Section 14

Quality Assurance and Quality Control

14.1 Quality assurance: ISO 9001: 2008

14.1.1 Development

Quality standards have been around for many years. Their modern-day development started with the US Military and NATO. First published in 1979, the British standard BS 5750 has been revised and adapted by the International Organization for Standardization (ISO) and by CEN (the national standards organization of the European countries) as an effective model for quality assurance. With recent harmonization of standards under the EN classification it has obtained (almost) universal status as *the* standard of quality assurance.

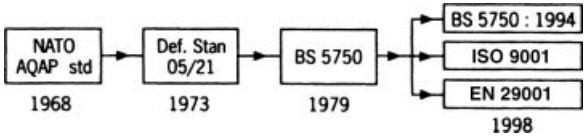

Figure 14.1

14.1.2 What is ISO 9001:2008?

The ISO 9000 documents were designed with the principle of 'universal acceptance' in mind – and to be capable of being developed in a flexible way to suit the needs of many different businesses and industries. The series was developed in the form of a number of sections, termed 'models' – intended to fit in broadly with the way that industry is structured. Inevitably, this has resulted in a high level of *generalization*. The current

Engineers' Data Book, Fourth Edition. Clifford Matthews.

standard ISO 9001:2008 was developed from the previous 2000 version.

The current standard shares several features with its predecessors. First, it is still all about *documentation*. This means that everything written in the standard refers to a specific document – the scope of documentation is very wide. This does not mean that it does not have an effect on the product or service produced by a company – merely that these are not controlled directly by what is mentioned in the standard. Second, ISO 9001:2008 is about the effectiveness of a quality *management* system – unlike its predecessors it attempts to have an improving effect on the design, usefulness, and fitness for purpose of the product produced. It is, however, still a quality *management* standard, not a product conformity standard. It is still, therefore, not impossible for a manufacturer with a fully compliant ISO 9001 system installed and working, to make a product which is not suited to its market.

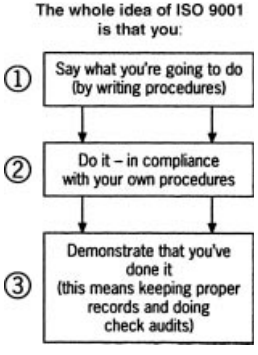

Figure 14.2

14.2 Quality system certification

Most businesses that install an ISO 9001: 2008 system do so with the objective of having it checked and validated by an outside body. This is called *certification*. Certification bodies are themselves *accredited* by a national body which ensures that

their management and organizational capabilities are suitable for the task. Some certification bodies choose not to become accredited – this is perfectly legal in the UK, as long as they do not make misleading claims as to the status of the certificates they award. Some other countries have a more rigid system in which the certification body is a quasi-government institution and is the only organization able to award ISO 9001:2000 compliance certificates.

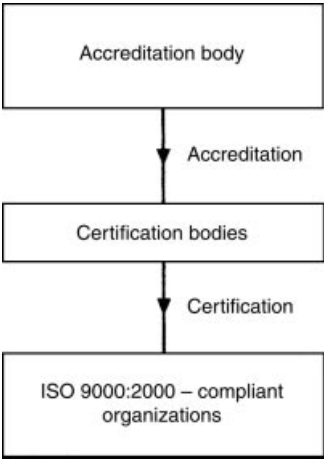

Figure 14.3

14.3 The ISO 9001 standard

Figure 14.4 shows the main outline contents of a company QA manual that mirrors the requirements of ISO 9001. Figure 14.5 shows the way that activities within an organization can be visualized as 'processes' (an important tenet of ISO 9001 since its year 2000 edition).

SECTION	*Management responsibility*
1.1	Quality Policy
1.2	Quality Objective
1.3	Scope of Service
1.4	Company Organization
1.5	Resources and Personnel
1.6	Management Review
1.7	Management Commitment
1.8	Customer Focus
2.0	**Quality Management System**
2.1	General Requirements
2.2	Documentation Requirements
2.3	Document and Data Control
2.4	Interaction between Processes
2.5	Quality Planning
3.0	**Resource Management**
3.1	Human Resources
3.2	Infrastructure
3.3	Work Environment
4.0	**Product Realization**
4.1	Planning of Product
4.2	Customer Related Processes
4.3	Design Control
4.4	Purchasing
4.5	Production and Service Provision
4.6	Inspection, Measuring, and Test Equipment
5.0	**Monitoring and Measurement**
5.1	Customer Satisfaction
5.2	Internal Audit and Monitoring of Processes
5.3	Monitoring and Measurement of Courses
5.4	Course Records, Examination Certificates
5.5	Inspection Status
5.6	Control of Non-conforming Service
5.7	Analysis of Course Data and Presentation
5.8	System Improvements
5.9	Corrective Action
5.10	Preventive Action

Figure 14.4 The structure of a typical ISO 9001 company quality manual

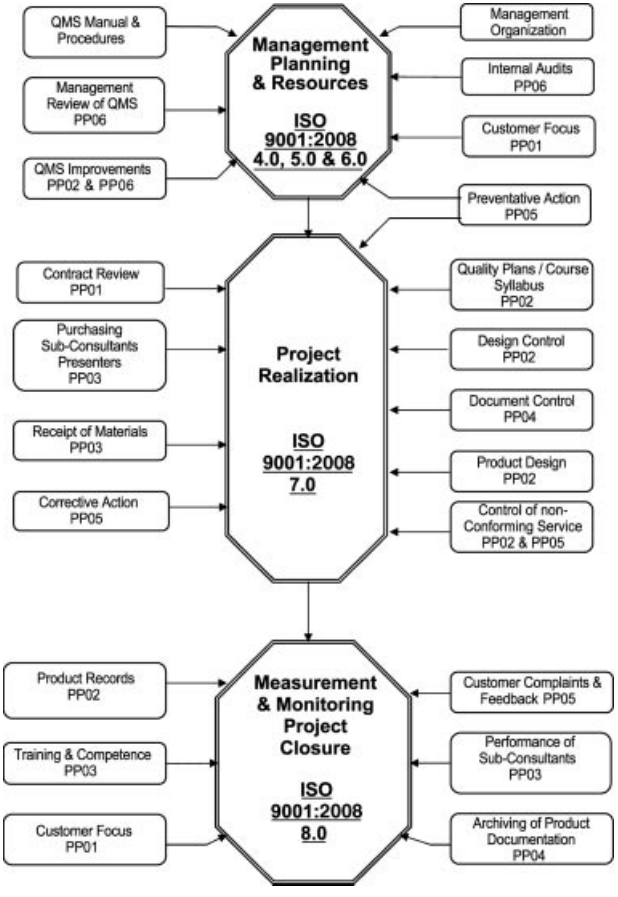

Figure 14.5

14.4 Taguchi methods

Taguchi is a specific type of SPC. It moves away from the estimation or counting of defective components to a wider view that encompasses *reducing* the variability of production, and hence the cost of defective items. The key points of the Taguchi idea are:

- Choose a manufacturing system or process that *reduces variability* in the end product.
- Design tolerances are chosen from the standpoint of costs – asking what is an acceptable price to pay for a certain set of tolerances.
- Push the quality assessment back to the *design stage* – again, the objective is to reduce the possible variability of the product.

Taguchi's basic principles are not, in themselves, new. Many of the principles coincide with the requirements for good, practical engineering design. The accepted reference sources are:

1. **Taguchi, G.** *Experimental Designs*, 3rd edition, 1976 (Marmza Publishing Company, Tokyo).
2. **Bendall, A.** *et al. Taguchi Methods – Applications in World Industry*, 1989 (IFS Publications, Bedford, UK).

14.5 Statistical process control (SPC)

SPC is a particular type of quality control used for mass production components such as nuts and bolts, engine and vehicle components, etc. It relies on the principle that the pattern of variation in dimension, surface finish, and other manufacturing 'parameters' can be studied and controlled by using *statistics*.

14.6 Normal distribution

The key idea is that by inspecting a sample of components it is possible to infer the compliance (or non-compliance) with specification of the whole batch. The core assumption is that of the *normal distribution*.

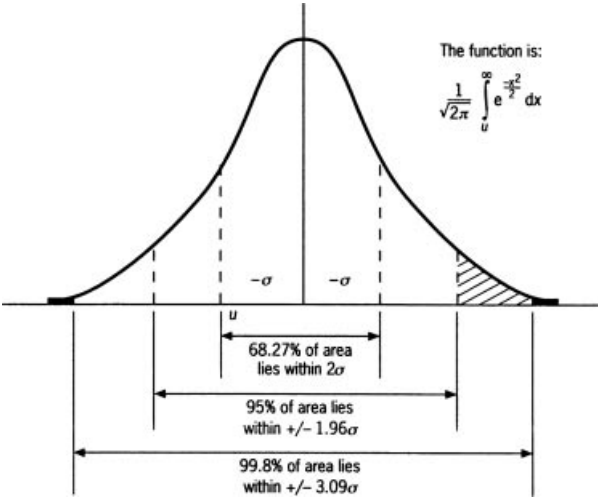

Figure 14.6

The quantities used are:

Standard deviation, $\sigma = \sqrt{variance}$

$$\sigma = \sqrt{\frac{f_1(x_1 - \bar{x})^2 + f_2(x_2 - \bar{x})^2 + \cdots}{N}}$$

$N =$ number of items
$f =$ frequency of items in each group
x_1, x_2, etc. $=$ mid size of the groups
$\bar{x} =$ arithmetic mean

From the normal distribution, a 'rule of thumb' is:

1 in 1000 items lie outside $\pm 3\sigma$
1 in 40 items lie outside $\pm 2\sigma$

14.6.1 Sample size

Symbols and formulae used for sample and 'population' parameters are shown in Table 14.1

Table 14.1

	Population	*Sample*
Average value	X	X
Standard deviation	σ	S
Number of items	N	n

Mean value $\bar{X} = \bar{x}$
Standard deviation of $\bar{x} = \sigma/\sqrt{2\pi}$
Standard error (deviation) of $s = \sigma/\sqrt{2\pi}$

14.7 The binomial and poisson distributions

This is sometimes used to estimate the number (p) of defective pieces or dimensions. An easier method is to use a Poisson distribution which is based on the exponential functions e^{x} and e^{-x}.

$$e^{-x}.e^{x} = e^{-x} + xe^{-x} + \frac{x^2e^{-x}}{2!} + \frac{x^3e^{-x}}{3!} + \cdots$$

This provides a close approximation to a binomial series and gives a probability of there being less than a certain number of defective components in a batch.

Useful Standards

1. BS 600: 1993: The application of statistical methods to industrial standardization and quality control.
2. BS 7782: 1994: *Control charts, general guide and introduction*. This is an equivalent standard to ISO 7870: 1993.
3. BS 6000: 1994: *Guide to the selection of an acceptance sampling system*. This is an equivalent standard to ISO/TR 8550: 1994.
4. BS ISO 3534-2: 1993: *Statistical quality control*. This is an equivalent standard to ISO 3534-2: 1993.

14.8 Reliability

It is not straightforward to measure, or even define, the reliability of an engineering component. It is even more difficult at the

design stage, before a component or assembly has even been manufactured.

- In essence reliability is about *how*, *why*, and *when* things fail.

14.8.1 The theoretical approach

There is a well-developed theoretical approach based on probabilities. Various methods such as:

- Fault tree analysis (FTA)
- Failure mode analysis (FMA)
- Mean time to failure (MTTF)
- Mean time between failures (MTBF)
- Monte Carlo analysis (based on random events)

14.8.2 MTTF and MTBF

Mean time to failure (MTTF) is defined as the mean operating time *between* successive failures without considering repair time. Mean time between failures (MTBF) includes the time needed to repair the failure. If a component or system is not repaired then MTTF and MTBF are equal (see Fig. 14.7).

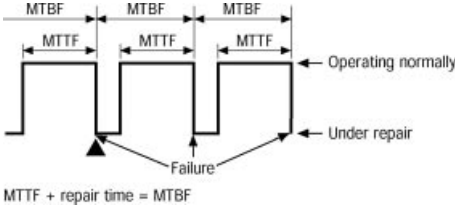

Figure 14.7

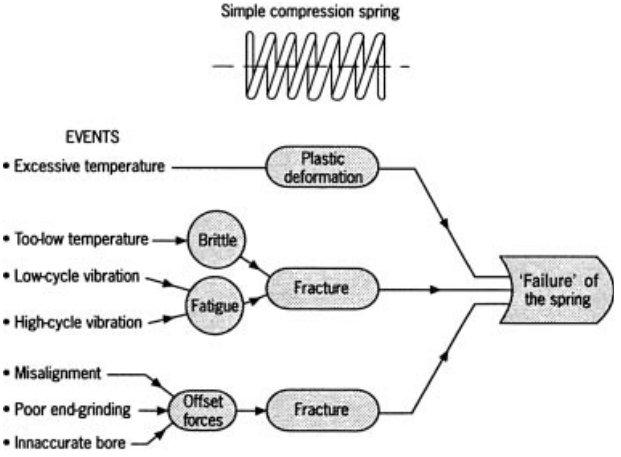

Figure 14.8 The principle of failure mode effects analysis (FMEA)

14.8.3 The practical approach

The 'bathtub curve' is surprisingly well proven at predicting when failures can be expected to occur. The chances of failure are quite high in the early operational life of a product item; this is due to inherent defects or fundamental design errors in the product, or incorrect assembly of the multiple component parts. A progressive wear regime then takes over for the 'middle 75 percent' of the product's life – the probability of failure here is low. As lifetime progresses, the rate of deterioration increases, causing progressively higher chances of failure.

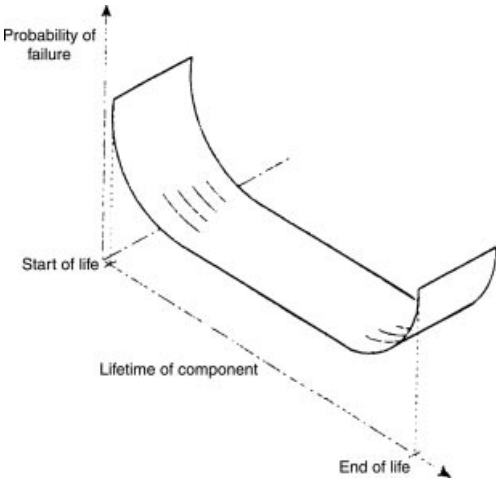

Figure 14.9 Component reliability–the 'bathtub curve'

The best way to improve the reliability of a mechanical engineering component is to eliminate problems at the design stage, before they occur.

14.9 Improving design reliability: main principles

- *Reduce static loadings* It is often the most highly stressed components that fail first.
- *Reduce dynamic loadings* Dynamic stress and shock loadings can be high.
- *Reduce cyclic conditions* Fatigue is the largest single cause of failure of engineering components.

- *Reduce operating temperature* Operation at near ambient temperatures improves reliability.
- *Remove stress raisers* They cause stress concentrations.
- *Reduce friction* Or keep it under control.
- *Isolate corrosive and erosive effects* Keep them away from susceptible materials.

14.10 'Design for reliability' – a new approach

Design for reliability (DFR) is an evolving method of stating and evaluating design issues in a way which helps achieve maximum reliability in a design. The features of this 'new approach' are:

- It is a quantitative but *visual* method – hence not too difficult to understand.
- No separate distinction is made between the functional performance of a design and its reliability – both are considered equally important.
- It does not rely on pre-existing failure rate data which can be inaccurate.

14.10.1 The technique

Design parameters are chosen with the objective of maximizing all of the safety margins that will be built in to a product or system. All the possible modes of failure are investigated and then expressed as a set of design constraints (see Fig. 14.10).

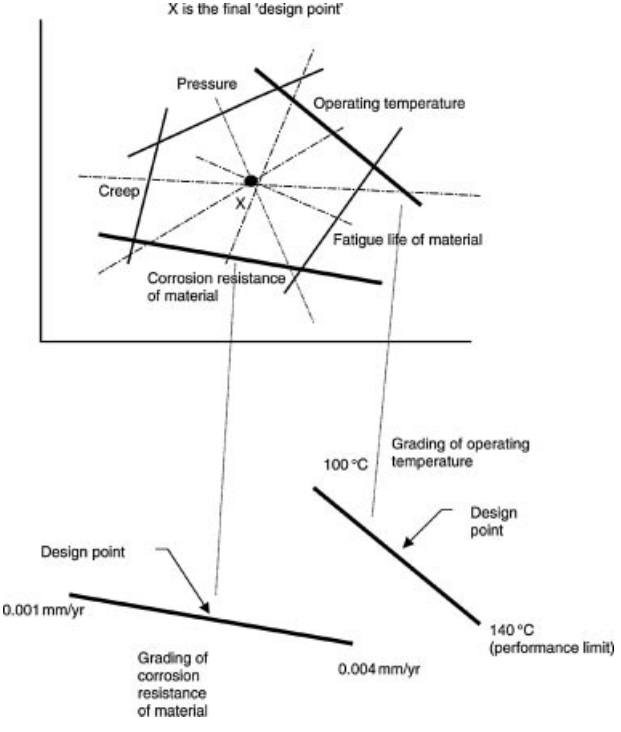

Figure 14.10

The idea is that a design which has the highest safety margin with respect to all the constraints will be the most reliable (point X in the figure).

Constraints are inevitably defined in a variety of units so a grading technique is required which yields a non-dimensional performance measure of each individual constraint. Figure 14.9 shows an example.

14.10.2 Useful references

Thompson, G., Liu, J. S., and **Holloway, L.,** 1999, An approach to design for reliability, *Proc. Instn Mech. Engrs Part E, J. Process Mechanical Engineering*, **213** (E1), 61–67.

Useful Standards

The standard reference in this area is BS 5760: *Reliability of systems, equipment and components.* Several parts are particularly useful:

1. BS 5760:
   Part 0: 1993: Introductory guide to reliability.
   Part 2: 1994: Guide to the assessment of reliability.
   Part 3: 1993: Guide to reliability practices: examples.
   Part 5: 1991: Guide to FMEA and FMECA.
   Part 6: 1991: *Guide to fault tree analysis*. Equivalent to IEC 1025: 1996.

Other useful standards are:

2. BS 4778: Part 3: 1991: Availability, reliability and maintainability terms.
3. BS ISO 2382-14: 1978: Reliability, maintainability and availability.