BRITISH STANDARD

BS 7373-2:2001

Product specifications —

Part 2: Guide to identifying criteria for a product specification and to declaring product conformity

ICS 03.120.20

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee MS/4, Design management systems, and its Panel MS/4/-/7, Product specifications, upon which the following bodies were represented:

Association of Innovation Management
Association of MBAs
Association of Project Managers
BEAMA Ltd.
British Standards Society
BSI Consumer Policy Committee
Chartered Society of Designers
Defence Manufacturers Association
Design Council
Department of Trade and Industry (Design Policy and Services)
Electricity Association
Federation of Small Businesses
Forum for Private Business
Institute of Quality Assurance
Institution of Civil Engineers
Institution of Engineering Designers
Institution of Electrical Engineers
Institution of Mechanical Engineers
Ministry of Defence
Royal Institute of British Architects
UMIST
University of Glasgow
University of Leeds

The committee and panel wish to acknowledge the invaluable contribution to the drafting of this standard, in terms of time and resources, of Cambridge Consultants.

This British Standard, having been prepared under the direction of the Management Systems Sector Policy and Strategy Committee, was published under the authority of the Standards Committee and comes into effect on
15 July 2001

Amendments issued since publication

Amd. No.	Date	Comments

The following BSI references relate to the work on this standard:
Committee reference MS/4/-/7
Draft for comment 00/402851 DC

ISBN 0 580 37630 3

Contents

Foreword

This British Standard has been prepared by Technical Committee MS/4 and its Panel MS/4/-/7.

BS 7373:1998, *Guide to the preparation of product specifications*, has been renumbered by amendment to become BS 7373-1:2001, *Product specifications — Part 1: Guide to preparation.*

Annex A, Annex B, Annex C, Annex D, Annex E, Annex F and Annex G are informative.

Annex F of this standard has been reproduced by kind permission of Cambridge Engineering Design Centre/Cambridge Consultants from SHEFELBINE, S., P.J. CLARKSON, and L.T.M. BLESSING. *Requirements capture for medical devices (Workbook)* (CUED/C-EDC/TR90). Cambridge: Cambridge Engineering Design Centre/Cambridge Consultants, December 1999.

Figure E.2 has been reproduced by kind permission of CSC Consulting & Systems Integration from: *The Manufacturing Industry Handbook ~ © 1996 CSC.*

This standard only provides generic guidance on the procedure for declaring product conformity. The preparation, content and ensuring that the product continues to meet the declaration is solely the responsibility of the producer/supplier.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 39 and a back cover.

The BSI copyright notice displayed in this document indicates when the document was last issued.

Introduction

This part of BS 7373 provides guidance on identifying criteria for the preparation of a product specification (alternatively known as a "product brief" in some sectors) essential when developing a new product or process. For organizations wishing to declare that their product conforms to a specification clause **10** provides guidance on declaring conformity.

While the provisions of this standard have been prepared with small- to medium-sized businesses in mind they are equally applicable to much larger organizations. This guide is aimed at those responsible for the product that the organization is planning to produce.

Guidance in this British Standard relates to new product development. For products already in production, and where a declaration of conformity is required, the guidance in clause **6**, clause **7**, clause **8**, clause **9** and clause **10** should be followed.

Many products fail to achieve their expected performance commercially and/or technically with disastrous results for the producer and dissatisfaction or worse for the customer.

Following the simple guidance in this British Standard can help manufacturers avoid problems commonly encountered such as:

— insufficient knowledge of the market/target customer;
— inadequate understanding between customer and producer;
— inadequate profit margins;
— the product being too expensive;
— failure to meet regulatory requirements;
— failure to meet performance targets;
— the time to market being too long;
— development expenditure being too high;
— insufficient in-house skills and knowledge to cover the process;
— excessive warranty, delivery or other commitments creating serious financial obligations.

The main benefit in dealing properly with these problems is a better product for which the commercial and technical risks have been assessed and eliminated or reduced to an acceptable level. The benefit to the producer can be significant both in reducing the cost of the product and/or in improving the quality, reliability and commercial viability of the product.

The purpose of this guide is to ensure attention is focused on the key areas that need to be addressed in order to assess viability and to acquire the data necessary to produce a product specification. These key areas are:

a) commercial considerations (see **4.2**);
b) product performance (see **4.3**); and
c) regulatory requirements (see **4.4**).

Each of these areas is introduced in clause **4**. Further information about the process of gathering information is contained in clause **5**, drawing up and reviewing specifications in clause **6** and clause **7**, verifying and validating the product in clause **8** and clause **9**, and declaring conformity in clause **10**.

Informative Annex A, Annex B, Annex C, Annex D, Annex E, Annex F and Annex G provide material to support the preparation of specifications.

1 Scope

This British Standard gives guidance on identifying the criteria necessary for producing a product specification. It also includes guidance on declaring the conformity of the product.

NOTE 1 This British Standard considers common themes applicable to many products, which when examined by those responsible for development, help them to focus on the important criteria for individual products.

NOTE 2 The context in which product information is gathered and ultimately transcribed into one or more specifications is explained in Annex A. The nature of the resulting specification(s) will vary widely depending upon the complexity and scope of the final product.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of this British Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. For undated references, the latest edition of the publication referred to applies.

BS 6001-0, *Sampling procedures for inspection by attributes — Part 0: Introduction to the BS 6001 attribute sampling system (ISO 2859-0:1995).*

BS EN ISO 9001:2000, *Quality management systems — Requirements.*

BS EN 45014:1998, *General criteria for supplier's declaration of conformity.*

3 Terms and definitions

For the purposes of this standard the following terms and definitions apply.

3.1
criterion

decisive factor, measure or standard by which something can be judged or decided

NOTE This is usually expressed in terms of a parameter with limits, or a "yes" or "no".

3.2
design review

documented, comprehensive and systematic examination of a design to evaluate its capacity to fulfil the requirements for quality and fitness for purpose, identify problems, if any, and propose the development of solutions

3.3
performance specification

document that specifies the totality of needs expressed by features, characteristics, process conditions, boundaries and exclusions defining the performance of a product or process, including quality requirements

3.4
product specification

documentation that details for production, end-use and other purposes the item concerned

3.5
test specification

documentation that describes in detail the methods of conducting tests including if necessary the criteria for assessing the results

NOTE A test specification may contain clauses for conformity and reliability assessment.

[BS 7000-10:1995]

3.6
requirement

need or expectation that is stated, generally implied or obligatory

NOTE 1 "Generally implied" means that it is custom or common practice for the organization, its customers and other interested parties, that the need or expectation under consideration is implied.

NOTE 2 A qualifier can be used to denote a specific type of requirement, e.g. product requirement, quality management requirement, customer requirement.

NOTE 3 A specified requirement is one which is stated, for example, in a document.

NOTE 4 Requirements can be generated by different interested parties.

[BS EN ISO 9000:2000]

3.7
verification

confirmation through the provision of objective evidence that specified requirements have been fulfilled

NOTE 1 The term "verified" is used to designate the corresponding status.

NOTE 2 Confirmation can comprise activities such as:

a) performing alternative calculations;

b) comparing a new design specification with a similar proven design specification;

c) undertaking tests and demonstrations; and

d) reviewing documents prior to issue.

[BS EN ISO 9000:2000]

3.8
validation

confirmation through the provision of objective evidence that the requirements for a specific or intended use of application have been fulfilled

NOTE 1 The term "validated" is used to designate the corresponding status.

NOTE 2 The use conditions for validation can be real or simulated.

[BS EN ISO 9000:2000]

4 Rationale for preparing a specification

4.1 Overview

It is easy to become obsessed with an innovative idea, or a new technology, without looking dispassionately at its overall viability or other justification to pursue it. By gathering sufficient information to understand the potential product its viability can be properly assessed. Gathering this information in a disciplined way facilitates decision making, and also exposes conflicts or trade-offs, allowing them to be resolved at an early stage and so avoiding problems later.

This clause looks at the three main areas that need to be understood when making decisions about the development of a new product. These areas are:

a) commercial considerations;

b) attributes of product performance necessary to satisfy the customer; and

c) regulatory requirements.

Only when all the requirements for a new product have been understood is it possible to ensure that the product is safe or to review or test it adequately. Thus the development of a specification is the precursor to assuring safety, quality and reliability. Background on the product development process is given in Annex B.

4.2 Commercial considerations

An overview of the commercial issues, skills and knowledge necessary in bringing the product to the market should be established. The potential size of the market and share of that market which is being targeted should be determined. The latter can be vital in determining the viability of the product. The financial implications to the company, particularly in terms of budgetary provision for the development programme and working capital, should also be considered.

The way in which the product reaches the customer (e.g. direct selling, agents, distributors, retailers) should be understood as should the promotional effort that will be necessary. This promotional effort should be understood both in terms of developing links with those selling the product and in terms of developing links with those producing the product advertising and literature. For indirect sales selling to agents may demand as much effort as selling to the final customer. Whichever route to market is chosen the financial cost of sales and marketing should be known. This will almost certainly be a significant contributor to the overall selling price.

By examining these and related commercial issues, the key parameters that make the product a success become apparent. This information should be recorded to ensure that the required facts are available. Recording this information reduces the likelihood of misunderstandings and increases the chances of the right design decisions being made.

In the case of one-off or special purpose equipment, where the justification or demand would appear to be self-evident, it is still important to consider the commercial issues.

4.3 Product performance

All the pertinent information on the features of the product's performance that make the new product attractive and enable the performance targets to be met should be gathered. Performance is used here in its broadest sense to incorporate the function, quality, reliability and durability of the product so that the end-user is satisfied at an acceptable price.

Recording this information for use in the specification document keeps the minds of the designers focused, helping them to reach appropriate design solutions. Ultimately the specification will provide the criteria against which the product performance can be assessed. These test and acceptance criteria are generally established by putting maximum/minimum limits on each of the relevant product requirements.

4.4 Regulatory requirements

Many products are covered by statutory regulations, other countries' national standards or product standards that agents or customers will seek. It is necessary to understand exactly which regulations, EC Directives and standards are going to apply. This is particularly important during the development of the product because the way the design is executed can have a bearing on which regulations or standards are invoked or what product approvals might need to be sought. Thus the inclusion of regulatory requirements in the specification is important to the success and acceptance of the product in the market-place.

Annex C and Annex D give examples of standards that may be relevant and their relationship with legislation.

5 Identifying the criteria

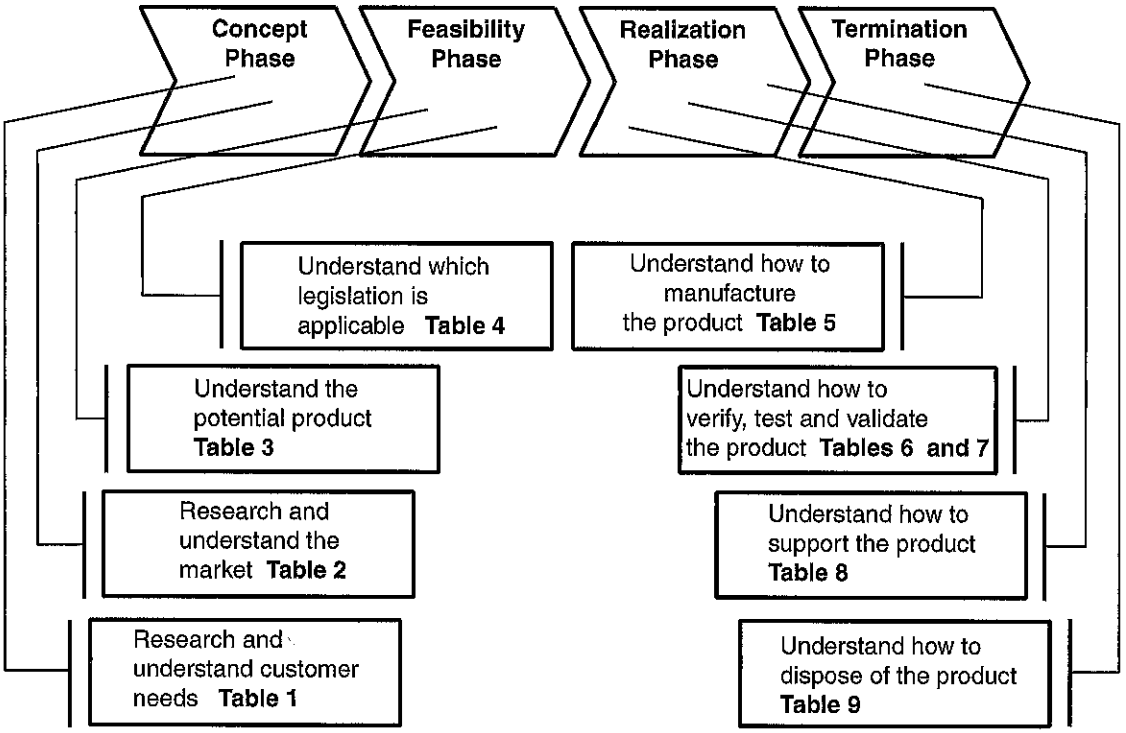
5.1 An overview of criteria to be gathered

This subclause describes the process of identifying criteria using a model and terminology consistent with BS 7000-2. Identification of the criteria is inevitably iterative as more information becomes available and decisions are made about user needs, design solutions, the detail of the design and how the product is to be manufactured. The most cost-effective approach is to concentrate on collecting the specific information necessary for immediate decisions. Over time, all of the criteria can be acquired. Prioritizing the criteria and arriving at the correct values is an iterative process throughout the early stages of product design.

In the case of trade-offs, conflicting requirements, or where there is a need to prioritize issues, the use of quality function deployment (QFD) can be a useful tool to aid decision making (see Annex E).

It is important to consider the whole life-cycle of the product and not just to concentrate on operation by the user. This means thinking about the market, product development, production, packaging, distribution, use, training, maintenance, repair, reuse, recycling, disposal and how each of these phases might affect the design, see Figure 1.

In evaluating which criteria relate to an individual product, it is recommended not only to use the checklists given in this standard, but also to think laterally about any other issues crucial to the success of the product and the satisfaction of customers. However the information is acquired it should be recorded.



NOTE The checklists in Table 1, Table 2, Table 3, Table 4, Table 5, Table 6, Table 7, Table 8 and Table 9 show typical activities for gathering and recording information about the product. These are intended only as a guide to good practice and are not to be taken as the content of the specification(s).

Figure 1 — Steps in identifying the criteria

5.2 Researching and understanding customer needs

In the preliminary phase information about customer requirements should be acquired. The criteria that are, or need to be, established should include those that will make the product a success. These are likely to be expressed in general terms but any limits on parameters such as size, weight, noise, power, colour or appearance should be included wherever practicable. Those product characteristics that give a market advantage over the competitors should be emphasized.

The concept of universal/accessible design should be embraced, considering the widest possible range of users, including children, older and disabled people. Guidance on how to take into account these groups is available in ISO/IEC Guide 71[1)].

A key issue is to ensure that the "voice of the customer" is heard throughout the organization in particular by those contributing to the new product design.

Conducting market research helps to identify customer needs, new market niches and customer acceptability. Initiating prototype testing, user trials, focus groups and user groups, involving consumers where appropriate, assists in achieving final model acceptance.

It is important to identify the customer.

[1)] In preparation.

EXAMPLE
Who is the customer for the toiletries in hotel bathrooms? In 1986 a well-known toiletries manufacturer increased its market share in this area by 400 %. The company had believed that the hotel guest was its primary customer. But after listening to hotel managers the company realized that the hotel managers wanted the products to communicate their hotel's image. Without changing the product's content, the manufacturer redesigned the packaging, concentrating on image, and quadrupled its market share.

Table 1 gives a recommended checklist for use when establishing customer needs.

Table 1 — Checklist for use when establishing customer needs

Customer needs
❑ Go and talk to all those interested in your product (e.g. as listed in clause **7**).
❑ Identify who exactly the customer and key stakeholders are.
❑ Form a team of key stakeholders to contribute to the design and its review.
❑ Probe customer needs, wants and preferred choices.
❑ Record the anticipated "hard" requirements (objective and measurable) of the product (e.g. functional attributes, non-functional attributes and constraints).
❑ Record the anticipated "soft" characteristics of the product (e.g. look and feel, i.e. subjective guidance).
❑ Identify the main/unique selling features.
❑ Identify what will make a customer buy this product rather than that of a competitor.
❑ Define the target selling price on the basis of what the market will stand.
❑ Establish the standards or regulatory requirements that are likely to apply (are these known, understood and/or achievable?).
❑ Establish the desired lifetime of the product.
❑ List any unresolved issues and unknowns (to revisit later).
NOTE There may be cases where nothing like this product has appeared on the market before; while some of the above items may not seem appropriate, due consideration should be given to all.

5.3 Researching and understanding the market

In order to assess the commercial viability of the product the size of the market, the competition, budgetary requirements, financial resources, return on investment, the window of opportunity and time to market should be understood. This information leads to conclusions about how and where to sell the product, the time-scales required, reliability and quality. All of these conclusions are criteria to be included eventually, as applicable, in the specification.

Table 2 gives a recommended checklist for use when identifying the market, competitor information and commercial viability.

Table 2 — Checklist for use when identifying the market, competitor information and commercial viability

The market

- ❑ Establish the potential size of the market.
- ❑ Establish if the market is growing or declining.
- ❑ Define the slice of the market you are aiming for (product positioning).
- ❑ Predict the level of sales (at least the minimum necessary for viability).
- ❑ Define how the product will reach the customer (direct selling, agents, distributors, retailers).
- ❑ Understand the needs of any distribution network to be used.
- ❑ Identify what promotional effort will be needed (both in terms of developing links with those selling your product and those producing your product advertising/literature).
- ❑ Establish what you should know and do for direct selling, including the use of e-commerce (e.g. internet, email and website).
- ❑ Consider how branding might assist in selling the product.
- ❑ Determine in which countries the product will be sold (it may be necessary to make changes to the product in order to conform to local regulations).
- ❑ Address the possible consequence of making product changes for different countries (if a single solution cannot satisfy all standards and regulations).
- ❑ Understand the formalities and procedures associated with exporting.
- ❑ Understand how you intend to market and sell your product in these countries.
- ❑ Understand the likely effect of fluctuating exchange rates on the product price.
- ❑ Record any requirements for point-of-sale packaging and product presentation.

Competitor information

- ❑ Identify competitors and/or potential competitors.
- ❑ Record what you know about them and their products.
- ❑ Investigate the price of competitive products.
- ❑ Compare competitors' product performance with what you are proposing to offer. Is there likely to be a threat? Can you enhance differentiation?
- ❑ Assess what future developments there are likely to be in competitive products before the launch of your product.
- ❑ Establish if the competition is based in the UK or overseas.
- ❑ Do you have a unique selling point (USP)?

Table 2 — Checklist for use when identifying the market, competitor information and commercial viability (*continued*)

Commercial viability
❑ Establish the "window of opportunity", i.e. the timescale in which the product should be launched in order to capture the desired market share.
❑ Estimate what financial resources will be required for product development.
❑ Estimate the cost of sales and marketing (this is almost certainly a significant contributor to the overall selling price).
❑ Estimate the cost of distribution.
❑ Estimate the cost of after-sales service and training (where applicable).
❑ Try and establish what price the market will stand.
❑ Check that the selling price can realistically accommodate product development, manufacturing and sales costs and provide adequate profit margins (exporting, or using different approaches to selling, can affect sales costs significantly).
❑ Check that the product can be made or bought-in at a viable cost (adequate margin).
❑ Ensure you have adequate knowledge of trends in the market or new developments, technological or otherwise, that may affect the product.
❑ Establish if there might be any political ramifications associated with the product.
❑ Establish proposed warranty terms (period and extent) and ensure they are viable.
❑ List any unresolved risks and concerns (to revisit later).
❑ Consider the cost of not proceeding with the development, e.g. commercial damage through competitor opportunism and/or loss of potential business.
❑ Is there a real need for this product?
❑ Is it financially justifiable?
❑ Does it look possible?
❑ Can you take the market share you need?
❑ What is its growth and development potential?
❑ Decide if you should proceed with the project.

5.4 Understanding the potential product

In this phase the preferred product design begins to emerge and it becomes clear how the concept is to be implemented. Decisions are made about the final look and feel of the product and its performance. Trade-offs quite often need to be made between the customer's perceived needs (see Table 1) and what is feasible within technical, financial and time constraints. Trade-offs might also be necessary in order to reach the best overall solution. Any relaxation of requirements should be checked for impact on the commercial or technical viability of the product.

Table 3 gives a recommended checklist for use when characterizing the potential product.

Table 3 — Checklist for use when characterizing the potential product

Product characteristics

- ❑ Where the product is dependent on scientific, technological, or engineering principles and know-how, ensure that they are understood and properly applied.
- ❑ Document an overview of the product including (as required):
  - ❑ key functions;
  - ❑ the architecture (the configuration and partitioning of the design);
  - ❑ a description and block diagram;
  - ❑ statements (to match the recommendations in Table 2) that describe in detail what the product has to achieve.
- ❑ Establish requirements for any embedded software, and document the architecture.
- ❑ List the ergonomic and aesthetic/graphic considerations.
- ❑ Establish if there are any relevant patents that might constrain the product.
- ❑ Consider patenting the idea yourself.
- ❑ Consider licensing.
- ❑ Describe user interface considerations, including design of labelling (size of font, permanence etc.).
- ❑ Record what environmental issues should be considered throughout the product lifecycle:
  - ❑ resources used;
  - ❑ energy consumption;
  - ❑ emissions to air;
  - ❑ emissions to water;
  - ❑ waste;
  - ❑ migration of hazardous substances;
  - ❑ impact on soil;
  - ❑ risk to the environment from accidents or misuse.
- ❑ Record the product's required life span in overall terms.
- ❑ Record what level of reliability is required.
- ❑ Record any special requirements for robustness, waterproofness, shock, vibration, acceleration, temperature (both operational and ambient), chemicals, etc.
- ❑ Establish that the product shelf-life allows adequate time for storage, distribution, retail display and use by the customer.
- ❑ Record any special requirements for materials (e.g. particular grades, recyclable materials).
- ❑ Establish if the product needs to be compatible with other products or systems either in its use, function or appearance.
- ❑ Undertake technical analysis of competitors' products where warranted.
- ❑ Consider "reverse engineering" competitor products to establish values for technical criteria.
- ❑ Establish a manufacturing strategy.
- ❑ Establish a testing strategy, to determine how testing will be performed to prove conformity to the specification, including for software.
- ❑ Confirm the technical feasibility.
- ❑ Define the customer acceptance criteria that should be met.
- ❑ Establish a strategy for product disposal (consider degradability/recycling).
- ❑ Consider methods of increasing life-span and designing and supplying easily replaceable parts.
- ❑ Consider the environmental impact of the product.

Table 3 — Checklist for use when characterizing the potential product (*continued*)

Product definition
❑ Record any technical limitations.
❑ Record any possible trade-offs (what priority the various requirements have).
❑ Establish the favoured technical solution and its feasibility.
❑ Analyse requirements for any embedded software and prepare system/module specifications as appropriate.
❑ Undertake the outline design.
❑ Consider manufacturability, serviceability, reliability and testability.
❑ Undertake analysis and/or modelling (as appropriate).
❑ Build prototypes and prove the viability of the design (as appropriate).
❑ Document the detailed design and ensure the level matches the needs of the customer.
❑ Consider how the design will be verified (see Table 6).
Skills and knowledge
❑ Assess the skills and expertise required to create and market the product.
❑ Establish if the organization has these skills and expertise in-house.
❑ If not establish how to buy-in or sub-contract and establish the associated costs.

5.5 Understanding which legislation and standards are applicable

For many products EC Directives or other national legislation are applicable and it is necessary to establish which Directives and thus which regulations and standards may have an impact on the design. In some cases the design approach may dictate whether particular Directives or standards are relevant.

EXAMPLE
A mains electricity powered product will usually be subject to the Low Voltage (L.V.) Directive (requiring a technical file, and CE marking) whereas the same product running from a mains adaptor will not be subject to the L.V. Directive (although the adaptor itself will be). Thus taking the latter approach might considerably loosen constraints on the design and manufacture of the product.

The specification should include reference to any standards it has been decided the design shall meet (e.g. ISO, EN, BS). If these standards in turn impose particular requirements that are not already implicit in the design then these requirements should be listed in the specification (e.g. a requirement for limited flammability printed circuit board material, UL 94v0, in an electronics product). If the standards impose requirements that will be met by default then these requirements should also be listed in the specification.

Table 4 gives a recommended checklist for identifying applicable legislation and standards.

Table 4 — Checklist for identifying applicable legislation and standards

Legislation

- ❑ Clarify the category of the product (e.g. IT equipment, machinery, toy, pressurized system, electrical).
- ❑ Identify and list the major hazards associated with the product (e.g. electrical, mechanical, chemical).
- ❑ Define the end-user market in terms of standards regimes (e.g. Europe, US, Canada, Japan, rest of world).
- ❑ Identify the applicable legislation (e.g. EC Directives, national regulations) (refer to Annex C and Annex D).
- ❑ Identify the relevant regulatory bodies.
- ❑ Identify the relevant safety standards or codes of practice for each market region using the appropriate standards body catalogue and by consulting expert bodies (refer to Annex G).
- ❑ Record the applicable standards in the specification.
- ❑ Obtain each standard identified and understand the implications of each.
- ❑ Make the contents of the standards available to the designer(s).
- ❑ Set out the requirements in the specification.
- ❑ Ensure that the product conforms to relevant standards and ensure the requirements are met by checking the design at reviews. (Do this at each stage of the design it is always much cheaper to correct a design or incorporate a new requirement at the earliest stage.)
- ❑ Record whether CE marking is a requirement.
- ❑ Record the route to CE marking (if applicable).
- ❑ Record who will certify/approve the product: self or third party. If the latter, which approval body?
- ❑ List the required contents of the product technical file.
- ❑ Specify requirements for product approval testing/type testing.
- ❑ Specify required content of CE Declaration of Conformity/prepare draft.
- ❑ Define what user/public liability risks there are.
- ❑ Specify requirements for product labelling to meet both legislative and commercial requirements.

5.6 Understanding how to manufacture the product

Once the detailed design has emerged (realization phase) product parameters can be finalized in the specification. The product's architecture and detailed design can now be recorded fully in the design documentation.

Criteria for manufacturing should be established in as much detail as practicable including methods of manufacture and test. Manufacturing staff (including those from any major sub-contractors) should be involved in this. Any special criteria for bought-in parts or sub-assemblies should be recorded.

Table 5 gives a recommended checklist for use when considering how to manufacture the product.

Table 5 — Checklist for use when considering how to manufacture the product

Product implementation

- ❑ Specify the way in which the product is going to be made (manufacturing strategy, e.g. make in-house or subcontract, test in-house or subcontract).
- ❑ Select and use appropriate software implementation and maintenance tools and techniques (e.g. reviewing, issue tracking, version control, integration, testing, release, baseline management).
- ❑ Specify what arrangements are necessary to ensure that the product is safe.
- ❑ List any special materials requirements.
- ❑ Check that there are not likely to be any special/long delivery materials or services necessary, or make the necessary provisions in the plan.
- ❑ Specify the materials and bought-out items that should be purchased (purchasing specifications).
- ❑ Define packaging requirements (e.g. size, shape, graphic design, labelling, protection), both individual product and bulk (where applicable).
- ❑ Specify requirements for user instructions and information for installation, storage, use and disposal, etc.
- ❑ Ensure the product documentation embodies all last-minute changes or modifications.
- ❑ Ensure production can match the customer's planned volumes.

Manufacturing plans

- ❑ Prepare a manufacturing plan.
- ❑ Specify the manufacturing processes.
- ❑ Specify the manufacturing quality control arrangements.
- ❑ Specify inspection points.
- ❑ Select the manufacturer(s)/supplier(s).
- ❑ Ensure the production processes are "capable".

Production set-up

- ❑ Specify the manufacturing tooling.
- ❑ Specify any special requirement for jigs and fixtures.
- ❑ Specify requirements for validation of manufacturing processes where necessary.
- ❑ Specify the minimum required manufacturing yield, and/or other parameters as necessary.
- ❑ Establish whether occupational health and safety requirements will have any effect on the product or manufacturing process.

5.7 Understanding how to verify, test and validate the product

When establishing the process of product conformity it is important to distinguish between verification, production testing and validation. Enquiries would seem to indicate that there is no common established protocol for this within industry although some organizations have defined conformity procedures.

— *Verification* establishes that the design meets its specification. This may be achieved, to a degree, during the design process through the use of design reviews, etc. This is then supported by a final record showing that the overall design meets all the requirements (clause 8 deals with the verification process).

— *Production testing* ensures that individual examples of the product function satisfactorily.

— *Validation* in its simplest form establishes that the product meets customer needs while at the other extreme it ensures that the product is fully fit for its intended purpose (clause **9** deals with the validation process in more depth).

In the verification and validation process all the attributes of the product should be considered. Production testing covers critical and/or safety-related aspects and is only a subset of the overall product performance. It is usually necessary to test examples of the product fully to acquire the data to satisfy the initial design verification. Validation will include physical testing of the complete product under operating conditions to ensure that it meets the needs of the customer. Validation will also include recording the data as evidence of the validation process. With some products validation may only be achievable with on-site testing.

In addition to proving the design (refer to clause 8) it is usually necessary to prepare a production test specification. The application of production testing ensures that in the unfortunate event that a non-conforming product is produced it is not released. A balance may have to be drawn between the cost and delay of testing and the risk of a faulty product being allowed through. It is common to concentrate on safety testing (where applicable, e.g. electrical safety) and basic functionality. For simpler products sampling inspection can be appropriate in which case an acceptable quality level (AQL) should be chosen, see BS 6001-0. If sampling inspection is used there is a finite and predictable risk of a defective product reaching the customer. For this reason sampling inspection is not appropriate for some criteria or products. If it is used this should be made clear on any declaration of conformity.

Table 6 gives a recommended checklist for identifying verification criteria.

Table 6 — Checklist for identifying verification criteria

Design verification
❑ Establish which product characteristics are to be verified (normally all those identified in the product specification with the possible exception of those that have no impact on performance), ensuring tests include impact, vibration, temperature cycling etc., as appropriate.
❑ Identify the test methods to be used.
❑ Prepare a design verification document to include the testing of any embedded software.
❑ Document the build state of any embedded software.
❑ Prepare a template to record verification results.
❑ Where appropriate, ensure design verification/testing is conducted by an accredited testing laboratory (see Annex G).
❑ If verification is done in-house, ensure all requirements for equipment calibration and traceability (see Table 7) are met.
❑ Assemble information into a product technical file (see any applicable EC Directives)
❑ Store the test result(s) and related documentation (e.g. product technical file) for at least the lifetime of the product.

Table 7 gives a recommended checklist for identifying production testing criteria.

Table 7 — Checklist for identifying production testing criteria

Production testing
❑ Establish which parameters are to be tested in production.
❑ Establish the accuracy of measurement necessary for each.
❑ Establish the approach to production testing (e.g. 100 %, first-off, sampling).
❑ Establish how testing the functionality of any embedded software/firmware is to be incorporated into the test regime.
❑ Establish what test equipment, jigs, harnesses, software will be required.
❑ Establish how measurements will be traceable to national standards.
❑ Calibrate the necessary test equipment.
❑ Obtain and archive the necessary certificates of calibration.
❑ Prepare a production test specification.
❑ Ensure test requirements are communicated to production.
❑ Prepare templates to record production test results.
❑ Review test results for conformity with the specification.
❑ Positively identify products which have successfully passed testing.

5.8 Understanding how to support the product

Criteria for supporting the product should be established as early as practicable. The nature of the design itself and the thoroughness of any instructions for use can have a bearing on the amount of support customers need. Arrangements for dealing with warranty claims, criteria for associated costs, response times and helpdesk performance should all be established, as applicable.

Table 8 gives a recommended checklist for establishing product support.

Table 8 — Checklist for establishing product support

Support
❑ Establish what should be covered in the user instructions (remember requirements of any relevant standards, see clause 4). These should be written at the earliest practicable opportunity.
❑ Establish what product support arrangements are to be provided.
❑ Establish how any complaints are to be handled.
❑ Establish how customer feedback is to be obtained and handled.
❑ Define helpdesk or customer support arrangements where applicable.
❑ Ensure instructions or product packaging includes "helpline" telephone number or support address (which could be that of a specialist subcontractor).
❑ Define any staff training that is necessary.
❑ Define spares provisioning.
❑ Ensure continuing availability of spares for the life of the product.
❑ Define warranty terms.
❑ Define how data from customer returns is to be gathered, analysed and fed back for future product improvement.
❑ Define how any embedded software is to be maintained or upgraded (e.g. bug tracking, implementing upgrades, documentation).
❑ Prepare a recall procedure.

5.9 Understanding how to dispose of the product

More and more importance is being placed on the need for proper disposal of all products, rather than simply throwing them away, either through reclamation or the practical recycling of their materials. Manufacturers have an ever-increasing responsibility in this process. Attention is drawn to the fact that some legislation already exists and more is being drafted and contemplated.

Table 9 gives a recommended checklist for disposal criteria.

Table 9 — Checklist for disposal criteria

Disposal
❑ Consider the options for product recovery.
❑ Consider what remediation equipment or supplies might be required.
❑ Determine if any materials are suitable for recycling.
❑ Establish the process for disposal.
❑ Describe disposal/recycling procedure in user instructions.
❑ Determine if any hazardous parts (e.g. batteries) have to be disposed of in a defined way.
❑ Consider the use of degradable material.

6 Recording the criteria

6.1 General

All relevant criteria identified in clause 5 should be recorded formally to build up the product specification document. Where criteria are known to be relevant, but their values are not yet established, they should be recorded as, for example, "TBD" (to be determined). This will reduce the likelihood of issues being overlooked later.

Figure 2 illustrates how, as criteria are acquired, they can be documented. For clarity, the process is summarized as a sequence, but it is more likely to be iterative within each step, or even between steps. The approach can be tailored to suit an individual product. Criteria should be covered to an extent that all interested parties will be satisfied.

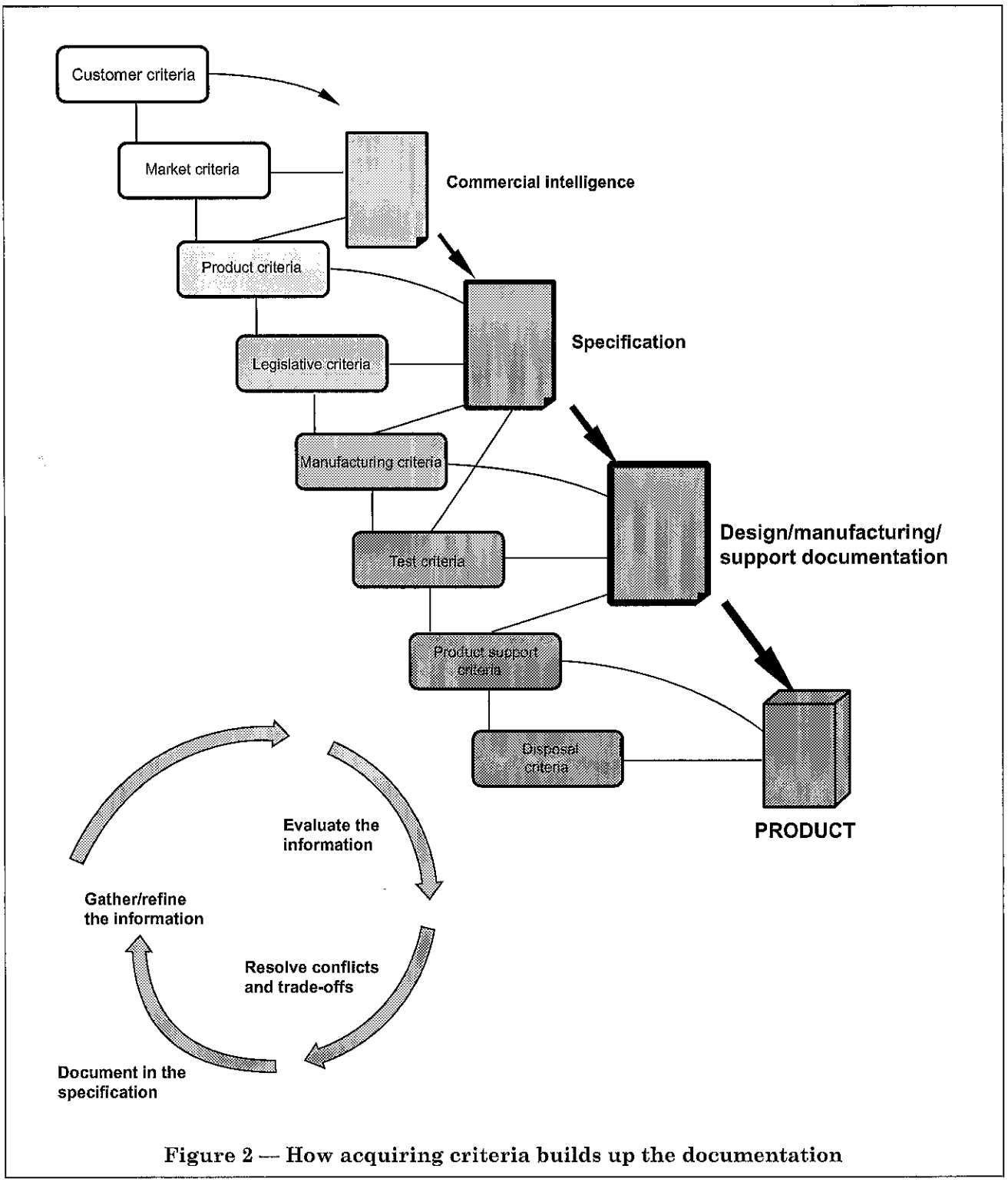


Figure 2 — How acquiring criteria builds up the documentation

It is useful to distinguish between the criteria to be recorded in the specification document and the associated commercial intelligence. It is vital to collect, assimilate and communicate the latter but for confidentiality reasons it may be prudent to keep it segregated from the product specification, particularly if this will be released outside the organization. Commercial intelligence can form an annex to the product specification.

Figure 3 shows a schematic representation of how commercial intelligence can be safeguarded.

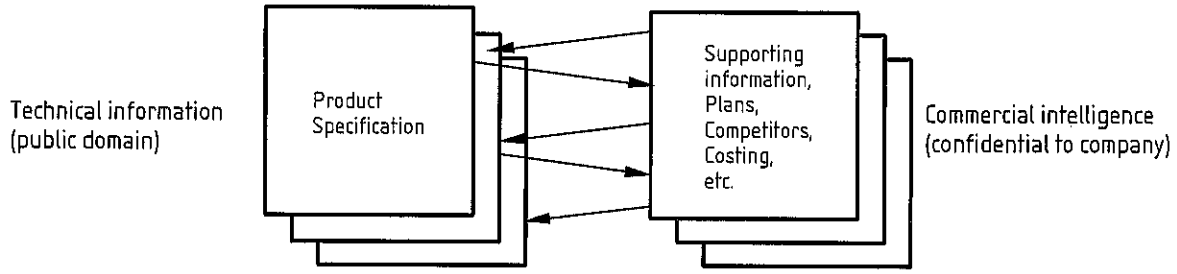


Figure 3 — Safeguarding commercial intelligence

All staff involved in the design process should be given ready access to all technical information and as much commercial intelligence as practicable. The specification may be in the form of handwritten text, a word-processed document, a computer database, or any other appropriate medium. Whichever method is chosen, some form of revision control should be in place (e.g. at least a date), to ensure users are working to up-to-date information as the document grows.

It is useful to adopt a formal structure for the document including numbered sections and sub-sections, or even numbered individual lines of the specification, so that references or changes to it can be made unambiguously at a later date. Guidance on the content and preparation of specifications is given in BS 7373-1:2001, clause 4. A more detailed template for a product specification is given in Annex F of this standard.

6.2 Some practical tips for writing a specification

The following are some practical tips for writing a specification.

— Start preparing the specification document very early on.

— Prepare it in a form that can easily be read and used by others.

— For complex products with multidisciplinary design, areas of the specification may be compiled by different people or sub-groups. Each should be aware of what the other is doing and the information brought together for review.

— Start by writing all the obviously applicable headings even if it is not yet possible to fill in any details (see Annex F for some suggestions).

— Put down all salient and useable information but be concise.

— Where possible be quantitative rather than qualitative: put down numbers, with tolerances where practicable.

— Avoid being unnecessarily restrictive: this can increase eventual product cost or limit design options.

— Always involve all the relevant people: research has shown that people tend to put too great an emphasis on areas of their own expertise and not enough on others. Multiple inputs help to counteract this effect.

— Writing a specification is an iterative process but try not to change the specification too often.

— Allow changes in the specification early on in order to refine it. However, changes will eventually become disruptive, so later unnecessary changes should be discouraged.

— Eventually changing the specification has to stop so that design work can proceed in a controlled way. It may be extremely wasteful to try to undertake detailed design while the specification is still changing.

— Good management is necessary to know when to change the specification and when not to: it will give stability to the subsequent design process. It is important to try to minimize disruption but nevertheless to be willing to accommodate important changes if they are necessary to keep the specification on target to produce a successful product.

— A good way of deciding if a change should be allowed late on is to consider the cost of the change compared with the loss in profit from leaving the design unaltered. Whilst impossible to assess accurately, prompting the person who wants the change to think about the degree of benefit compared with the cost of the disruption, helps to filter out unnecessary cosmetic or minor changes, while allowing those that affect the product's function or reliability.

7 Reviewing the criteria

The criteria in the specification should be periodically revisited and checked for relevance to ensure that the assumptions made about the product are still correct (looking backwards) and that all the necessary information for product development and manufacture is available (looking forwards).

NOTE Too frequently, reviews can concentrate on immediate technical issues, without looking back and checking that underlying assumptions have not changed.

Formal reviews are generally held following completion of principal tasks or phases in the design process.

Rigorous review is difficult if there are no real antecedents for the work. Thus mechanistic checks can be impossible to carry out, and probing to demonstrate the validity of the information has to be relied on, e.g. "how realistic, believable and achievable is this requirement? Is this requirement appropriate for the actual intended use?"

An important activity is to review each of the required elements of the specification to see if they are in fact essential in the light of the overall product performance. It is always tempting for those involved to add features along the line even though the user may not need them. The review should challenge each requirement of the specification to ensure that it genuinely adds value considering the cost of actually providing it.

One fruitful line of enquiry might be to consider the criteria from the point of view of every person who comes into contact with the product remembering to consider their range of capabilities as affected by their age, any physical or mental impairment etc. The list to consider includes the following people:

— buyer, supplier;
— production controller, stores keeper;
— assembler, inspector, calibrator, tester;
— packer;
— distributor, retailer;
— customer;
— user;
— user's family;
— cleaner, maintainer, spares supplier, provider of logistics support;
— insurer, regulatory authority, legislator;
— disposer, recycler;
— competitor;
— criminal, enemy.

Reviews should be formally documented and it is essential that any actions arising are progressed to a satisfactory conclusion.

8 Verifying product design against chosen criteria

8.1 General

In today's competitive market creating a successful new product is not just dependent on making a good product at the right price. It is often necessary to demonstrate, not only to customers but also to backers, agents, distributors, regulators, etc., that the product meets its specification on performance, quality, reliability, durability, safety, and other essential attributes. One route to achieving this is by conducting design verification. The extent of this verification will depend on the complexity of the product but it should always cover at least the attributes claimed and implied in product literature and advertising. Verification should only be done once, or whenever, any design changes take place.

8.2 Design verification

The objective of design verification is to show that the design conforms to its product specification. A good way of achieving this objective is to define a verification activity for each item in the product specification describing how each parameter is to be checked. This has the advantage that all of the requirements of the product specification are then automatically considered. It is possible that some parameters are not critical in which case this should be stated.

A verification document should be written and for each verifiable feature in the product specification the following items should be included:

— a brief narrative on the performance aspect to be tested;
— the test principle to be used (e.g. visual inspection, dimensional or electrical measurement);
— the criteria for acceptance or rejection (e.g. dimension with upper and lower tolerance limits);
— test conditions, test rig or test harness, power supplies, services required etc.

8.3 Conducting product verification

A necessary precursor to testing is the availability of working examples of the design, free from faulty components and flaws, on which tests can be conducted. The products for initial testing might typically be pre-production prototypes.

Testing should be carried out in a controlled manner. The following should be recorded for each test session:

— the test set-up and method;
— the date and time of testing;
— the test environment (e.g. temperature, humidity, cleanliness);
— the type and serial numbers of the test equipment used;
— the details of, and build-state/version numbers of, any software used;
— the staff responsible for performing the testing.

NOTE Attention is drawn to the fact that the calibration of measurement equipment may need to be traceable to national standards. In addition it is useful to remember that for CE marking of certain products testing may need to be carried out by a notified body or accredited test house.

8.4 Recording the results of verification

A verification record should be prepared, recording the results for each of the design verification activities. The record may be prepared as a separate results sheet numbered so as to correspond to each item in the verification document. Alternatively the record may be made an integral part of the verification document itself.

The level of detail included in the verification documentation should be such that someone else could repeat identical tests at a later date, which might be necessary, for example in the event of a customer dispute.

A declaration of product conformity should only be issued (see clause **10**) when design verification, and an appropriate level of validation, have been properly performed and production testing is in place (with acceptable products passing all parameters in the product test specification).

Where a product is already in production it should be clear that a declaration of product conformity cannot be claimed until all the relevant steps of the process from clause **5**, clause **6**, clause **7**, clause **8**, clause **9** and clause **10** have been carried out.

9 Validation

9.1 Product validation

The objective of validation is to show that the product meets customer needs. Activities relating to validation should be considered early in the design process as planning is an essential requirement of product validation. The degree of validation will typically depend on the complexity and/or degree of risk inherent in the product.

The aim of a validation plan is to ensure customer requirements are correctly identified and embodied in the design so that on completion of the work there is confidence in the product meeting the customer's demands.

The validation plan should as a minimum:

— describe the product and the attributes to be validated;
— identify any regulatory process that has to be followed;
— identify how and when the validation tasks are to be performed;
— take into account the operational environment and any special conditions;
— ensure the results are adequately recorded.

9.2 Conducting product validation

Validation activities should be carried out as set out in the validation plan. Some validation activities will have already been carried out during the design process (as appropriate), for example:

— risk assessment;

— failure modes, effects and criticality analysis;

— specification review;

— design review.

These should be supplemented by checking against the user needs, using for example:

— Trials; including trials with older persons, disabled people and children (to ensure that the product fulfils its intended use).

— Environmental testing (as appropriate).

— Product verification (see **8.3**).

— Validation of the manufacturing process (where relevant).

9.3 Recording the results of validation

A file of validation results should be compiled containing results of all relevant reviews, risk assessment(s), tests, analyses, trials and verification activities. This may be required not only to underpin any conformity declaration statement but also for regulatory and/or product liability purposes.

10 Declaring product conformity

Before conformity can be declared the specifications and the results of verification, testing and validation should be reviewed to ensure that all documentation is complete and consistent. If it is desired to declare the conformity of a product that has already been designed then these documents should still be prepared to the required level of detail and any conflicts resolved (e.g. by modifying the product, manufacturing processes, or information or publicity material).

This documentation should include:

— the commercial information, costing, plans, etc. (see **5.2** and **5.3**);

— the product specification (see clause **6**);

— the design verification plan (see **8.2**);

— the design verification records (see **8.4**);

— the production test specification (see Table 7);

— the production test results (see **5.7**);

— the validation plan (see **9.2**); and

— the validation records (see **9.3**).

NOTE The only way of substantiating a declaration is by having this complete and consistent set of records.

Once the product has been proven to conform to the product specification, the appropriate level of validation has been carried out (ensuring customer needs are met) and the necessary records prepared and reviewed for completeness then a declaration of conformity can be prepared.

In the context of this standard such a declaration is only valid if the product specification is explicitly identified in the declaration (i.e. by number, title, date/version) and this same specification is available without unreasonable additional cost to the customer preferably with the product.

The declaration should either take the form of a separate document, or be printed or stamped on, for example, a statement, advice note, invoice, or user's instruction relating to the product in question. This should be consistent with BS EN 45014.

The following is the recommended minimum wording as given in BS EN 45014:1998.

Supplier: .....
Address: .....
Product: ..... (*name, type or model*).....
The product described above is in conformity with ..... (*reference to product specification*) ..... following the provisions of BS 7373-2.
Place and date: .....
Signed: ..... (*name and signature, or equivalent mark, of authorized person*) .....

All activities affecting the quality of the product should be controlled (i.e. production quality assurance) to ensure that the specification and user needs to which this declaration refers continue to be met. Product and production testing is part of this to ensure that all batches of product conform.

NOTE BS EN ISO 9001 gives information relating to quality management.

This standard only provides generic guidance on the procedure for declaring product conformity. The preparation, content and ensuring that the product continues to meet the declaration is solely the responsibility of the producer/supplier.

Annex A (informative)
The interrelationship of product documents

The traditional approach to preparing specifications for large or complex products is to generate a series of ever more focused documents. Detail in these specifications grows as the product becomes better understood and the design more refined. Thus it can be seen that specifications are living documents throughout the design and planning for manufacture phases of a project.

A specification can act both as a series of requirements to be met and as a benchmark against which products can be assessed (product performance testing). Design planning and design reviews are thus an integral part of preparing a good specification.

Documentation will typically start with an initial design brief or target specification giving the scope or overview of the product requirements. Next comes a requirements (or performance) specification, which describes the attributes of the product but not how it is to be made. Then comes a functional specification which will explicitly dictate the form of the product. Finally individual specifications for parts of the product are prepared and the detail design documentation emerges.

Where this standard is applied to simpler products, or smaller organizations, a suggested method is to consolidate all the technical information into one product specification (as shown in the top left-hand circle in Figure A.1) and confidential information into a commercial appendix or file. The consequence is that the specification becomes one or two evolutionary documents rather than the traditional series where the earliest becomes obsolete.

The design verification results and design validation results illustrated in Figure A.1 are necessary in order to be able to demonstrate that the final product meets the requirements of the product specification.

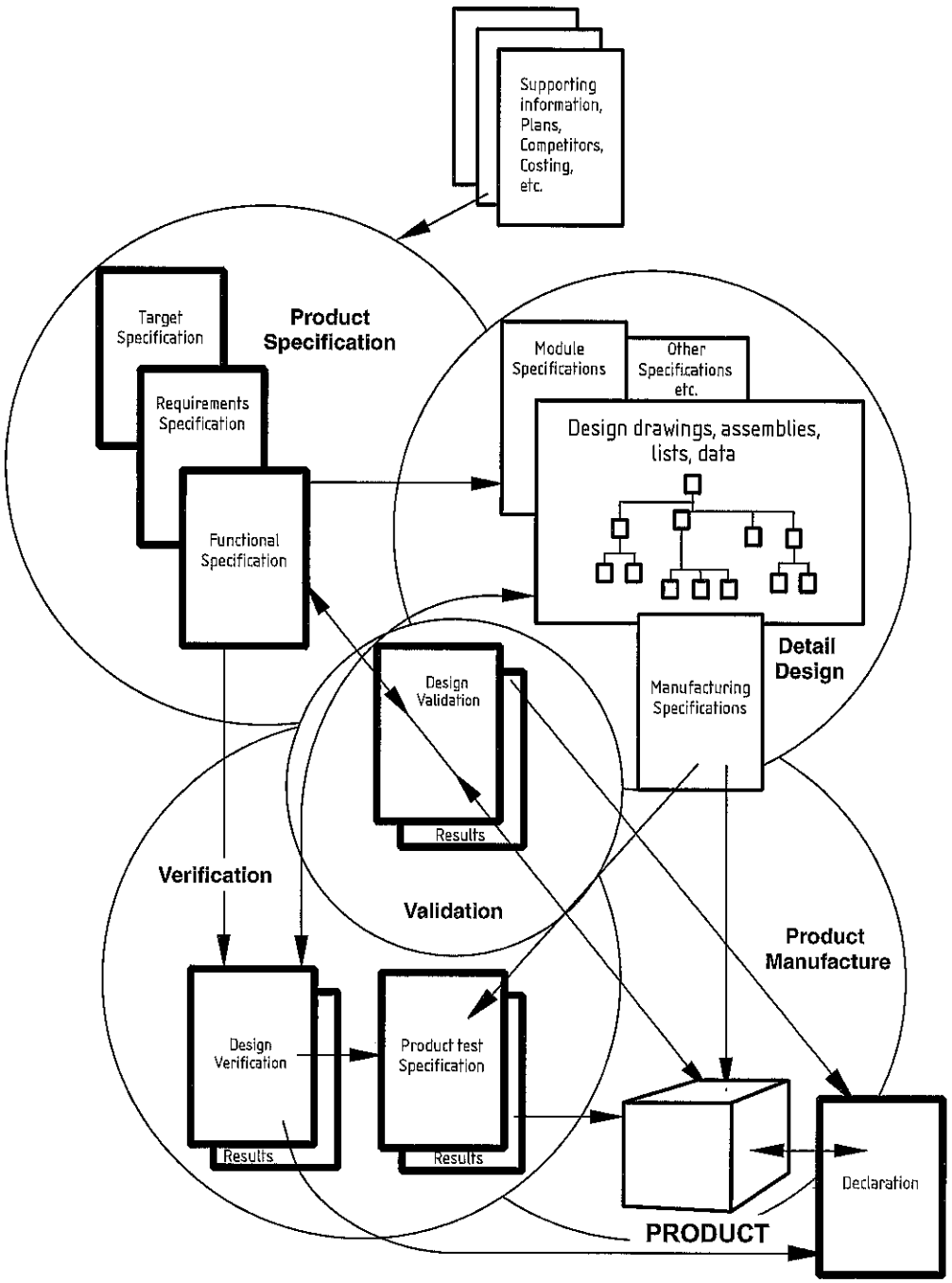


Figure A.1 — Interrelationship of product documentation

Annex B (informative)
Product development process

This annex contains a generic overview of the product development process, showing the inputs and the relationships between the tables and the clauses of this guide. See Figure B.1.

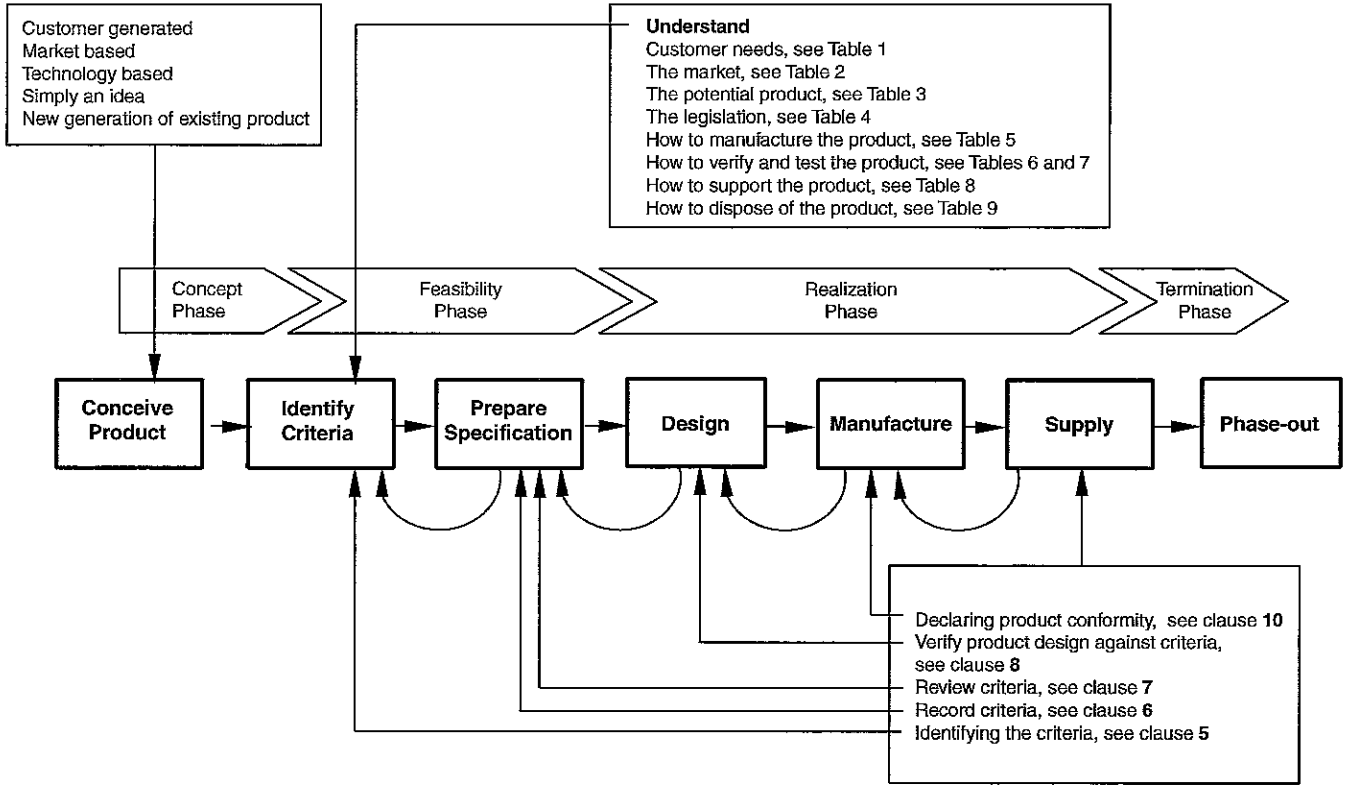


Figure B.1 — Product development process

Annex C (informative)
Related management standards and guidance publications

The standards and publications in Figure C.1 take different perspectives on managing the realization of the final product. The publication's relevance and relative importance depend on the nature of the product and the way in which the organization goes about developing, manufacturing and selling it.

NOTE The designation "HB" plus a series of digits is the BSI identifier (i.e. catalogue number) for a "Handbook".

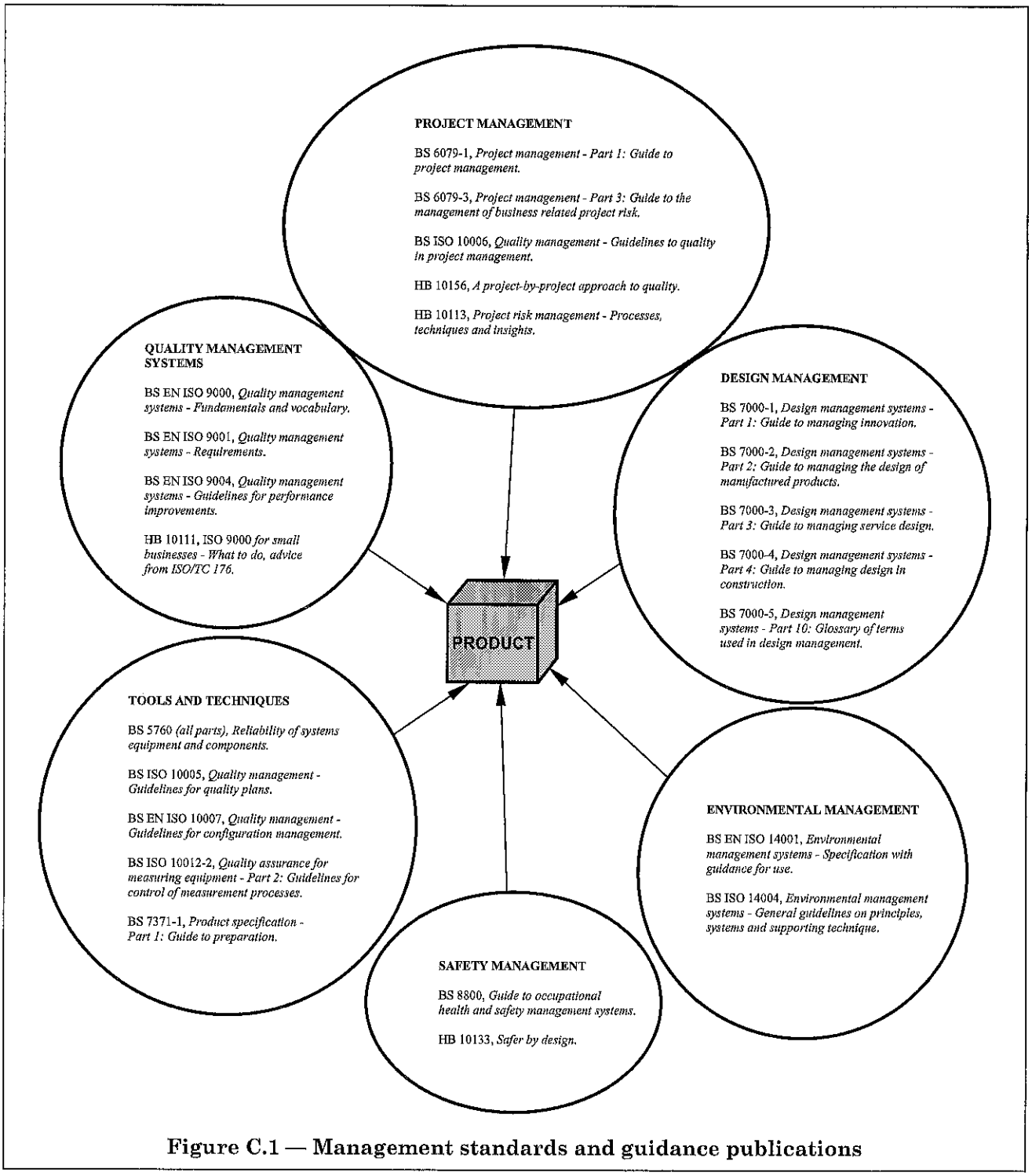


Figure C.1 — Management standards and guidance publications

Annex D (informative)
Legislation and technical standards

EC Directives are implemented in member states through their national regulations. Although these vary from country to country the harmonized standards that support the Directives are shared within the community. These standards have a "presumption of conformity", so although they are voluntary, they provide a straightforward route to compliance. Figure D.1 illustrates how EC Directives are implemented in UK law (the UK Statutory Instruments) and in turn supported by harmonized standards. Note the UK reference numbers quoted here are generally the latest amendments to earlier regulations. In the case of harmonized standards there are very many different standards covering different aspects of products. Those shown are merely examples. It will be necessary to search out the relevant standards for your particular product through the standards catalogues and by seeking technical help.

There are frequent updates to EC Directives, the national Statutory Instruments that implement them, and the supporting standards. It is important to ensure that the information you use is current. Up-to-date information is available from the UK Department of Trade and Industry Standard and Technical Regulations Directorate. The European Commission's website has EC Directives available for downloading and identifies the standards that relate to each.

Figure D.1 gives some examples of the relationship between legislation, Statutory Instruments and standards with a "presumption of conformity".

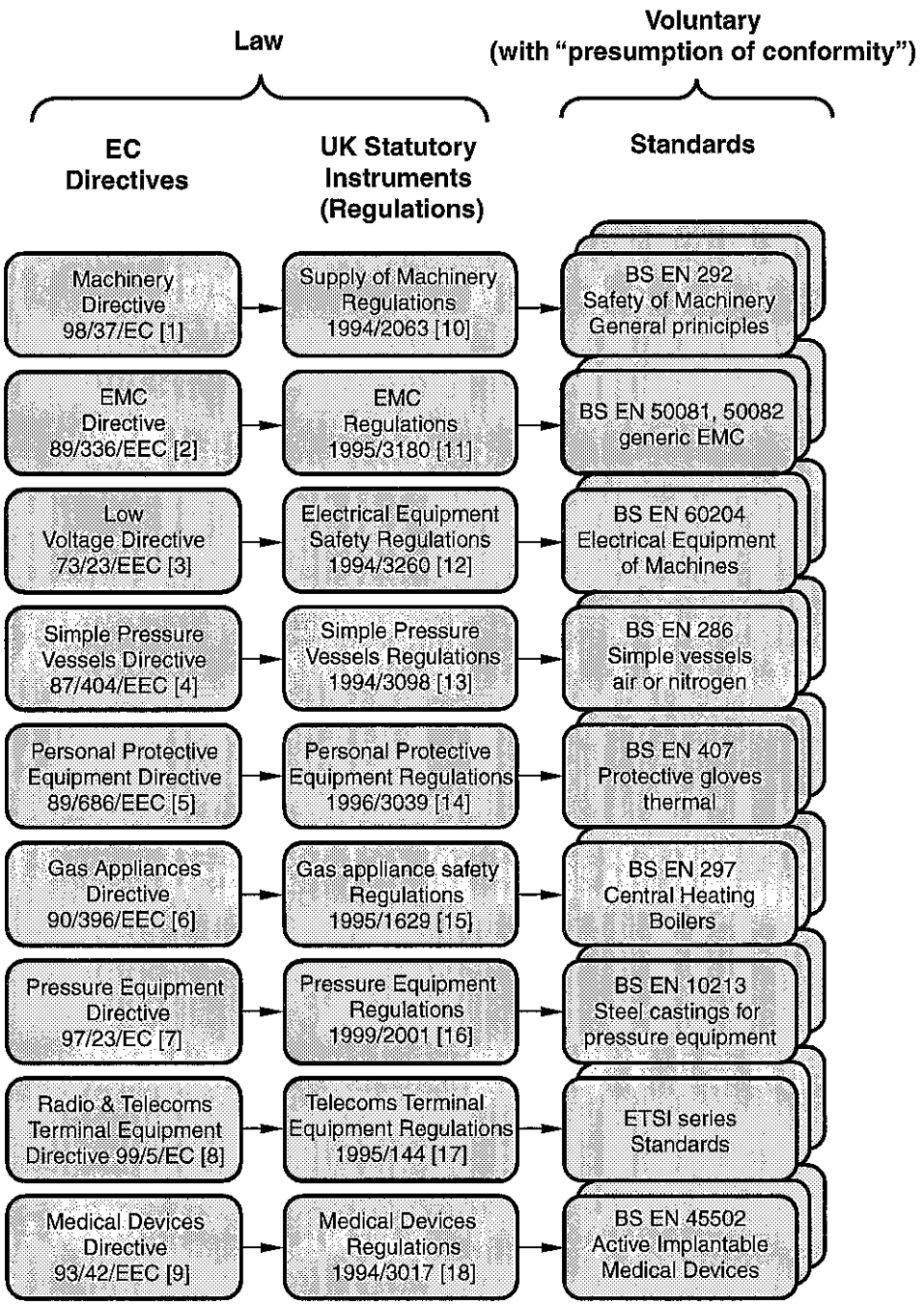


Figure D.1 — Some examples of the relationship between legislation and standards

Annex E (informative)
Quality function deployment (QFD)

QFD is a methodology that originated in Mitsubishi's Kobe shipyard in Japan and was developed and extended by Toyota and its suppliers. The big US automotive manufacturers, and some other leading companies in other sectors, notably electronics, subsequently took it up.

QFD is a tool that aids the development of a product/process from the concept stage through to its manufacture and beyond. QFD is particularly useful in identifying critical customer requirements and creating specific links between these requirements and design parameters. The method uses matrices to organize information and help the various stakeholders agree on critical parameters and trade-offs. Figure E.1 shows a typical example of a simple matrix. The extent of its use will depend on the size and complexity of the product/process being undertaken. It is a technique that takes time to absorb but, when properly applied, can bring substantial benefits in terms of market share, a more competitive product/process and in ensuring that design changes are made prior to the start of production or its manufacture and not afterwards.

The use of QFD in product/process design may require a substantial investment of resources initially in terms of time, money and staffing which tails off as the design progresses. This is in contrast with the more traditional use of resources which start modestly and peaks as the design approaches completion. Once the team has become proficient in its use the QFD approach has benefits over the more traditional approach to product design. For those using QFD for the first time, and/or where the project is complex, it may be worth considering the use of an expert in QFD to provide guidance and advice.

QFD is often used in conjunction with other techniques such as Taguchi Methods and "just in time/total quality management" (JIT/TQM) operating principles, Figure E.2 shows the relationship between them.

One of the major benefits of QFD is the virtual elimination of engineering/product changes that frequently occur during the design/development stage by the time production is due to commence.

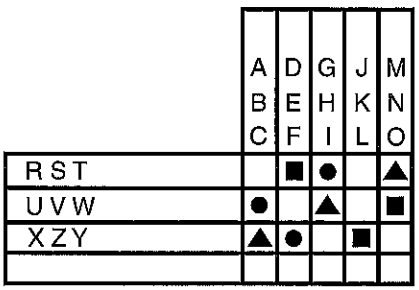


Figure E.1 — Simple QFD analysis matrix

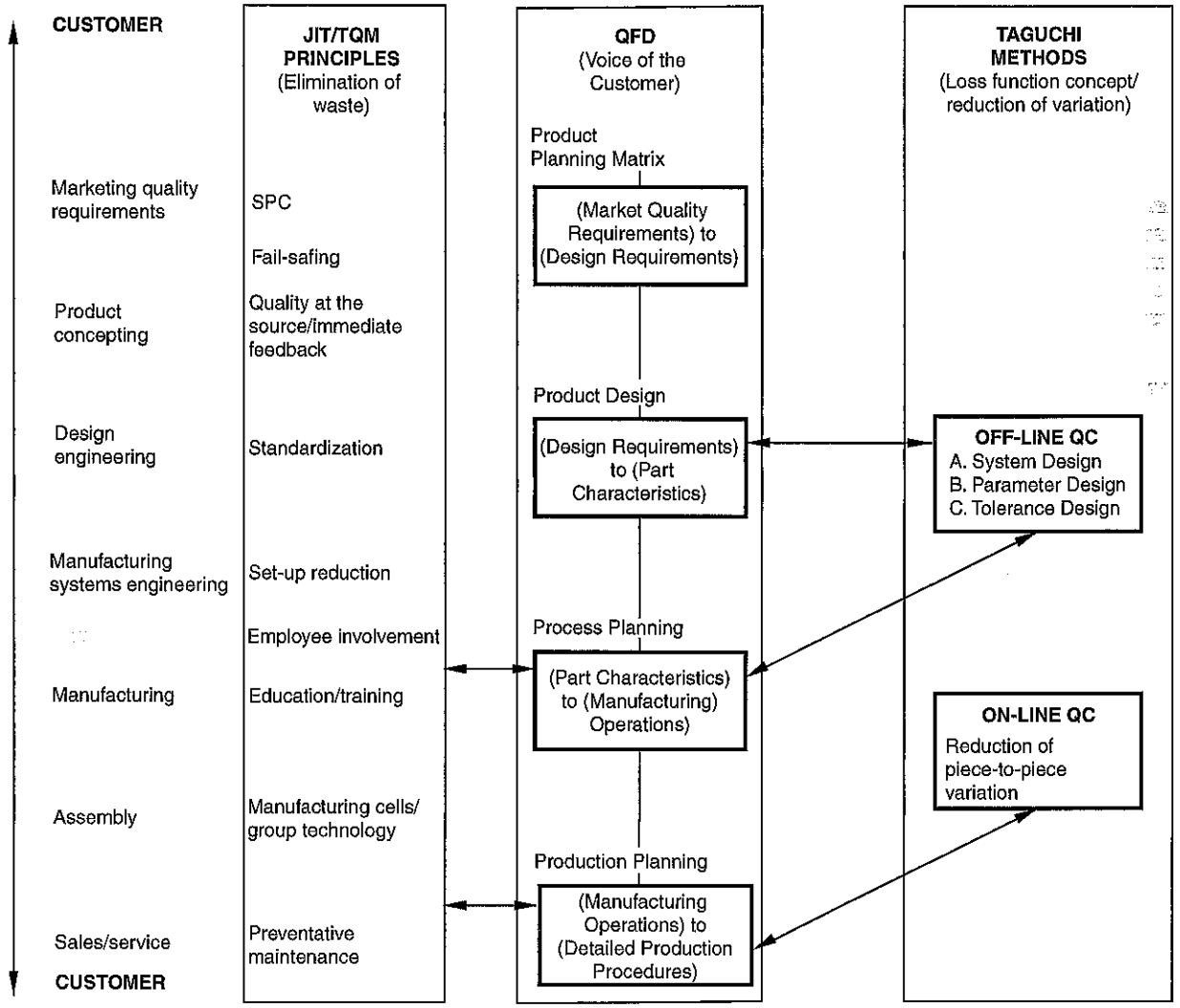


Figure E.2 — Relationships among QFD, Taguchi Methods, and JIT/TQM operating principles[2)]

[2)] This figure has been reproduced by kind permission of CSC Consulting & Systems Integration from: *The Manufacturing Industry Handbook ~ © 1996 CSC.*

Annex F (informative)
Example of a product specification template[3)]

NOTE This annex describes a suggested list of elements to be covered in a product specification, with examples of the criteria to be included.

F.1 Introduction

Describe the purpose of the product and how it is used.

Describe the business case that justifies proceeding with this product.

F.2 Functional criteria

F.2.1 *Functional requirements*

Describe the functions the product performs. Each requirement needs to be quantified and testable. Include nominal values, ranges and tolerances such as the following:

— motion;
— velocity;
— acceleration;
— vibration;
— forces;
— loading;
— output efficiency;
— loss;
— friction;
— ventilation;
— heating/cooling;
— supply;
— storage;
— capacity.

F.2.2 *Use/modes of operation*

Describe the modes of operation or ways of using the product. Include such items as the following:

— intended use;
— start-up;
— normal mode;
— maintenance mode;
— shutdown;
— misuse;
— operator error;
— failure mode(s);
— storage and distribution;
— transportation;
— standby/protection mode;
— storage mode.

[3)] This annex has been reproduced by kind permission of Cambridge Engineering Design Centre/Cambridge Consultants from: SHEFELBINE, S., P.J. CLARKSON, and L.T.M. BLESSING. *Requirements capture for medical devices (Workbook)* (CUED/C-EDC/TR90). Cambridge: Cambridge Engineering Design Centre/Cambridge Consultants, December 1999.

F.2.3 *Environmental conditions*

Indicate the environmental conditions in which the product needs to function. Include environmental conditions for transport and storage. The items to be covered should include the following:

— temperature;
— humidity;
— moisture;
— pressure;
— vibration;
— shock;
— ventilation;
— noise level;
— climate;
— dust and dirt;
— corrosion from fluids;
— gases and vapours;
— shock;
— geographic location.

F.3 Performance criteria

F.3.1 *Operational performance*

Define operational criteria and performance parameters. These should include the following items:

— quality/tolerances;
— quietness;
— wear;
— ease of use;
— marketing area;
— destination;
— shelf life;
— surface temperature.

F.3.2 *Durability and reliability*

Define the reliability of the product, including the following criteria:

— mean time to failure;
— mean time to repair;
— robustness;
— drop test;
— diagnostic methods for detecting failure (if relevant);
— dependability;
— product life span.

F.3.3 *Availability*

Define the product availability, including the following criteria:

— product operating capability, running time;
— failure mode operation;
— recovery from failure.

F.3.4 *Adaptability*

Define any previous products with which the product should be compatible. Identify provisions for future adaptations or developments, such as the following:

— future improvements;
— ease of modifying;
— enhancement potential;
— spare capacity required to support future expansion;
— design features to support future enhancements;
— anticipated future requirements;
— recyclability of materials and/or components.

F.3.5 *Manufacturability*

Define requirements relating to the manufacture of the product, such as the following items:

— preferred method of production;
— factory limitations;
— labour availability;
— production quantity.

F.4 Physical properties

The physical properties to be covered should include the following items.

Geometry:

— shape;
— size;
— height;
— breadth;
— length;
— volume;
— diameter;
— space requirements;
— arrangement;
— connection;
— maximum dimensions;
— weight.

Aesthetics:

— appearance;
— finish;
— colour.

F.5 Interface requirements

Describe information to and from the user, signals etc., as shown in Table F.1.

Table F.1 — Information useful when describing interface requirements

User	Ergonomics	Signals
man–machine relationship	height	inputs
skilled/unskilled user	reach	outputs
type of operation	posture	form (analogue, digital, serial, parallel)
clarity of layout	lighting	display
operator input	strength	audible signals/instructions
visual displays	dexterity	control equipment
visual instructions	manipulation	timing
tactile displays	ease of operation	feedback

F.6 Support requirements

F.6.1 *Supporting systems*

Describe any other requirement or services necessary in order to use the product. Examples of the requirements or services to be covered include the following items:

— electrical;
— voltage;
— frequency;
— current;
— power;
— heat applied or removed;
— mechanical loading;
— use of existing products to support.

F.6.2 *Maintenance*

Describe the requirements relating to the upkeep of the product. The items to be described should include the following:

— installation;
— inspection interval;
— diagnostic methods;
— servicing interval;
— support period;
— ease of access for servicing;
— maintenance;
— painting;
— cleaning;
— compatibility with cleaning fluids;
— calibration:
— drift;
— calibration interval;
— repair;
— exchange of parts;
— modularity of parts;
— repair time;
— expected life;
— disposal/recycling.

F.6.3 *Training*

Describe what training may be necessary to use or maintain the product. The training could relate, for example, to the following items:

— intuitive operation;
— self support;
— helpline;
— required training;
— instructions.

F.6.4 *Labelling and packaging*

Information on labelling and packaging should include the following items:

— label size and font size;
— label warnings (should be labelled in a permanent way);
— type of packaging, disposal of packaging;
— volume (bulk packaging/pallet size);
— required protection;
— vacuum packaging;
— accessibility/opening of packaging.

F.6.5 *Transport*

Information on the transportation of the product could, for example, include the following items:

— limitations;
— means;
— conditions;
— ease;
— use of existing facilities;
— clearance;
— size of pallet;
— lifting capabilities;
— modular components for;
— transportability;
— lifting points;
— safety of product during transport;
— safety of transport.

F.7 Safety

Describe any safety features or interlocks that are required for the safe operation and maintenance of the product. The following are examples of items to be described:

— standards;
— features;
— interlocks;
— user safety;
— safety during maintenance;
— safety hazards associated with use;
— preventative measures to safeguard against hazards;
— design features required to achieve safety requirements;
— electrical safety;
— labelling, warnings;
— safety factors;
— protective clothing and equipment.

F.8 Regulations and standards

Describe international or regional standards that apply. The following items should be described:

— national standards;
— international standards;
— product classification (e.g. electrical insulation, class 1, class 11);
— customs/export regulations;
— environmental regulations;
— environmental compatibility disposal criteria.

F.9 Verification/validation

Describe what verification methods are to be used. The following are examples of verification methods:

— verification of design to demonstrate design meets user needs;
— verification of manufacturing equipment to show product consistently meets specification;
— what should be verified;
— verification of test equipment.

F.10 Cost

Describe the cost of manufacturing, marketing, distribution, sales, intended consumer price, etc. The following are examples of the costs to be described:

— design costs;
— target manufacturing costs;
— tooling costs;
— transport and shipping costs;
— investment;
— depreciation;
— target consumer price;
— maintenance costs;
— inspection costs;
— recycling possibilities.

Annex G (informative)
Sources of information

British Standards Institution (BSI)
389 Chiswick High Road
London
W4 4AL
Tel: 020 8996 9000
Fax: 020 8996 7400
www.bsi-global.com

DTI Enquiry Unit
1 Victoria Street
London
SW1H 0ET
Tel: 020 7215 500
www.dti.gov.uk

The Stationery Office Ltd (Norwich)
PO Box 29
St Crispins
Duke Street
Norwich
NR3 1PD
www.the-stationery-office.co.uk
www.tsonline.co.uk
www.clicktso.com
Tel: 0870 600 5522

HSE Infoline 08701 545 5000

HSE Books
PO Box 1999
Sudbury
Suffolk
CO10 6FS
Tel: 01787 881165
Fax: 01787 313995
www.hse.gov.uk/

European Union affairs and legislation
http://europa.eu.int/

Bibliography

Standards publications

BS 5760 (all parts), *Reliability of systems equipment and components.*

BS 6079-1, *Project management — Part 1: Guide to project management.*

BS 6079-3, *Project management — Part 3: Guide to the management of business related project risk.*

BS 7000-1, *Design management systems — Part 1: Guide to managing innovation.*

BS 7000-2, *Design management systems — Part 2: Guide to managing the design of manufactured products.*

BS 7000-3, *Design management systems — Part 3: Guide to managing service design.*

BS 7000-4, *Design management systems — Part 4: Guide to managing design in construction.*

BS 7000-10:1995, *Design management systems — Part 10: Glossary of terms used in design management.*

BS 7373-1:2001, *Product specifications — Part 1: Guide to preparation.*

BS 8800, *Guide to occupational health and safety management systems.*

BS EN 292 (all parts), *Safety of machinery — Basic concepts, general principles for design.*

BS EN 297, *Gas-fired central heating boilers — Type B_{11} and B_{11BS} boilers fitted with atmospheric burners of nominal heat input not exceeding 70 kW.*

BS EN 407, *Protective gloves against thermal risks (heat and/or fire).*

BS EN 10213-1 (all parts), *Technical delivery conditions for steel castings for pressure purposes.*

BS EN 45502-1, *Active implantable medical devices — Part 1: General requirements for safety, marking and information to be provided by the manufacturer.*

BS EN 50081 (all parts), *Electromagnetic compatibility — Generic emission standard.*

BS EN 50082 (all parts), *Electromagnetic compatibility — Generic immunity standard.*

BS EN 60204 (all parts), *Safety of machinery — Electrical equipment of machines.*

BS EN ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary.*

BS EN ISO 9001, *Quality management systems — Requirements.*

BS EN ISO 9004, *Quality management systems — Guidelines for performance improvements.*

BS EN ISO 10007, *Quality management — Guidelines for configuration management.*

BS EN ISO 14001, *Environmental management systems — Specification with guidance for use.*

BS ISO 10005, *Quality management — Guidelines for quality plans.*

BS ISO 10006, *Quality management — Guidelines to quality in project management.*

BS ISO 10012-2, *Quality assurance for measuring equipment — Part 2: Guidelines for control of measurement processes.*

BS ISO 14004, *Environmental management systems — General guidelines on principles, systems and supporting techniques.*

HB 10111, *ISO 9000 for small businesses. What to do — advice from ISO/TC 176.*

HB 10113, *Project Risk Management — Processes, Techniques and Insights.*

HB 10133, *Safer by Design.*

HB 10156, *A project-by-project approach to quality.*

Legislation and Statutory Instruments

[1] EUROPEAN COMMUNITIES. EU Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery (Document No. 398L0037). Luxembourg: EU-OP (Office for the publications of the European Communities).

[2] EUROPEAN COMMUNITIES. Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility (Document 389L0336). Luxembourg: EU-OP (Office for the publications of the European Communities).

[3] EUROPEAN COMMUNITIES. Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (Document 373L0023). Luxembourg: EU-OP (Office for the publications of the European Communities).

[4] EUROPEAN COMMUNITIES. Council Directive 87/404/EEC of 25 June 1987 on the harmonization of the laws of the Member States relating to simple pressure vessels (Document 387L0404). Luxembourg: EU-OP (Office for the publications of the European Communities).

[5] EUROPEAN COMMUNITIES. Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (Document 389L0686). Luxembourg: EU-OP (Office for the publications of the European Communities).

[6] EUROPEAN COMMUNITIES. Council Directive 90/396/EEC of 29 June 1990 on the approximation of the laws of the Member States relating to appliances burning gaseous fuels (Document 390L0396). Luxembourg: EU-OP (Office for the publications of the European Communities).

[7] EUROPEAN COMMUNITIES. Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment (Document 397L0023). Luxembourg: EU-OP (Office for the publications of the European Communities).

[8] EUROPEAN COMMUNITIES. Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity (Document 399L0005). Luxembourg: EU-OP (Office for the publications of the European Communities).

[9] EUROPEAN COMMUNITIES. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (Document 393L0042). Luxembourg: EU-OP (Office for the publications of the European Communities).

[10] GREAT BRITAIN. The Supply of Machinery (Safety) (Amendment) Regulations 1994 (Statutory Instrument 1994/2063). London: The Stationery Office.

[11] GREAT BRITAIN. The Electromagnetic Compatibility (Amendment) Regulations 1995 (Statutory Instrument 1995/3180). London: The Stationery Office.

[12] GREAT BRITAIN. The Electrical Equipment (Safety) Regulations 1994 (Statutory Instrument 1994/3260). London: The Stationery Office.

[13] GREAT BRITAIN. The Simple Pressure Vessels (Safety) (Amendment) Regulations 1994 (Statutory Instrument 1994/3098). London: The Stationery Office.

[14] GREAT BRITAIN. The Personal Protective Equipment (EC Directive) (Amendment) Regulations 1996 (Statutory Instrument 1996/3039). London: The Stationery Office.

[15] GREAT BRITAIN. The Gas Appliances (Safety) Regulations 1995 (Statutory Instrument 1995/1629). London: The Stationery Office.

[16] GREAT BRITAIN. The Pressure Equipment Regulations 1999 (Statutory Instrument 1999/2001). London: The Stationery Office.

[17] GREAT BRITAIN. The Telecommunications Terminal Equipment (Amendment) Regulations 1995 (Statutory Instrument 1995/144). London: The Stationery Office.

[18] GREAT BRITAIN. The Medical Devices Regulations 1994 (Statutory Instrument 1994/3017). London: The Stationery Office.

Background reading

AKAO, Yoji, ed. *Quality Function Deployment: Integrating Customer Requirements into Product Design.* Translated by Glenn Mazur. (ISBN 0-91299-41-0). Portland, Oreg.: Productivity Press, 1990.

CSC CONSULTING & SYSTEMS INTEGRATION, *The Manufacturing Industry Handbook.* CSC Consulting & Systems Integration. Farnborough, 1996.

HAUSER, John R., and Don CLAUSING. *The House of Quality.* Harvard: Harvard Business Review, May–June 1988.

HOLLINS, W., and S. PUGH. *Successful Product Design — What to do and when.* London: Butterworth Ltd, 1990.

SHEFELBINE, S., P.J. CLARKSON, and L.T.M. BLESSING. *Requirements capture for medical devices (Workbook)* (CUED/C-EDC/TR90). Cambridge: Cambridge Engineering Design Centre/Cambridge Consultants, December 1999.

TERNINKO, J. *Step-by-Step QFD* (ISBN 1-57444-110-8). Boca Raton: St Lucie Press, 1997.

BSI — British Standards Institution

BSI is the independent national body responsible for preparing British Standards. It presents the UK view on standards in Europe and at the international level. It is incorporated by Royal Charter.

Revisions

British Standards are updated by amendment or revision. Users of British Standards should make sure that they possess the latest amendments or editions.

It is the constant aim of BSI to improve the quality of our products and services. We would be grateful if anyone finding an inaccuracy or ambiguity while using this British Standard would inform the Secretary of the technical committee responsible, the identity of which can be found on the inside front cover. Tel: 020 8996 9000. Fax: 020 8996 7400.

BSI offers members an individual updating service called PLUS which ensures that subscribers automatically receive the latest editions of standards.

Buying standards

Orders for all BSI, international and foreign standards publications should be addressed to Customer Services. Tel: 020 8996 9001. Fax: 020 8996 7001. Standards are also available from the BSI website at http://www.bsi-global.com.

In response to orders for international standards, it is BSI policy to supply the BSI implementation of those that have been published as British Standards, unless otherwise requested.

Information on standards

BSI provides a wide range of information on national, European and international standards through its Library and its Technical Help to Exporters Service. Various BSI electronic information services are also available which give details on all its products and services. Contact the Information Centre. Tel: 020 8996 7111. Fax: 020 8996 7048.

Subscribing members of BSI are kept up to date with standards developments and receive substantial discounts on the purchase price of standards. For details of these and other benefits contact Membership Administration. Tel: 020 8996 7002. Fax: 020 8996 7001. Further information about BSI is available on the BSI website at http://www.bsi-global.com.

Copyright

BSI
389 Chiswick High Road
London
W4 4AL