Learning Text

Quality Assurance

Contents **Page**

Introduction

This learning text covers the subject of quality assurance. First, it considers the history of quality and the development of the quality discipline together with the creation of the function of dedicated quality personnel. It then considers the development of standards on quality and the various types of assessment and quality schemes that exist. The elements of a quality system are then discussed.

The topic of quality assurance and its relevance in relation to European standardization, including CE marking, is considered. A glossary of terminology is included.

History and evolution of the quality discipline

A cursory consideration of this topic could give the false impression that quality assurance is a recent innovation. This is completely untrue, as rules on quality existed at the time of the Roman Empire. The Roman Emperor Quintus instructed that suppliers of goods to the imperial and senatorial households had to affix their mark to the goods that they supplied. If these failed in service the manufacturer was likely to be punished.

In the United Kingdom early mention of quality assurance dates from the reign of Edward I, (1272-1307), when in 1300 legislation on the hallmarking of jewellery was introduced. A further development in 1340 was legislation creating the role of clerks of the markets, whose job it was to check weights and measures. The medieval trade guilds acted as controllers of quality, laying down regulations for the training of apprentices, the behaviour of members of the guild and the regulation of prices. A famous individual who worked in the quality field was Geoffrey Chaucer, who for a period was employed as a quality representative to the royal armoury.

In early times when the skilled craftsman was at the pinnacle of the workforce, he would make an object, a piece of furniture or some other item. At each stage of its production he would carefully examine it to ensure that it was an acceptable piece of work according to standards determined by himself. A second, essentially identical item produced after the first, would probably not be exactly the same. It would nevertheless have the same known skills of the craftsman embedded in it, and would have been produced to the same high standards which the craftsman imposed on himself.

The decline of the agricultural society and the emergence of manufacturing industry, initially as small production units (factories), created new problems. Initially factories produced complete products or sub assemblies, which were either accepted by customers, or rejected by them.

Gradually, two factors necessitated the creation of a culture of more rigorous inspection:

- Advances in engineering demanded production to greater dimensional accuracy.
- The increasing tendency to manufacture components separately and then assemble them elswhere.

These developments created the need for inspection personnel who initially reported to the production department. However, conflicts of interest soon arose and in some cases separate inspection departments were set up.

The impetus for many changes in society has been war. Lloyd George, prior to becoming Prime Minister was minister of war. He was concerned that more planes fell from the sky during World War One because of electrical and mechanical failure than our military opponents shot down, and this led to the introduction of inspection systems into military procurement.

The establishment of the process of inspection was an acknowledgement that the production process was not as efficient as it might have been. If the primary process of inspection was to ensure that sub-standard goods never reach the customer then it soon became apparent that the objective had not been achieved. The creation of inspection departments brought a number of new issues into prominence, such as the recording of data, the precision of measuring instruments and the introduction of uniform standards. It soon became apparent that in addition to product inspection, other duties were required and gradually quality control departments evolved.

In the early part of the 20th century, Fredrick W Taylor, chief engineer of the Mid Vale steel works in the USA introduced the concept of scientific management. Around the same time, statistical theory began to be applied to quality control. One of the first individuals to apply the new methods was Walter A Shewhart of the Bell Telephone company. In 1924 Shewhart put forward the idea of a control chart and in 1931 he published a book entitled “Economic Control of Quality of Manufactured Products”.

In the United Kingdom, the Institution of Engineering Inspection was set up in November 1922. This organization was open to all those engaged in inspection activities both within the governmental and the private sectors. The Second World War led to a dramatic rise in demand for munitions and there simply was not sufficient time to check that they were manufactured to the desired quality. It therefore became very important that quality was built into the manufacturing process. Inspection had been the system used by almost all manufacturers to prevent unacceptable products from reaching their customers. Gradually it was realised that the implementation of a system that detected faults as they occurred was a more efficient method to prevent those faults occurring in the first place.

Following the Second World War, the industrial system in Japan had been virtually destroyed. Additionally, Japan had acquired a reputation for producing cheap imitation products. The Japanese recognised their problems and started to take action to resolve them. They received assistance in the area of quality improvement from the civil communication section of the occupation forces. Further assistance was provided by one of the leading figures in American quality management Dr W Edwards Deming, who had worked very closely with Shewhart. Over a number of years adoption of the systems put forward by Deming transformed Japanese industry.

Development of quality standards

Formalised quality requirements were introduced by the American military forces with a series of written standards. Mil-Q-9858 was published in 1959 and covered quality control systems for industry. Other standards dealt with the subject of inspection (e.g. Mil-I-45208A). The creation of NATO (The North Atlantic Treaty Organization) led to the concept of formal quality standards moving from a national to an international arena. NATO published a series of quality standards entitled Allied Quality Assurance Publications (AQAPs) in 1968.

Colonel Rabey of the British defence establishment advocated a fundamental change in the way that the Ministry of Defence (MOD) approached its suppliers. He recommended that the supplier be made responsible for the quality of product or service delivered, that the technical competence of potential suppliers was assessed before contracts were awarded and that the ministry should ensure that suppliers had effective systems in place. The recommendations put forward led to the introduction of a series of quality standards (the 05 series) being introduced across all MOD contracts.

The success of the 05 series of standards led to the publication of British Standard BS 5750: Quality Systems, which was first published in 1979. This was revised in 1987. Increasing international interest in quality standards led to ISO (the International Standards Organization) publishing the ISO 9000 series of standards in 1987 and updating and re-issuing them in 1994. CEN (Comite Europeen De Normalisation) had also published a series of quality standards as the EN 29000 series but these were withdrawn and the requirements incorporated into the 9000 series. The British Standards Institution (BSI) also withdrew BS 5750 and adopted the International Standard as BS EN ISO 9001. This standard was in three parts:

BS EN ISO 9001:1994	Quality Systems – Model for quality assurance in design, development, production, installation and servicing.
BS EN ISO 9002:1994	Quality Systems – Model for quality assurance in production, installation and servicing.
BS EN ISO 9003:1994	Quality Systems – Model for quality assurance in final inspection and test.

Organizations selected the part that was most appropriate to their sphere of operation. In addition to the three parts of the standard, which prescribed the requirements, other parts, which provided guidelines on their implementation were also published.

BS EN ISO 9001: 2000

Structure and philosophy

The year 2000 version of the quality standard has the requirements in a single standard and there is no longer a 9002 and 9003. The standard is now composed of the following:

BS EN ISO 9000:2000 – Quality management systems – Fundamentals and vocabulary
BS EN ISO 9001:2000 – Quality management systems – Requirements

BS EN ISO 9004:2000 – Quality management systems – Guidelines for performance improvement

BS EN ISO 9000:2000 contains the vocabulary and the underlying philosophy of the standard. This document is descriptive and although it does not contain any mandatory material, it does contain a description of eight key management principles.

BS EN ISO 9001:2000 is the standard against which an organization will be audited and certificated.

BS EN ISO 9004:2000 has been prepared to give guidance on continuous improvement within the organization.

The standard (BS EN ISO 9001) has been structured in to eight main clauses, these being:

- Scope.
- Normative reference.
- Terms and definitions.
- Quality management system.
- Management responsibility.
- Resource management.
- Product realization.
- Measurement, analysis and improvement.

The main requirements are contained within clauses 4 to 8. The standard has adopted a process approach rather than the procedure based approach of the 1994 version. The year 2000 version has been based on eight quality management principles, these being:

a) A customer focused organization. The view was taken by the writers of the standard that companies or organizations depend on their customers and therefore they should understand their current and future needs. This objective also recognises that companies should meet customer requirements and make efforts to exceed customer expectations.

b) Leadership. Emphasis has been placed on leaders establishing unity of purpose, direction and the internal working environment of the organization (company). The standard has been drafted to take account of the view that leaders can create the environment in which individuals can become fully involved in achieving the organization's objectives.

c) Involvement of people. The standard recognises that people at all levels are the essence or lifeblood of a company and the importance of harnessing their abilities for the company's benefit.

d) A process approach. This recognises that the desired result can be achieved more efficiently when related resources and activities are managed as a process.

e) A system approach to management. This involves identifying, understanding and managing a system of interrelated processes for a stated objective contributing to the efficiency and effectiveness of a company.

f) Continual improvement. The standard recognises that continual improvement is a prime requirement.

g) A factual approach to decision-making. This recognises that effective decisions are based on logical analysis of data and information.

h) A mutually beneficial relationship. This is based on the philosophy that the ability of a company and its suppliers to create value is embraced by mutually beneficial relationships.

Perhaps the most radical change in the year 2000 version of BS EN ISO 9001 is the process approach. A process is a sequence of related tasks with inputs and outputs. A process can also be represented as a loop, which emphasises the interlinking of the component parts of a process. In any organization, there are three principal types of approach:

- A procedure based organization focuses on doing the right things, although not necessarily based on stakeholders' needs.

- A process based organization focuses on doing the right things based on stakeholder needs.

- A process based organization with appropriate procedures, focuses on doing the right things correctly, in line with stakeholder's needs.

Standard requirements

The quality standard BS EN ISO 9001: 2000 requires that a documented system be established.

Clause 4.1 states "The organization shall establish, document, implement and maintain a quality management system." The standard requires that, as a minimum, documentation is required in respect of just six procedures:

- Document control.
- Record keeping.
- Nonconformance control.
- Auditing.
- Corrective action.
- Preventative action.

The management of the company must decide in all other cases whether they need additional information to facilitate control. It is normal practice to maintain the quality system requirements within the quality manual.

Clause 4.2.4 requires that records be maintained to provide evidence of the effective operation of the quality management system.

Clause 5.3 which is entitled “Quality Policy” requires that:

- The quality policy is appropriate to the purposes of the organization.

- A commitment to comply with requirements and continually improve the effectiveness of the quality management system is stated.
- A framework for establishing and reviewing quality objectives is implemented.
- The quality policy is communicated within the organization.
- The quality policy is reviewed and updated.

Clause 5.6 of the standard prescribes the management review, a prime requirement of any quality system. This is generally undertaken on an annual basis and should examine all aspects of the quality scheme, (e.g. the reports of audits, customer complaints, preventative and corrective action requests and areas for potential improvements). Clause 5.6.2 of the standard lists the items that should be considered during the management review.

Clause 8.5.2 of BS EN ISO 9001 states "the organization shall take corrective action to eliminate the cause of the nonconformities in order to prevent recurrence".

Clause 8.5.3 of BS EN ISO 9001 states "the organization shall identify preventative action to eliminate the causes of potential nonconformities in order to prevent their occurrence". Thorough auditing frequently identifies potential nonconformities.

The two terms corrective and preventative action sometimes cause confusion. A corrective action is essentially a backward looking phenomenon, which identifies the last point from which action can be taken to rectify a mistake. Preventative action is essentially a forward-looking process to determine at the earliest point what action is necessary in order to prevent an error occurring.

Quality Schemes

Quality assessment may be classified as first, second or third party:

First party assessment involves an organization setting up a quality system, documenting the structure and procedures and subsequently notifying customers that a quality system has been implemented.

Second party assessment involves documenting a quality system and inviting the customer to collaborate in its development for quality as specified by the customer. Alternatively a client or customer may undertake their own assessment of an organization's quality assurance scheme. Historically second party assessment was undertaken in the construction industry by consulting engineers or clerks of works acting on their behalf.

Third party assessment involves an organization independent of the producer or purchaser (customer) undertaking the assessment process.

The number of third party quality assurance schemes grew in the late 1970's and early 1980's. Central government was concerned that the lack of uniformity of standards between the various schemes was leading the certification industry into disrepute. This was also having an adverse effect on the reputation of United Kingdom industry in the international trading market. This led to a government white paper entitled "Standards, Quality and International Competitiveness" being published in July 1982.

In 1984 the Department of Trade and Industry set up the National Accreditation Council for Certification Bodies (NACCB) under a memorandum of understanding with BSI. The NACCB were empowered to grant recognition to certification bodies who reached a prescribed minimum standard. These bodies were given the privilege of using the symbol of the crown and the gold tick of approval on their stationary. The mark symbolising approval was also permitted to be used by companies whose quality scheme was approved by a NACCB certification body. Once a certification body was accredited by NACCB, it was subject to regular surveillance visits to ensure standards were maintained.

In addition to a regulator for certification bodies the government also established under the auspices of the National Physical Laboratory schemes for the certification of testing (NATLAS) and calibration laboratories (NAMAS). In 1985 these two organizations were merged under the NAMAS banner.

Central government commissioned a report from independent management consultants on the future of certification activities in the United Kingdom. This led in 1995 to the creation of a single overseeing body for all testing and certification activities – the United Kingdom Accreditation Service (UKAS). However a number of independent certification bodies which are not recognised by UKAS still continue to operate.

UKAS now operates as a company limited by guarantee under a memorandum of understanding with the Department of Trade and Industry. A number of industry panels have been created to advise UKAS staff on the needs of different sectors of industry.

Multi product/ sector schemes

Certification bodies can be categorised under two headings:

- Certification under a registered industry sector scheme. Some industries have set up quality assurance organizations which have been accredited by UKAS to provide certification for a particular industry sector.

- Direct certification. This is where an organization approaches an independent certification body directly for third party certification.

There are a number of sector schemes; two that are especially relevant to the construction industry are CARES (the Certification Authority for Reinforcing Steels) and QSRMC (the Quality Scheme for Ready Mixed Concrete). Other well known schemes include CORGI, which is applicable to the installation of gas appliances.

Sector schemes only offer certification in a limited range or even only for a single product. Multi product organizations (e.g. British Standards Institution Quality Assurance Services, Lloyds Register Quality Assurance, SGS Yarsley) offer certification across a diverse range of products, often on a global basis. A number of the multi product schemes also operate sector schemes, e.g. the cement industry certification scheme operated by BSI-QAS.

Department of Trade and Industry

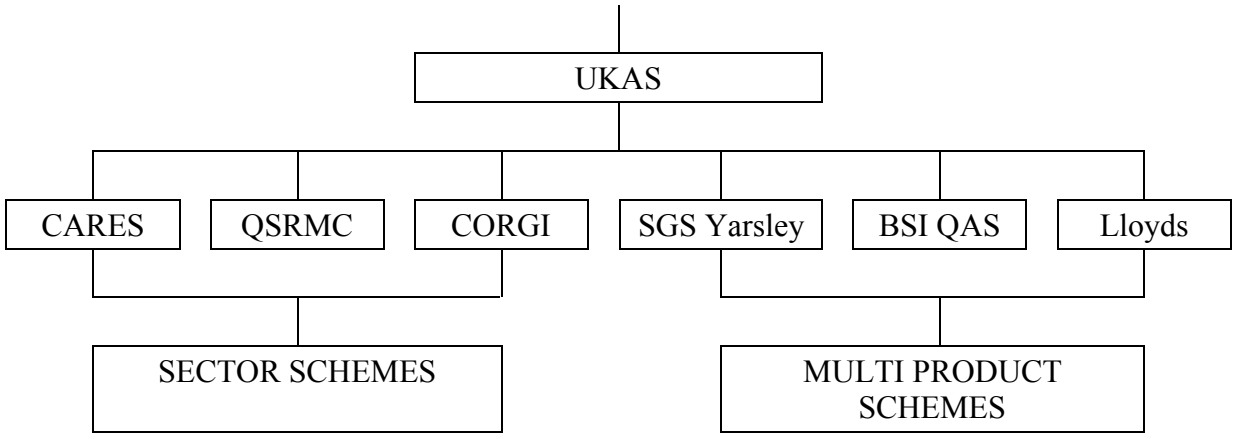

Figure 1: The organization of Quality Schemes

Management systems / product conformity

Some organizations do not have a physical product to test (e.g. law firms, educational establishments) but nevertheless wish to have their management systems certified by a third party quality assurance organization. Other organizations only elect to have their management systems accredited by a third party. This is known as Category 1 certification and is often a transitional step prior to seeking product conformity certification. Product conformity certification, known as Category 2, not only provides certification that the quality management system is operating in accordance with the required standard, but that the product is also complying with the appropriate quality standard.

British Board of Agrément

The British Board of Agrément (BBA) was established in 1966. It was originally called the Agrément Board with the present name being adopted in 1982. It is involved in the testing, assessment and certification of products used within the building and construction industry. The types of product assessed are wide ranging but are generally characterised by being new or innovative, although existing products may also be assessed.

The BBA is an independent company limited by guarantee and is controlled by a governing board nominated by the government. It is based at the Building Research Establishment near Watford in Hertfordshire.

An Agrément certificate provides assurance that a product or system to which the certificate relates, if properly used in accordance with the terms of the certificate, will meet the relevant requirements. Some publications refer to BBA approval as Category 3 certification.

The Kitemark

British Standards Institution was set up in 1901 and has operated a certification scheme since 1903: the first British Standard Mark was granted for tramway rails in 1903. The Kitemark symbol was adopted in 1922 and the first licence granted to the General Electric Company in 1926. A licence to use the Kitemark can be obtained by a manufacturer who can demonstrate to the satisfaction of BSI that he can consistently manufacture the product in accordance with

the requirements specified in the appropriate standard. The capability of the manufacturer is assessed by evaluating their quality system against the requirements of BS EN ISO 9001 and testing the product against the requirements of the product standard. Surveillance of the quality system and the product is also undertaken on an ongoing basis.

The elements of a quality system

The section of this learning text on the history and evolution of the quality discipline stated the importance of building quality into the manufacturing process. To ensure a quality product or service all those involved must:

- Be aware of what is to be done which may involve having the appropriate standards, specifications and, where appropriate, drawings.
- Be aware of how the task is to be performed, which involves the provision of suitable training and the availability of appropriate work instructions.
- Possess the necessary resources, plant and materials.
- Be aware if the task has been properly completed, which may involve inspection, measurement or testing of a product.
- Possess suitable motivation to accomplish the task at the required quality level.
- Maintain appropriate records.

European standardization and quality requirements

The change from national standards to European standards will increase the necessity to implement quality assurance. For some products third party quality assurance will be mandatory.

Now that the European Union are determined to remove barriers to trade, National standards are believed to be a major obstacle to the free movement of goods and services. In different industrial sectors legislative statements, known as directives, have been introduced to attempt to remedy this situation. The change to European Standards has resulted in some new terminology being introduced (e.g. mandate, harmonized standard, etc). Definitions of these terms are given in the glossary of terms (page 14).

The Construction Products Directive (CPD) has the objective of breaking down barriers to trade within the design, materials and component supply industries of the construction sector. To achieve this the CPD has a number of elements:

- A system of harmonized technical specifications.
- The CE marking of products(to demonstrate product conformity).
- A system of Notified Bodies (to administer CE marking).

To comply with the requirements of the CPD, a product subject to a mandate and placed on the market has to comply with the following essential requirements:

- Mechanical strength and stability.
- Security in the case of fire.
- Health, safety and the environment.
- Security for user.
- Noise protection.
- Energy economy and thermal insulation.

A product that meets the essential requirements of a harmonized standard may be placed on the market. It is a requirement that conformity to the standard is indicated by the affixing of the CE mark to the product, to the product packaging or to the commercial documentation where the product is not packaged. The CE mark is not a quality mark, it only signifies that the essential requirements of the CPD have been complied with. The CE mark may be regarded as a passport to assist in the movement of goods within the European Union. Figure 2 shows an example of the CE mark.

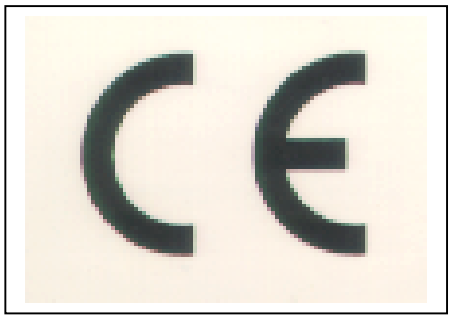

Figure 2 – The CE Mark

It is important to note that where a mandate has been issued only products that comply with the requirements of the technical specifications (i.e. standards) may be placed on the market.

Not all products are regulated. In order for a harmonized standard to be produced the European Commission must issue a mandate to CEN. A mandate is an instruction given by the European Commission to CEN to prepare a harmonized standard.

Where such a harmonised standard has been issued, EU member countries are required to withdraw conflicting national standards within a given time period. The time period may vary because some product standards are dependent on supporting testing standards being available. Normally CEN identifies the supporting standards and groups these into packages. The date of withdrawal of conflicting national standards is generally fixed at a number of months after the last standard in the package becomes available.

Within a harmonized standard not all requirements are covered by the mandate - normally the essential requirements are listed in an “Annex ZA” to the standard. The process of judging whether a product meets the requirements for the affixing of a CE mark is called attestation of conformity.

Not all products are judged at the same level. Each harmonized product standard prescribes the level for judging attestation of conformity. The levels range from self certification (level 4) to third party product testing (level 1+) as well as the operation of a third party Quality Assurance System. The levels of attestation of conformity that have been set for mortar, screed and their constituent products are:

Cement: level 1+

Admixtures: level 2+

Aggregates: level 4

Mortars: level 2+ (designed masonry mortars)
level 4 (other masonry mortars and rendering mortars)

Screeds: level 4 (for some applications level 3 may be required)

Table 1 lists the requirements for each of the levels:

Conformity numbering system	1+	1	2+	2	3	4
Tasks for the manufacturer						
Factory production control	✓	✓	✓	✓	✓	✓
Extra testing of samples taken from the production unit in accordance with a prescribed test plan	✓	✓	✓	•	•	•
Initial type testing	•	•	✓	✓	•	✓
Tasks for the notified body						
Initial type testing	✓	✓	•	•	✓	•
Initial certification of factory production control	✓	✓	✓	✓	•	•
Continuous surveillance of factory production control	✓	✓	✓	•	•	•
Audit testing of samples taken from the factory or the market place or site	✓	•	•	•	•	•

Table 1: Attestation of Conformity Systems
(See the Glossary for further information on terminology).

The monitoring of CE marking in each country is regulated by the Notified Bodies (which may be some of the quality assurance organizations).

In addition to harmonized standards, voluntary standards also exist. This means that the standard does not have the force of European law and a product covered by a voluntary standard cannot be CE marked. However under an agreement between the national standards bodies conflicting national standards will have to be withdrawn.
Glossary of Terms

a) **Attestation of conformity** - This is a declaration required by Chapter V of the CPD, attesting that a product meets the requirements of a harmonized European Standard.

The process of testing and quality assurance to achieve this is called the evaluation of conformity.

b) **BSI** – British Standards Institution

c) **CEN** – This is the European organization for standardization and is the abbreviation for Comité Européen De Normalisation.

d) **CE marking** – This mark signifies that a product complies with the essential requirements of the CPD and with a harmonized European technical specification or standard.

e) **Class** – A combination of two levels between which the performance must fall: (e.g. strength between 32.5 – 52.5 N/mm_.)

f) **Compliance** – Compliance with the standards - an area of confusion exists as to what has to be complied with. There are two levels of compliance to be considered:

- Compliance with the voluntary parts will be necessary to claim one is supplying in accordance with the standard. This will be necessary for commercial reasons.
- Compliance with the harmonized part will be necessary to comply with the law

g) **CPD** – This is the Construction Products Directive (published by the European Commission in 1988; incorporated into European Law in 1989 and passed into UK law by the Construction Products Regulations, 1991), potentially, it applies to all products produced for permanent incorporation in buildings and civil engineering works. A directive is a legal device used by the European Union to establish policy at European level.

h) **Harmonized Standard** - A harmonized standard has the objective of satisfying the essential requirements of a directive. Harmonized standards define the relationships between national regulators and producers. The national regulators (normally UKAS in the U.K.), will delegate powers to notified bodies (third party quality assurance bodies, e.g. British Standards Institution: Quality Assurance Services), to carry out much of the work. Some standards will not have a mandate and will therefore only satisfy a need between the producer and the purchaser. A standard that does not have a mandate cannot be harmonized and the product cannot carry a CE mark. This type of standard is called a "voluntary standard".

Once a harmonized standard is published, conflicting national standards have to be withdrawn within a set time period. Any product that satisfies the CPD and has a CE mark must be allowed to be placed on the market in all European Union Countries.

i) **Level** – Performance which will be exceeded:

e.g. strength greater than 32.5N/mm_.

j) **Mandate** – A mandate is a political request from the European Union to CEN to produce a standard in a specific product area. The issuing of a mandate leads to the production of a harmonized standard.

k) **Voluntary Standard** - A voluntary standard is produced by CEN, normally to assist in free trade. Under CEN rules, national standard bodies, e.g. BSI, have to withdraw conflicting national standards. Concrete for instance, has not yet been granted a mandate and therefore, the concrete Standard EN 206-1 cannot be harmonized and no CE mark will be applicable to concrete.

Note: Most standards are prepared at the request of industry, but the European Commission may also request that some standards are prepared to implement European legislation.

Self assessment questions

1	What is the number and title of the main quality standard in use in the UK?
2	When was BS 5750 first published?
3	Designed masonry mortar requires level 2+ attestation of conformity, what are the requirements involved?
4	What item of European legislation governs the CE marking of mortar?
5	What are the eight main clause headings in BS EN ISO 9001:2000?
6	What is the role of UKAS?
7	The year 2000 version of BS EN ISO 9001 requires as a minimum procedures in respect of six activities - what are they?
8	What is the difference between a category 1 and a category 2 quality scheme?
9	When was the first BSI kitemark awarded?
10	What is the difference between preventative and corrective actions?

Answers to self assessment questions

1	BS EN ISO 9001:2000 Quality management systems – Requirements
2	1979
3	The implementation of a factory control system, initial type testing and the taking of samples in accordance with a prescribed plan. Additionally the notified body has to certify the factory production control system and undertake continuous surveillance of the system.
4	The Construction Products Directive
5	Scope, Normative references, Terms and definitions, Quality management system, Management responsibility, Resource management, Product realization and Measurement analysis and improvement.
6	The accreditation of certification bodies and laboratories.
7	Document control, record keeping, nonconformance control, auditing, corrective action and preventative action.
8	A category 1 scheme only covers management systems, a category 2 scheme covers management systems and product conformity.
9	1926
10	Preventative action is intended to eliminate the occurrence of potential nonconformities. Corrective action is taken to eliminate the recurrence of nonconformities.