

Standards and quality management — *An integrated approach*

ICS 01.120; 03.120.10

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This Published Document, having been prepared under the direction of the Management Committee of the British Standards Society, was published under the authority of the Standards Committee and comes into effect on 15 November 1998

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First published November 1991
Second edition October 1995
Third edition November 1998

The following BSI references relate to the work on this publication:
Committee reference OC/34

ISBN 0 580 28223 6

Amendments issued since publication

Amd. No.	Date	Text affected
10467 Corrigendum	April 1999	See page viii

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Foreword

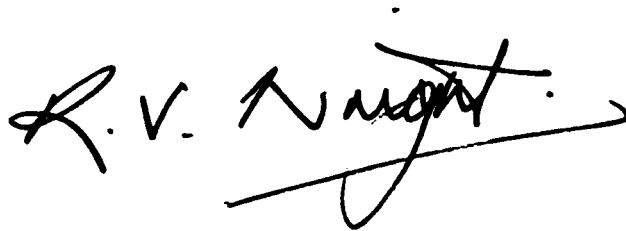
Established in 1960, the British Standards Society has, as one of its key aims, assisting management in the application of standards in design, manufacture, quality assurance, in-service support, information technology and other relevant activities. The title of this publication, *Standards and quality management — an integrated approach*, reflects the development of the British Standards Society over recent years and the continuing interest of our members in management system standards. Quality, environment and health and safety are important issues for all organizations reflecting, as they do, the wider interests and concerns of the community at large and exchange of experience as BSS events have increasingly highlighted the practical benefits of an integrated approach to the management of these issues.

It is now three years since the last edition of PD 3542 was published. During that time, considerable developments have taken place affecting standards, legislation, information technology and the organization of BSI which the BSS Management Committee considered should be reflected in a revision of the document. Given that a revision of ISO 9000 is due to be published in 2000, followed shortly by a revision of ISO 14001, it was however decided that a comprehensive revision of PD 3542 should await publication of these documents so that full account could be taken of them in the revised Published Document. The society's Publications Panel will be working on the revision over the next 12 months and would welcome users' views on the usefulness of PD 3542, its content and presentation and any additional guidance or information which they would like to see included in the revision. Comments should be sent to the BSS Secretary at the address on the inside front cover of this document.

In the meantime, however, the BSS Management Committee is anxious to ensure that the wealth of information contained in PD 3542 is as up-to-date as possible and has therefore published an update of the document as an interim measure, prior to the full revision referred to above. The Society is most grateful to Jonathan David, Chairman of the BSS Building Standards Group, for taking on the major task of updating and for producing the index, which is an addition to the original document and will greatly enhance its value as an indispensable source of reference.

Thanks are also due to the Society's Publications Panel, the staff of BSI and to Pam Hall, Secretary to BSS, for their contributions.

Standards and quality management — An integrated approach is an invaluable aid to the individual standards user and to senior managers in business seeking to improve performance and overall organizational effectiveness.



R. V. Wright
Chairman, British Standards Society

This Published Document has been prepared by Committee OC/34, British Standards Society Management Committee. It supersedes PD 3542:1995, which is withdrawn.

Corrigendum No. 1 replaces Figures 4.3, 4.5, 4.9, 4.10, 5.8, 5.9, 5.10, 5.12, 6.1 and 7.2. The document identifier and year are also corrected at the head of pages 109 and 110.

This Published Document is not to be regarded as a British Standard.

Acknowledgements

The original of this publication was first published by the Standards Associates of BSI, under the sponsorship of the Institute of Production Engineers in 1959. The banner of standards users at that time was carried by the enthusiasm and hard work of the late Fred Butcher, himself a company standards engineer with Joseph Lucas and inspirational to the cause of company standardization in that era. It was revised and reissued in 1970. A major revision of PD 3542 was undertaken in 1980 and another advance was made in the 1995 edition. This edition is an update rather than a full revision, as explained in the foreword.

The Standards Associates is now known as the British Standards Society and over a span of 35 years there have been a number of catalysts and milestones to the progress of standardization both in-company and nationally, with metrication, decimalization, the growing interest in quality management systems and the introduction of legislation concerning product liability, health and safety at work, control of substances hazardous to health (COSHH), consumer protection and environmental management, precipitated by our closer ties with Europe. It is the intention to reflect all these developments in the contents of this publication whilst maintaining an awareness of the importance of standardization as a prime mover.

I am grateful for the constructive comments from members of the British Standards Society Management Committee who have pored over the drafts, and particularly the Society's Publications committee and members of BSI staff who have contributed their experience and expertise to a work which I hope will be as useful as the previous edition PD 3542 entitled *The role of standards in company quality management*.

Trevor Ashton, BSS Region 3,

Editor

Personal acknowledgements for help and encouragement are due to (1995 unless otherwise stated):

My wife Cynthia for her tolerance of my long absences whilst at the computer

Tom Chapman from the North East, (1980)

Dr. J T Grayson, Professor of East European Studies at Birmingham University (1970)

Sandy Forbes from the Scottish region

General "Jim" Gavin ex chairman BSS (1980)

Management and Staff of GEC Alsthom T & D Protection & Control Limited, Stafford who have assisted with their unguarded comments in the daily course of business.

RH Industries

Renlon Ltd.

George Orton, ex president IFAN

Harold Towse, from the North West (1980)

Bob Vallance, Electronic components

John Wall, Midland Region

Bob Wright, Chairman, BSS and his associates in Trading Standards at Barnsley

Richard Wright and David Lunn of the North West region (1980)

Jonathan David (1998)

Cliff Evans (1998)

Section 1. General

1.1 Scope

This Published Document has been prepared by the British Standards Society to provide commentary on standardization, and the organization of standards and documentation as the basis for an integrated approach to the management of quality, environment and occupational health and safety in an organization.

1.2 Informative references

This Published Document refers to other publications that provide information or guidance. Editions of these publications current at the time of issue of this standard are listed in the bibliography on page 108, but reference should be made to the latest editions.

1.3 Terms and definitions

For the purposes of this Published Document, the following terms and definitions apply.

1.3.1

catalogue

published list of information on equipment, parts or materials presented primarily for the retrieval of information

NOTE 1 A catalogue usually incorporates the code, and sufficient information for the user to identify his requirements.

NOTE 2 The user may be the designer, the storeman, the buyer, the inspector or the customer. Every one is both a "user" and a "supplier" at some stage.

1.3.2

classification

grouping set in order shown, i.e. alphabetically into categories and classes, of parts or materials that share common attributes

1.3.3

code of practice

document that recommends practices or procedures for the design, manufacture, installation, maintenance or utilization of equipment, structures or products

NOTE A code of practice may be a standard, a part of a standard or independent of a standard.

[BS EN 45020:1998, definition 3.2]

1.3.4

coding

designation of items by reference numbers or letters in place of the full description

NOTE A code may be allocated according to a classification system, but this is not essential. The simplest code may be allocated by consecutive accession to a list.

1.3.5

performance specification

specification of requirements of an item or material in terms of the performance in service rather than in terms of its physical or other characteristics

1.3.6

procedure

specified method of carrying out a particular task

1.3.7

process specification

specification of the conditions and methods to be adopted, arranged sequentially, to define a process

1.3.8

purchase specification

specification prepared for the purpose of ordering goods and services

NOTE This term may be used in place of "purchase order description" but it usually implies a more comprehensive specification issued as a separate document.

1.3.9

rationalization

procedure for reducing variety by the simplification of existing ranges

1.3.10

specification

document stating requirements

NOTE 1 A qualifier should be used to indicate the type of specification such as "product specification", "test specification".

NOTE 2 A specification should refer to or include drawings, patterns or other relevant documents and indicate the means and the criteria whereby conformity can be checked.

[BS EN ISO 8402:1995, definition 3.14]

1.3.11

standard

document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context)

NOTE Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.

[BS EN 45020:1998, definition 3.2]

1.3.12

standardization

activity of establishing, with regard to actual or potential problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context

NOTE 1 In particular, the activity consists of the processes of formulating, issuing and implementing standards.

NOTE 2 Important benefits of standardization are improvement of the suitability of products, processes and services for their intended purposes, removal of barriers to trade and facilitation of technological cooperation.

[BS EN 45020:1998, definition 1.1]

NOTE 3 In this publication the term also covers action in all areas of company operation to improve efficiency by unification or simplification.

1.3.13

variety control

selection of the optimum number of sizes or types of products, processes or services to meet prevailing needs

NOTE Variety control is usually concerned with variety reduction.

[BS EN 45020:1998, definition 2.4]

1.4 Summary

This publication provides a commentary on the standards and legislation covering quality, health and safety and environmental management at the workplace. The contents are biased towards offering practical advice on the sources of standards information and the creation and application of in-house standards as required for the installation of a complaint management system. It has been compiled both as a reference and as a training aid for anyone involved in the production of standards in their organization whether as a one-off task, in a permanent situation or as a management project.

Over thirty years of technological development and experience of standardization needs have confirmed and consolidated the basic principles described in the first (1959) edition and re-emphasized the need for a comprehensive and up-to-date guide to standardization practice and the legal framework affecting it. The experience of members of the British Standards Society, including that coming from the work of the International Federation for the Application of Standards (IFAN), has been incorporated in subsequent editions.

The last few years have seen a change in the emphasis of standardization at both corporate and national levels and a decline in specialization in this subject.

Traditional dedication to product standardization has been overlaid by the promotion within government and industry of the generic standards on which to base effective management systems and related capability assessment and registration schemes. Various parts of BS 5750 *Quality systems* have been superseded by the BS EN ISO 9000 series. BSI also issued BS 7750 *Specification for environmental management systems* which has been replaced by BS EN ISO 14001:1996 *Environmental management systems — Specification with guidance for use*, and there is a trend towards integrated management to deal with the documentation demanded for both quality and environmental management systems, and health and safety systems. Standardization is a vital ingredient of business efficiency and a prerequisite of management systems. In revising this publication the emphasis has shifted to positive guidance to the many industrialists, quality and environmental managers, or safety or trading standards officers who have been more recently involved with their application. It recognizes the need for background knowledge about standards-making both

within organizations and on an international level, as well as regulations and certification facilities. For this reason, the organization of standardization in the context of the law, and, particularly, of European Union developments, is explained first. Later sections cover management systems and the contribution to be expected from providing internal standards, and aim to help with the introduction of standardization to a business, providing a basis for comparison with readers' own theories and experiences. Finally, some exchanges of working standards have been included.

The 1995 revision took account of new developments and techniques and for this reason the title was changed to encompass a wider scope, both of the type of standards and users. The opportunity was taken to incorporate the use of information technology, the relevance of recent developments for improving quality on a national and European scale, and legislation concerned with health, safety, the environment and product liability. The 1998 update does not change the basic text but corrects and updates information where relevant. Since 1983 some 1.3 million public sector jobs have been transferred to the private sector. This publication is therefore compiled with the requirements of the growing sector of small firms and the occasional user in mind whilst incorporating the experiences of large business organizations. Emphasis on the employment of a single person occupied entirely with standardization has been removed. It is recognized that standards may be used in manufacturing and service industries, for example with regard to health and safety, quality assurance, environmental management and meeting statutory regulations, but points out the need for creating supporting standards. The functions described in this publication cover many areas likely to be encountered in typical manufacturing, distribution, consumer or service organizations.

The work of many standardization and quality organizations is aimed at improving communications, industrial competitiveness and drawing attention to legislation. Agreements reached globally or at European level permeate through national bodies such as the British Standards Institution (BSI) via the British Standards Society into the grass roots of business and are applied as company standards. Successful standardization techniques are universal and will only vary in detail according to the needs of the country, the business, and the practitioner; and those described herein have proved to be well capable of the sort of flexibility demanded.

Section 2. Standardization, the law and the European Union

2.1 Standardization: aims and principles

The extent to which standardization techniques can be of value to a business is illustrated by the aims promoted by the International Organization for Standardization (ISO):

- a) overall economy in terms of human effort, materials, power etc. in the production and exchange of goods;
- b) the protection of consumer interest through adequate and consistent quality of goods and services;
- c) safety, health and protection of life;
- d) the provision of a means of expression and of communication between all interested parties (see Table 2.1).

Table 2.1 — Aims and results of standardization

Aims	How achieved
Overall economy	Simplification (variety control) Interchangeability Removal of trade barriers
Consumer protection	Rules of manufacture, test and use Standards of and for quality
Safety and health	Standards recognized by legislation
Improved communication	Terminology, methodology, specification and codified practice

2.2 Definition of a standard

For the definition of a standard, see 1.3.11. The content of a standard is determined by its scope, and that is agreed collectively by the representative interests involved. What they want may be an agreed terminology or classification, or methods of measurement or testing, or they may want verifiable criteria for a standard product or some practical recommendations or guidance for its use. The possibilities are almost limitless.

Standards should be drafted in objective terms; the compliance criteria should relate to verifiable attributes of a product or service, which will then conform because it is what it is, not because someone says it has to conform.

Standards are made publicly available mainly by the national standards bodies, which collaborate in the European and global standards organizations. These bodies cannot, however, compel the use of the standards they adopt. Use of standards may be enforced by law only through their incorporation in contracts, in trade descriptions or in legislation. Such actions are outside the control of the standards bodies. Standards should not be confused with regulations. Regulations are part of the law.

2.3 Standardization in the UK

The UK national standards body is BSI, the British Standards Institution, incorporated by Royal Charter since 1929 as a non-profit distributing association of members. In 1982, following the Department of Trade White Paper on standards, quality and international competitiveness (Cmnd 8621), Government signed a Memorandum of Understanding endorsing BSI as the national standards body and the UK member of international and European regional standards organizations. An updated Memorandum of Understanding was signed in 1995. As an independent and impartial body, BSI serves all interests, in both the public and the private sector. The Memorandum of Understanding is reproduced verbatim in BS 0-1:1997, annex C.

NOTE Since the publication of the third edition of BS 0 in 1997, the means by which parts of a standard are indicated has changed. Parts of standards which were previously identified using the word "Part" (e.g. BS 5760 : Part 8) are now indicated by a hyphen between the main identifier and the part number (e.g. BS 5760-8).

Standards work in BSI depends on income from sales of standards and from subscriptions. Additionally, in recognition of its importance to industry, to the consumer and to the country's economy as a whole, it receives supporting funds through the Department of Trade and Industry.

As a guide for those involved in standards work, BSI provides BS 0 *A standard for standards*, explaining the principles of standardization, committee procedures and drafting rules. Study of BS 0-1 and BS 0-2 particularly should enable a committee member to attend national and international meetings with confidence.

Under the overall supervision of the Standards Committee, standards work in BSI is organized through eight Sector Committees which control the work of the many technical committees responsible for standards. The technical committees may set up subcommittees or panels as appropriate to progress their separate projects or particular aspects of them.

The national standards body frequently takes the blame for the shortcomings of the standards it publishes. However, such criticism overlooks the fact that the content of British Standards is determined not by BSI officials but by voluntary contributions of those who are willing and able to serve on BSI committees. If a standard is considered inadequate, it should be within the power of the critic to contribute to its improvement.

As users of industrial products, materials and processes, it is important for all companies, regardless of their own interests as suppliers, to participate actively in the establishment and continuing improvement of standards. To influence standardization with a view to enhancing their competitiveness, businesses should contribute through trade associations, professional or other representative bodies and communicate among themselves, e.g. via the British Standards Society.



Documents

Document Sharing Hub

All BSI standards publications are listed in numerical series in the BSI Standards Catalogue, published in paper and electronic formats, see 9.4.4. The paper catalogue is published annually, and it is essential that the information it contains is kept up to date by reference to the monthly announcements of new, revised, amended or withdrawn publications listed in BSI's monthly *Standards Update*. Monthly updates of the electronic catalogue are also issued.

Also listed in *Standards Update* every month are new standards projects on which work is starting, whether at UK national, European or international level, and draft standards for public comment. These announcements enable interested parties who may not be involved with the committees to contribute to the timely drafting of new and revised standards.

Annex A provides a list for further reading, and the bibliography includes a number of BSI publications. Brief details are given in section 9 of the range of information and consultancy services provided by BSI to suit the needs of its members and clients.

2.4 International and European standardization

Standards are as international as the markets they serve. BSI's outlook has always been towards world markets, helping to promote the acceptability of UK exports and imports.

ISO and IEC

Through the British Electrotechnical Committee, BSI is a member of the International Electrotechnical Commission (IEC) established in 1906 to provide international standards in the electrical field.

Alongside the national standards bodies of more than 80 other countries, BSI is also a member of the International Organization for Standardization (ISO), founded in 1947.

In the past ISO and IEC have pursued separate and distinct paths with separate procedures and format of documents. The operations of the two bodies are nowadays closely aligned. Joint committees exist to avoid duplication of work, and common drafting rules apply.

Starting in the 1970s, BSI published ISO and IEC standards as identical British Standards, with a national foreword and a parallel BS number. BSI has now abandoned dual numbering on the grounds that the standards will be best known by their international identity.

CEN and CENELEC

At the European level, BSI represents the UK in the European Committee for Standardization (CEN), the counterpart of ISO and, again through the British Electrotechnical Committee, in the European Committee for Electrotechnical Standardization (CENELEC), the counterpart of IEC. Both CEN and CENELEC originated in the early 1960s and draw their membership from the respective national bodies within the 18 European Union (EU) and European Free Trade Organization (EFTA) countries.

As voluntary associations of ISO/IEC members, CEN and CENELEC aim to harmonize their members' national standards wherever possible on the basis of ISO and IEC work. Cooperation is underpinned by two mutual agreements: the Vienna Agreement between CEN and ISO, and the Dresden Agreement between CENELEC and IEC. Like their members, CEN and CENELEC are not empowered to compel anyone to use their standards. The standards that are adopted therefore remain voluntary unless the law intervenes.

ENs, HDs and ENVs

The main types of CEN and CENELEC publication are European Standards (designated EN), Harmonization Documents (HD) and European Prestandards (designated ENV). ENs and HDs constitute CEN and CENELEC standards, whilst ENVs are prospective standards for provisional application, akin to BSI Drafts for Development.

An EN carries the obligation on CEN or CENELEC members to implement it at national level by giving it the status of a national standard and by withdrawing any conflicting national standards. The technical content of an EN is therefore presented in identical form in each country and is of equal validity (except, possibly, in EFTA countries whose members had not supported its adoption).

An HD carries the same obligation to withdraw any conflicting national standards but public announcement of its number and title is otherwise sufficient. HDs are established if transposition into national standards is unnecessary – as in the case when a CEN or CENELEC member has already adopted the ISO or IEC standard being endorsed in Europe – or impracticable, and particularly if agreement is subject to the acceptance of national technical deviations.

Sector arrangements

CEN and CENELEC have the facility to administer, or formally to associate with, such other organizations as may exist on a sufficiently authoritative and participative basis for the purpose of preparing standards in particular sectors. The European Coal and Steel Community used to maintain a separate, official committee structure for drawing up its iron and steel standards (issued then as “Euronorms”). Now, instead, it sponsors ECISS, the European Committee for Iron and Steel Standardization, administered by CEN. UK input to ECISS is concerted within the BSI Engineering Sector Committee.

AECMA, the European Aerospace Manufacturers' Association, is recognized by CEN as an “Associated Body”, competent to conduct all preparatory standards work in the aerospace field prior to formal CEN voting. CEN also has a protocol with ECSS (European Committee for Space Standardization) for the development of European Standards. CEN also provides the secretariat to EBS (the European Board for EDIFACT Standardization) which supports the UN/EDIFACT process in Europe.



A third European standards organization, quite separate from CEN and CENELEC, the European Telecommunications Standards Institute (ETSI) was formed in 1988 at the initiative of the European Congress for Posts and Telecommunications (CEPT). It relies on direct membership from all interested bodies and is active in formulating standards across the whole range of telecommunications systems.

Joint arrangements have been agreed with CEN and CENELEC to avoid duplication of effort and, by arrangement with the Department of Trade and Industry (DTI), BSI coordinates UK interests in ETSI work on telecommunications terminal equipment standards.

Assisted international travel

The benefits of European harmonization will primarily reward the efforts of those who work hardest to achieve it. European work takes priority in the BSI standards programme. In order to encourage UK participation in international and particularly European standards work, Government, through the DTI, provides a contribution towards the travel costs of certain UK participants attending international and European standards meetings. Details may be obtained from BSI Standards, 389 Chiswick High Road, London W4 4AL.

2.5 Standards and the law

2.5.1 Implications of the law

There are many Acts of Parliament that relate to businesses and some, including supporting Regulations and Orders, are part of the criminal law. In some cases compliance with designated British Standards is specifically required by legislation – the British Standard becomes “mandatory” – and the failure of a product to conform to the standard would be an offence. However, in other cases products supplied or offered for supply and described or marked as conforming to any standard could, if falsely described, infringe the provisions of the Trade Descriptions Act, 1968 [1]. In the UK this Regulation is enforced by the Local Trading Standards Authorities.

This legislation creates wide-ranging offences for false and misleading statements applied to all types of products and services. Civil action may also be possible by one company against another for misrepresentation or similar failure to comply with a specific description or implied quality of product.

Codes of practice, guidance notes and practice notes are increasingly being used to complement statute law. They underpin the law and provide further guidance on standards, implications and procedures. Failure to comply with an approved code of practice may be cited in criminal proceedings against a company or an individual. Other codes merely indicate practices which would support a company's claim to have exercised “due diligence” or, in the case of “occupational exposure levels” determine acceptable standards for healthy working with substances.

The European Union is providing an even wider framework of law and, given the range and scope of the new approach directives linked to completion of the single market, it is clear that standards are taking on an even greater significance as means of compliance with the law.

Certain standards are also used as benchmarks against which to make a legal assessment, e.g. of product safety. Some major pieces of legislation relating to businesses are briefly outlined below.

2.5.2 The Health and Safety at Work, etc. Act, 1974 [2]

The scope of the 1974 Act was “to make further provision for securing the health, safety and welfare of persons at work, for protecting others against risks to health or safety in connection with the activities of persons at work, for controlling the keeping and use of dangerous substances, and to make provision with respect to the Employment Medical Advisory Service”. The Act is an overarching framework measure superimposed over existing more detailed health and safety legislation. The existing requirements under, for example, the Factories Act, 1961 [3] and the Offices Shops and Railway Premises Act, 1963 [4] remained when the Act came into force. This provided one comprehensive and integrated system of law to deal with health and safety at work, and the protection of the public affected by the activities of people at work.

The enforcement structure for the earlier Acts has been replaced by the Health and Safety at Work etc. Act, 1974 [2]. This includes powers to issue improvement and prohibition notices and to prosecute. The general duties of employers to their employees are set down in Section 2 of the Act.

Section 2(1)

Establishes “the duty of every employer to ensure, so far as is reasonably practicable, the health, safety and welfare at work of all his employees”.

Section 2(2)(a)

Requires the safe provision and maintenance of plant, which the Act defines as including machinery, equipment and appliances used at work. It embraces the more detailed and specific provisions also remaining which cover certain equipment contained in existing legislation, but also relates to other plant which is not subject to other safety legislation.

Section 2(2)(b)

Requires “arrangements for ensuring, so far as is reasonably practicable, safety and absence of risks to health in connection with the use, handling, storage and transport of articles and substances”.

This subsection is concerned with materials and substances whether in solid or liquid form or a gas or vapour, so that the subsection covers everything used at work and all work activities.

Section 2(2)(c)

Requires of an employer “the provision of such information, instruction, training and supervision as is necessary to ensure, so far as is reasonably practicable, the health and safety at work of his employees”.

Section 2(2)(d)

Requires “so far as is reasonably practicable as regards any place of work under the employer’s control, the maintenance of it in a condition that is safe and without risks to health and the provision and maintenance of means of access to and egress from it that are safe and without such risks”.

Section 6

Places specific duties on those who can ensure that articles and substances which may be used at work are as safe and without risks to health as it is reasonably practicable to make them. Articles must also be properly erected and installed. The section was amended with effect from 1 March 1988 by the Consumer Protection Act, 1987 [5]. It covers:

- a) new and second-hand articles designed for use at work, whether for sale or hire, and their component parts;
- b) items which, though capable of domestic use, are designed to be used also at work;
- c) new and second-hand items of fairground equipment;
- d) all substances, including micro-organisms, which are supplied to workplaces or to certain other non-domestic premises.

The safety of goods intended for domestic use is subject to other legislation, particularly the Consumer Protection Act, 1987 [5] and Regulations relating to consumer goods.

In addition to providing a framework for specific regulations, the Act was complemented in 1994 by the General Product Safety Regulations [9] which extended the general safety requirements.

2.5.3 Food Safety Act, 1990 [7]

In the same way that the Health and Safety at Work, etc. Act, 1974 [2] provided a universal framework for occupational safety and health, the Food Safety Act, 1990 [7] is the encompassing legislation for the safety of food. Food must be fit for consumption and of the nature, substance, and quality, demanded. Each of these parameters must of course be evaluated against a benchmark.

If the proprietor of a food business wishes to protect himself or herself from the possibility of legal action, they must put in place such practices as will ensure “due diligence” against a mishap occurring. A due diligence defence obviously will owe much to a quality assurance system.

The EU-related food hygiene regulations adopted under the Food Safety Act, 1990 [7] also look for proper systems of control. A logical and evaluative approach, such as hazard analysis and critical control points (HACCP) is already in use in parts of the food industry and again will rely on a formal quality control methodology.

2.5.4 Risk assessment

Recent changes to health and safety legislation, much of it stimulated by EU law, have been based around risk assessment. The Management of Health and Safety at Work Regulations, 1992 [8] provide a general framework for the management of health and safety at work and enhance the implied requirements of the Health and Safety at Work etc. Act, 1974 [2].

From 1 January 1993 they impose the following duties on employers (and the self-employed).

- a) Carry out suitable and sufficient assessment of risks to employees and others affected. Record in writing if five or more are employed. Self-employed to assess risks to self and others affected (Regulation 3).
- b) Record arrangements for health and safety in writing if five or more persons are employed, including the planning, organization, control, monitoring and review of “protective and preventative measures” (Regulation 4).
- c) Provide health surveillance, where appropriate, for any risk identified by the assessment (Regulation 6).
- d) Appoint competent person(s) to assist in meeting the “requirements and prohibitions” (Regulation 6).
- e) Introduce procedures for serious or imminent danger and identify danger areas (Regulation 7).
- f) Provide relevant and comprehensive information to employees on risks and precautions (Regulation 8).
- g) Develop joint arrangements with other employers in shared workplaces for the safety of their employees (Regulation 9).
- h) Make arrangements for the safety of employees of other companies or of the self-employed.
- i) Provide safety training at induction, or upon transfer to new work and upon any change in the technology employed or system of working (Regulation 11).
- j) Advise employment agencies of any safety requirements for temporary workers to be engaged (Regulation 13).

In particular, this approach has been taken regarding the control of substances hazardous to health (COSHH) at work, as well as safety management, manual handling and noise at work. The Control of Substances Hazardous to Health Regulations, 1994 [9] came into force on 16 January 1995.

The principles are that employers must:

- a) evaluate what hazards exist;
- b) assess the risk of the hazards translating to injury or ill-health;
- c) eliminate the substance, article or practice posing the risk, if possible;
- d) if it is not practicable to eliminate the risk, institute control measures and systems to maintain and monitor the risk;



- e) where feasible, monitor any ill-effects on workers;
- f) inform, instruct and train employees about the risks and countermeasures.

Other legislation developing the theme of risk assessment also prescribes certain standards of practice or provision. Such legislation includes that which relates to visual display units and personal protective equipment. Regulations are issued by government to implement statutory legislation, including the timing.

New regulations

The Construction (Design and Management) Regulations, 1994 (CDM) [10] aimed at the construction industry came into force on 31 March 1995. These place duties on all involved in construction work, such as contractors and designers, to minimize risks to workers. Regulations on the minimum requirements for the provision of safety and/or health signs at work were also implemented at the same time.

A useful commentary on the wide variety of changes to regulations and bulletins affecting occupational health and safety both in the UK and Europe can be obtained by reading the Health and Safety Commission's *Newsletter*.

2.5.5 The Consumer Protection Act, 1987 [5]

2.5.5.1 General

The Consumer Protection Act, 1987 [5] covers responsibilities to the customer, rather than the employee, and encompasses product liability and consumer safety.

2.5.5.2 Product liability

Part I of the Consumer Protection Act, 1987 [5] came into force on 1 March 1988 and introduced product liability provisions into UK law for the first time. Under the legislation, manufacturers, importers and "own-branders" are strictly liable for any damage caused by a defect in their product.

Although standards are not specifically referred to in Part I of the Act, one of the defences in Section 4 of the Act depends upon the ability of a producer to show that, at the time of production, the state of scientific and technical knowledge was not such that a producer of products of the same description as the product in question might be expected to have discovered the defect. As standards are based on scientific and technical knowledge, they can clearly play a vital role in defining expected safety levels. Furthermore, the operation of standards-based quality management systems and procedures designed to identify and control components, materials and methods to ensure a safe and reliable product, would be a significant factor in establishing such a defence.

2.5.5.3 Consumer safety

Part II of the Consumer Protection Act, 1987 [5] came into force on 1 October 1987. It consolidated earlier legislation which required goods to conform to the requirements of safety regulations (many of which refer to the specifications drawn up in standards). It also introduced, for the first time, a "general safety requirement" which required all consumer goods to be

reasonably safe, taking into account all the circumstances including the existence of published safety standards.

The general safety requirement was extended by the General Product Safety Regulations, 1994 [6] which came into force on 3 October 1994. These Regulations implement into UK law the requirements of the EU Directive on General Product Safety. They apply to all products which are intended for consumers, or are likely to be used by consumers, and cover second-hand, as well as new, goods. The use of standards is specifically referred to in Regulation 10, and will provide benchmarks for assessing the safety of products.

2.5.6 The Environmental Protection Act, 1990 [11]

There is concern to improve the environment in our cities, towns and places of work as well as the surrounding countryside. Of growing concern is waste disposal with 350 000 tonnes of waste being produced in the UK every day.

Most of the Act is relevant to industry and can be briefly summarized as follows.

Part 1(a) Integrated pollution control (IPC)

This applies to some of the potentially worst polluting industries and is the enforcement responsibility of Her Majesty's Inspectorate of Pollution. Industries scheduled for IPC have to employ "best available techniques not entailing excessive cost" (BATNEEC) and the controls apply to all discharges whether to land, air or water. The combined Environment Agency originated from the IPC concept.

Part 1(b) Air pollution control

This was introduced for industries slightly less polluting than those scheduled for IPC and covers a wide range of uses from glass works to coating processes. Again BATNEEC applies and industries have to apply to their local authority Environmental Health Officers for prior authorization. British Standards relate to air pollution monitoring methods.

Part 2 Waste on land

Responsibility for waste extends from "the cradle to the grave". This involves waste originators and carriers as well as disposal site operators.

Part 3 Statutory nuisance

These provisions re-enacted the previous nuisance provisions of the Public Health Acts and the noise nuisance provisions of the Control of Pollution Act. British Standards particularly relate to the methods of noise monitoring.

Part 5 Amendments to the Radioactive Substances Act, 1960

These remove exemptions from the UK atomic energy authority and crown premises and introduce enforcement and prohibition procedures.

Part 8 Miscellaneous

This part brings in wide ranging controls over the importation and export of wastes, including powers to obtain information. It introduces the concept of public registers for potentially contaminated land and extends the controls over disposal of substances and articles at sea.

Other relevant environmental legislation, such as that relating to water uses, and discharge to water courses (Water Industries Act, 1991 [12]) or that relating to protection of food crops etc. (Food and Environment Protection Act, 1985 [13]) also relies on the setting and monitoring of standards.

2.5.7 Environmental audit

Environmental audits and environmental management systems involve checking against existing legislative and in-house standards to ensure protection of the environment. Quality assurance techniques are employed to ensure consistent compliance with the legal or adopted standards.

The design stage for systems could incorporate factors such as energy conservation, waste reduction and recycling of materials. This would mean a review of the materials used, the waste produced or the energy consumed and could mean altering processes, for example, painting or spraying to use fewer or no solvents.

The EC Eco-Management and Audit Scheme (EMAS) Regulation of 1993 (see **A.1**) was implemented as from spring 1995. The UK Government initially appointed the Department of the Environment (now the Department of the Environment, Transport and the Regions) to be the competent body and the National Accreditation Council for Certification Bodies (now absorbed into the United Kingdom Accreditation service) for the accreditation of independent environmental verifiers. In May 1998, the Institute of Environmental Assessment was appointed as the competent body for EMAS.

Environmental Accreditation Criteria (EAC) guidelines form the basis for certification bodies for BS EN ISO 14001 and environmental verifiers for EMAS. In February 1998 the European Commission issued document EA7/02 *EA guidelines for the accreditation of certification bodies for environmental monitoring systems* [14] to replace earlier guidance. In July 1998 UKAS issued *The accreditation of environmental verifiers for EMAS. UKAS supplement to EA7/02 EA guidelines for the accreditation of certification bodies for environmental monitoring systems* [15]. These documents together set out the criteria against which AKAS accredits environmental verifiers.

EMAS provides for the European Commission to recognize standards and certification procedures as meeting the requirements for environmental management systems in the regulation. In April 1997 two commission decisions were published. One decision recognizes that ISO 14001 and EN ISO 14001 fulfil the environmental management system elements of the EMAS regulation. The second decision acknowledges those ISO 14001 certification and accreditation procedures that meet the relevant requirements of the Commission and includes the EAC guidelines. For companies already certified to BS EN ISO 14001, who then seek EMAS registration, all that will be required over and above certification to

BS EN ISO 14001 will be validation of the environmental statement by an accredited environmental verifier.

2.5.8 Removing trade barriers within the European Union

The old approach

An ambitious European Community programme intended to eliminate technical barriers to trade was launched in 1969. Directives issued under Article 100 of the Treaty of Rome established free circulation objectives for Member States, linked to detailed annexes setting out technical requirements. Keeping these annexes up-to-date proved an unexpectedly heavy burden, the flow of new directives dried up and the Commission reviewed its policy 10 years later.

The Low Voltage Directive

As an exception to what was then normal practice, the 1973 Low Voltage Directive (see **A.1**) was drafted in such a way that national standards harmonized through CENELEC would provide the detailed criteria for assessing the safety of a wide range of products, against a list of the minimal essential requirements to be taken into account. Much of the work of CENELEC has since been directed towards providing the necessary standards, mostly in the form of HDs, as far as possible by endorsement of pre-existing IEC standards.

Mutual recognition

The Cassis de Dijon judgment in 1979 (see **A.1**) established the principle that any product lawfully produced or marketed in one Member State must be admitted to the market of any other Member State by virtue of Article 30 of the Treaty of Rome (general prohibition of quantitative restrictions on imports between Member States and all measures having equivalent effect), unless Article 36 can be invoked (justification of restrictions on grounds of public morality, public policy, protection of health and life etc.). Following this principle it was recognized that directives should promulgate only the essential requirements needed as a harmonized basis for national regulations, relying on the subsequent provision of voluntary safety standards that would not fall foul of safeguard clauses or the general application of Article 36.

The principle of mutual recognition was restated in the Commission's 1985 White Paper on completion of the internal market (see **A.1**), which first listed the programme of Community measures to be adopted no later than 1992.

"In cases where harmonization of regulations and standards is not considered essential from either a health/safety or an industrial point of view, immediate and full recognition of differing quality standards, food composition rules etc. must be the rule. In particular, sales bans cannot be based on the sole argument that an imported product has been manufactured according to specifications which

differ from those used in the importing country. There is no obligation on the buyer to prove the equivalence of a product produced according to the rules of the exporting state. Similarly, he must not be required to submit such a product to additional technical tests nor to certification procedures in the importing state. Any purchaser, be he wholesaler, retailer or the final consumer, should have the right to choose his supplier in any part of the Community without restriction. The Commission will use all the powers available under the Treaty, particularly Articles 30-36, to reinforce this principle of 'mutual recognition'."

The new approach

Directives under the new approach are based on the new Article 100A introduced by the Single European Act [16], no longer dependent on unanimity in the Council of Ministers but subject to the requirement that the Commission, in its proposals concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection.

Under these directives:

- a) legislative harmonization is limited to the adoption of essential requirements only;
- b) preparation of supporting technical specifications is entrusted to standardization organizations;
- c) such technical specifications maintain their status as voluntary standards;
- d) but national authorities are obliged to recognize products conforming to harmonized standards as presumed to conform to the essential requirements.

Annex A includes a list of the New Approach Directives adopted as at 30 June 1998. Most provide for flexible transitional arrangements, to be reflected in the corresponding national legislation. In each case, it seems unlikely that trade will be facilitated until suitable harmonized standards become available.

CE marking

The Low Voltage Directive originally provided for nominated bodies' certification marks and test results to be accepted by the relevant national authorities. The New Approach Directives instead provide for a single, distinctive marking (the letters "CE") to be displayed on products marketed as conforming with the applicable essential requirements. (CE marking is now additionally required by the Low Voltage Directive as amended.) Such marking might be sufficient for a frontier official, but it could mislead purchasers and end users if the criteria underpinning it were not immediately apparent. Nor is it expected to reduce customer demand for voluntary certification of product conformity with standards.

On 1 January 1996 new legislation came into force which means that domestic gas appliances sold in the EU countries must by law bear the CE mark. To apply the CE mark products must have been tested by an independent third party.

Procurement directives

Article 6 of the Treaty establishing the European Community (formerly Article 7 of the Treaty of Rome) prohibits discrimination on grounds of nationality within the scope of application of the Treaty. Liberalization of public procurement is seen as an important element in establishing the Single Market, i.e. an area in which the free movement of goods, persons, services and capital is assured.

Under the amended Public Supplies and Public Works Directives, and the new Public Services and Utilities Directives, those responsible for inviting tenders for contracts above certain values are required to define their technical specifications by reference to national standards implementing European Standards, where these exist, subject to permissible derogation. On this basis, no authority likely to be bound by the outcome can afford to ignore European standardization developments.

In the absence of suitable European specifications, the Utilities Directive envisages that contract specifications should as far as possible be defined by reference to other standards having currency within the Community. The Supplies and Works Directives indicate more explicitly that in this case it is appropriate to make reference in order of preference to:

- 1) national standards implementing international standards accepted by the country of the contracting authority;
- 2) other national standards (and national technical approvals) of the country of the contracting authority;
- 3) any other standard.

Contracting entities bound by the directives are advised, however, to qualify with the words "or equivalent" any specification requirement referring to a purely national standard, in order to be able to verify compliance with their technical conditions without running the risk of unlawfully restricting the initial opportunity to tender.

2.6 Conformity assessment

Conformity assessment is defined in BS EN 45020:1998, **12.2** as "any activity concerned with determining directly or indirectly that relevant requirements are fulfilled". This very general definition conceals a complexity and wide-ranging applicability to the activities of UK industry, which uses conformity assessment to examine a product, process or service to determine whether it fulfils a defined expectation. The defined expectation may be a standard or it may be a contractual requirement, stated or implicit.

Four levels of conformity assessment activity can be recognized. The first level is the determination of the characteristics of a product, process or service. There are three main ways in which this can be done. Testing is a technical process which uses a specified procedure to measure one or more characteristics of a product.

The closely related activity of calibration provides traceability of physical measurements to the national measurement system. Physical inspection can be carried out on either newly-manufactured products, or as an in-service check on the continued operation of plant and equipment. The third activity is the assessment of a quality management system.

At the second level, conformity of the results of the determination of characteristics with an appropriate standard is evaluated. This may be done by:

- the supplier or manufacturer;
- the purchaser;
- an organization independent of, but contracted to, either manufacturer or purchaser;
- an independent agency for the purpose of enforcement or regulation.

Action by the manufacturer leads to the supplier's declaration of conformity. Action by the purchaser leads to the acceptance of a piece of equipment, batch of products or service, all of which were the subject of a contract. Many major purchasers, such as the former nationalized industries, have for many years carried out their own "second party" assessment of suppliers.

There has been a general move towards greater reliance upon independent certification. An independent organization may be contracted by either supplier or purchaser to certify either a quality management system or products in the form of a piece of equipment, batch or consignment. Use of the term certification in a generic sense has tended to obscure the distinction between product testing and conformity certification on the one hand, and systems capability assessment and registration of firms on the other. The generic term "registration" is now preferred as an indication of third party endorsement of a firm's capability following systems assessment to one of the BS EN ISO 9000 series of standards.

These standards list the key requirements of a quality system, and registration gives independent assurance that systems are in place, so that the need for customers to carry out their own assessments is reduced or eliminated. This confers operating and market advantages to the supplier and provides confidence to the purchaser. This latter point has developed to the stage that it may be a contractual requirement in many cases. Product certification is a procedure under which a distinctive mark may be applied to a product certified as having been manufactured to conform to a specific product standard. In addition to product testing and inspection, it may require compliance by the manufacturer with a quality management standard. It will also usually involve regular surveillance.

Completion of assessment procedures leads to the assurance of conformity of a certified product or a registered manufacturer's quality system. This assurance is strengthened if the third party body has been through the procedure of accreditation, in which

an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. Accreditation demonstrates the competence of a conformity assessment body to certify that a product can conform to a product standard; a system can conform to a system standard (e.g. BS EN ISO 9000 series). For conformity assessment activities the BS EN 45000 series of system standards provides relevant accreditation criteria. (The EN 45000 series of standards will shortly be replaced by new documents in the EN ISO 17000 series.)

Accreditation of testing and calibration was until recently the responsibility of NAMAS (National Measurement Accreditation Service), whereas accreditation of certification was the responsibility of NACCB (National Accreditation Council for Certification Bodies). These two organizations merged in 1995 to form a unified national accreditation service, the United Kingdom Accreditation Service (UKAS). Accreditation of inspection bodies and environmental verifiers are covered by the new organization.

The aim of all these conformity assessment procedures is to achieve acceptance of a product on the market. They may have a part to play in the enforcement of regulations or in reducing technical barriers to trade.

The European dimension

Technical barriers to trade stem from two sources. They are caused by differences between national regulatory regimes, which require manufacturers to make their products to different specifications for different markets. They also arise from the actions of individual purchasers and customers, who may lack confidence in the quality and consistency of the goods and services they buy and use, and therefore require products to be checked and re-checked for each part of the market on which they are to be sold. A solution to these problems was sought in the Global Approach to certification and testing adopted by the European Council of Ministers in December 1989 (see A.1).

A key feature of the Global Approach was the establishment of the European Organization for Testing and Certification (EOTC) as the focal point for the rationalization of voluntary conformity assessment activities in Europe. EOTC provides encouragement and a mechanism for the providers of conformity assessment services to enter mutual recognition arrangements product by product. In this way it provides assurance that mutual recognition is technically sound, and so reduces the need for repeat testing or certification. It ensures that mutual recognition arrangements are market responsive, and not anti-competitive in structure.

EOTC is still a relatively new organization, and there is ample opportunity for industry and the conformity assessment community in the UK to influence its development in ways which meet their needs. The National Forum for Conformity Assessment and Quality Policy, administered by BSI, provides the channel for co-ordination of UK input to EOTC.

In the regulatory context, the New Approach Directives set out the necessary attestation procedures for demonstrating, through CE marking, conformity of products with the applicable essential requirements. Detailed attestation procedures vary from directive to directive, but they are described by reference to a range of conformity assessment modules which was adopted by the Council of Ministers in December 1990. Where the products are required to be independently tested, inspected or certified, this has to be done by a body approved by a member government and notified to the European Commission. Such Notified Bodies in the United Kingdom are expected to comply with the EN 45000 series (to become the EN ISO 17000 series) of European Standards, and a relevant accreditation is normally taken as evidence of compliance.

There are still problems with some of the New Approach Directives, and there is a great deal of confusion in the market. Convergence between voluntary and regulatory conformity assessment activities remains controversial. ETOC was set up to deal with the voluntary sector alone, and there are those who believe that it should not become involved in the regulation of the market. The view of the European Commission is that the New Approach and the Global Approach were designed to provide the necessary levels of confidence for the placing and circulation of products in the market. The Single European Act did not differentiate between private and public sectors, and the Commission would like to see the development of a single, transparent system for both voluntary and regulatory needs. The Commission recognizes the need for advice and technical assistance from EOTC for the regulatory sector. From a more practical viewpoint, conformity assessment bodies which are members of EOTC Agreement Groups are in some cases also authorized to act as Notified Bodies. As EOTC grows in influence, it seems likely that the distinction between voluntary and regulatory conformity assessment may break down.

2.7 Public authorities

2.7.1 General

Public authorities include:

- district, borough, unitary, city or county councils (not town or parish councils);
- Commission for the New Towns or new town development corporations (housing matters only);
- housing action trusts;
- police authorities;
- fire authorities etc.

2.7.2 Public purchasing

Major public purchasing authorities are tending to place more stress on quality assurance and guarantees of satisfactory procedures are requested in many of the contracts they draw up.

The Local Government Act, 1987 [17] includes a requirement that, if local authorities wish to carry out certain defined activities using direct labour services, then they must put out contracts to competitive tender. This is called compulsory competitive tendering (CCT). The essential conditions of the Act require that the invitation to tender includes detailed specification of the work to be carried out, and that, if the local authority direct labour unit is awarded the contract, it fully complies with the specification. Further legislation in 1992 widened the range of local authority CCT. Many aspects of public sector work have been brought within the scope of the legislation, from grounds maintenance and school meals to sports and leisure management and property related services.

The result is that local authority direct labour services now function more like industrial businesses seeking approvals to the BS EN ISO 9000 series or from UKAS. They therefore need to become as efficient and competitive as possible, and registration to the BS EN ISO 9000 series can be a means of ensuring that organizations are competing on equal terms.

Meanwhile, many of the companies which have won contracts out such work for public sector organizations have also opted to seek quality system certification to the BS EN ISO 9000 series of standards as a means of ensuring that their businesses are efficiently run.

2.7.3 Home authority principle

The home authority principle applied to all trading standards, food hygiene, product safety and consumer protection laws enforced by local authorities. The aims of this principle are to prevent infringements by offering advice at source and by encouraging enforcement authorities and enterprises to work in liaison with a particular authority called the “home authority” in order to retain high standards of protection, whilst minimizing duplication and public expenditure. It is designed to assist businesses to comply with the law in a spirit of consultation rather than confrontation, although none of the guidelines can remove from an enterprise the onus of compliance, or the primary duty for the enforcement of laws from the authority in whose area a specific incident has taken place.

The most important element of the principle is to accept that the function of giving advice is a legitimate aspect of enforcement. A home authority should, therefore, be willing to offer counsel and guidance on policy issues, compliance with the law, adherence to recognized standards, codes and good practice and advice on remedial actions.

Section 3. Quality systems and standards

3.1 Quality and design

UK quality in the industrial context began because of a military need in World War I to ensure the safety and interchangeability of products and spares. It concentrated, however, on the inspection of goods against specification and drawing. Later, it was realized that this only separated conforming from non-conforming components and that it would make more sense to prevent non-conforming components being produced by controlling production processes, but it was some years after World War II before quality assurance was introduced into the design stage. This appreciation now also extends to all types of services such as banking, health and insurance. It is realized that there are two major aspects of quality: first the quality of the design/specification which concerns the degree to which the design of the service or product suits the purpose, and secondly the conformity of the parts produced to meet the specification. Poor execution can easily debase a good design but a poor design can never result in high quality. Other possible shortcomings in the management of design are: lack of feedback from market research or from employees in the course of providing the service; isolation of design from other business functions; inadequate design procedures; and insufficient information available to the designer.

3.2 International quality management systems

A quality management system should be capable of creating a quality policy related to organizational goals and customer needs and expectations and one which accords with the international standard ISO 9000 should provide consistency and universal acceptance. The written procedures cover responsibilities and methods for design, production and delivery but they do not cover the cost effectiveness of these operations. The discipline of having to describe, literally how things are done and by whom, has the effect of revealing outmoded practices, inefficient methods and sometimes lack of clear responsibility. It leads to better communication, better management control, improved working conditions, greater productivity and increased profit. Obtaining a certificate of compliance to a quality management system is a benchmark of the company's commitment, and a movement towards total quality and product certification, but should not be seen as an end in itself.

An assessor is concerned that the procedures meet the requirements of the system standards and that the business is working to them. The concern is not whether these are the most efficient procedures or even whether they are economically viable for the company to operate, or whether the quality of design could be improved from a cost effective and minimum risk point of view.

A quality system such as that described in the BS EN ISO 9000 series is a catalyst to benefits over and above the successful achievement of assessment. The disciplines of describing what and how things are done to a third party frequently reveals outmoded practices or lack of specified responsibility. The correction of these deficiencies improves the efficiency of the business.

3.3 Quality and standards

The development of international quality systems has a knock-on effect of demanding an improvement in standardization at both national and business levels. The maintenance of business standards relies on the diligence of the quality audit team to provide feedback when non-compliances are encountered.

Standards have the following roles in the quality management system:

- a) to communicate to customers the management technique of quality assurance itself and criteria against which a company's quality management can be assessed;
- b) to control management systems throughout the business from design to delivery of the product or service;
- c) to standardize tests which form the basis of quality control and, if required, product certification (conformity assessment);
- d) to record design and manufacturing instructions including those for process control, purchased goods or services;
- e) to provide a base for conformity assessment and registration.

Aspect a) is covered by the BS EN ISO 9000 series of British Standards which is applicable to all types of organizations. The others, if achieved successfully, support the requirements of these standards.

3.4 National and international standards for quality systems

3.4.1 BS EN ISO 9000 series and BS 5750

Early editions of BS 5750 *Quality systems* were the basis for the development of the ISO 9000 series of international standards which provide a guide to the management of quality systems. Parts 0, 1, 2 and 3 of BS 5750, ISO 9000 to 9004 and EN 29000 to 29004 were identical. Most parts of BS 5750 and the EN 29000 series were withdrawn in 1994 and replaced by the ISO 9000 standards. BSI has published these as the BS EN ISO 9000 series which acknowledges the compatibility with the European and international standards. The survivors are two of the guides, BS 5750-8 and BS 5750-14. To simplify the description, this chapter will frequently refer to BS EN ISO 9000

when inferring one or all of the applicable standards in that series. The latest revisions of the BS EN ISO 9000 standards take account of the international agreement involved in their development and are identical with the international standards. The international standards have become the basis for harmonization within the European standardization organizations CEN and CENELEC and hence among the EU and EFTA countries. The ISO 9000 standards are therefore of great significance in world trade. They are issued as individual standards for different applications, not to reflect different levels of quality but to specify different scopes. BS EN ISO 9000 is the reference basis for the *Register of quality assessed United Kingdom companies* issued by the Department of Trade and Industry (published by The Stationery Office).

The BS 5750 to BS EN ISO 9000 review process in 1994 also resulted in some changes to the text of the standards to make them more applicable to the service sectors, where many small businesses operate. The revised standard incorporates the latest best management practice, gives clearer management responsibility, and focuses more on improvement procedures. It is not a major revision of the standard, it retains the structure and much of the text of the 1987 version. *Vision 2000* produced by ISO committee TC 176, which is available from BSI as PD 6538:1993, calls for a two-phase programme for the updating of ISO 9000, the first of which is to address inconsistencies and errors as well as improving it to more easily apply to a wider scale of usage. The next revision of ISO 9000, expected to be completed by the year 2000, will aim to simplify the language used and make the standards generally applicable to all types of organization.

3.4.2 BS EN ISO 9000 and AQAP

BS EN ISO 9000-1:1994 Quality management and quality assurance standards — Part 1: Guidelines for selection and use

Clarifies the principal quality-related concepts and provides guidance on the selection and use of the ISO 9000 family on quality management and quality assurance.

BS EN ISO 9001:1994 Quality systems — Model for quality assurance in design, development, production, installation and servicing

Specifies quality system requirements for use where a contract between two parties requires the demonstration of a supplier's capability to design and supply conforming product. It is used when design is required and the product requirements are stated principally in performance terms, or they need to be established; and confidence can be demonstrated in capability of design development, installation and servicing.

BS EN ISO 9002:1994 Quality systems — Model for quality assurance in production, installation and servicing

Specifies quality system requirements for use where a supplier's capability to supply conforming product to an established design needs to be demonstrated. The requirements specified are aimed primarily at achieving customer satisfaction by preventing non-conformity at all stages from production through to servicing.

BS EN ISO 9003:1994 Quality systems — Model for quality assurance in final inspection and test

Specifies quality system requirements for use where a supplier's capability to detect and control the disposition of any product non-conformity during final inspection and test needs to be demonstrated. It is applicable in situations when the conformity of the product to specified requirements can be shown with adequate confidence provided that certain suppliers' capability for inspection and test conducted on finished product can be satisfactorily demonstrated.

BS EN ISO 9004-1:1994 Quality management and quality system elements — Part 1: Guidelines

Describes a basic set of elements which can be developed and implemented for an in-house quality system with a view to ensuring customer satisfaction. The selection of appropriate elements and the extent to which these elements are adopted and applied by a company will depend on factors such as the market being served, nature of product, production processes, and customer and consumer needs.

These standards are also equivalent, with some minor differences, to the NATO allied quality assurance publications AQAPs 1,4 and 9 which superseded Ministry of Defence standards DEF STAN 05-21 to 05-29. A company which is registered to BS EN ISO 9000 should have no difficulty in being assessed to the equivalent AQAP and vice versa. It is expected that it (or its international equivalents) will supersede the AQAP series.

Quality audits conducted on a supplier by the purchaser's representative or by third party assessment will test the effectiveness of the business documentation as well as its systems. Failure to carry out effective documentation and maintain standards policies may result in failure to satisfy the purchaser or assessor and thus in loss of business.

3.4.3 Handbook on quality management systems

While British Standards on quality management are referenced individually and may be obtained individually, some have been classified in QMH 100 *Quality management handbook*, which brings them together under one cover and forms a convenient and economical way of obtaining and holding them. QMH 100 is published in two parts: *Part 1: Quality assurance* and *Part 2: Reliability and maintainability*. They include standards which can be grouped under three headings:

- a) terminology standards which set down agreed terms and definitions in current quality assurance practice;
- b) basic or generic standards which are written in the form of guides (not involving contractual requirements);
- c) definitive system specifications (with guides), i.e. BS EN ISO 9000 series (see above).

Wherever possible, terms and definitions from EOTC, ISO and IEC publications have been adopted. BS 5760 *Reliability of systems, equipment and components* is currently in 19 parts. Part 0 is an introductory guide to the principles of reliability; part 1 discusses the essential features of a comprehensive reliability and maintainability programme and is concerned mainly with what has to be done and why, when and how; part 2 recommends general procedures for the assessment of reliability; part 3 contains authentic practical examples; part 4 gives guidance on specification clauses concerned with the achievement of reliability. The titles of the others are as follows:

- Part 5: Guide to failure modes, effects and criticality analysis (FMEA and FMECA);*
- Part 6: Guide to programmes for reliability growth;*
- Part 7: Guide to fault tree analysis;*
- Part 8: Guide to assessment of reliability of systems containing software;*
- Part 9* renumbered as BS EN 61078 (see below);
- Part 10: Guide to reliability testing;*
- Part 11: Collection of reliability, maintainability and maintenance support data from the field;*
- Part 12: Guide to the presentation of reliability, maintainability and availability predictions;*
- Part 13: Guide to reliability test conditions for consumer equipment;*
- Part 14: Guide to formal design review;*
- Part 15: Guide to the application of Markov techniques;*
- Part 16: Guide to stress screening;*
- Part 17: Reliability growth — Statistical test and estimation methods;*
- Part 18: Reference conditions for failure rates of electronic components and stress models for conversion;*
- Part 20: Guide to the specification of dependability requirements;*
- Part 23: Guide to life cycle costing.*

BS 5760-9 has been renumbered as BS EN 61078 *Reliability of systems, equipment and components — Guide to the block diagram technique*. BS 6143 gives advice on determination of costs associated with defect prevention and appraisal activities, failures, and the operation of quality related cost systems.

The BS 7000 series on *Design management systems* gives guidance based on five prerequisites:

- 1) commitment to good product design at all levels of management;
- 2) motivation of staff involved;
- 3) clear objectives;
- 4) adequate resources;
- 5) organizational systems.

BS 7000-2:1997 *Design management systems — Guide to managing the design of manufactured products* is relevant to the development of all types of product that undergo a manufacturing process and for every stage of alteration from raw material through fabrication, delivery and use to ultimate disposal. It also addresses all levels of staff and management, in all types of organizations involved in design.

BS 7000-3:1994 *Design management systems — Guide to managing service design* describes the formative stage of developing services that meet the reasonable and foreseeable requirements of the users. The concepts and principles are applicable to all forms of service ranging from a situation where the service is directly related to a tangible product to one where there is little or no association with products.

In BS 7000-3:1994 the prerequisites for design management are:

- i) awareness of customer's interests and needs;
- ii) commitments to quality and reliability;
- iii) sincere and visible commitment to good design;
- iv) motivation of all staff involved;
- v) a vision of the future and the provision of clear objectives;
- vi) provision of adequate resources in terms of personnel and equipment;
- vii) provision of organizational systems;
- viii) awareness of competitors;
- ix) awareness of relevant activity and innovation in other fields;
- x) understanding organizational capabilities and limitations.

BS 7000-4:1996 *Design management systems — Guide to managing design in construction* describes a process for the management of design activities throughout the life cycle of a construction project; a process that should enable sufficient information to be produced to satisfy client requirements. It is applicable to construction design at all levels, for all organizations and for all types of construction project.

BS 7000-10:1995 *Design management systems — Glossary of terms used in design management* will assist those who have a responsibility for, or an interest in, design and its management processes. It also supports the application of other parts of BS 7000 and BS 7373.

BS 7373:1998 *Guide to the preparation of specifications* covers the drafting and management of product and process specifications across all sectors of industry, commerce and the public sector. It is applicable to all technical, services, software, production and design areas and also recognizes the importance of intellectual and other rights.

BS EN 30011 *Guidelines for auditing quality systems*, gives guidance which can be applied to:

- a quality systems audit carried out by an organization on its own;
- an audit by one organization on another;
- third party audits by independent agencies.

Guidance is also available on operating product certification systems (see BS EN 45011).

3.4.4 Dependability standards

Also relevant to quality systems are several standards dealing with dependability (also referred to as reliability). The principal documents are as follows.

BS 5760 *Reliability of systems, equipment and components*;

BS 6548 *Maintainability of equipment*;

BS 8444-3:1996 *Risk management — Guide to risk analysis of technological systems*.

Many of the standards listed in 3.4.2, 3.4.3 and 3.4.4 are implementations of International Standards and, as such, are dual-numbered. The policy has now been changed and future implementations will use the international number. Those already implemented are:

BS IEC 60300 *Dependability management*

BS IEC 60605 *Equipment reliability testing*

BS IEC 61124 *Reliability testing — Compliance tests for constant failure rate and constant failure intensity*

BS IEC 61650 *Reliability data analysis techniques — Procedures for comparison of two constant failure rates and two constant failure (event) intensities*

BS CECC 00804 *Harmonized system of quality assessment for electronic components — Interpretation of EN ISO 9000:1994 — Reliability aspects for electronic components*

3.5 Quality systems outside the UK

For a description of conformity assessment policy see 2.6.

Organizations in the UK seeking to expand their export market naturally want to know if registration to BS EN ISO 9000 is going to be beneficial. A short resumé of the history is therefore given here.

BS EN ISO 9000 and its predecessors have been in use since about 1980. The European document EN 29000 was published in 1987 and was superseded by EN ISO 9000 in 1994. European countries are adopting these systems but it may be some time before registration schemes are widespread on the continent.

The advantage of UK approval to BS EN ISO 9000 has therefore to be considered in the light of the situation in each of the possible target markets.

However it is an advantage to European trade that most countries have adopted the (EN) ISO 9000 series as their national standard but they do not have as many independently assessed and registered companies as there are in the UK. Germany and France have both developed schemes similar to those operated by BSI and other assessment organizations in this country.

Registration may not always confer advantage in particular markets for particular products, but registered firms are increasingly likely to be specified for the purpose of contracts governed by the EU Procurement Directives.

It is important to realize that as well as registering the business it is necessary in some European countries to be able to show compliance with a national product standard in order to achieve maximum market penetration. Approvals from such as IMQ (Italy), VDE (Germany), AFNOR (France) etc. have been the norm for generations and the presence of a “mark” on the product can be critical (see also 2.5.9).

Outside Europe each country has to be examined separately. In parts of the USA, local laws require getting approval from a local testing laboratory but “Listing” by one of the better-known laboratories is preferred, e.g. UL (Underwriters’ Laboratories), FM (Factory Mutual), ETL (Electrical Testing Laboratory). In Canada recent legislation may now allow US certification to be accepted. Canada and the USA are moving slowly along the “registered to ISO 9000” route. In Japan, ISO 9000 is recognized but assessment to it is not a way into the Japanese market.

ISO 9000 has a high potential value in Europe and companies and organizations in the USA are taking an active interest, but ISO 9000 has yet to be adopted universally worldwide.

3.6 Installing a quality system

3.6.1 Is it expensive?

BS 5750 was criticized for being in a form which was more suited to large companies that deal with relatively few contracts of large value. The most recent revisions to BS EN ISO 9000 address this concern to include the needs of service industries and small firms. Smaller companies that have a large number of small-value orders may still find that some interpretation and guidance is necessary. Installing a quality system does not need to cost a great deal, although it does need careful planning. Experience has proved that the cost is moderate and in a matter of months it can be saved by more cost-effective methods of operation. Obtaining registration to enhance the company image is an additional bonus to improving the efficiency of operations. First reflections after reading the standard may leave one feeling slightly confused and fearful of the effort required and the volume of paperwork likely to be produced. This is a common reaction but fortunately avoidable by sensible planning and control.

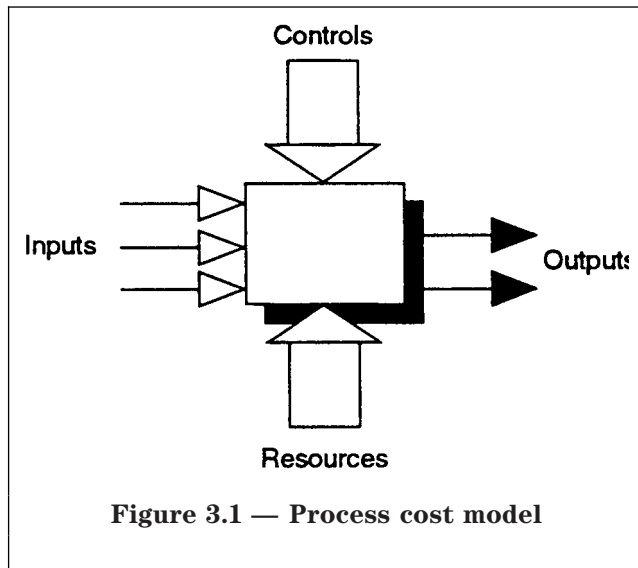
Establishing a quality system is well worth doing. Most businesses embarking on the BS EN ISO 9000 route are already doing the right things but lack the formality and assurance of documented standards and records. In many small companies having little or no formal documentation, the provision of a quality system can produce dramatic improvements.

3.6.2 Economics of quality control

BS 6143 *Guide to the economics of quality*, is in two parts: *Part 1: Process cost model* which applies quality costing to any process or service and *Part 2: Prevention, appraisal and failure model* (PAF) being a revised version of the “traditional” method used in manufacturing industries. Integrated management requires the management of processes. The standard emphasizes this and points out the contribution required from every person within the organization.

The process model is shown in Figure 3.1. Cost elements are recorded as people, materials and equipment and each is identified with a cost of conformance (COC) or a cost of non-conformance (CONC). Some useful examples of the technique are given in appendices to BS 6143.

It expresses the view that allocation of costs to prevention, appraisal or failure tends to divert from the purpose of cost reporting, which should be the constant drive to achieve lower costs. The true value of cost reporting is the opportunity to measure performance and introduce and monitor changes.



3.6.3 What should a quality system consist of?

A formalized management system is part of good management practice and should cover all operations in the business. The quality system should encompass all aspects of the business, management policies, procedures, health and safety instructions and environmental policies. The business mission should be defined and shared with the customers and employees. Goals need to be commonsense and aligned behind the all needs of the business.

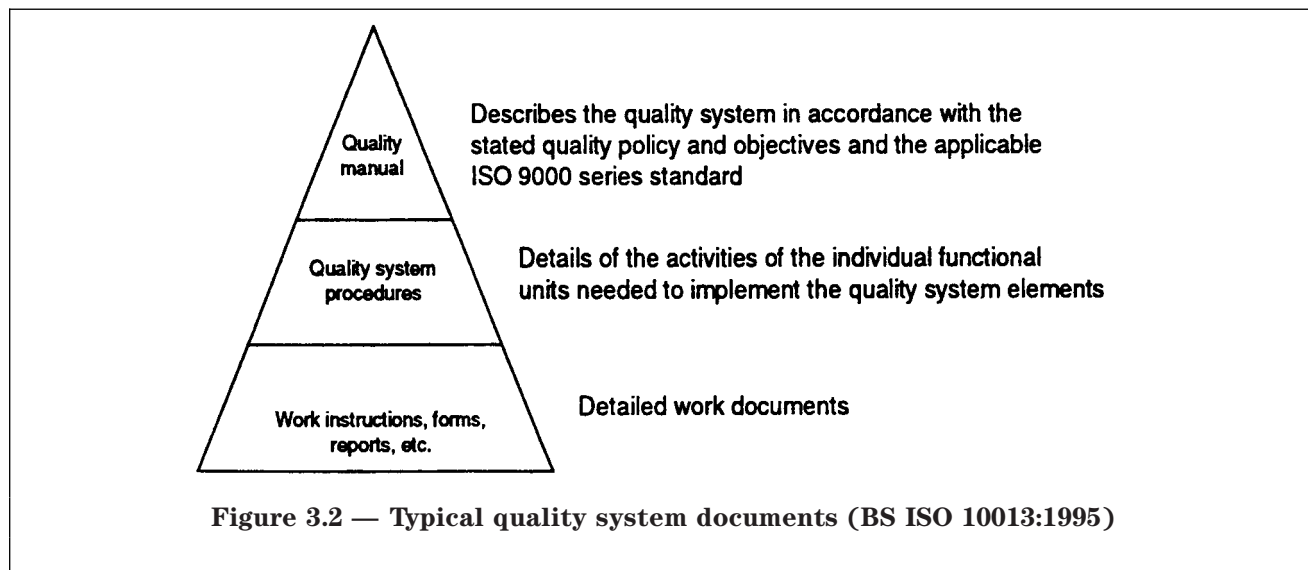
Some of the most important aspects of a quality system are constant attention to customers' needs, specified organizational policies, responsibilities and special processes, with regular review and corrective action, control of documentation, including review procedures, control of purchasing and calibration of measuring and test equipment, and process control and training.

Communication of these points requires documentation which needs to be easy to read and understand. The purpose is to convey necessary information to enable management and employees to maintain or improve their performance. The documents have to be available at the point of use, short and to the point. To meet the requirements of BS EN ISO 9000, documents may be categorized into three groups (see Figure 3.2): a quality manual, a set of quality system procedures and work instructions.

A quality manual need not be a lengthy document if restricted to describing concisely the quality management system. It should give a short resumé of the business and its capabilities together with statements of its quality management policy and systems for service or workmanship, control of documentation, and the organization and authority for implementing the quality system. These building blocks include the business's critical success factors with statements on how they are to be achieved. The quality manual may end with a summary of these procedures. As well as meeting the requirements of the standard, such a quality manual can form a brochure for sending to prospective customers providing the reasons why they should buy the company's service or products. Further scope and guidelines may be found in BS ISO 10013:1995 *Guidelines for developing quality manuals*. A set of quality system procedures is required which describes how the company operates, who has the responsibility for the actions required and what documentation is used. The procedures should not contain detailed information which is only of concern to the operator. Such information should be contained in a group of work instructions to control specific work activities. The procedures need to be issued to those concerned with managing the process whereas the work instructions are the concern of personnel involved with the activity.

3.6.4 Writing the documents

The first steps are to research and record how the business operates. Information is needed from all functions and sections if a true picture is to be obtained and this is more likely to be gathered by someone without vested interests in departmental operations with the support of the local management. As people are naturally resistant to change and probably will have been doing the right things anyway, it is sensible in the initial stages to restrict changes to those essential to the requirements of the standard. Further improvements will undoubtedly be possible but they can be deferred until the benefits of the quality system become obvious. There is no



seeing in writing what happens has a very salutary effect and can lead to staff making their own proposals for improvement.

Procedures need to meet the requirements of the standard in a way which will improve, not hinder, the functioning of the organization. They should allow room for manoeuvre wherever it is sensible to do so, in order to meet changing situations which arise. After all, the purpose is to increase the competitiveness of the business not to cripple it with unnecessary additional costs. Procedures need to be introduced with common sense and it is not feasible to cover every possible situation. However they will need updating regularly to meet changing circumstances such as market forces, process development, changing technology and personnel turnover, as well as improved control revealed by retrospective examination of the procedure in use.

Process specifications largely comprise the technical know-how and should be produced by those with the necessary knowledge. The specifications should provide information which controls the consistency of the process and which the operative is unlikely to know from his or her normal training or of which the operative may need to be reminded because of its complexity, e.g. instructions for internal calibrations, instructions on how to operate a special machine, instructions on how to process the receipt of cash or invoices, packaging instructions to ensure safe delivery. A review procedure is essential to ensure that modifications and improvements are considered and authorized correctly.

Implementing a quality system can lead to cleaner stores and tidier workplaces that are more pleasant to work in and therefore more productive. It also leads to more effective communication across the company, which could lead to more successful working relationships.

3.6.5 In-house quality procedures

3.6.5.1 General

A summary of a typical set of procedures which meets the overall requirements of the business, as well as those of BS EN ISO 9001:1994 is given below. This is intended for the purpose of illustration, but the majority of these sample procedures will probably apply to all organizations.

Advice on the format and content of each of the following can be found in greater detail in BS EN ISO 9000-2:1997 and in later sections of this publication. The methods described therein can be selected and combined to produce a quality handbook for your own organization.

3.6.5.2 Documentation

This would detail the actions to be taken to ensure that the documentation in the form of a quality manual, the associated procedures, customers' specifications and other relevant standards are kept up to date. It would cover the control of all specifications (procedures, process specifications and drawings) including distribution, change control and withdrawal of obsolete and superseded documents. Documentation may be electronic media as well as printed.

3.6.5.3 Enquiries and quotations

This would ensure that a proper record of quotations made to customers is kept for use in handling both written and telephone enquiries. A record of any costing exercise would also be kept, together with all correspondence, specifications etc., at least until the quotation is accepted or rejected.

3.6.5.4 Customer order, entry and control

This would list the action to be taken on receipt of the customer's order through to completion of the order. It would specify that checks are carried out and state who is responsible for each action or check.

The aim would be to ensure that the customer's order is complete and correct, and then to enter it correctly into the work system. It would also ensure that amendments to the order are dealt with correctly and that when the order is completed, customer quality record files are raised and all associated documents

3.6.5.5 Customer specifications, entry and control

This would amplify the customer order procedure with respect to control of customer's instructions including any new or updated specifications subsequently received. In the latter case, the procedure would ensure that the superseded documents are withdrawn before issue of the new. It would also ensure that on completion of the order, the drawings are put in the customer quality record files or returned to the customer if so requested.

3.6.5.6 Customer-supplied materials and tooling

This would ensure that customer-supplied materials and tooling are included in the quality system and are clearly identified and kept segregated at all times.

3.6.5.7 Quality plans

This would ensure that the correct level of quality assurance would be applied to each customer order through the appropriate quality plan. For example, plans may be categorized into groups to make the procedure more economical. The following are given as possible examples.

Quality plan 0, to cover the case where the raw material is not in the quality system.

Quality plan 1, normal commercial, to involve all the procedures except those for material traceability and the provision of a certificate of conformity, which are covered by quality plan 2.

Quality plan 3, to cover the situation where a customer wishes to verify that a purchased product conforms to specified requirements.

Quality plan 4, applies when a customer requires an individual quality plan for his contract.

See BS ISO 10005:1995 *Quality management — Guidelines for quality plans*.

3.6.5.8 Traceability

This would cover the extra requirements when traceability of the purchased material or service is involved, including the need for work instructions, purchasing, marking and records.

3.6.5.9 Calibration of measuring and test equipment

This would lay down the actions and controls required to maintain, within prescribed limits, the accuracy and condition of all measuring and test equipment used during provision of the service or product, including equipment privately owned by an operator when used in the business.

3.6.5.10 Design policy and control

This would ensure that new products are developed to meet customer requirements, and that their performance figures and tests are obtained and recorded. It would also ensure that any regulatory and safety requirements are met.

3.6.5.11 Purchasing including vendor assessment

This would ensure that purchased materials, items and services meet the required quality levels and satisfy contract requirements. It would require that purchase orders specify what is required including the appropriate level of inspection at receipt. Finally, it would include the selection, approval and monitoring of suppliers and subcontractors through vendor assessment.

3.6.5.12 Goods receipt control

This would detail the methods and responsibilities for receiving goods including customer-supplied materials and tooling, to ensure that, as far as possible, unsatisfactory goods are identified early.

This would cover acceptance and rejection procedures including identification, labelling and location.

3.6.5.13 Stock control, storage and handling

This would detail the methods for stock control, storing and handling material and parts, to ensure the necessary identification, preservation and segregation of material and the provision of handling methods to prevent misuse, damage or deterioration. It may also cover the disposal and recording of surpluses on completion of service.

3.6.5.14 Manufacture, inspection and test

This would cover the use of jigs and fixtures, for example, and the methods of inspection which are required to ensure that the products or services are in accordance with the customer's requirements and are to the required quality. It would also cover identification, inspection status and segregation together with procedures for acceptance or rejection.

3.6.5.15 Non-conforming items and corrective actions

The aim would be to ensure that non-conforming items cannot inadvertently be retained, without further action in the system, when they should have been scrapped or remedial action taken. It would detail the methods for determining what remedial action should be taken including, where appropriate, obtaining the approval of the customer, as design authority, for the proposed action.

It could also cover continuing analysis of concessions granted, material scrapped, reworked, modified or otherwise repaired, to determine the causes and to decide on the corrective action.

3.6.5.16 Handling, storage, packaging, preservation and delivery

The objective here would be to ensure that, as far as possible, the product or service as received by the customer is to the level of quality to which it was designed, i.e. that it is in no way damaged and has not deteriorated during delivery.

3.6.5.17 *Quality records*

This procedure would state how long quality records should be kept and the method of disposal. For example:

- customer orders and drawings;
- associated purchase orders and traceability records;
- enquiry/estimate forms, works orders, route cards, certificate of conformity, defect report plus records of corrective and preventive action, delivery sheets, customer complaints;
- training records, lists of suppliers, list of forms.

Three years is typical for many records but some, such as drawings, training records and document control records, are referred to continually and should be retained permanently. Others such as a list of approved suppliers and stock requisitions may be of lesser duration depending on whether product liability applies.

3.6.5.18 *Quality audit and system review*

This would detail the audit and review procedures for checking the company's quality system over a specific period depending on the situation. It would also cover the procedures to be followed to correct the quality system if defects or shortcomings are discovered.

3.6.5.19 *Training*

This would cover the actions necessary to ensure that the training needs of personnel are catered for, planned and recorded.

3.6.5.20 *Assistance to customer representatives*

This would cover the provision of assistance to the customer's representative to evaluate the adequacy of the organization's quality system.

It would indicate that prior notice is required of any visit and that any information obtained or made available is to be treated as confidential.

3.6.5.21 *Servicing*

This would cover the actions necessary for the performing, verifying and reporting that servicing after delivery meets specified requirements.

3.6.5.22 *Statistical techniques*

This would detail the methods for implementing the application of statistical techniques and verifying process capability and product characteristics. see BS 5703 *Guide to data analysis and quality control using cusum techniques* which is published in several parts, BS 6000:1996 *Guide for the selection of an acceptance sampling system, scheme or plan for inspection of discrete items in lots* and BS 6001 *Sampling procedures for inspection by attributes*.

3.7 *Quality management in business*

3.7.1 *In-house standards*

Quality management has become significant in the business world. This has led to a greater concern with standards because of the influence they exert on the specification and control of quality. In particular, quality managers employ those standards which define quality systems such as in the BS EN ISO 9000 series but the adoption of standardization throughout the business is a prerequisite to successful implementation. Many medium and small companies previously feeling exempt from standardization now have the justification to involve themselves directly. Although it is only in the larger companies, and certainly not in all of them, that a standards specialist may be employed, a quality manager should assume responsibility for raising the standards in any organization with ambitions to sell a successful service or product, particularly if the organization also wishes to become recognized as a market leader.

The basis for quality assurance is the control achieved by the cooperation of all concerned in designing or providing the product or service. Any integrated documentation and specification system should be designed to avoid ambiguity and duplication, and define the standards established and expected. This should cover particularly the specification of raw materials and other bought-in services, parts, control of processes, packaging and proper use of sampling schemes in place of 100 % inspection.

National and international activity in the fields of quality assurance, certification and dependability is so extensive that an organization's policies should be checked regularly in relation to these activities and it should have a systematic procedure for advising the appropriate departments or managers. An eye should also be kept on changing legislation.

Although quality audit specifications can be issued in a separate series, other quality requirements such as process specifications and change control are inescapably part of the process function and should be included therein. The quality manual should therefore be designed and compiled so that it can be maintained as an integral part of the normal specification system and relate as closely as possible with BS EN ISO 9000.

3.7.2 *Registration*

As well as the demands on a business for quality assessment, legislation covering health and safety and product liability imposes a requirement on employers to be diligent in the protection of the workforce as well as the customer or consumer. Neither BS EN ISO 9000 nor the majority of quality system documentation is necessarily product related but in-house and national quality standards can be used both to ensure that safe practices are maintained and to demonstrate the fact in the event of claims being made.

Some of the largest organizations in this country are not the primary manufacturers or service providers but are users of plant and equipment and related spares and consumables provided by others. The Post Office, the Ministry of Defence, the public utilities, and many organizations in the chemical and petrochemical, coal and steel industries have very large capital investment in engineering goods but they do not themselves market engineering products/services except, in some cases, through relatively small subsidiary companies or divisions.

It has been common practice for such organizations to produce their own standards, thus imposing a wide variety of extra requirements on their subcontractors or suppliers, particularly if they supply to several of these bodies. Thankfully present trends have seen the rationalization of many of these systems by concentrating on and contributing to the production of national standards. BS EN ISO 9000 and related schemes are an example of the success of this policy to the benefit of the customer and the supplier. The UK has the greatest number of companies registered to BS EN ISO 9000. At the end of 1996 the official number of registrations worldwide was 127 000, compared with 45 000 in January 1994.

Adoption of BS EN ISO 9000 systems yields many benefits to recoup the effort involved. For example, as well as advantages such as reduced wastage and reworking, it provides assurance to reinforce the quality image of an organization to its customers. Also there is the clear signal it gives its employees of its commitment to quality. Surveys have shown that though most companies are persuaded to go for registration for external reasons, the benefits are mostly internal.

Organizations in more than 90 countries have established quality management systems based on the ISO 9000 family of international standards. UK enterprises have invested in independent verification by “registration” or “certification” bodies. In order for organizations to obtain the maximum value from their investment, they want a single certificate to be recognized and accepted anywhere in the world. ISO and IEC have responded to this need by supporting Quality Systems Assessment Recognition (QSAR) in the foundation of a voluntary system, though accreditation body support for it has been very limited.

3.7.3 Software: TickIT

Almost every business depends on the correct manipulation of information by computer systems. Software is the key to the successful operation of these systems — poor quality software can severely affect efficiency and competitiveness.

To meet customers’ quality expectations, software suppliers, including in-house developers, need to define and implement a quality system which covers all the essential business processes in the product life cycle. TickIT guides the developer to achieve this objective within the framework of ISO 9001. TickIT is about improving the quality of software and its application.

TickIT objectives

An important purpose of TickIT, which is supported by the UK and Swedish software industries, has been to stimulate software system developers to think about what quality really is in the context of software development and how it may be achieved.

Although certification of compliance to ISO 9001 or ISO 9002 is mandatory for suppliers in certain market areas, it should be a by-product of this more fundamental aim, otherwise much effort will be wasted.

With regard to certification itself, the objectives are to:

- a) improve market confidence in third party quality system certification through accredited certification bodies for the software sector;
- b) improve professional practice amongst quality system auditors in the software sector;
- c) publish authoritative guidance material (the TickIT Guide) for all stakeholders.

TickIT procedures

TickIT procedures relate directly to the requirements set out in ISO 9001:1994 and ISO 9002:1994, and are based on the additional guidance contained in:

ISO 9000-3 *Guidelines for the application of ISO 9001 to the development, supply and maintenance of software*

ISO/IEC 12207 *Information technology — Software life-cycle processes*

TS 1:1998 *Issue 4.0 of the TickIT Guide*.

Certification practice

Certification is conducted by third party certification bodies. The certification bodies use technically qualified TickIT auditors who have been specially trained and subjected to rigorous professional vetting. This process is administered by the International Register of Certificated Auditors (IRCA) with the support of the British Computer Society.

To assure market confidence in the certification process, the certification bodies offering TickIT services are accredited as being fully competent to manage and conduct software sector audits, currently by either the United Kingdom Accreditation Service (UKAS) or the Swedish Board for Accreditation and Conformity Assessment (SWEDAC). Procedures exist to enable other accreditation agencies to join the scheme.

A successful audit by a TickIT-accredited certification body results in the award of a certificate of compliance with ISO 9000, endorsed with a TickIT logo.

Thus, TickIT gives software developers an accredited quality system certification scheme that meets the special needs of the industry, enjoys the confidence of professional staff and commands respect from purchasers and suppliers.

When is TickIT relevant?

TickIT applies to all types of information systems supply which involve software development processes. Typical systems suppliers include system houses, software houses and in-house developers. TickIT disciplines are also relevant to the development of embedded software. A full definition of the Scope of TickIT is included in the *TickIT Guide*; it may also be obtained by contacting the DISC TickIT Office, 389 Chiswick High Road, London W4 4AL.

Is TickIT a recognized mark?

In the UK, TickIT is recognized by all Government departments and major purchasers and it is compatible with European requirements for accredited quality system certification.

World-wide, some 1 500 TickIT certificates have now been issued. Currently, 50 % of all new certificates are being granted to organizations outside the United Kingdom.

Management and maintenance

TickIT is managed and maintained by DISC, the department within BSI Standards with responsibility for all aspects of standardization in information systems and communications.

DISC has set up the TickIT Industry Committee (BRD/3) to oversee and make policy decisions. Committee members from the UK and Sweden represent the interests of IT systems purchasers, suppliers, the certification industry and professional institutions; collectively they possess a wealth of experience of the software industry and of quality systems certification.

The TickIT message

By implementing a quality system and gaining certification, an organization is demonstrating management's commitment to quality and is sending a clear signal to users and competitors that the delivery of quality is a principal management objective. The TickIT logo indicates that the certificated organization is involved in software development and that TickIT guidance and certification procedures have been followed.

For more information and to purchase TickIT guidance material, contact the DISC TickIT Office at 389 Chiswick High Road, London W4 4AL, Tel: +44(0)181 996 7427, Fax: +44(0)181 996 7429, e-mail: tickit@bsi.org.uk

3.7.4 Component/material quality

By the regular use of preferred components and materials, the task of compiling a history of quality and dependability information is made easier. Inspection methods can then be adjusted accordingly for supplier quality control and routine sampling.

However, when non-preferred or unproven sources or materials are used, the risk of poor quality is increased and no history for assessment of reliability exists. Before there are any additions to a standard range, evaluation testing should therefore be carried out.

3.7.5 Management commitment

Commitment has to be made in terms of time to understand and resolve the political problems which inevitably surface. Time pressure may be particularly acute on project managers and leaders and the most difficult problems to solve are those that involve other sections; however these interface difficulties need to be tackled. The most difficult and expensive part of a quality management system initiative is changing the way people work. Practical and tightly focused training is a key component of success.

Work pressure frequently makes it difficult to find the time to read, understand and implement new standards. They should therefore be short, instructive and written in plain English. The minimum requirement should be documented with guidelines to show how they should be implemented. Form-based solutions may be an acceptable alternative to customized systems.

3.7.6 Quality systems and the small firm

ISO has published a handbook *ISO 9000 for small businesses — what to do. Advice from ISO/TC 176* which gives guidance to small businesses on putting ISO 9000 quality systems in place. It explains how quality systems standards apply to the small business sector, before giving guidance on the three quality assurance models ISO 9001, ISO 9002 and ISO 9003. The actual text of each requirement is included, followed by clear explanations and examples of what is wanted. The handbook takes the perspective that a small business is not a matter of the number of employees, but rather a philosophy of the way the business is run, and tailors its advice accordingly.

Section 4. Managing standards in business

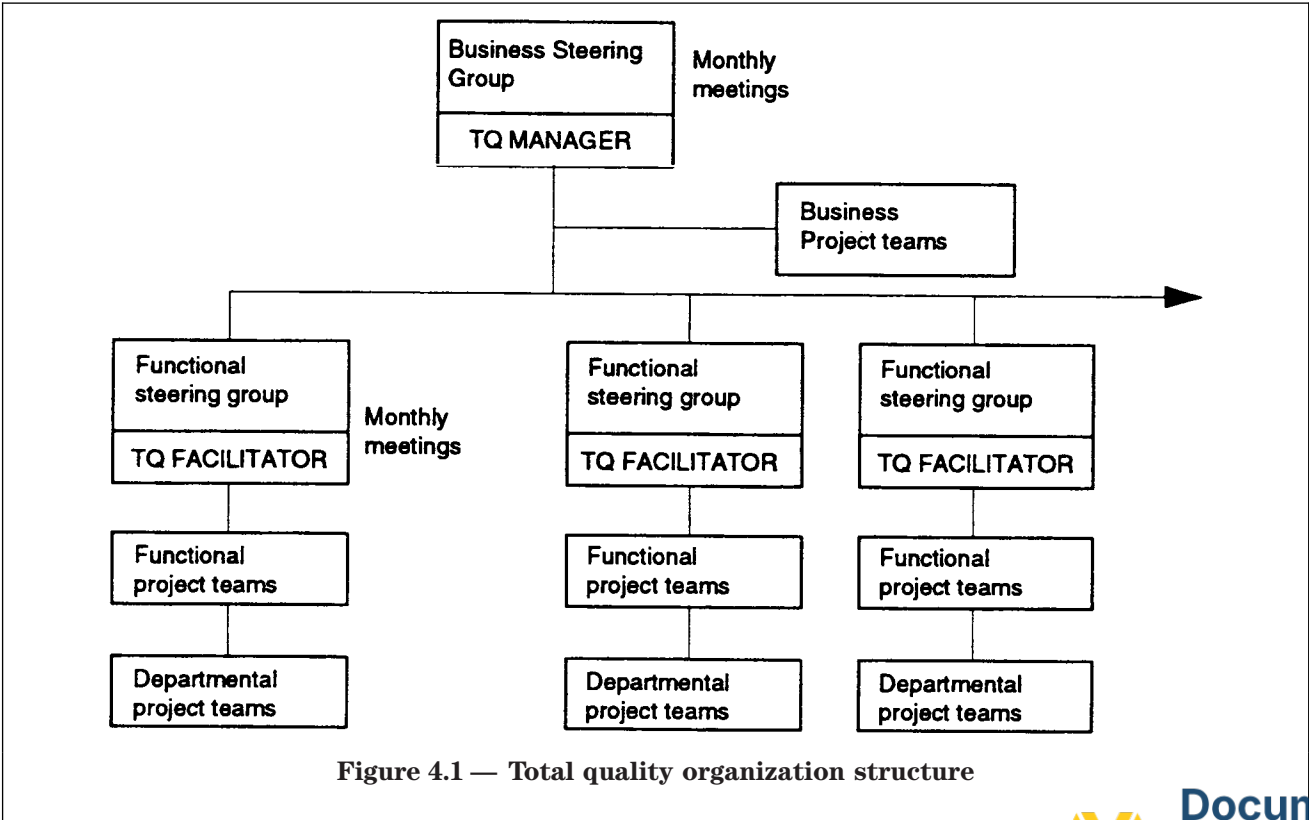
4.1 Total quality management

4.1.1 Introduction

Total quality management (TQM) is being employed by businesses seeking to extend the awareness and involvement of the workforce in quality improvement; it embraces some aspects of both quality control and standardization in its techniques and implementation. The term “TQM” describes a management philosophy to improve the quality of an organization to satisfy customers agreed requirements first time and every time at the lowest possible cost. It also recognizes that health and safety and environmental considerations are dependent on these quality objectives. The technique should empower all employees from the top to bottom of the organization to achieve continuous improvement by training and communication. It needs to be led by the directors indicating their support and authorizing the operations. TQM is not a part-time function any more than the pursuit of quality. It requires dedicated organization and motivation if it is to gain sufficient momentum to have a lasting effect.

4.1.2 Teams

The principle is to set up teams of identifiably linked business groups within the organization. This should start with a business group overseeing several functional steering groups which themselves set up working groups to pursue problems which have been identified by themselves. The working groups should include employees from the sections identified as having problems. The business steering group consists of board members. The functional steering groups are headed by a member of the board with his departmental heads. A member of staff should be chosen as a “facilitator” to liaise between the steering group and the working teams. The facilitator will work on a day to day basis arranging training, and advising on both the organization of meetings and reporting to the steering group. The functional steering groups will approve TQM projects and appoint team leaders. The team leaders nominate the team which should not comprise more than six members. In this way all aspects of the business are covered and all employees encouraged to participate. The structure is shown in Figure 4.1.



4.1.3 Projects

Projects are best identified by suggestions from the workforce, endorsing from the outset the principle of involvement. The projects should address problems which can be measured and considerable care is required to determine a suitable measurement method. Acceptance of a project is on the basis that it is capable of being solved by the team over a definable period. Practically this should be no more than six to twelve months from identification of the problem to presenting a solution. All team members are expected to fit TQM work into their normal working day. No special concessions are made other than permitting absence from the normal work place for team meetings. Within a working department the savings should cover the expenses. The teams are allowed limited working expenses.

They are expected to:

- a) identify the problem;
- b) propose a solution;
- c) make recommendations for implementing the solution giving all costs and proposed savings.

The functional steering groups ensure that these stages are well defined and progress is maintained using appropriate techniques.

4.1.4 Training

TQM techniques involve extensive training: it is one of the principal benefits that one can progressively retrain the workforce. Training starts with an introduction by the TQM manager to the board of directors, "selling" the principles of TQM to them. Senior managers should then be involved as they will have to support and sell the ideas on. The selling aspects should progress as far as middle management before any implementation. The next stage of training needs to be introduced to develop the necessary skills and techniques, first to the functional steering groups and then to the team leaders. The training at this level will include topics such as holding effective meetings and using statistical techniques. No one is allowed to participate within a working group until this basic training has been undertaken.

4.1.5 Conclusions

Topics should not be confined to those directly involving the final product or service of the business. It is of prime importance to eventually have each employee considering himself as providing a service for a "customer" even if that customer is another employee in the firm. The meaning of the term "customer satisfaction" should be taken in its broadest sense. Projects therefore will be diverse and cover subjects such as the efficiency of the works canteen or explaining the piecework system as well as technical problems such as delays in the design process or customers' complaints and customer service.

BS 7850 *Total quality management* may be referred to for further guidance and is published in two parts: *Part 1: Guide to management principles* and *Part 2: Guidelines for quality improvement*.

BS 7850-1:1992 gives guidance to management on ways to make the organization structure, management system and quality system more effective in meeting objectives by improving and harmonizing the skills of the workforce. The guide emphasizes the need for measurement of performance and analysis to confirm that planning for problem solving has led to improvement. BS 7850-2:1994 is identical with ISO 9004-4 *Quality management and quality system elements — Part 4: Guidelines for quality improvement*. More detail is included on the fundamental concepts and the statistical techniques which may be adopted. Implementation of the recommendations should be organized within the normal management organization to avoid introducing another level of management. There is a danger of solutions being temporary unless the normal management structure is reverted to at the implementation stage. Failure to use this route may introduce undesirable friction at middle management level.

4.2 Scope for standardization in business

4.2.1 Purpose

The international and national standardization organizations such as ISO, IEC and BSI may be regarded as business intelligence units. They provide a facility for keeping in contact with technical developments at home and abroad and incorporate an early warning system on new legislation as it affects employees and business. Awareness of the state of the art and the effect of legislation in a particular area of operations can to some extent be maintained by referring to standards. International bodies such as ISO and national organizations such as BSI in the UK share responsibility with others for identifying the needs of the public, ensuring that users have a chance to comment and facilitating a consensus. Participation of manufacturers or users is usually via a trade association or professional body.

In business, standardization should be used as part of the management system to establish and maintain corporate identity; the techniques are invaluable as a training aid, and do not need to be inhibiting to design or service. Standards are the medium for removing much of the mystique of jargon from specialized services, industry, finance or education. The evidence of good standardization is plain to see in the consistency and interchangeability of many commodities in daily use such as electrical goods, photographic equipment and videos. In the high street, successful chainstores are appreciated for their standardized presentation providing a consistently high

grade image and similar standards of service regardless of geographic location. As well as internal rationalization and quality management the purpose of a standardization policy in business is to take maximum advantage of information already published as internal, national or international specifications and adopt the proven mechanism of document control in an integrated quality, health and safety and environmental management system.

The scope for standardization both at business and national level is wide, covering the specification of management policies, responsibilities, services, and procedures for design; purchasing, stores; processes, quality control; employees' and customers' health and safety; control of hazardous substances; environmental management; or the use of foreign and international standards. As part of the closed loop (see Figure 4.2), involvement with national and international standardization is a means to exert influence or be influenced. The scope extends to all operational areas of a business. DISC, the department of BSI which deals with IT standards, has published DISC PD 0011, which gives a very clear exposition of the importance of standards to business.

The consequent improvement in quality is likely to bear fruit when every person in an organization has the awareness and initiative to apply standards effectively in his or her own sphere of operations, with

professional assistance if necessary to identify existing national standards and coordinate formal documentation applying the principles described herein. Such consideration needs to be built in to business training programmes. Naturally a complex business will require expansive and detailed documentation to cater for the greater communication problems but a small firm will be satisfied with simple expressions of responsibilities and uncomplicated process specifications.

Success is measured against objectives which are set purposefully for the specific business or the individual and are maximized if objectives are set at a corporate level.

4.2.2 Participation

The methodology described here has been compiled from industrial experience gained by use of such systems and standards in many industries over several decades. However as BS EN ISO 9000 is applicable to services and construction and engineering industries, both large and small; the contents have been reviewed with their needs also in mind. Direct participation in international standardization is not essential for the small firm where resources may be restricted but the benefit of belonging to a suitable trade association should be noted if a contribution needs to be made.

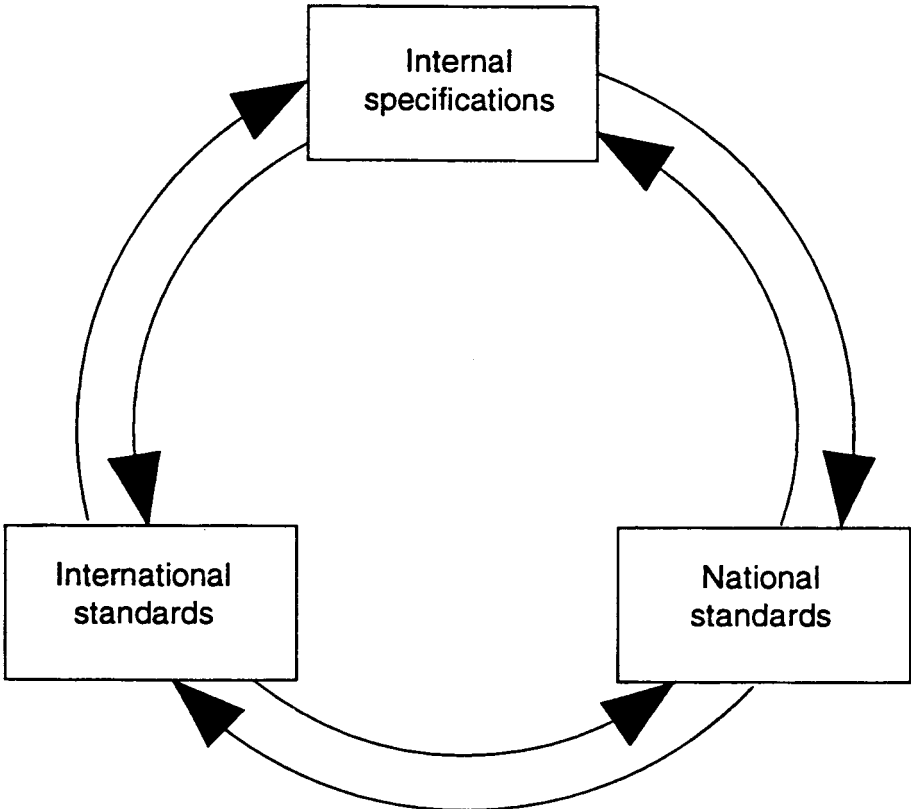


Figure 4.2 — The closed loop

Standards created within business are usually concerned with the implementation of national and international standards, control of documentation and the “nuts and bolts”, such as the specification of bought-in components and material. Extension to the development of product or service performance standards has to be the concern of the designers or administrators. Two levels of standardization are visible within a business. The first level is a vertical system, concerned with the product or service provided and its certification, and entails participation in the international and national standards-making functions, starting with membership of an appropriate trade association. A manufacturer of threaded fasteners for instance would have a direct interest in standards for screw threads. This ensures that the product maintains a proper position in the market and guards against unwittingly falling foul of changes in legislation, both domestic and international. This level usually demands the resources of the executive or research and development team and because of its importance to the business requires and justifies a significant investment in attending committee meetings, which may be geographically anywhere in the country for national meetings or practically anywhere in the world for international committees.

The second level concerns the internal organization and the interest of the business as a user of products and comprises both “horizontal” and “vertical” systems. It may involve internally specifying the horizontal management systems, and vertically specifying the procedures used, the raw materials and the items that make up the product or service by reference to standards. From this point of view it is not practical for an organization to attend every national committee or even a majority of those affecting the components and materials that it uses. These aspects are therefore attended to by consumer groups or a more general surveillance locally on a regular basis, monitoring the development and implementation of the relevant standards and communicating these data appropriately within the organization. It may involve anything from component specification changes notified by suppliers to improvements in the international standard for the quality management system. The second level also needs to control the introduction and use of hazardous materials.

Failure on either of these levels of standardization may result in the demise of a product because it no longer satisfies the market, or manufacturing methods prone to variation and swings in product reliability and quality or even undefendable health and safety law suits.

Consistency of test methods is critical to evaluation or comparative quality checks. As well as establishing safety margins, methods of test provide a basis of acceptance for the interchangeability and satisfactory performance of goods. Lack of standardization in this area will inhibit attempts to quantify and rationalize

performance. Automatic testing is an essential feature of modern manufacture so has to be considered as part of the design specification. Rationalization of such matters as the position and size of electrical test points will aid efficient use of the equipment. Nationally and internationally accepted standards can be used both within and outside the business to avoid misunderstandings when comparing products or assessing outside suppliers.

Standards are not restricted to technical matters. When used for administrative procedures they improve communication, and provide permanent reference and training documents lessening the likelihood of misunderstandings and are valuable for maintaining continuity during staff absence and turnover of labour.

4.2.3 Integrated management systems

Annual general meetings are no longer confined to financial affairs and shareholders' demands. They could now be joined by environmental groups, consumer associations, banks, insurers and pension fund members demanding information and action. There are increased expectations on economics, quality, occupational health and safety, environmental and social responsibility. There are three facets of management demanding integrated systems and documentation. They are quality, environmental, and health and safety management systems (see Figure 4.3).

Standards are a core element of business management, particularly in rationalizing similar systems. The last decade has seen a growth in the recognition of quality management and the expansion of registration to ISO 9000. The next decade one can expect a similar explosion in environmental and health and safety standards with varying performance requirements but needing parallel guidance and documentation. Environmental management requires a system to be applied to areas such as energy efficiency, emission control, reduction of waste and efficient disposal at the end of a product's life. Such a system has to be capable of reacting dynamically to changing regulatory requirements and business needs and to advances in environmental science. There is a new impetus for management of environmental standards as a result of BS EN ISO 14001 with scope for the application of sound management principles to public and industrial sectors. As well as protecting global resources the specification of environmental items such as lighting, signs, or design, and layout of furniture can have an improving effect on the confines of the workplace and provide more reliable instructions.