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History

In response to an initiative by the German standards institute DIN (= Deutsches Institut für Normung), a Technical Committee was set up under the designation TC 176 "Quality Management and Quality Assurance" within the International Organisation for Standardisation (ISO). The aim was to harmonise the national quality systems already in existence. Today, the ISO 9000 series which was the result of these efforts serves as a worldwide reference and basis for mutual understanding in the definition of quality requirements and is helping to overcome obstacles to international trade. By now, 48 countries have adopted these standards unchanged into their own national standards systems. At the level of the European Union and EFTA, the standards of the ISO 9000 series have been adopted as European Standards under the series designation EN 29000. In Germany, the series designation is DIN ISO 9000, and the title blocks of these standards specifically state that they are identical in content with the corresponding ISO and EN standards.

Because they are formulated in very general terms, the standards of the ISO 9000 series are being followed in more and more branches of industry and have recently met with interest from the services sector and even from public institutions.

Quality systems

The ISO 9000 series of standards was conceived as an analytical instrument to help companies cope better with the plethora of technological, administrative and human factors that account for the quality of their products and services. Ultimately, this makes them more competitive in the international market.

The ISO 9000 series is an attempt to standardise the analysis of the causes of defects. An "attempt" because it is a quality standard which aims to model the entire sequence of business operations, including the management and communication functions, throughout the "value-added" chain as it applies to a given organisation and which thus must accommodate numerous features that are characteristic of specific business organisations. For a "standard" in the classical meaning, the "systemic" approach of this series is rather unusual.

When we speak of ISO 9000, we actually mean a series of five internationally recognised standards, ISO 9000 to ISO 9004.

Specific related standards apply, for instance, to the performance of quality audits (ISO 10011, Parts 1–3) and to the quality assurance of measuring and test equipment (ISO 10012).

The ISO 9000 series

ISO 9000 is a guideline for the selection and use of standards ISO 9001 to ISO 9003. Standards 9001 to 9003 are three models for quality assurance in specific contexts.

ISO 9001 is a model for quality assurance in design/development, production, installation and servicing.

ISO 9002 is a model for quality assurance in production and installation.

ISO 9003 describes a possible model for quality assurance in final inspection and testing.

The model to be applied in any organisation will depend on the processes that organisation intends to verify and document.

ISO 9004 explains the requirements established for a quality management system and interprets the elements of the ISO quality system.

Quality management (QM)	High quality, low costs, a broad product range, good service and great versatility are among the strategic factors that add up to sustainable business success. Only a universal approach that links the performance of all divisions of the organisation in a quality loop can generate the quality that is essential to this success. The ISO 9000 series of standards can serve as a basis for installing an efficient quality management system. The great advantage companies can gain by applying these standards lies in the potential they afford for improvement and rationalisation. The formulation of a coherent quality policy by corporate management and consistent motivation of all personnel at all levels are crucial to success. A documented quality system is the best basis from which to identify potential improvements; modern management methods such as Total Quality Management (TQM) should build upon this foundation. When ISO 9000 is to be applied in the services sector, some critical thought must be given to whether quality considerations that originally arose out of production requirements are actually valid outside the production sector and to what extent their adaptation to the services context could give rise to overlapping prescriptions.
	A quality management system is built up as follows:
The 20 elements of quality assurance (from ISO 9004)	
1. Management responsibility	Quality begins at the top. If the company management does not demand, promote, and set an example of quality, quality management has not got a chance.
2. Quality system principles	Management establishes the principles of quality policy, and also delegates responsibilities and the requisite authority. These should be broad enough to allow the assigned quality objectives to be achieved with the desired efficiency.
3. Internal quality audits	All the elements, aspects and components pertaining to a quality system should be internally audited on a regular basis. An audit plan is helpful in this context.
4. Quality-related costs	It is now common practice to identify and measure "quality costs", both those spent on quality assurance procedures and those resulting from inadequate quality.
5. Marketing – contract review	Contracts and market needs should be reviewed regularly to accurately determine customer requirements. These customer requirements must be communicated clearly and precisely within the company.
6. Design control	The function of design is to translate the customer needs from the product brief into technical specifications. In this phase an unambiguous product definition is particularly important. At the conclusion of the design phase a systematic and critical review of the design results should be conducted.
7. Procurement	Purchased materials, components and assemblies directly affect the quality of the product. Receiving inspection is giving way more and more to reliance on the supplier's quality assurance system. However, it is not enough just to demand a quality certificate from the supplier for purely formal reasons or so as to be able to assign liability; there is no substitute for proper testing.

8. Process control in production and installation	It must be ensured that production/services are performed under controlled conditions and with the desired results.
9. Control of production	The quality loop involves the control of quality in a manufacturing cycle.
10 Product identification and traceability	A programme of preventive maintenance should be established to ensure continuing process capability, i.e. all the conditions and requirements upon which production/performance of the service is contingent should be known and reviewed on a regular basis. Clear responsibilities must be defined, especially for authorisation of process changes.
11. Inspection and test status	Control of verification status. Nonconforming materials and products must be clearly identified. The identification should include the ability to distinguish between verified and unverified material.
12. Inspection and testing	Various methods for in-process inspection and completed product verification.
13. Inspection, measuring and test equipment	Control of inspection, measuring and test equipment and its adequacy.
14. Control of non-conforming products	The identification of nonconformities and their logical or historical causes is of cardinal importance to the entire quality management process. The reviews to be performed for this purpose should be established in written procedures backed up by suitable examples.
15. Corrective action	In the analysis of a quality-related problem, the root cause should be determined before the corrective action is planned. Particular attention should be paid to permanent changes resulting from corrective action.
16. Handling, storage, packaging and delivery	A sensitive and potentially costly complex that calls for utmost diligence.
17. After-sales servicing	Suitable equipment and adequate logistic back-up are essential to, market reporting and product supervision are feedback effects from after-sales servicing.
18. Document control and quality records	The records from the entire quality system are compiled in the Quality Manual. The Manual should be kept in a safe place but should be accessible to all authorised users, since it contains all essential information on the quality system.
19. Training	Quality begins in the mind, i.e. not only in the minds of the management but in the awareness of all personnel. It is therefore indispensable that all personnel be suitably trained and motivated.
20. Statistical methods	Correct application of modern statistical methods is an important element at all stages in the quality loop.
	Once an organisation has built up its quality system along the lines of ISO 9000, it can apply for certification.

Certification

Certified quality, that is quality verified against an accepted standard, is becoming more and more a key to market success and at the same time helps to cut the costs associated with non-conformance, because it relaxes the hitherto strict principle of separation between fabrication and quality inspection.

Certification by an accredited agency documents that a company's quality system meets the requirements of ISO 9000. The major advantages to be gained from certification are:

- competent assessment of quality assurance procedures already in place;
- enhanced efficiency and lower costs;
- less risk of being held liable for deficiencies;
- customer confidence in the company's quality;
- compliance with international standardised quality requirements.

If a company applies for certification, inspectors from an accredited agency check out the company's quality system and its documentation before issuing a Quality Certificate. The certificate is valid for up to three years, subject to review audits. After the three years, the entire certification audit must be repeated for the certificate to be extended for a further period.

Various organisations have by now been accredited as certification auditors, for instance in Germany the quality audit society Arbeitsgemeinschaft Qualitätssicherung e.V. (AGQS), the quality system certification society Deutsche Gesellschaft zur Zertifizierung von Qualitätssicherungssystemen (DQS), the technical inspection agencies (TÜV), the inspection and certification institute of the association of German electrical engineers (VDE) and the indemnity insurers association (VdS), or in Switzerland the quality assurance certificates association (SQS).

There are currently about 40,000 certificate holders in Europe, 28,000 of them in the UK alone. In Germany, about 860 organisations had been issued a certificate by May 1993, by January 1994 the number had already risen to over 2000. The certification trend has been in full swing in Germany since 1994; hardly a day passes without some proud company announcing it has earned its prized certificate. Japan adopted ISO 9000 in 1991; by 1992 there were already 250 Japanese certificate holders.

As a rule, it takes at least two years to build up a quality system and have it certified.

Tips for the underwriter

Liability insurance

Quality assurance has been a subject of discussion between manufacturers, suppliers and insurers for some years now. Inspection of goods on receipt is giving way more and more to reliance on the supplier's quality assurance work. The resulting quality agreements often have complicated legal and insurance implications. If a company is a certificate holder to ISO 9000, this provides a good basis for assessing the quality assurance standards it applies. However, how the specific product is used or further processed by the purchaser must also be taken into account.

In terms of product liability, application of the ISO 9000 series of standards is advantageous in that on the one hand they cover product liability aspects, e.g. in their provisions on documentation, while on the other the Total Quality approach they embody promotes efforts towards loss prevention. Although German product liability legislation does not directly reference ISO 9000, it is reasonable to assume that evidence of compliance with general quality requirements in accordance with ISO 9000 could help to simplify legal disputes.

Marine insurance

Operators transporting hazardous goods are subject to particularly stringent statutory requirements and are also obliged to comply with the principles governing organisers' liability, particularly if they employ subcontractors to do the actual transporting. In this context, the requirements described in ISO 9000 can serve as the basis for assuring the quality of the operation and thus the safe delivery of the hazardous cargo. The definition of duties, authorities and responsibilities for everybody in the company involved in the shipment of hazardous goods (from the managing director down to the driver on the road) makes the organisation transparent and helps to avoid duplication of functions and problematic interfaces. An ISO 9000 certificate can boost customer confidence and documents the holder's pro-active interest in loss prevention.

Property insurance

Companies manufacturing or installing fire control and safety equipment will in future need to have quality systems certified to DIN ISO 9001 or 9002 to gain the approval of the German indemnity insurers association VdS. As of 1995, the association will not approve any new applicants without a certified quality system, and existing approval-holders will be required to have their quality systems certified to DIN ISO 9001 or 9002 by 31 December 1996.

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