Chapter 12
Fundamentals of Statistical Quality Inspection

12.1 Measured Quality of Manufactured Products

Measured quality of manufactured products is always subject to a certain amount of variation as a result of chance. A system of chance causes is inherent in any particular scheme of production as well as of inspection. Variation within this pattern is inevitable. The reasons for variation outside this pattern should, however, be discovered and corrected.

Nothing walks on a straight line, said Werner Heisenberg, the physicist. This is reflected in statistical quality control systems (SQC) and procedures—the theme of this and of the next three chapters. SQC systems and procedures can be defined as the use of probability theory in problems of quality inspection and product assurance. The charts associated to them are the visualization of a quality control analysis.

- Instrumental in inspecting, improving, or restructuring production systems
- Able to provide secure information to be used in establishing more effective inspection and/or acceptance procedures
- Coming forward with evidence to hunt for causes of variation, and taking action intended to correct them
- Providing a basis for current decisions on acceptance or rejection of manufactured or purchased products, and
- Capable of familiarizing personnel with the importance and use of control charts, as well as information on product quality and process accuracy derived from them.

Both products and also manufacturing processes have tolerances. Through the disclosure of natural tolerances and control limits of a production process, the control chart permits better decisions on engineering tolerances and improved comparisons between alternative designs and/or between alternative production methods.

Through improvement of conventional acceptance procedures, SQC can provide a significantly higher quality assurance at lower inspection cost. It can as well

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tell in a documented manner the process behaves as expected and, therefore, it should be left alone.

The first conscience of the need of a well established procedure for quality control goes back to the nineteenth century, when industry became aware of the impact of product quality—placing responsibility for it on the line organization. At that time, however, there were no inspectors as we conceive them today and few designers appreciated the need and impact of quality assurance. A major step forward was made in the 1920 and 1930s with:

- The production line becoming an independent department,
- Advent of scientific management, and the realization that inspection and was a specialized job which work differed from production work.

With this, inspection gradually emerged a recognized self-standing function, called to screen the bad stuff from the good products prior to shipment. The number of inspectors grew as factories became bigger and their tools sharpened up. Statistical methods were developed during World War II, making quality control a sophisticated enterprise.

With these evolutionary steps in mind and the growing emphasis on product assurance quality control, and most particularly SQC should be viewed as a tool which initiates and documents—therefore influences—decisions about product acceptance. This is in a nutshell a definition of what *quality control* is all about, and it can have two interpretations:

- A narrow one centered on measured quality of manufactured products which in Part I we called quality control in the small, and
- A much wider interpretation which promotes quality and reliability from engineering design to production, inspection, and field maintenance which has been labeled quality control in the large.

Sustaining quality is a demanding process (and so are, incidentally the famed apple pie and motherhood). Whether in the small or in the large product assurance confronts two problems: errors in measurement and faulty procedures. Both can be seen as opportunities for action. Errors, John von Neumann has said:

- Are not adverse or unwanted aftermaths of the study we do, or the method we are using.
- They are integral part of our work, and we should be using their existence to our advantage.

In control systems, for example, errors make feasible to use of *feedback* which has opened wide perspectives in engineering design and product development. Figure 12.1a presents the simple feedback most frequently found in applications from servomechanisms to automatic controls. In a more sophisticated implementation, which capitalizes on expert systems, the feedback uses knowledge engineering and learns as it goes along. This is the example of the block diagram in Fig. 12.1b.

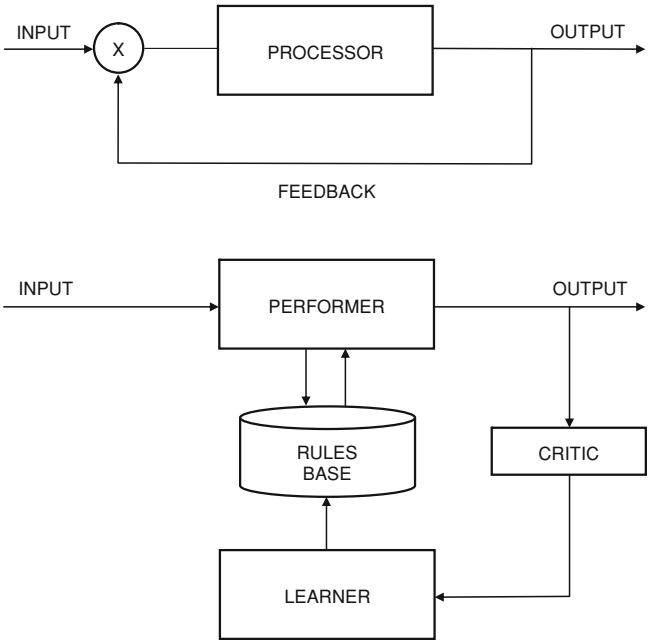

Fig. 12.1 Feedback can be simple as in a servomechanism or sophisticated based on knowledge engineering

A sophisticated approach to feedback and inspection is a leap forward from the classical theory of measurements and their errors, which has assumed that they were independent and normally distributed. That near-sighted approach was developed mainly as a model for the distribution of errors of measurements occurring in astronomy, where sources of variability existed in the nonuniformity of experimental techniques.

By contrast, the modern, scientific way of looking at errors is that they are produced by a system of chance causes which exist not only in manufacturing and the provision of services, but as well in any type of experiment, or measurement, we are doing. The causes may be quite diverse. Errors might find their origin in:

- Heterogeneity of experimental materials, or
- Variations of manufacturing conditions not being under control.

In many cases of quality control endeavors we practically have no clear-cut assignable causes, yet we must deal with the existence of such errors. To our advantage, we have some clues of cause and effect. For instance, the heterogeneity of the experimental materials might show a *systematic* and relatively large variation of experimental results. But random errors do not behave that way.

Errors can have many causes, some of them transparent. There is indeed a significant difference between errors due to instruments and methods, and those

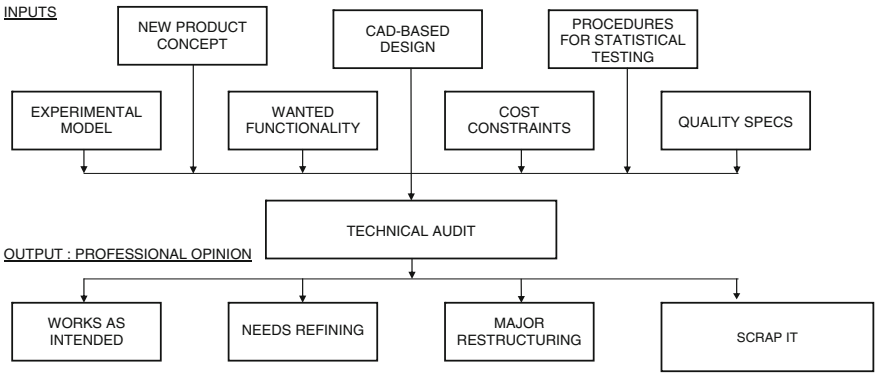

Fig. 12.2 Inputs to a technical audit and professional opinion provided as output

resulting from the experimental factors themselves. The principle in scientific experimentation is that:

- *If* variations caused by nonexperimental factors are not in a state of statistical control,
- *Then* the experiment should not be administered.

Factors which bring the experiment outside the range in which statistical experimental control is effective, have first to be corrected or compensated. Only then can valid conclusions be drawn by means of statistical methods. (The first known compensation has been to allot the treatments to the experimental units at random. R.A. Fisher, the British statistician, was the first to produce randomized experiments). As we saw in Chap. 11 factor analysis and Latin squares are the modern way for dealing with this problem.

A similar statement can be made about quality control in manufacturing. As the opening paragraph of this chapter brought to the reader's attention measured quality of manufactured products is always subject to a certain amount of variation due to chance. Ideally this is the stuff to which, ideally SQC addresses itself. Gross errors may as well be due to organizational reasons. When this happens, responsible for their correction is senior management.

12.2 Organization for Quality Control

Based on the principle that quality has to be embedded into the product at the drafting board, which has been brought to the reader's attention in Part I, the block diagram in Fig. 12.2 defined the inputs and the outputs of the quality equation in an enterprise. The variables of technological development have to be enlarged to reflect the use of statistical tools.

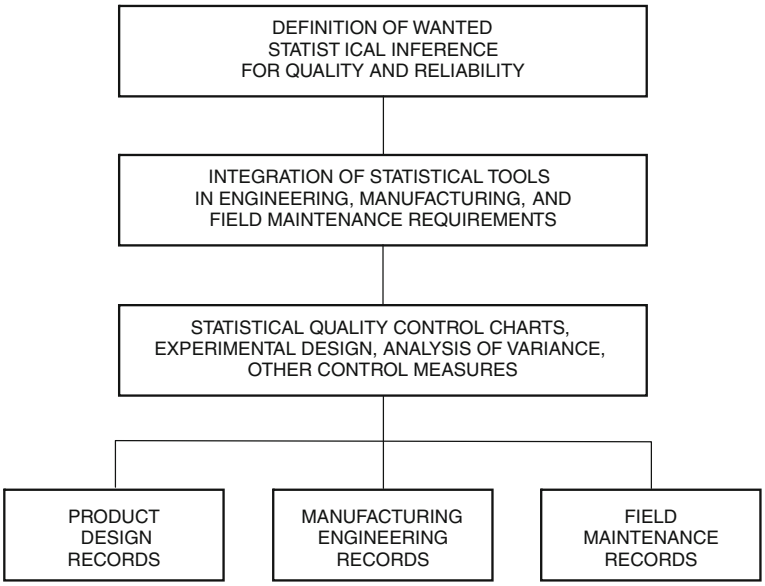

Fig. 12.3 Senior management should audit whether means for statistical inference have been incorporated since the drafting board

The purpose of this simplified graph is to aid in recognition of the level of product design where procedures for statistical testing must join the product assurance premises already in product design. Quality assurance will be significantly assisted by statistical analysis of data, keeping well in mind that statistical methods useful in engineering design are far from having been exhausted.

As far as quality control in the large is concerned design engineers can perform so much better if they are familiar with, and incorporate in their work, a statistical testing procedure. Later on, this will become a milestone in the company's inspection system enabling it to assure that all components and finished products (as well as all supplies and services) conform to specification requirements.

Though participants to my seminars do not particularly like to hear me saying so, I never fail pointing out that in several cases the quality control systems and practices that manufacturing organizations are using to guarantee quality levels for their products are of the 1920 and the 1930s. This is in dissonance to:

- Higher quality demands by customers, and
- The use of more technologically sophisticated materials.

Taken together, these background quality testing conditions suggest that in many plants quality assurance practices are now obsolete, or fast becoming so, which explains why quality costs have increased astronomically in the last decades. In many companies they are between 7 and 10% of sales. To bend the cost curve, senior management should be keen to audit whether means for statistical inference have been incorporated since the drafting board.

Figure 12.3 gives a concise view of the steps involved in this function, which is needed to substantiate the emergence of holistic quality control as a technically recognized full-time function. In a way quite similar to that of risk management in a financial firm, the quality control in the large responsibility in a department of a manufacturing enterprise should be standing high up in the organization.

There are several reasons for this structural position, foremost among them being the fact that independence of opinion in quality control is a "must." Therefore the quality control department should depend neither from engineering (a rare case) nor from manufacturing (its usual remit).

It should be free of conflicts of interest to perform inspections and tests required to substantiate product conformance in terms of drawings, specifications, and other requirements. A quality in the large function must also perform all inspections and tests required of products and processes, informing in the most timely manner engineering, manufacturing, and maintenance of their deliverables.

Quality control is promoted if the results of testing and inspection are prescribed in a clear, complete, and unambiguous way. The results of tests inspections and audits should be readily available through online access. The management of adequate records of all inspections and tests is not an option; it is a responsibility including the:

- Nature and number of observations made by product or process,
- Number and type of deficiencies found,
- Quantities approved and rejected, and
- Nature of appropriate corrective action being taken.

Corrective action is the alter ego of quality control. The responsible department must always be ready to correct assignable conditions which resulted, or could result, from testing or inspection. Database mining can be instrumental in defining patterns for repeated events which time and again handicap product performance.

Another requirement is that the company's inspection system also audits whether procedures are in place to assure that drawings, specifications and instructions required by production are always up to date and accessible online. Such procedures should be integral part of the inspection system with certification regarding the timeliness, accuracy, and condition of updates.

Like well-planned experiments, quality inspections require the maintenance of detailed records throughout all stages of product performance. In fact, not only data on inspections and tests *per se*, but also checks made to assure accuracy of inspection and testing people and equipment should be data based. In short, all quality control related records should be available for consultation and review, and this will also be useful in the next quality control study.

The objective of never relinquishing the quality assurance responsibility is to obtain a high degree of exactness and efficiency which may also contribute to reducing the cost of the inspection function while assuring product quality. Example of an area where investigation may provide welcome inputs are the sampling plans we examine in Chaps 13– 15 which supply rational techniques, for:

- Mass observations, and
- Assessment of frequencies, means, variances and other elements of individual, and collective description.

Quality control will be often asked by senior management explanations based on observational data, particularly in connection to quality costs which are mainly:

- Prevention costs, incurred in keeping defects from occurring in the first place. Included here are such costs as quality control engineering quality training, and quality maintenance.
- Failure costs caused by materials and products that do not meet quality specifications—scrap, spoilage, field complaints which can rise above 25% of total costs, and
- Appraisal costs including expense of maintaining company quality levels by means of evaluations of product quality. They cover such elements as inspection and laboratory acceptance testing.

Costs of any type, and to this quality costs are in no way an exception, should always be under scrutiny. In the connection, a statistical quality control plan can contribute in reduction of overall costs by a cut in failure costs; swamping defects; improving the general level of product quality; lower appraisal costs; and improving inspection and test methods. An example is the replacement of routine inspections by fewer but more effective SQC inspections.

12.3 Responsibilities in Quality Control

Section 12.2 made the point that though with modern techniques we try to minimize the sources of variation, variation still exists, and will continue doing so. Therefore, the manufacturer must have a sound quality control system in order to be sure of what he is going to offer to the market is a product whose quality leaves nothing to be desired.

This in no way means that every product has to hit an unprecedented quality level. As a matter of principle, too high quality may be just as bad as too low, because it prices the product out of the market. The outgoing product quality has to be balanced and correspond to that which is demanded by the market and offered by the product. This being said, it is a wise strategy to assure that (other things equal) *our* product is of somewhat better quality than that of competitors. This involves five basic quality control responsibilities aimed to uphold quality while swamping costs:

1. *New design control*. This involves analyzing the "quality ability" of a new product or process, as well as "debugging" quality problems to give a defect-free outcome. Part of this mission is the planning of inspections and tests to be carried on when production is under way on a new product, incremented by establishing continuous control of in-process quality. Another responsibility, of

which the reader is already aware, is the design of inspection and testing equipment that can be integrated into manufacturing processes to permit them to check their own work.

2. *Incoming materials control*. In performing this duty quality control engineering must assist in the establishment of sound quality relationships with vendors by means of planning the periodic rating of quality performance of present suppliers, evaluating the quality capability of potential suppliers; working with vendors in understanding the quality requirements; and establishing quality-certification programs for all purchased materials, component parts, and equipment.

3. *Cost control*. The exercise of this responsibility requires that quality control engineering carries on the cost measurement and quality cost reduction activity required for cost optimization. This requires handholding with both design engineering and manufacturing, enriching each product or process with checks and tests against subjective evidence. Evidently also integrating statistical methods into the decision process.

4. *Special process studies*. This includes analysis of complex in-process quality problems that have been fed back by engineering, manufacturing, field maintenance, or special inspection. The core of this work should be experimental design techniques (Chap. 11) which allows to objectively examining quality control premises, tearing down the citadel of medieval practices which are still around—largely untouchable because their need is "obvious."

5. *Outgoing product control*. In this the most obvious mission is that of making sure that the customers are supplied with dependable quality and that the outgoing product meets specifications and tolerances. Well-managed organizations appreciate that outgoing product control will be so much more effective if the different company departments are not "silos" but collaborate in the development of testing procedures, sampling plans, outgoing quality database, and timely examination of feedback data for corrective action.

As we have already seen quality inspection is promoted by both observational and experimental data. Observational inspection is done by variables or by attributes (respectively Chaps 13 and 14). In attributes sampling, randomly selected samples are inspected to determine whether the quality characteristics of the item are within specification limits through a "go, no go" approach. By contrast, in variables inspection a specific quality characteristic is actually measured, sample means plotted, and inspected whether they fall within control limits.

It is irrational not to use effective sampling plans developed over the years. These are associated to normal, reduced, or tightened inspection. The latter is invoked when the process average exceeds the statistically based control limits for a specified quality level. Existing systems and procedures make it feasible to proceed with frequent periodic computations of mean values which enable to detect, at an early stage downward trends in quality.

As we have seen in Chap. 10, when quality levels and sampling risks (producer's and consumer's risk) associated to valid statistical procedures are employed, the result is a dependable estimate of quality levels and risk values. Normally, these must be based on full knowledge of technical design requirements of the product and of its manufacturing process. Experience in SQC is a major "plus."

A mark of distinction in quality control is to be ahead of the curve of adverse events and bend it before it raises its head. This cannot be achieved without experimentation, and the standardization of reporting procedures. Chapter 11 brought to the reader's attention that it is sound practice to carry out tests under identical conditions, even if it is difficult to obtain such uniformity, due to the natural variability of test equipment which (bought over a period of time) does not follow always the same standard.

The effect of human elements conducting the study, procedural changes happening over time, and environmental influence add to the variability. Its planned elimination, whenever this is possible, is welcome because in a way it broadens the experienced conclusions rendering our data more applicable. Within this perspective, it is advisable to randomize:

- Sequence of testing, and
- Selection of test materials.

Having randomized with respect to test sequence (subjects, material, and time), we are more confident that if time, material, or operators have a definite effect, this too will be randomly scattered throughout the results. The downside of this procedure is that it might increase experimental error, but at the same time it eliminates possible bias. In a well-planned experiment on product assurance, all sources of variation should be considered in order to reach objective conclusions.

Objective conclusions are one of the quality control's most basic responsibilities, and this underlines the importance of statistical methods in conjunction to sound engineering practices. "Systematize, then mechanize" is a sound guideline in quality control, because what is most important is not technically elaborate quality control equipment, but skill on behalf of those who choose them and use them in a systematic, well-ordered manner.

The automation of part of quality control assurance work requires far better procedures for determining the quality capability of new designs prior to production, than that which was required in conjunction to manual intervention. The preparatory work demands skill and detail and has to take place ahead of the use of complex test equipment. This policy requires that senior management:

- Emphasizes the need for on planning and designing the quality inspection system;
- Evaluates through tests and inspections the quality capability of current and potential suppliers, and
- Gears quality control to detect problems before they become costly like the not-so-infrequent recalls by auto manufacturers of their motor vehicles.

Section 12.2 has underlined the need for quality control records to be utilized not only for in-process but as well for incoming product inspections. Inspection during manufacturing and final assembly will be half-baked if the procurement sources are not subjected to quality control. A similar statement is valid of the calibration of inspection equipment and certification of special processes even if one tantum.

When statistical process controls are utilized as quality evidence for determining acceptability of a lot, product or process, control charts and frequency distributions, are important inspection records. In addition, it is imperative that a manufacturing firm maintains suitable records of the quality performance of its suppliers. Integral part of supplier quality records, particularly valuable for corrective action is the evaluation of:

- How rapidly the supplier responds,
- How thorough and complete is the corrective action, and
- Whether that action is limited to particular lots or provides basic correction to prevent repetition of unwanted events or errors in the production of subsequent lots.

Whether they come from the production line or from examinations and tests, quality control information elements provide much of the objective quality evidence required to determine the acceptability of the quality of *our* company's products. In the general case, quality control records are considered adequate if they identify quality characteristics as well as inspection and test results. Such records can also be used to provide evidence that required inspection has been performed, when and by whom.

12.4 Six Sigma: A Quality Culture

Quality control's responsibility is in no way limited to the observance of engineering specifications, though most evidently this is very important. The responsibility is much wider and it includes the creation of a *quality control culture* in the organization, as well as a permanent environment for product sustenance with a steady stream of quality improvements.

A steady stream of quality improvements requires experimentation able to answer deeper quality questions such as: Why? How? How much? (Sect. 12.5). The lessons learned from study and analysis, however, may be fast forgotten as the responsibilities of people change or the quality control process drifts. Without appropriate organization (Sect. 12.2) even the most splendid improvements may be lost. Two issues are outstanding in this connection:

- The development and maintenance of any culture is not done just by word of mouth. It requires an appropriate structure, and

- In quality control terms the best available structural example is Six Sigma (6σ), the theme of this section.

It needs no explaining that σ stands for the standard deviation of the population; s is the standard deviation of the sample. Correspondingly, the notation of the mean is: μ for the population and $\bar{x}$ for the sample. μ and σ are parameters; $\bar{x}$ and s is statistics. In this methodology σ is used as a statistic, not as a parameter.

Originally the Six Sigma methodology was developed by Motorola, but it was made famous through its high-profile implementation at General Electric (GE). The best way to look at 6σ is as a structured quality control program that has been successfully applied in a number of companies—all the way from manufacturing to finance.

A keyword with Six Sigma is *collaboration* between all quality priests and factors of technology. As I never tire repeating the time when every designer, every industrial engineer, every maintenance specialist, and each enduser were living in an environment of their own without sharing experience, is past. Today, if they wish to prosper they will have to collaborate in regard to quality assurance and cost control. Failing to exploit the potential provided by collaboration means that we are not working for but against the best interests of *our* company.

What has been stated about the collaboration of internal departments is also true regarding *our* company and the market. Cornerstone to the implementation of Six Sigma methodology is the ability to understand and appreciate customer needs and expectations in quality terms. These are defined by the customers themselves when they set basic requirements and standards, as well as target values and tolerances (more on this later).

Well-governed producers do appreciate that defects are sources of customer irritation and they are costly to clients, not only to the manufacturers themselves and other service providers. Vigilance in regard to quality and costs should exist at all management and workmen levels, still it is the board's responsibility to instill an organizational culture whereby everybody looks at quality as being his or her personal responsibility.

With the preceding references in mind it is not difficult to see that the best way to look at GE's consistent effort in quality improvement through 6σ has been by appreciating the benefits of a disciplined process. That helped company management to focus on developing and delivering error free products and services, while at the same time it provided an excellent training ground of all employees.

Six Sigma's foremost goal is *total quality management* through high level statistical analysis aimed to drive out both defects and unnecessary costs. Low quality is too expensive. As the preceding sections underlined, the synergy between a quality assurance policy and a cost control program is critical to business success—but it is not made in a vacuum.

- It starts with decisions by the board on the necessity of both high quality and low cost, and
- It is followed by a definition in depth of the methodology, tools, and standards to be used to reach such goal.

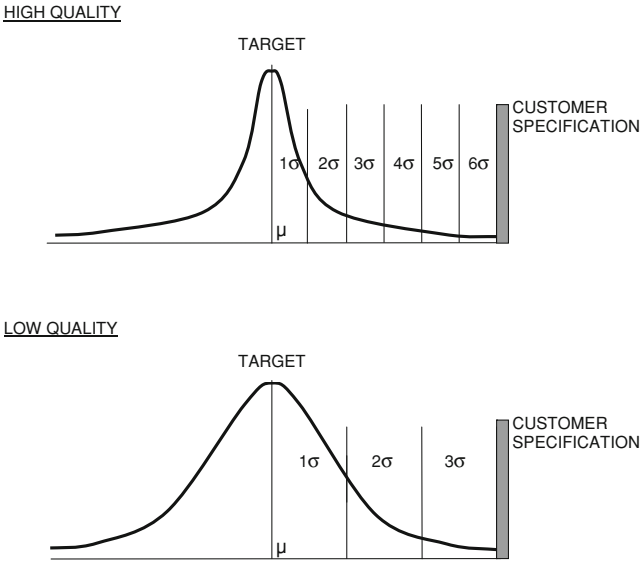

Fig. 12.4 The challenge is to fit six or more standard deviations between mean value (or target) and customer specifications

In so many occasions it has been said that a small standard deviation is evidence of quality. That is also a basic principle of Six Sigma. As Fig. 12.4 shows, the challenge is to fit six or more standard deviations between mean value (the *target*), which represents the manufacturer's tolerances, and customer specifications.

As a visual inspection of Fig. 12.4 confirms 6σ between company specs and customer specs is high quality; by contrast, 3σ is low quality. Six Sigma is not attained only by establishing firm guidelines on product assurance (Chap. 1), doing timely supervision and attracting new talent impacts on quality results—it also requires a high quality oriented company culture.

Speaking from personal experience, high quality is a catalyst to an attractive work environment, which adds to reputation. Motivated technical talent wants to work on high quality projects, because the work one is doing defines his or her self worth. That is high quality's psychological side.

As manufacturers prepare to introduce the next generation of products, and these days of rapid innovation products follow one-another in quick succession, everybody working for the company must not only adapt to changes in the methodology and technology, but also improve cost and quality performance. Firms which would not or could not do so, are not going to be around for long as independent entities.

Internal control can effectively reinforce the culture of quality assurance if and only if, top management's goal is one of dramatic improvements in quality, and if the CEO looks at it as being a crucial organizational performance parameter. Usually, firms find difficulties in adopting this stand because they have not taken

care in a comprehensive form of the quality of their produce. For such firms; Six Sigma is an excellent means for policy change, provided internal organization studies:

- Define which quality target is needed, and how it must be reached,
- Which information collected at design level, production floor and in field maintenance usable in deriving a quality pattern, and
- How data collection and analysis should be done to have a reasonable degree of confidence in the results of analysis.

In conclusion, product quality, cost containment, fast time to market, reputation and a challenging work environment lead to improved job performance and create a virtuous cycle which increases personal satisfaction. It is not secret that successful companies are careful to populate their work groups with people who are creative, decisive, and productive and care for quality and costs. By doing so, they gain an advantage over their competitors.

12.5 Using Six Sigma

An excellent example of practical results obtained through Six Sigma is GE's Medical System Performix CT X-ray tube when it was a new product, just introduced to the market. The stated goal has been 0% *dead on arrival* (DOA) which happens with several electronic products, including computers, as one of their components malfunction, and this does not permit the vendor to tell the customer the equipment is *ready for use*.

Reaching the objective of ready for use is vital both to the producer of the equipment (who gets his money earlier) and to the user (the clinic or hospital) as there are no patient rescheduling. Other goals targeted at GE through 6σ have been guaranteed tube availability, and an order of magnitude reduction in what the company calls *unquality cost*.

Every one of these benefits is food for thought to practically every firm in every industry. The sequential steps in reaching such goals are dramatized by the torrent of normal distributions in Fig. 12.5, from a practical Six Sigma implementation at general electric. Since nothing walks on a straight line, there will be a variance around the mean:

- At the top of the graph this variance is too wide resulting in 6.6% defects.
- Six Sigma has been instrumental in reducing the variance; but this did not happen overnight.
- With consistent effort the quality of production improved so much, that six standard deviations separated the mean from customer's specification.

Let me repeat the reference. As this general electric application has documented, it is not possible to go from 6.6% defects to 0.0% defects overnight. Such

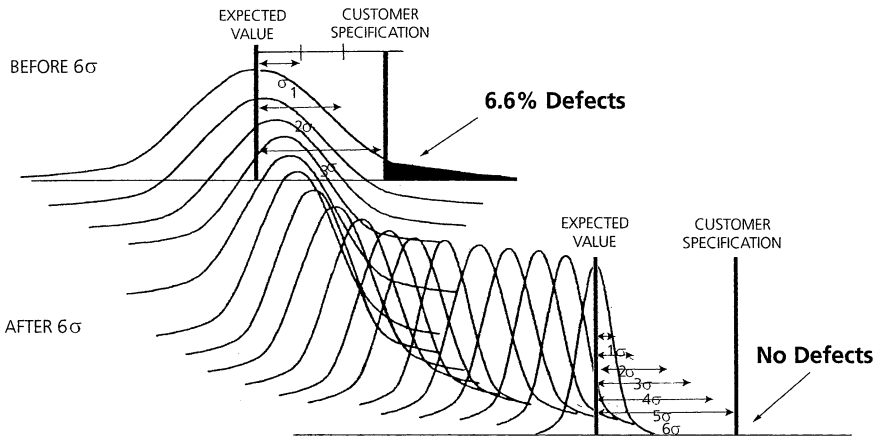

Fig. 12.5 The application of the Six Sigma (6σ) method led from low quality to high quality results

an improvement is doable over a period of time, *if* there is a will, a method and a well-trained team. This is precisely the reason why the 6σ methodology:

- Starts by identifying, qualifying, and quantifying all factors Critical To Quality (CTQ).
- Co involves the customers in pinpointing those aspects of product or service deemed critical from a quality perspective, and
- Establishes a process which permits steady quality improvements till the goal of no defects is reached.

These basic steps to Six Sigma deliverables are valid not only with proactive quality control at the factory floor but also for service quality reasons, at sales outlets or the backoffice. The Morgan Bank has implemented Six Sigma through 300 projects that, squeezed costs out of widely ranging process channels while improving the deliverables.

Companies which adopted Six Sigma have been active in developing and implementing a whole methodology around it. They also claim that its implementation has changed their DNA in everything they do and in every product or service they design and market. The basic tools underpinning GE's methodology, for example, include:

- *Statistical process control* methods analyzing data and helping to monitor process quality, capability, and performance.
- *Control charts* which monitor variance in a process over time, and alert to unexpected jumps in variance which may cause defects.
- *Process mapping* illustrating how things get done, by visualizing entire processes, their strength, and weaknesses.

- *A tree diagram* which graphically shows goals broken into levels of detailed actions, encouraging creative solutions.
- *A defect measurement method* accounting for number and frequency of defects that hit product or service quality.
- *Chi-square testing* evaluating the variance between two different samples, detecting statistical differences in case of variation.
- *Experimental design* permitting to carry out methodologically *t*, *z,* and Chi-square tests of the null hypothesis.
- *Root cause analysis* targeting original reason for noncompliance or nonconformance, aiming at their elimination.
- The *Dashboard mapping* progress towards customer satisfaction. Targets may be: percent defective, billing accuracy, and more.
- *A Pareto diagram* exhibiting relative frequency and/or size of events; searching for the 20% of the sources which cause 80% of problems.

At GE, the entire approach is guided by *Design for Six Sigma* (DFSS), a systematic methodology utilizing training tools and measurements to produce at high quality level, keep costs in check, and meet customer expectations. Associated to this is a process for continued improvement known as *Define, Measure, Analyze, Improve, and Control* (DMAIC).

DMAIC is a closed-loop process, characterized by its developers as systematic, scientific, and fact based. It helps to eliminate unproductive steps, focus on in-process measurements, and apply the best available technology for improvement. Through DMAIC, 6σ provide a vision of quality permitting people to strive for better results. The underlying *quantitative* approach is to:

- Multiply the number of units processed by the number of potential defects per unit, which gives the *opportunities for error*, and
- Then divide the number of actual defects by the number of these opportunities for error. Multiplying the result by 10^6 provides an impressive number which dramatizes the need for action.

In Six Sigma methodology, each combination of adjustments and quality correction measures becomes a system of equations that can be solved as a matrix. *Experimental design* (Chap. 11) allows users to efficiently test a significant number of variables, and hypotheses connected to them, in a dependable manner. As with other mathematical tools experimental design is at everyone's disposal, but the organization aiming to employ it must become so familiar with the method that it can take advantage of it in its daily work.

In conclusion, a methodology like Six Sigma must be exploited for maximum impact. In addition, the performance of a quality assurance process should be audited. Internal control should bring both matter-of-course quality reporting and technical auditing results to senior management's attention. This can be done in an able manner *if* there is the will to be ahead of the curve—which in turn requires increasing the product assurance sensitivity of the firm as a whole.

12.6 Evaluating Results from Observation and Experimentation

Since 1953, in my graduate studies at UCLA I have been exposed to a going debate on whether the statistician needs a thorough knowledge of the field in which he or she performs data analysis and/or an evaluation of experimental results. To my mind, whether he deals with experimental or observational data the statistician must either be an expert in the field in which he is working or collaborate very closely with an expert in that field.

For instance, with design engineers who work on quality but are not necessarily expert statisticians or experimental design professionals. Hence, GE's policy of close interdepartmental collaboration (Sect. 12.4).

Another issue to be brought to the reader's attention is the question of what sort of background in statistics assists in statistical inference. This is a matter of some controversy. Should not it be that the design engineer is also a statistician in order to enlarge the knowledge he acquires in the field in which he is working?

Opinions vary widely in regard to these queries. To my mind, even if a statistical investigation may have no purpose other than description, data analysis requires a statistical background. Not only is this needed for evaluation reasons, but also obtained results affect the way of collecting and providing data for subsequent causal analysis (Sect. 12.7). A complete statistical evaluation process involves four phases:

- Data collection satisfying specific criteria such pertinence to the problem being investigated and sample size (if based on sampling).
- Description including primary measurements, tabular and graphic presentation of information, and assessment of collective characteristics.
- Explanation which may involve specification of causal hypotheses and their testing against empirical data.
- Application, which might incorporate some element of prediction, or inferences, as in conclusions primarily drawn from observed data.

Extending facts in time and/or space through statistical inference is an important goal of experimentation for quality control and other reasons. We can put muscle to it by developing scenarios based on *what if* questions. The inverse is also true; rewards from inference underpin and expand our interest in experimentation.

Whether taken in a broad or narrow sense successful experimentation requires planning and control from the side of the experimenter. In a narrow sense, for example, it may be a *controlled experiment* which we specify by requiring conditions to be fulfilled, more, or less rigorously.

- Replications of the experiment are made under similar conditions, so as to yield an internal measure of uncontrolled variation.
- Such replications are mutually independent and uncontrolled variation in them is subjected to randomization (Chap. 11).

The causal hypothesis of an explanatory experiment frequently takes the form of a relationship in which the variable under investigation is expressed as a function of causal factors. Some of the latter are controlled in the sense of being subjected to systematic variation while others are uncontrolled. In this case randomization helps in making the controlled variables independent of the uncontrolled variables.

In contrast to an experimental input, the empirical data may be observational, as in the case of time series; or assumptions being adopted may be stochastic. In the case of industrial quality control these assumptions may be connected to an SQC chart which is under investigation on whether it is or it is not under *statistical control*. Shifts of emphasis can be examined, for instance, with regard to the:

- Phrasing of hypotheses,
- Estimation procedures,
- Hypothesis testing, and
- Tracking a prevailing trend in quality of production.

With observational data which consists of direct input on quality variables from the production line, the statistical analysis becomes dependent on good co-ordination with the subject under investigation. A tandem of samples and associated statistical graphics are needed to test against past evidence. The benefits being obtained from a consistent inspection are:

- A clear view of trend in quality of production, and
- The integrated picture provided by statistical methodology

While an explanatory approach can be carried out by the use of averages, frequency distributions or other elementary devices, this is not the way to go. Neither should the significance of results be judged just by common sense[1] without refined techniques. Statistical evidence requires tests which go beyond causal assumptions by involving experimental tools able to bring an uncontrolled variation under statistical control. Equally critical are the assessment of:

- Confidence intervals for parameter estimates,
- Significance levels in hypothesis testing, and.
- Models which aim to substantiate causal inference.

The test of hypothesis can be based on either or both experimental and observational data. What should be carefully considered *a priori* is the relative importance of the causal and stochastic assumptions, degree of complexity of the causal assumptions and systematic coordination of these two sets of assumptions. The technical control of causal factors enables the experimenter to breakdown a problem into subproblems, each explored by a separate series of experiments.

A critical element of the work described in these paragraphs, whether we talk of experimental or observational approaches, is the unambiguous specification of

[1] Which, as a saying has it, is widely available—and that is why each one of us has so little.

what we are targeting by the test of hypothesis. We can generally distinguish between two mutually supporting parts which can also work independently of one-another, but whether stand-alone or in unison form the basis of statistical data treatment.

- *Causal assumptions* forming the main explanatory approach.

Causal assumptions are typically obtained from prior experience. In the case of experimental situations, the design of the experiment must be made so as to test or demonstrate the underlying causal assumption.

- *Stochastic assumptions*, which are part of the content of the study inasmuch as they give an interpretation of deviations between observed and theoretical or expected values.

In a variety of cases, stochastic assumptions supplement the causal assumptions in providing the rationale of the statistical approaches for hypothesis testing. Statistical treatment of experimental data is typically done by the *t*-test for means[2] or by analysis of variance (Chap. 11).

In this case, the causal assumption is embodied in the parameter which indicates the varying mean for the different treatments of a quality factor. On the null hypothesis the parameter takes the same value for all treatments.

In conclusion, stochastic assumptions specify the frequency distributions of various treatment effects. Replications are assumed to be mutually independent and the distributions are taken to be normal with the same variance and with means given by the treatment parameters. As we have already seen, this is an approximation, but at the same time it is an important tool in quality assurance.

12.7 Cause, Effect, and Causal Inference

In his "*Essai-Philosophique sur les Probabilités*" Pierre–Simon de Laplace, the 19th mathematician, astronomer and philosopher, stated:"Present events are connected to preceding ones by a tie based upon the evident principle that a thing cannot occur without a cause that produces it." In a similar way, a great lot of future events are based on the after effect of present causes—which may be events or decisions.

Mathematicians look at causal inference as interplay between empirical and theoretical analysis which, sometimes, involves stochastic thinking. Stochastic assumptions play an essential part in establishing the efficiency of statistical techniques, accuracy of estimation, and of hypothesis testing.

[2] The *t*-test developer is Walter A. Shewhart, an American statistician, who in the 1930's published his algorithm under the pseudonym student.

Engineers consider causation as part of the more general concept of association. Many practical problems in causal inference can be solved with recourse to the theory of association. Techniques associated to the search of cause and effect is the result of thinking along the following lines:

- Every effect has one or more contributing causes.
- These usually known causes do not contribute equally to the effect. One or a few causes have a much higher impact than others.

According to Pareto's[3] principle, a very large part of the total effect almost invariably comes from relatively few causes. These few causes which quite often may be only *one* cause are not constant in their presence and impact. Frequently enough, the aim of analysis is to provide valid clues as to the nature (or concise area) of the important cause or causes.

Not every method employed in the analysis of cause and effect comes up with the results we would like to have. This obliges us to search for new tools and there should be no limit in developing more powerful tools and methods. Today, one of the better procedures permitting to test for causal inference is based on three steps:

- Examine cause-and-effect underpinning data sets, time series, observational, or experimental information.
- Project on likely aftermath, taking stock of hypotheses, and observable effect(s). The hypotheses are proxies for causes.
- "Forecast the past." for instance, by turning back a time series; choosing a tranche (e.g., 10 years); applying the pattern being developed or tested to that tranche; and comparing the emulated results with real-life statistics.

Plenty of evidence can be provided by examining how close a model's results approximate statistics and other data from the years following the selected tranche. The advantage of testing by "forecasting the past" is that it benefits from real-life data which permit to evaluate how well the model's output fits with events which have already taken place.

Among the main factors conditioning the efficiency of statistical techniques used in causal analysis are observational errors and sampling errors. The most frequent *observational error* is inaccuracy in measurement. Corrections for errors related to inaccuracy in measurements are made on the assumption that:

- Such errors are independent of the error-free variables.
- The error variances are known *a priori*.

In the general case observational errors are of larger order of magnitude than sampling errors. *Sampling errors* in statistical estimates are considered to be of the order of $\frac{1}{\sqrt{n}}$, where n is the size of the sample. Hence in large samples they tend to

[3] Vilfredo Pareto was a Swiss mathematician and economist, professor at the University of Lausanne in the late 19th.

be smaller. However, because plenty of work in statistical inference is made with relatively smaller samples, it is a mistake to ignore the sampling errors.

A type of sampling error affecting the results of causal inference is failure to take into consideration the lack of randomization in a causal interpretation of an interdependent variable. This result in inconsistency, bias, and inefficiency of estimates obtained through analysis.

For instance, because of lack of randomization the statistical interpretation may lead to an underestimate of the uncontrolled variation, resulting in an underestimate of the standard errors of the estimates. The need for correct randomization illustrates the close correspondence which exists between experimental design (Chap. 11) and model building.

At the origin of *observational data errors* are measurements and transcriptions. Observational errors tend to cluster, but they may also be characterized by diffusion patterns.

One of the tools which worth considering in trying to make sense out of test results or observational data is known as *meta-analysis*—a discipline whose impact has grown up over the past several years. Originally invented in 1948, it blossomed more recently as a way of:

- Extracting statistically meaningful information which can be used in modeling from lots of smaller trials.
- Doing so, even if the tests have been conducted in ways that makes it rather difficult to compare obtained results.

The downside of meta-analysis is that its output is valid only *if* all trials are included, not only those with positive results. *If* the negative trials are left out, *then* the output may be too optimistic—something that often happens with the interpretation of experimental data.

An interesting feature of interdependent modeling exercises is that they involve identities which are introduced by way of assumptions and of definitional relations. Such identities form a constraint for the effect variables. This implies that the relations under study are not autonomous in causal sense because there is an interdependent system.

Identities may as well represent instantaneous feedbacks. In this case, the downside lies in questions raised with regard to the operational significance of the model. Nevertheless, according to a dictum based on experience from mathematical modeling in banking and the financial industry: "All models are wrong, but some are useful." This usefulness comes from the fact that:

- Fulfilling the modeling prerequisites acts as an eye-opener.
- Different types of data can be treated on the basis of the same theoretical principles underpinning model development.
- The rationale of the statistical procedure can be examined by subjecting the empirical results to rigorous tests.
- Empirical results can be studied for agreement with theoretical relationships, and vice versa.

One of the issues working to the advantage of modeling is that it helps in searching for patterns. This is important in causal and statistical interpretation. A mathematically correct casual inference opens the way for applying statistical methods for controlling quality. Causal analysis is a powerful tool for quality-assurance-by objectives based on the laws of probability.