in the design of the *control chart* delays *corrective action* and changes the risk levels on which control charts are calculated. Resampling should not be used to replace sample results that indicate a *nonconformity*, but it is appropriate if the sample was known to be defective or invalid, or to obtain additional information on the material sampled.

residual analysis—The method of using *residuals* to determine appropriateness of assumptions made by a statistical method.

residual plot—A plot used in *residual analysis* to determine appropriateness of assumptions made by a statistical method. Common forms include a plot of the *residuals* versus the *observed values* or a plot of the residuals versus the *predicted values* from the fitted model.

residuals—The difference between the observed result and the *predicted value* (estimated treatment response) based on an empirically determined model.

resistance to change—Unwillingness to change beliefs, habits, and ways of doing things.

resistant line—A line derived from using *medians* in fitting lines to data.

resolution—(1) The smallest measurement increment that can be detected by the *measurement system*; (2) In the context of *experimental design*, resolution refers to the level of *confounding* in a *fractional factorial design*. For example, in a resolution III design, the *main effects* are confounded with the two-way *interaction effects*.

response surface design—A design intended to investigate the functional relationship between a *response variable* and a set of *predictor variables*. It is generally most useful when the predictor variables are continuous. See *Box–Behnken design*.

response surface methodology (RSM)—A methodology that uses *design of experiments*, *regression analysis*, and optimization techniques to determine the best relationship between a *response variable* and a set of *predictor variables*.

response variable—A variable representing the outcome of an experiment.

responsibility assignment matrix (RAM)—A structure that relates the project organizational breakdown structure to the work breakdown structure to help ensure that each component of the project's scope of work is assigned to a responsible person/team.

resubmitted lot—A *lot* that previously had been designated as not acceptable and that is submitted again for acceptance inspection after having been further tested, sorted, reprocessed, and so on.

Note: Any *nonconforming units* discovered during the interim action must be removed, replaced, or reworked.

RETAD—Rapid exchange of tooling and dies. This includes changing over the tools and dies in a manufacturing line.

rework—Action taken on a nonconforming product so that it will fulfill the specified requirements (may also pertain to a service).

right the first time—A term used to convey the concept that it is beneficial and more cost-effective to take the necessary steps up front to ensure that a product or service meets its requirements than to provide a product or service that will need rework or not meet customers' needs. In other words, an organization should engage in defect prevention rather than defect detection.

risk—A measure of the potential inability to achieve overall program objectives within defined cost, schedule, and technical constraints; risk has two components:

1. The probability (or likelihood) of failing to achieve a particular outcome
2. The consequences (or impact) of failing to achieve that outcome

risk, consumer's (β)—See *consumer's risk* (β).

risk, producer's (α)—See *producer's risk* (α).

risk assessment/management—Organized, analytic process to identify what might cause harm or loss (identify risks); to assess and quantify the identified risks; and to develop and, if needed, implement an appropriate approach to prevent or handle causes of risk that could result in significant harm or loss.

robust—In statistical use, a *characteristic* of a *statistic* or statistical method. A robust statistical method still gives reasonable results even though the standard assumptions are not met. A robust statistic is unchanged by the presence of unusual data points or *outliers*.

robustness—The condition of a product or process design that remains relatively stable with a minimum of variation even though factors that influence operations or usage, such as environment and wear, are constantly changing.

robust parameter design—A design that aims to reduce the performance variation of a product or *process* by choosing the setting of its *control factors* to make it less sensitive to variability from *noise factors*.

ROI—Return on investment. Umbrella term for a variety of ratios measuring an organization's business performance, calculated by dividing some measure of return by a measure of investment and then multiplying by 100 to provide a percentage. In its most basic form, ROI indicates what remains from all money taken in after all expenses are paid. ROI is always expressed as a percentage.

root cause analysis—A quality tool used to distinguish the source of defects or problems. It is a structured approach that focuses on the decisive or original cause of a problem or condition.

ROTI—Return on training investment. A measure of the return generated by the benefits from the organization's investment in training.

RPL—See *rejectable process level*.

RQL—See *rejectable quality level*.

RSM—See *response surface methodology*.

run—See *experimental run*.

run—(control chart usage) An uninterrupted sequence of occurrences of the same *attribute* or *event* in a series of observations, or a consecutive set of successively increasing (run up) or successively decreasing (run down) values in a series of *variable* measurements.

Note: In some *control chart* applications, a run might be considered a series of a specified number of points consecutively plotting above or below the *center line*, or five consecutive points, three of which fall outside warning limits.

running weighted average—An equation used to smooth data sequences by replacing each data value with the *average* of the data values around it and with weights multiplied in each averaging operation. The weights sum to 1.

S

***s*—**See *standard deviation*.

***s*²—**See *variance*.

sales leveling—A strategy of establishing a long-term relationship with customers leading to contracts for fixed amounts and scheduled deliveries in order to smooth the material flow and eliminate surges.

sample—A group of *units*, portions of material, or observations taken from a larger collection of units, quantity of material, or observations that serves to provide information that may be used for making a decision concerning the larger quantity (the *population*).

Note 1: The sample may be the actual units or material, or the observations collected from them. The decision may or may not involve taking action on the units or material, or on the *process*.

Note 2: *Sampling plans* are schemes set up statistically in order to provide a sampling system with minimum bias.

Note 3: There are many different ways, random and nonrandom, to select a sample. In survey sampling, sampling units are often selected with a probability proportional to the size of a known variable, giving a biased sample.

sample covariance—See *covariance*.

sample mean—The sample mean (or *average*) is the sum of random variables in a *random sample* divided by the number in the sum. It is generally designated by the symbol $\bar{x}$.

Note: The sample mean considered as a *statistic* is an estimator for the *population mean*. A common synonym is the *arithmetic mean*.

sample size (*n*)—The number of sampling *units* in a *sample*.

Note: In a multistage sample, the sample size is the total number of sampling *units* at the conclusion of the final stage of sampling.

sample standard deviation—See *standard deviation*.

sample variance—See *variance*.

sampling interval—In systematic sampling, the sampling interval is the fixed interval of time, output, running hours, and so on, between samples.

sampling plan (acceptance sampling usage)—A specific plan that states the *sample size*(s) to be used and the associated criteria for accepting the *lot*.

Note: The sampling plan does not contain the rules on how to take the sample.

sampling scheme (acceptance sampling usage)—A combination of *sampling plans* with rules (acceptance for changing from one plan to another).

saturated design—A design where the number of *factors* studied is nearly equal to the number of *experimental runs*. Saturated designs do not allow for a check of model adequacy or estimation of higher-order *effects*. This design should only be used if the cost of doing more experimental runs is prohibitive.

scatter diagram (or scatter plot)—A graphical technique for analyzing the relationship between two variables. Two sets of data are plotted on a graph, with the *y*-axis being used for the variable to be predicted, and the *x*-axis for the variable being used to make the prediction. The graph will show possible relationships (although two variables might appear to be related, they might not be; those who know most about the variables must make that evaluation). The scatter diagram is one of the seven basic tools of quality.

***s* chart**—See *standard deviation chart*.

screening design—An experiment intended to identify a subset of the collection of *factors* for subsequent study. Examples include *fractional factorial designs* or *Plackett–Burman designs*.

secondary customer—Individuals or groups from outside the process boundaries who receive process output but who are not the reason for the process's existence.

segmentation—See *customer segmentation*.

self-directed learning—See *learner-controlled instruction*.

self-managed team—A team that requires little supervision and manages itself and the day-to-day work it does; self-directed teams are responsible for whole work processes, with each individual performing multiple tasks.

sequential sampling—An *acceptance sampling inspection* in which, after each item has been inspected, the decision to accept the *lot*, not accept the lot, or inspect another item is taken based on the cumulative sampling evidence.

Note 1: The decision is made according to defined rules.

Note 2: The total number of items to be inspected is not fixed in advance, but a maximum number is often agreed on.

servicing—The performance of any act to keep an item in operating condition (that is, lubrication, fueling, oiling, cleaning, and so on), but not including other preventive maintenance of parts or corrective maintenance.

setup time—The time taken to change over a process to run a different product or service.

seven basic quality tools—Tools that help organizations understand their processes in order to improve them. The tools are the *cause-and-effect diagram, check sheet, control chart, flowchart, histogram, Pareto chart*, and *scatter diagram*. See individual entries.

seven basic tools of quality management—The tools used primarily for planning and managing are the activity network diagram (AND), or arrow diagram,

affinity diagram (KJ method), interrelationship digraph, matrix diagram, priorities matrix, process decision program chart (PDPC), and tree diagram.

Shewhart control chart—A *control chart* with *Shewhart control limits* intended primarily to distinguish between variation due to *random causes* and variation due to *special causes*.

Shewhart control limits—*Control limits* based on empirical evidence and economic considerations, placed about the *center line* at a distance of ± 3 *standard deviations* of the *statistic* under consideration and used to evaluate whether or not it is a *stable process*.

Shewhart cycle—See *plan–do–check–act (PDCA) cycle*.

σ (sigma)—Greek letter (σ) that stands for the standard deviation of a process. See *standard deviation*.

σ^2 (sigma square)—See *variance*.

σ_{wt}—The *standard deviation* of the *exponentially weighted moving average*:

$$\sigma_{w_i} = \sigma\sqrt{\lambda/(2-\lambda)}\ \text{[Asymptotic value]}$$
$$\sigma_{w_i} = \sigma\sqrt{\lambda/(2-\lambda)\left[1-(1-\lambda)^{2i}\right]}\ \text{[Initial values]}$$

See *exponentially weighted moving average chart*.

$\sigma_{\bar{x}}$ (sigma $\bar{x}$)—The *standard deviation* (or *standard error*) of $\bar{x}$.

$\hat{\sigma}$ (sigma-hat)—In general, any estimate of the *population standard deviation*. There are various ways to get this estimate depending on the particular application.

signal—An indication on a *control chart* that a *process* is not *stable* or that a shift has occurred. Typical indicators are points outside *control limits*, *runs*, *trends*, cycles, patterns, and so on. See also *average run length*.

signal-to-noise ratio (S/N ratio)—A mathematical equation that indicates the magnitude of an experimental effect above the effect of experimental error due to chance fluctuations.

significance level—The maximum *probability* of rejecting the *null hypothesis* when in fact it is true.

Note: The significance level is usually designated by α and should be set before beginning the test.

significance tests—Significance tests are a method of deciding, with certain predetermined risks of error, (1) whether the *population* associated with a *sample* differs from the one specified, (2) whether the populations associated with each of two samples differ, or (3) whether the populations associated with each of more than two samples differ. Significance testing is equivalent to the testing of *hypotheses*. Therefore, a clear statement of the *null hypothesis*,

alternative hypotheses, and predetermined selection of a *confidence level* are required.

Note: The level of significance is the maximum *probability* of committing a *type I error*. This probability is symbolized by α, that is, P (type I error) = α. See *confidence interval*; *means, tests for*; and *proportions, tests for*.

simple linear regression—See *regression analysis.*

single-level continuous sampling—A continuous *acceptance sampling inspection* of consecutively produced items where a single fixed sampling rate is alternated with *100 percent inspection* depending on the quality of the observed *process* output.

single-minute exchange of dies (SMED)—A goal to be achieved in reducing the setup time required for a changeover to a new process; the methodologies employed in devising and implementing ways to reduce setup time.

single-piece flow—A method whereby the product proceeds through the process one piece at a time rather than in large batches, eliminating queues and costly waste.

single sampling (acceptance sampling usage)—An *acceptance sampling inspection* in which the decision to accept, according to a defined rule, is based on the inspection results obtained from a single *sample* of predetermined size, *n*.

SIPOC—A macro-level analysis of the suppliers, inputs, processes, outputs, and customers.

Six Sigma approach—A quality philosophy; a collection of techniques and tools for use in reducing variation; a program of improvement.

Six Sigma quality—A term used generally to indicate that a process is well controlled, that is, within process limits $\pm 3\sigma$ from the center line in a control chart, and requirements/tolerance limits $\pm 6\sigma$ from the center line. The term was initiated by Motorola.

skewness—A measure of symmetry about the *mean*. For a *normal distribution*, skewness is zero because the distribution is symmetric.

skip-lot sampling—An *acceptance sampling inspection* in which some *lots* in a series are accepted without *inspection* when the sampling results for a stated number of immediately preceding lots meet stated criteria.

slope—See *regression analysis*.

SMART goals—A template for setting goals that are specific, measurable, achievable, realistic, and time-bound.

SMART WAY—A template for setting objectives: specific, measurement, achievable, realistic, time, worth, assign, yield.

s_p—See *pooled standard deviation*, *t-test (two sample)*, and *proportion*, *tests for.*

spaghetti chart—A before-improvement chart of existing steps in a process with lines showing the many back-and-forth interrelationships (can resemble

a bowl of spaghetti). It is used to see the redundancies and other wasted movements of people and material.

SPC—See *statistical process control*.

special cause—A source of process variation other than *inherent process variation*.

Note 1: Sometimes special cause is considered synonymous with *assignable cause*, but a special cause is assignable only when it is specifically identified.

Note 2: A special cause arises because of specific circumstances that are not always present. Therefore, in a process subject to special causes, the magnitude of the variation over time is unpredictable.

specification—The engineering requirement used for judging the acceptability of a particular product/service based on product characteristics such as appearance, performance, and size. In statistical analysis, specifications refer to the document that prescribes the requirements to which the product or service has to conform.

specification limit(s)—The limiting value(s) stated for a *characteristic*. See *tolerance*.

split-plot design—A design where there is a hierarchical structure in the *experimental units*. One or more principal *factors* are studied using the largest experimental unit, often called a whole plot. The whole plots are subdivided into smaller experimental units, often called split-plots. Additional factors are studied using each of the split-plots. This type of design is frequently used with a principal factor whose levels are not easily changed, and the other factors can be varied readily within the runs assigned to the principal factor.

sponsor—The person who supports a team's plans, activities, and outcomes; the team's "backer." The sponsor provides resources and helps define the mission and scope to set limits. The sponsor may be the same individual as the *champion*.

spread—A term sometimes synonymous with *variation* or *dispersion*.

stable process—A *process* that is predictable within limits; a process that is subject only to *random causes*. (This is also known as a *state of statistical control*.)

Note 1: A stable process will generally behave as though the results are simple random samples from the same *population*.

Note 2: This state does not imply that the *random variation* is large or small, within or outside of *specification limits*, but rather that the variation is predictable using statistical techniques.

Note 3: The *process capability* of a stable process is usually improved by fundamental changes that reduce or remove some of the *random causes* present and/or adjusting the *mean* toward the *target* value.

staggered nested design—A *nested design* in which the *nested factors* are run within only a subset of the *levels* of the first or succeeding *factors*.

stakeholder—People, departments, and organizations that have an investment or interest in the success or actions taken by the organization.

stakeholder analysis—The identification of stakeholders and delineation of their needs.

standard deviation—A measure of the *spread* of the *process* output or the spread of a sampling *statistic* from the process. When working with the *population*, the standard deviation is usually denoted by σ (sigma). When working with a *sample*, the standard deviation is usually denoted by *s*. They are calculated as

$$\sigma = \sqrt{\frac{1}{n}\sum(x-\mu)^2}$$

$$\sigma = \sqrt{\frac{1}{n-1}\sum(x-\bar{x})^2}$$

where n is the number of data points in the sample or population, μ is the *population mean*, x is the observed value of the quality characteristic, and $\bar{x}$ is the sample mean. See *standard error*.

Note: Standard deviation can also be calculated by taking the square root of the *population variance* or *sample variance*.

standard deviation chart (*s* chart)—A *variable control chart* of the *standard deviation* of the results within a *subgroup*. It replaces *range chart* for large subgroup samples (rule of thumb is subgroup size of 10 to 12):

$$\text{Central line: } \bar{s}$$

$$\text{Upper control limit: } B_4\bar{s}$$

$$\text{Lower control limit: } B_3\bar{s}$$

where $\bar{s}$ is the average value of the standard deviation of the subgroups and B_3 and B_4 are factors from Appendix D. See *standard deviation*.

standard deviation of proportions—See *proportions, tests for*.

standard deviation of the intercept—See *regression coefficients, tests for*.

standard deviation of the slope—See *regression coefficients, tests for*.

standard deviation of *u* or *c*/*n*—See *u chart*.

standard error—The *standard deviation* of a *sample statistic* or estimator. When dealing with sample statistics, we either refer to the standard deviation of the sample statistic or to its standard error.

standard error of predicted values—A measure of the variation of individual predicted values of the *dependent variable* about the *population* value for a given value of the *predictor variable*. This includes the variability of individuals about the sample regression line and the sample line about the population line. It measures the variability of individual observations and can be used to calculate a *prediction interval*.

standardized work—Documented and agreed-on work instructions that express the best-known methods and work sequence for each manufacturing or assembly process.

state of statistical control—See *stable process*.

statistic—A quantity calculated from a sample of observations, most often to form an estimate of some *population parameter*.

statistical measure—A *statistic* or mathematical function of a statistic.

statistical process control (SPC)—The use of statistical techniques such as *control charts* to reduce variation, increase knowledge about the *process*, and to steer the process in the desired way.

Note 1: SPC operates most efficiently by controlling variation of the process or in-process *characteristics* that correlate with a final product characteristic, and/or by increasing the *robustness* of the process against this variation.

Note 2: A supplier's final product characteristic can be a process characteristic of the next downstream supplier's process.

statistical thinking—A philosophy of learning and action based on the following fundamental principles:

- All work occurs in a system of interconnected processes.
- *Variation* exists in all *processes*.
- Understanding and reducing variation are keys to success.

statistical tolerance interval—An interval estimator determined from a random sample so as to provide a specified level of confidence that the interval covers at least a specified proportion of the sampled *population*.

storage life—The length of time an item can be stored under specified conditions and still meet specified requirements.

storyboarding—A technique that visually displays thoughts and ideas and groups them into categories, making all aspects of a process visible at once. Often used to communicate to others the activities performed by a team as they improve a process.

stratified sampling—*Sampling* such that portions of the *sample* are drawn from different strata and each stratum is sampled with at least one sampling *unit*.

Note 1: In some cases, the portions are specified proportions determined in advance; however, in post-stratified sampling the specified proportions would not be known in advance.

Note 2: Items from each stratum are often selected by random sampling.

subgroup—(control chart usage) A group of data plotted as a single point on a control chart. See *rational subgroup*.

subsystem—A combination of sets, groups, and so on, that performs an operational function within a system and is a major subdivision of the system, for example, data processing subsystem, guidance subsystem.

supplier—Any provider whose goods and services may be used at any stage in the production, design, delivery, and use of another company's products and services. Suppliers include businesses, such as distributors, dealers, warranty

repair services, transportation contractors, and franchises, and service suppliers, such as healthcare, training, and education providers. Internal suppliers provide materials or services to internal customers.

supply chain—The series of processes and/or organizations that are involved in producing and delivering a product to the final user.

supply chain management—The process of effectively integrating and managing components of the supply chain.

survey—An examination for some specific purpose; to inspect or consider carefully; to review in detail (survey implies the inclusion of matters not covered by agreed-on criteria). Also, a structured series of questions designed to elicit a predetermined range of responses covering a preselected area of interest. May be administered orally by a survey taker, by paper and pencil, or by computer. Responses are tabulated and analyzed to surface significant areas for change.

switching rules—Instruction within an *acceptance sampling scheme* for changing from one *acceptance sampling plan* to another of greater or lesser severity of sampling based on demonstrated quality level. *Normal*, *tightened*, *reduced inspection*, or discontinuation of inspection are examples of severity of sampling.

symptom—An indication of a problem or opportunity.

system—A network of interdependent processes that work together to accomplish a common mission.

system, general—A composite of equipment, skills, and techniques capable of performing or supporting an operational role, or both. A complete system includes all equipment, related facilities, material, software, services, and personnel required for its operation and support to the degree that it can be considered self-sufficient in its intended operational environment.

system effectiveness—The result of a combination of availability, dependability, and capability. The definition of *system effectiveness* is a measure of the degree to which an item or system can be expected to achieve a set of specific mission requirements, which can be expressed as a function of availability, dependability, and capability.

availability—A measure of the degree to which an item or system is in the operable and committable state at the start of the mission when the mission is called for at an unknown point in time. The point in time is a random variable.

dependability—A measure of the item or system operating condition at one or more points during the mission. It may be stated as the probability that an item will (a) enter or occupy any one of its required operational modes during a specified mission and (b) perform the functions associated with those operational modes.

capability—A measure of the ability of an item or system to achieve mission objectives given the conditions during the mission.

T

t distribution—A theoretical distribution widely used in practice to evaluate the *sample mean* when the *population standard deviation* is estimated from the data. Also known as Student's distribution. It is similar in shape to the *normal distribution* with slightly longer tails. See *t-test*.

T^2 (Hotelling's T^2)—A multivariate test that is a generalization of the *t-test*.

Taguchi design—See *robust parameter design*.

Taguchi loss function—Pertains to where product characteristics deviate from the normal aim, and losses increase according to a parabolic function; merely attempting to produce a product within specifications does not prevent loss (loss is that inflicted on society after shipment of a product).

takt time—The available production time divided by the rate of customer demand. Operating to takt time sets the production pace to customer demand.

tally sheet—Another name for check sheet.

target value—The preferred reference value of a *characteristic* stated in a specification.

***t*-confidence interval for means (one-sample)**—When there is an unknown *mean* μ and unknown *variance* σ^2. For a *two-tailed test*, a $100(1-\alpha)\%$ two-sided confidence interval on the true mean:

$$\bar{x} - t_{\alpha/2,n-1}\frac{s}{\sqrt{n}} \le \mu \le \bar{x} + t_{\alpha/2,n-1}\frac{s}{\sqrt{n}}$$

where $t_{a/2,n-1}$ denotes the percentage point of the t *distribution* with $n-1$ *degrees of freedom* such that

$$P(t_{n-1} \le t_{\alpha/2,n-1}) = a/2.$$

See *confidence interval*.

***t*-confidence interval for means (two-sample)**—When there is a difference in *means* (μ_1 and μ_2) and the *variances* are unknown. The combined or pooled estimate of the common variance s_p is:

$$s_p^2 = \frac{(n_1-1)s_1^2 + (n_2-1)s_2^2}{n_1+n_2-2}$$

The $100(1-\alpha)\%$ two-sided confidence interval on μ_1 and μ_2 is

$$(\bar{x}_1 - \bar{x}_2) - t_{\alpha/2,n_1+n_2-2}s_p\sqrt{\frac{1}{n_1}+\frac{1}{n_2}} \le \mu_1+\mu_2 \le (\bar{x}_1 - \bar{x}_2) + t_{\alpha/2,n_1+n_2-2}s_p\sqrt{\frac{1}{n_1}+\frac{1}{n_2}}$$

where $\bar{x}_1$ and $\bar{x}_2$ are the sample means, $t_{a/2}$ is the value from a t-*distribution* table, and α is $1 -$ *confidence level*/100. See *confidence interval*.

team—A group of two or more people who are equally accountable for the accomplishment of a task and specific performance goals; it is also defined as a small number of people with complementary skills who are committed to a common purpose.

team-based structure—Describes an organizational structure in which employees are organized into teams performing a specific function of the business, such as handling customer complaints or assembling an engine.

team building/development—The process of transforming a group of people into a team and developing the team to achieve its purpose.

team dynamics—The interactions that occur among team members under different conditions.

team growth, stages of—Refers to the four development stages through which groups typically progress: forming, storming, norming, and performing. Knowledge of the stages helps team members accept the normal problems that occur on the path from forming a group to becoming a team.

team leader—A person designated to be responsible for the ongoing success of the team and keeping the team focused on the task assigned.

temporary/ad hoc team—A team, usually small, formed to address a short-term mission or emergency situation.

testing—A means of determining the ability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating actions and conditions.

tests for means—See *means, tests for*.

tests for proportions—See *proportions, tests for*.

tests for regression coefficients—See *regression coefficients, tests for*.

tests for significance—See *significance test*.

tests for variances—See *variances, tests for*.

threshold control—Threshold control applies to *process control* where the primary interest is in events near *control limits*. Typical *control charts* used for this purpose are *h*, *g*, *c*, *u*, *np*, *p*, *x* (individuals), MR, $\bar{x}$, *R*, and *s* charts. This type of control is most often used in the early stages of a quality improvement process. See also *deviation control*.

throughput time—The total time required (processing + queue) from concept to launch or from order received to delivery, or raw materials received to delivery to customer.

tightened inspection—An *inspection* more severe than *normal inspection* to which the latter is switched when inspection results of a predetermined number of *lots* indicate that the quality level achieved by the *process* is poorer than that specified.

time, active—That time during which an item is in an operational inventory.

time, checkout—That element of *maintenance time* during which performance of an item is verified to be in a specified condition.

time, delay—That element of downtime during which no maintenance is being accomplished on the item because of either supply or administrative delay.

time, down (downtime)—That element of active time during which an item is not in condition to perform its required function. (Reduces *availability* and *dependability*.)

time, supply delay—That element of *delay time* during which a needed replacement item is being obtained.

time, up (uptime)—That element of *active time* during which an item is in condition to perform its required functions. (Increases *availability* and *dependability*.)

time series—The sequence of successive time intervals.

tolerance—The difference between upper and lower *specification limits*.

tolerance limit—See *specification limit*.

top management commitment—Participation of the highest-level officials in their organization's quality improvement efforts. Their participation includes establishing and serving on a quality committee, establishing quality policies and goals, deploying those goals to lower levels of the organization, providing the resources and training that the lower levels need to achieve the goals, participating in quality improvement teams, reviewing progress organization-wide, recognizing those who have performed well, and revising the current reward system to reflect the importance of achieving the quality goals. Commitment is top management's visible, personal involvement as seen by others in the organization.

total productive maintenance (TPM)—Reducing and eventually eliminating equipment failure, setup and adjustment, minor stops, reduced speed, product rework, and scrap.

total quality management (TQM)—A term initially coined by the Naval Air Systems Command to describe its management approach to quality improvement. Total quality management (TQM) has taken on many meanings. Simply put, TQM is a management approach to long-term success through customer satisfaction. TQM is based on the participation of all members of an organization in improving processes, products, services, and the culture they work in. TQM benefits all organization members and society. The methods for implementing this approach are found in the teachings of such quality leaders as Philip B. Crosby, W. Edwards Deming, Armand V. Feigenbaum, Kaoru Ishikawa, Joseph M. Juran, and others.

training—The skills that employees need to learn in order to perform or improve the performance of their current job or tasks, or the process of providing those skills.

training evaluation—The techniques and tools used and the process of evaluating the effectiveness of training.

training needs assessment—The techniques and tools used and the process of determining an organization's training needs.

transformation—A reexpression of data aimed toward achieving *normality*.

treatment—The specific setting of *factor levels* for an *experimental unit*.

tree diagram—A management and planning tool that shows the complete range of subtasks required to achieve an objective. A problem-solving method can be identified from this analysis.

trimodal—A *probability distribution* having three distinct statistical modes.

TRIZ—(Russian) The theory of the inventive solution of problems. A set of analytical and knowledge-based tools that are typically hidden in the subconscious minds of creative inventors.

true value—A value for a *quantitative characteristic* that does not contain any sampling or measurement variability. (The true value is never exactly known; it is a hypothetical concept.)

***t*-test**—A *test for significance* that uses the *t distribution* to compare a *sample statistic* to a hypothesized *population mean* or to compare two means. See *t-test (one sample)*, *t-test (two-sample)*, *t-test (paired data)*.

Note: Testing the equality of the means of two normal populations with unknown but equal variances can be extended to the comparison of k population means. This test procedure is called *analysis of variance (ANOVA)*.

***t*-test (one-sample)**—

$$t = \frac{\bar{x} - \mu_0}{s/\sqrt{n}}$$

where $\bar{x}$ is the mean of the data, μ_0 is the hypothesized *population mean*, s is the *sample standard deviation*, and n is the *sample* size. The degrees of freedom are $n - 1$.

***t*-test (paired data)**—Samples are paired to eliminate differences between specimens. The test could involve two machines, two test methods, two treatments, and so on. Observations are collected on pairs of the two machines, tests, treatments, and so on. The differences of the pairs of observations on each of the n specimens: $d_j = x_{1j} - x_{2j}$, $j = 1$,

$$t = \frac{\bar{d}}{s_d/\sqrt{n}}$$

where

$$\bar{d} = \frac{1}{n}\sum_{j=1}^{n} d_j$$

and

$$s_d^2 = \frac{\sum_{j=1}^{n} d_j^2 - \frac{\left(\sum_{j=1}^{n} d_j\right)^2}{n}}{n-1}$$

***t*-test (two-sample, equal variances)**—When there are two *populations* with unknown *means* and unknown *variances* that are assumed to be equal, the variances can be pooled to determine a pooled variance:

$$s_p^2 = \frac{(n_1 - 1)s_1^2 + (n_2 - 1)s_2^2}{n_1 + n_2 - 2}$$

where s_1 and s_2 are the individual sample variances, and n_1 and n_2 are the respective *sample sizes*.

The *t*-test is

$$t = \frac{\overline{x}_1 - \overline{x}_2}{s_p\sqrt{\frac{1}{n_1} + \frac{1}{n_2}}}$$

where s_p is the pooled variance calculated, $\overline{x}_1$ and $\overline{x}_2$ are the means of the respective populations, and n_1 and n_2 are the respective *sample* sizes.

The degrees of freedom, n are $n = n_1 + n_2 - 2$.

***t*-test (two-sample, unequal variances)**—When there are two *populations* with unknown *means* and unknown variances that are assumed to be unequal, the sample standard deviation of $(\overline{x}_1 - \overline{x}_2)$ is:

$$s = \sqrt{\frac{s_1^2}{n_1} + \frac{s_2^2}{n_2}}$$

The degrees of freedom are:

$$v = \frac{\left(s_1^2/n_1 + s_2^2/n_2\right)^2}{\left[\left(s_1^2/n_1\right)^2/(n_1 - 1)\right] + \left[\left(s_2^2/n_2\right)^2/(n_2 - 1)\right]} - 2$$

2^k factorial design—A factorial design in which k factors are studied, each at exactly two levels.

two-tailed test—A *hypothesis* test that involves tails of a distribution. Example: We wish to reject the *null hypothesis, H_0,* if the true *mean* is within minimum and maximum (two tails) limits.

$$H_0: \mu = \mu_0$$

$$H_1: \mu \leq \mu_0$$

type I error—The *probability* or risk of rejecting a *hypothesis* that is true. This probability is represented by α *(alpha)*. See diagram. See *operating characteristic curve* and *producer's risk*.

	H_0 true	**H_0 false**
Do not reject H_0	Correct decision	Error type II
Reject H_0	Error type I	Correct decision

type II error—The *probability* or risk of accepting a *hypothesis* that is false. This probability is represented by β *(beta)*. See *power curve* and *consumer's risk*.

U

***u* (count per unit)**—The *events* or events per *unit* where the opportunity is variable. More than one event may occur in a unit.

Note: For *u*, the opportunity is variable; for *c*, the opportunity for occurrence is fixed.

U—See *upper specification limit*.

***u* chart**—An *attributes control chart* for number of *events* per unit where the opportunity is variable.

Note: Events of a particular type (e.g., number of absentees or number of sales leads) form the count. In the quality field, events are often expressed as nonconformities, and the variable opportunity relates to *subgroups* of variable size or variable amounts of material.

$$\text{Central line: } \bar{u}$$

$$\text{Control limits: } \bar{u} \pm 3\sqrt{\bar{u}/n}$$

where $\bar{u}$ is the average number of events per unit and n is the total number of samples. $\bar{u}$ is calculated as $\bar{u} = \bar{c}/n$.

Note: If the *lower control limit* (LCL) calculates ≤ 0, there is no LCL.

UCL—See *upper control limit*.

unacceptable quality level (UQL)—See *limiting quality level*.

uncertainty—A *parameter* that characterizes the *dispersion* of the values that could reasonably be attributed to the particular quantity subject to measurement or *characteristic*. Uncertainty indicates the variability of the measured value or characteristic that considers two major components of error: (1) *bias* and (2) the random error from the *imprecision* of the measurement process.

unconditional guarantee—An organizational policy of providing customers an unquestioned remedy for any real or perceived product or service deficiency.

unique lot—A *lot* formed under conditions peculiar to that lot and not part of a routine sequence.

unit—A quantity of product, material, or service forming a cohesive entity on which a measurement or observation can be made.

universe—A group of *populations*, often reflecting different *characteristics* of the items or material under consideration.

upper control limit (UCL)—The *control limit* on a *control chart* that defines the upper control boundary.

upper specification limit or **upper tolerance limit (U)**—The *specification limit* that defines the upper limiting value.

UQL—See *limiting quality level*.

URPL—See *rejectable process level*.

USDA—US Department of Agriculture.

useful life—The number of life units from manufacture to when an item has an unrepairable failure or unacceptable failure rate.

V

validation—Confirmation by examination of objective evidence that specific requirements and/or a specified intended use are met.

value-added—Tasks or activities that convert resources into products or services consistent with customer requirements. The customer can be internal or external to the organization.

value chain—See *supply chain*.

value stream—The primary actions required to bring a product from concept to placing the product in the hands of the end user.

value stream mapping—The technique for mapping the value stream.

variable—(control chart usage) A quality *characteristic* that is from a *continuous scale* and is *quantitative* in nature.

variables, inspection by—See *inspection by variables*.

variables control chart—A *Shewhart control chart* where the measure plotted represents data on a *continuous scale*.

variance—A measure of the *variation* in the data. When working with the entire *population*, the population variance is used; when working with a *sample*, the sample variance is used. The population variance is based on the mean of the squared deviations from the *arithmetic mean* and is given by

$$\sigma^2 = \frac{1}{n}\sum(x-\mu)^2$$

The sample variance is based on the squared deviations from the *arithmetic mean* divided by $n - 1$ and is given by

$$s^2 = \frac{1}{n-1}\sum(x-\bar{x})^2$$

where n is the number of data points in the sample or population, μ is the *population mean*, $\bar{x}$ is the *observed value* of the quality characteristic, and $\bar{x}$ is the sample mean. See *standard deviation*.

variances, tests for—A formal statistical test based on the *null hypothesis* that the *variances* of different groups are equal. Many times in *regression analysis* a formal test of variances is not done. Instead, *residual analysis* checks the assumption of equal variance across the values of the *response variable* in the *model*. For two variances, see *F-test*.

variation—The difference between values of a *characteristic*. Variation can be measured and calculated in different ways, such as *range*, *standard deviation*, or *variance*. Also known as *dispersion* or *spread*.

verification—The act of reviewing, inspecting, testing, checking, auditing, or otherwise establishing and documenting whether items, processes, services, or documents conform to specified requirements.

virtual team—A boundaryless team functioning without a commonly shared physical structure or physical contact, using technology to link the team members.

visual control—A technique of positioning all tools, parts, production activities, and performance indicators so that the status of a process can be understood at a glance by everyone; it provides visual clues to aid the performer in correctly processing a step or series of steps, to reduce cycle time, to cut costs, to smooth flow of work, and to improve quality.

vital few, useful many—A term used by J. M. Juran to describe his use of the Pareto principle, which he first defined in 1950. (The principle was used much earlier in economics and inventory control methodologies.) The principle suggests that most effects come from relatively few causes; that is, 80% of the effects come from 20% of the possible causes. The 20% of the possible causes are referred to as the vital few; the remaining causes are referred to as the useful many. When Juran first defined this principle, he referred to the remaining causes as the trivial many but, realizing that no problems are trivial in quality assurance, he changed it to useful many.

voice of the customer (VOC)—An organization's efforts to understand the customers' needs and expectations (voice) and to provide products and services that truly meet such needs and expectations.

W

w—The span of the *moving average*.

warning limits—There is a high *probability* that the *statistic* under consideration is in a *state of statistical control* when it is within the warning limits (generally two standard deviations) of a *control chart*. See *Shewhart control limits*.

Note: When the value of the statistic plotted lies outside a warning limit but within the *action limit*, increased supervision of the *process* to prespecified rules is generally required.

waste—Activities that consume resources but add no value: visible waste (e.g., scrap, rework, downtime) and invisible waste (e.g., inefficient setups, wait times of people and machines, inventory).

WBS—See *work breakdown structure*.

wear-out—The process that results in an increase of the *failure rate* or probability of failure with increasing number of *life units*.

Weibull distribution—A distribution of continuous data that can take on many different shapes and is used to describe a variety of patterns; it is used to define when the "infant mortality" rate has ended and a steady state has been reached (decreasing failure rate); relates to the bathtub curve.

work analysis—The analysis, classification, and study of the way work is done. Work may be categorized as value-added (necessary work) or non-value-added (rework, unnecessary work, idle). Collected data may be summarized on a Pareto chart, showing how people within the studied population work. The need for and value of all work is then questioned and opportunities for improvement identified. A time use analysis may also be included in the study.

workbook—A collection of exercises, questions, or problems to be solved during training; a participant's repository for documents used in training (e.g., handouts).

work breakdown structure (WBS)—A project management technique by which a project is divided into tasks, subtasks, and units of work to be performed.

work group—A group composed of people from one functional area who work together on a daily basis and whose goal is to improve the processes of their function.

work instruction—A document that answers the question, "How is the work to be done?"

w_t—The *exponentially weighted moving average (EWMA)* at the present time t.

w_{t-1}—The *exponentially weighted moving average (EWMA)* at the immediately preceding time interval.

X

x—The observed value of a quality characteristic; specific observed values are designated x_1, x_2, x_3, and so on. x is also used as a predictor value. See *input variable* or *predictor variable*.

$\bar{x}$ **(pronounced x-bar)**—The *average*, or *arithmetic mean*. The average of a set of n observed values is the sum of the observed values divided by n:

$$\bar{x} = \frac{x_1 + x_2 + \ldots + x_n}{n}$$

$\bar{x}_0$—See *control chart, standard given*.

$\bar{x}_i$—The average of the ith subgroup (when $n = 1$, $\bar{x}_i = x = x_i$).

$\bar{x}$ **chart (averages control chart)**—A *variables control chart* for evaluating the *process* level in terms of *subgroup averages*:

$$\text{Central line} : \bar{\bar{x}} \text{ (if standard given, } \bar{x}_0)$$

$$\text{Control limits} : \bar{\bar{x}} \pm A_3\bar{s} \text{ or } \bar{\bar{x}} \pm A_2\bar{R} \text{ (if standard given, } \bar{x}_0 \pm As_0 \text{ or } \bar{x}_0 \pm A_2R_0)$$

where $\bar{\bar{x}}$ is the average of the subgroup values; $\bar{s}$ is the sample *standard deviation*; A, A_2, and A_3 are *control chart factors* (see Appendix D); s_0 is the standard value of the population standard deviation; and R_0 is the standard value of the *range*. (Use the formula with $\bar{R}$ when the sample size is small, the formula with $\bar{s}$ when the sample is larger—generally > 10 to 12.)

x **chart**—See *individuals chart*.

$\bar{\bar{x}}$ **(pronounced x-double-bar)**—The average for the set under consideration of the subgroup values of $\bar{x}$.

Y

y—y is sometimes used as an alternate to x as an observation. In such cases, y_0, should be substituted where appropriate. See *output variable* or *response variable*.

$\bar{y}$ **(pronounced y-bar)**—The *average*, or *arithmetic mean*, of y. It is calculated exactly the same as $\bar{x}$.

$\bar{y}_0$—See y and *control charts, standard given*.

$\bar{\bar{y}}$ **(pronounced y-double-bar)**—The average for the set under consideration of the subgroup values of $\bar{y}$. See y.

Z

***z*-confidence interval for means (one-sample)**—Given an unknown *mean* μ and known *variance* σ^2, then the $100(1-\alpha)\%$ *two-sided* confidence interval on μ is

$$\bar{x} - Z_{\alpha/2}\frac{\sigma}{\sqrt{n}} \le \mu \le \bar{x} + Z_{\alpha/2}\frac{\sigma}{\sqrt{n}}$$

where $\bar{x}$ is the *mean* of the data, σ is the *population standard deviation*, and *n* is the *sample* size.

zero defects—A performance standard popularized by Philip B. Crosby to address a dual attitude in the workplace: people are willing to accept imperfection in some areas, while in other areas they expect the number of defects to be zero. This dual attitude has developed because of the conditioning that people are human, and humans make mistakes. The zero-defects methodology states, however, that if people commit themselves to watching details and avoiding errors, they can move closer to the goal of perfection.

zero investment improvement—Another name for a kaizen blitz.

***z*-test (one-sample)**—Given an unknown *mean* μ and known *variance* σ^2:

$$z = \frac{\bar{x} - \mu_0}{\sigma/\sqrt{n}}$$

where $\bar{x}$ is the mean of the data, μ_0 is the standard value of the *population mean*, σ is the *population standard deviation*, and *n* is the *sample* size.

Note: If the variance is unknown, then the t-*test* applies.

***z*-test (two proportions)**—To test if two binomial parameters are equal, the null hypothesis is H_0: $p_1 = p_2$ and the alternate hypothesis is H_1: $p_1 \neq p_2$. If the null hypothesis is true, then $p_1 = p_2 = p$, and

$$\hat{p} = \frac{n_1\hat{p}_1 + n_2\hat{p}_2}{n_1 + n_2}$$

The test is then

$$z = \frac{\hat{p}_1 - \hat{p}_2}{\sqrt{\hat{p}(1-\hat{p})\left(\frac{1}{n_1} + \frac{1}{n_2}\right)}}$$

and H_0 should be rejected if $|z| > z_{\alpha/2}$.

***z*-test (two-sample)**—Given unknown *means* μ_1 and μ_2, and known *variances* σ_1^2 and σ_2^2:

$$z = \frac{\bar{x}_1 - \bar{x}_2}{\sqrt{\frac{\sigma_1^2}{n_1} + \frac{\sigma_2^2}{n_2}}}$$

where $\bar{x}_1$ is the mean of the first *population* and $\bar{x}_2$ is the mean of the second population, σ_1 is the *standard deviation* of the first population and σ_2 is the standard deviation of the second population, and n_1 and n_2 are the respective *sample* sizes.

Note: If the variance is unknown, then the t-*test* applies.

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About the Editor

Sandra L. Furterer is an Associate Professor and Department Chair at the University of Dayton in the Department of Engineering Management, Systems, and Technology. Dr. Furterer has over 25 years of experience in business process and quality improvements in multiple service industries, including healthcare, retail, consulting, information systems, and financial services. She previously was a VP of Process Improvement for two financial services firms in Columbus, Ohio. She also was the Enterprise Performance Excellence leader that deployed Lean Six Sigma in a hospital system in south Florida. She holds a PhD in Industrial Engineering from the University of Central Florida, an MBA from Xavier University, and bachelor's and master's degrees in Industrial and Systems Engineering from Ohio State. She is an ASQ Certified Manager of Quality/Organizational Excellence, an ASQ Certified Six Sigma Black Belt, an ASQ Certified Quality Engineer, an ASQ fellow, and a certified Six Sigma Master Black Belt. Dr. Furterer is an author or coauthor of several textbooks and journal articles. She has refereed conference papers and proceedings publications on systems engineering, Lean Six Sigma, process improvement, operational excellence, and engineering education. Her research interests include Lean Six Sigma, quality management, and systems engineering applied to service industries.

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