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A guide to quality assurance

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British Standards Institution · 2 Park Street · London W1A 2BS
Telephone 01-629 9000
Telex 266933

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Foreword

As a consequence of representations made by the Inspection and Quality Assurance Panel of the Confederation of British Industry, BSI circulated for public comment, early in 1971, a draft guide to quality control procedures, in which account had been taken of several documents from various sources but in particular the following publications:

AQAP–1 NATO quality control system requirements for industry (May 1968)
AQAP–2 Guide for evaluation of a contractor's quality control system for compliance with AQAP–1 (September 1968)

} Incorporated in DEF STAN 05-8 (Issue 2) Ministry of Defence March 1970

Encouraging support both from at home and abroad was received for developing the draft document and as a consequence of the review of comments submitted, it was eventually felt that maximum benefit would ensue from publication by BSI of a basic document dealing with quality assurance generally. This objective presented many difficulties – aiming for a concise balanced document giving sufficient guidance on the fundamental issues involved without over-emphasizing particular aspects in too much detail.

It is hoped that this document will contribute toward satisfying some of the needs of industry and commerce in general. Although it has been issued as a guide and *not* in the form of a specification with mandatory requirements, it should assist companies or organizations engaged in developing their own capabilities to meet contractual requirements specified in documents such as AQAP–1.

NOTE. It is a responsibility of the supplier to provide goods or services in conformity with a contract and nothing in this document is intended to reduce this responsibility. However, on large scale contracts a viable system of quality control necessitates mutual co-operation and at some points the participation of the purchaser, as is indicated in several parts of this document.

Introduction

Quality, or 'the totality of features or characteristics of a product or service that bear on its ability to satisfy a given need', is something most contractors, manufacturers or suppliers would claim to achieve and indeed, the majority devote considerable effort towards attaining this objective. Often however, much of this effort is absorbed in the correction of defects and failures in service. Coupled with this, the complexity, cost of development, production and maintenance of modern equipment emphasizes the need for management to integrate effectively their objectives in design, development, production and marketing to ensure the quality of the service desired by purchasers.

In recent years new concepts, disciplines and techniques have emerged to facilitate the achievement of these objectives. These concepts are collectively identified in most countries as quality control or as quality assurance. The use of these particular terms can mean different things to different people but in this document the terminology utilized is in accordance with the terms and definitions of BS 4778, 'Glossary of general terms used in quality assurance', where *quality assurance* is defined as, 'all activities and functions concerned with the attainment of quality' (referred to by some as 'total quality control'), rather than in the more narrow sense of the provision of proof associated with the word assurance. As such, it is involved with all quality tasks from market demand through to and including post-delivery services which can involve various forms of external liaison, co-operation and involvement with purchasers and sub-contractors or surveillance by independent certification authorities. *Quality control* is defined as, 'a system for programming and co-ordinating the efforts of various groups *in an organization* to maintain or improve quality, at an economical level which allows for customer satisfaction'. Defined as such, quality control is a subset of quality assurance i.e. a substantial integral part of it and not a separate addition to it.

It would not be feasible in this guide to suggest the adoption of any particular system of management control or organizational structure. However, it is hoped that Fig. 1 might assist in illustrating *some* of the basic elements involved and possible inter-relationships, correlated in terms of:

(1) design/specification adjustment;
(2) process/procedural operation.

Suppliers should be prepared to institute such control of quality as is necessary to ensure that their products or services conform to purchasers' requirements and are delivered on schedule at the agreed price. Except in the case of the simpler type of product, the purchaser can rarely protect himself sufficiently just by inspection of a

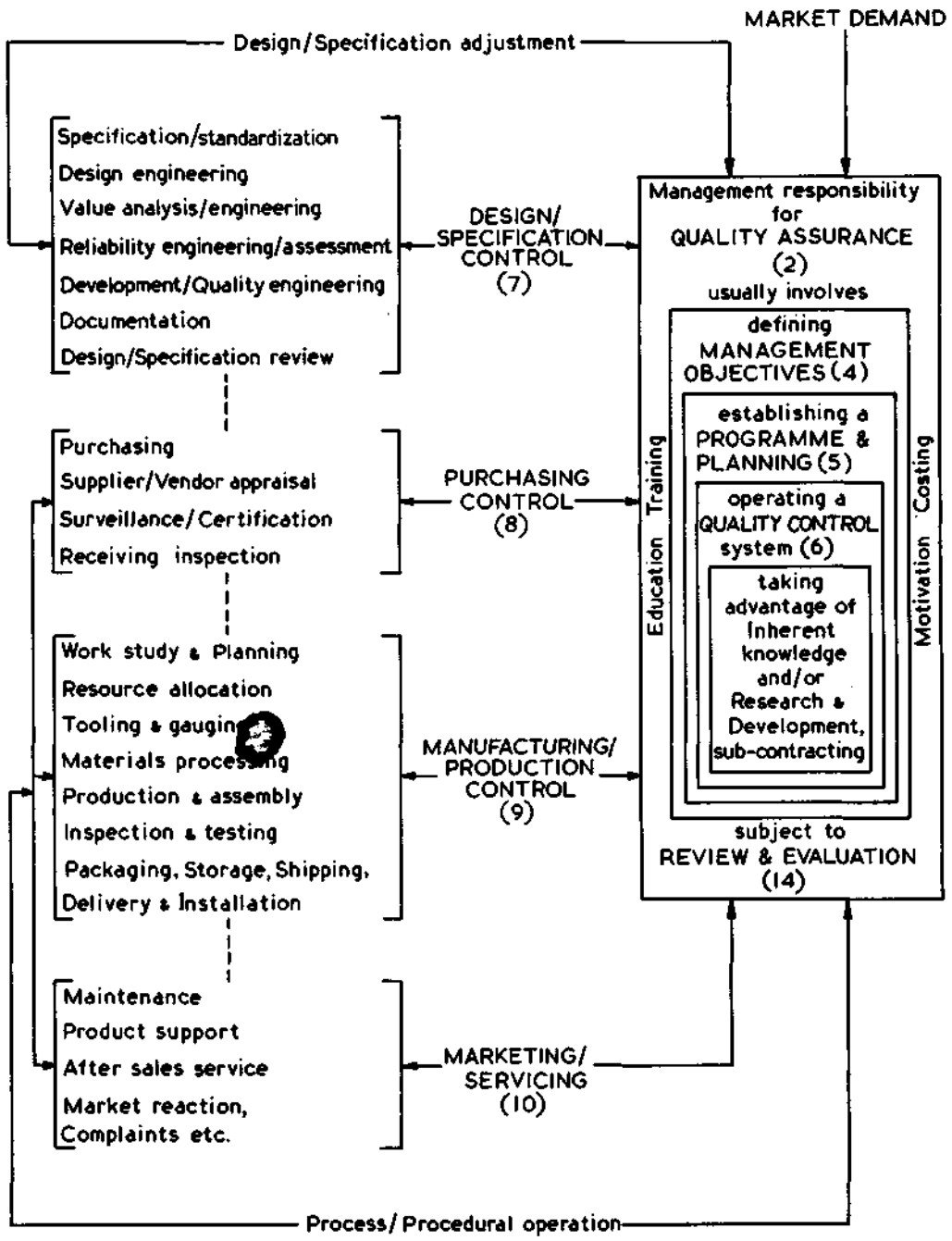

Fig. 1. Some basic elements involved in quality assurance

NOTE 1. The above diagram is intended as an example only, of probable inter-relationships and lines of communication. It should not be taken as indicating any form of precedence either vertically or horizontally or as implying that any particular organization will necessarily need to so organize itself.
NOTE 2. Figures shown in brackets refer to the relevant clause numbers in this guide.

finished article. In such situations suppliers may be expected to provide objective evidence, perhaps in the form of development engineering or production test reports, that the specification requirements will be achieved. For their part, the purchasers must define clearly their own requirements, preferably in the form of a specification, detailing desired functional and operational characteristics and environmental conditions. Alternatively, a purchaser might advantageously specify requirements in accordance with established national or international standards or develop an agreed specification in conjunction with a supplier.

A major task of management is that of persuading personnel to have the correct attitude of mind towards quality; to behave in a manner which is not always 'the easiest'; and to remember that 'prevention' is usually less costly than 'cure'. Management for their part can assist this process by ensuring adequate definition and communication of their objectives, leading to the establishment of the programme for quality assurance which can provide the basis upon which periodic reviews and evaluations may be made after taking account of essential data feedback.

In the majority of small companies overall responsibility for quality assurance rests with the chief executive, but irrespective of whether quality specialists or quality departments are established, executive management is ultimately responsible for making balanced judgements, assessing the significance of variations in this sphere and taking decisions. In arriving at such decisions the quality and personal integrity of staff are of fundamental importance and management should ensure that each person in the organization (1) understands that quality assurance is important to his future, (2) knows how he can assist in the achievement of adequate quality, and (3) is stimulated and encouraged to do so (incentives).

It is emphasized throughout this document that the supplier is responsible for providing goods or services in accordance with specification. It is also emphasized that a precise specification is required whether or not this is submitted by the purchaser, developed jointly by the purchaser and the supplier, developed by the supplier on behalf of the purchaser or developed by the supplier to satisfy potential or existing market demands. Such provisions require adequate communication to ensure:

(1) that the supplier knows what is required of him;

(2) that he is capable of doing what he is required to do;

(3) that he understands his responsibilities and undertakes to meet them;

(4) that he can be seen to have done so.

The supplier, whilst maintaining a systematic approach, should be sufficiently flexible in the procedural sense not to be adversely affected by chance variations, such as changes in key personnel, materials obtainable etc., which might impair his ability to fulfill specified requirements. The nature of industry and commerce is such that the roles of supplier and purchaser are continually being reversed. However, the criterion of 'value for money' is usually the major factor governing choice, acceptance and satisfaction, to all concerned (see Appendix A).

A guide to quality assurance

1. Scope

The intention of this document is to provide *general* guidance on activities and functions concerned with the attainment of quality. Every effort has been made to deal concisely with the fundamental issues without becoming too involved in particular aspects, some of which are referred to in the appendices. This guide is in no way intended to give exhaustive coverage of this subject but it is hoped that it will provide some assistance, particularly to newly developing companies and organizations currently reappraising their function in society.

2. General principles

2.1 The general pattern of events from conception to fulfilment of a need is similar for all undertakings, and the differences are usually due to size, complexity, the particular nature of the business in hand and the degree of assurance required to have confidence in the satisfactory completion of one activity prior to initiating the next.

2.1.1 The *need* has to be recognized, stated and all relevant features and characteristics and their criteria specified, defined and communicated to those concerned, or otherwise published.

2.1.2 The *means* by which the need is satisfied, the service or the product, and all relevant features and characteristics and their criteria have to be devised, proposed, and their feasibility demonstrated to those concerned.

2.1.3 The *arrangements* or the contracts for the supply of the service or the product, and any associated requirements, have to be devised, established, and communicated to those concerned.

2.1.4 The *ways and means* by which a service is to be given, or a product is to be manufactured and supplied and by which quality is to be ensured and verified, have to be devised, established, communicated, provided, maintained and applied.

2.1.5 The *methods* by which the service or product is to be used and maintained for the continuance of quality verified, have to be devised, established, and communicated to those concerned.

2.2 The success of any activity depends on having the proper aims or needs; on having, at the right time and place, proper and adequate resources (e.g. capital, information, methods, materials, men, tools, handling and measuring equipment, environment etc.) to enable the activity to be carried out and its effectiveness to be verified; on having adequate and proper facilities (e.g. management, organization, authority, communication, co-ordination, logistics, planning, programming, analysis etc.) to enable the activities to be carried out smoothly and efficiently; and on the proper use of all such resources and facilities.

2.3 The success of any undertaking, scheme, process, project, business or enterprise, directed to the fulfilment of a need, depends on the collective and individual success of its several activities and functions, of which some are concerned with the attainment of the quality of the service or product and hence directly affect success, while the remainder are concerned with enabling and ensuring that the direct activities can be, are being and have been effective and hence have an indirect effect on success.

Thus, all activities and all functions in any undertaking, and all personnel engaged in them, are concerned with the attainment of quality and are inherently involved in quality assurance.

NOTE 1. Typical functions are planning, procuring, buying, selling, feasibility studies, contracting, research, design, development, production, inspection, testing, calibrating, delivering, installing, training, operating, maintenance, servicing, managing, retiability studies.

NOTE 2. Typical people concerned are users, customers, purchasers, salesmen, engineers, technicians, programmers, assemblers, craftsmen, foremen, managers, inspectors, testers, consultants, operators, manufacturers, stockists, dealers, consumers.

3. Definitions

For the purposes of this guide the terms and definitions given in BS 4778 apply.

NOTE. The following glossaries also provide useful related information.
BS 3138 'Glossary of terms used in work study'
BS 4335 'Glossary of terms used in project network techniques'

4. Management objectives

4.1 As companies grow in size and divide it becomes possible for different departments to pursue their own objectives, which may not necessarily aid the overall objectives of an organization in satisfying purchaser requirements. The precise definition of management objectives is closely linked with the market where the need has to be satisfied. Thus a knowledge of the market with regard to quality, quantity, time and costs is required before taking the essential basic decisions.

4.2 Management should pay particular attention to specifying the overall objectives of an organization and should ensure that these are brought to the attention of all personnel concerned for their implementation. In the hierarchy of decisions concerned with the control of an organization basic decisions are of prime importance in activating the development cycle, stimulated by market requirements, leading to the establishment of a programme and planning for quality assurance. As more decisions are taken the scope or area of flexibility decreases and consequently the number of mistakes which may be remedied also decreases. In the more advanced stages of development it becomes increasingly difficult to apply modifications to the complex as a whole, for example, well constructed buildings, poorly located below flood level and lacking essential services (e.g. drainage and power) are likely to remain permanently deficient.

4.3 It is often said that 'quality cannot be inspected into a product, it must be manufactured into it'. This statement pre-supposes that the specification and design are adequate to satisfy the given need but, if we are unable to make such an assumption it will be realised that an inadequate design or specification (caused perhaps by incorrect calculation of dimensions, specification of unsuitable materials, or failure to make adequate provision for operational and environmental conditions) will rarely lead to an adequate product being supplied even when the finest manufacturing and production control methods are in operation. The provision of an adequate design is consequent upon a sound programme and planning and pre-supposes that the correct basic decisions have been taken initially by management.

4.4 Effective management for quality assurance should be clearly prescribed, and delegated personnel should be given both the responsibility and the authority to identify and evaluate quality problems and to initiate, recommend or provide solutions. A management representative, preferably independent of other functions, should be appointed with authority to resolve matters pertaining to quality. This should not be construed as meaning that management must assign responsibility for the fulfilment of this recommendation to a single division, department or person, although a large proportion of existing organizations now have quality and/or inspection departments that are concerned primarily with quality matters. These departments alone cannot satisfy the overall requirement and many other departments in an organization contribute to the quality efforts. Some of the organizational aspects related to quality assurance are referred to in Appendix C.

5. Programme and planning

5.1 **General.** Management should establish and maintain an adequate overall programme for quality assurance, which is planned and developed in conjunction with other functions and is capable of being effectively and

progressively reviewed. The programme and planning form the link between the functional necessities of market demand and the technical and economic possibilities of supply. In the larger type of organization it is possible that this inter-disciplinary function may be initiated and co-ordinated by a management services unit or project planning office. In many cases, and particularly in small organizations, management, after taking the basic decisions, places this responsibility on the design function. In such cases management should ensure that the design function has sufficient resources to perform such a task. Where established separately, standardization and/or quality departments usually assist with this work.

NOTE. Fundamental information on standardization and variety control is given in PD 3542, 'The operation of a company standards department'.

5.2 **Programme.** The programme should define the system of management necessary for quality assurance and indicate the intended proceedings from conceptual design through to post delivery services, including education, training/motivation and costing procedures. A complete programme might contain definitions relating to operational ability, capacity or life span on the one hand, and the possibilities of production and distribution on the other hand. To establish such a programme, numerous decisions have to be taken involving such factors as the types, sizes and ranges of products to be manufactured (or services provided). Of paramount importance is the need for quality to be defined effectively to give adequate confidence of achievement either in terms that are agreed contractually with an individual purchaser or as judged to be required by the general market. The programme can thus form a basis for the subsequent development of:

(1) functional specifications;

(2) product specifications and/or designs;

(3) manufacturing/production specifications/instructions;

(4) quality manuals and plans;

(5) review and evaluation procedures.

5.3 **Planning.** One of the main objectives of planning is to identify any special or unusual contingencies/requirements. If such requirements are found there is often a need for feasibility studies and planning to be undertaken to ensure the provision of appropriate resources. In such cases planning should precede the initiation of the appropriate operations and provide for reviews to assure compatibility between the programme requirements and affected manufacturing operations, processes and techniques. A management's quality assurance programme is incomplete unless it is planned and developed in conjunction with other functions such as research and development, production engineering and sub-contracting. In this respect the use of project network techniques and work study can prove useful (see BS 3138 and BS 4335).

Management should conduct during the earliest practicable phase of design/specification development, a sufficiently extensive review of target specification requirements to ensure:

(1) The timely identification and acquisition of any controls, processes, inspection equipment, fixtures, tooling and skills (personnel) that may be needed to ensure product quality.

(2) The up-dating of inspection and testing techniques including the development of new instrumentation and calibration of existing equipment.

(3) The compatibility of manufacturing and inspection procedures and applicable documentation before production is commenced.

(4) The deployment of appropriate resources for the design and production of the product or service.

(5) The feedback of data is no more than is necessary to optimize results and minimize costs.

6. Principles of control

6.1 All control requires the establishment of a standard for the means of comparison, the assessment of conformity with the standard, and the application of suitable corrective action where necessary.

6.2 The general pattern of events is similar in all the applications of quality control and any differences are due to the size and the nature of the business in hand.

(1) An *assessment* or measurement of the quality of a product or service is carried out by comparison with established criteria or standards.

(2) The *acceptance* of the product or service if deemed satisfactory.

(3) The *rejection* of the product or service if deemed unsatisfactory.

(4) A *review* of rejected products or services to determine causes of failure and sources of error, to recommend suitable corrective action to the product or the service, to the resources, to the facilities, to the processes and to the design which led to the unsatisfactory product or service.

(5) *Action*, as necessary and as deemed suitable, to bring the quality of the product or service to that required.

(6) *Verification* that the recommended and applied action has fulfilled its aim.

6.3 The collective success of quality control depends on having an adequate system, organized and managed to ensure that all proper information, resources and facilities are provided and are properly used and that all activities are carried out in an economic, efficient and effective manner.

7. Design/specification control

7.1 **General.** Quality must be designed into a product before manufacture by the translation of purchaser requirements (which should be detailed in the programme) into practical designs and specifications that permit production, maintenance and servicing to be technically and economically feasible. Irrespective of whether purchaser requirements are fully detailed in the programme, management should ensure that the design function is given adequate information concerning:

(1) minimum functional requirements;

(2) maximum environmental expectation;

(3) cost limitations;

(4) safety and reliability requirements.

7.1.1 The design function is fundamental to the creation of product quality and it is of paramount importance that all concerned should be agreed on the quality aspects of the design and/or any resulting specification which should be unambiguous and adequately define acceptance and rejection criteria i.e. appropriate levels of quality. The usual cycle of events is:

(1) functional specifications;

(2) product specifications and/or designs;

(3) manufacturing/production specifications/instructions.

NOTE. Depending upon the nature of the organization, the involvement of the design function in (1) and (3) may vary appreciably and in the larger type of organization (3) may be the responsibility of the manufacturing/production function.

7.1.2 During this phase it should be realized that failure to take *full* account of environmental conditions, or simple errors of judgement can have far reaching consequences and usually have a greater effect on quality generally than poor workmanship e.g. a design error reaching production undetected will affect all of the commodity being produced and will probably necessitate additional retooling costs. Conversely, a fault or error in manufacturing is usually recognized at a stage where perhaps only 10 per cent of production is affected. In general terms the quality of a design is determined by:

(1) The degree to which the functional requirements included in the programme have been expressed in the design.

(2) The degree to which the specification requirements have been realized.

(3) The degree to which the design permits rational production and marketing.

(4) The efforts made to attain a reasonable life (or failure rate) with low maintenance costs.

7.2 Detail design. It is of prime importance that acceptance and rejection criteria are *specified* at this juncture e.g. material and system requirements, limits and fits etc. While it is implicit that tolerances should be sufficiently close and precise to the extent that the required level of quality is assured, tolerances on manufacturing and testing parameters should be no more stringent than necessary. Waste of usable but theoretically out of tolerance items adds to overall costs. However, unduly restrictive tolerances on dimensions can create requirements for machine capabilities or operator skill and time beyond that which is really essential.

7.3 Manufacturing/production specifications. Manufacturing/production specifications including drawings, heat treatment/material specifications etc., should be compiled in conjunction with other departments involved e.g. manufacturing/production, development, tooling etc. and the quality control system employed should provide for the detection and resolution of dimensional discrepancies, irrational tolerance limits and incomplete, ambiguous or conflicting requirements which form part of specified requirements or which are prepared as a result of such requirements.

7.4 Safety. Many sectors of industry are now subject to legislation which places certain constraints on design which must be taken account of prior to the manufacture of products for sale. Irrespective of this, a manufacturer or supplier can be held responsible in common law for distributing products which present hazards to the public (if professional negligence can be proved). Certain risks, e.g. cutting edges of knives or folding parts of deck chairs, are commonly accepted; however, with the advent of more complex equipment the design function should endeavour to recognize factors that may have concealed danger potential. As far as possible such elements should be eliminated from the design or the equipment should be made in accordance with 'fail safe' principles, for example, when a hazard is imminent the appliance should immediately cease to operate pending the correct positioning of a machine guard.

7.4.1 The increasing use of new materials and 'performance' specifications can present certain safety problems for designers, e.g. although mechanical performance figures quoted for metallic and non-metallic items may be identical, a non-metallic component may additionally require a flammability test if used at elevated temperatures, whereas a metallic component might require corrosion tests if used in adverse climatic conditions.

7.4.2 It should also be recognized that whilst certain hazards may be readily accepted in the manufacturing or servicing fields, it is unlikely that they would be tolerated in the domestic sector where technical knowledge cannot be assumed e.g. with regard to young people. Although the provision of additional safety devices may increase the basic costs of an item, this cost can sometimes be counter-balanced by increased sales if sufficient attention is drawn to these features in the marketing/servicing field.

7.5 Reliability. Purchasers are tending to demand a more comprehensive specification of goods and services they wish to purchase, such that not only do they require to be informed of how a product should be used and/or maintained, they also require some indication of how long they can expect it to remain servicable and the rate at which random failures may occur (primarily because of the financial implications involved i.e. its cost effectiveness).

7.5.1 Reliability (one of the measures of quality) exists as a characteristic of a product from its inception to the end of its working life. The creation of reliability lies essentially in the sphere of design and on products where this is of prime importance appropriate requirements should be included in the quality assurance programme. Traditionally, satisfactory reliability has been achieved by the evolution of design procedures, codes of practice or methods of working which have been shown by experience to give good results. Consequently, the vast majority of products in use today are usually referred to as 'reliable' or 'unreliable' in the qualitative sense.

7.5.2 The specification of quantitative requirements can involve a design function in attempting to cater for a very large number of variables leading to the expression of the reliability as a probability. Many of the practical problems associated with this subject are referred in the following series of Drafts for Development.

DD 10 Guide on the reliability of engineering equipment and parts. Introduction
DD 11* Guide on reliability programmes for engineering equipment and parts
DD 12 Guide on reliability of engineering equipment and parts
DD 13* Guide on assessment of reliability for engineering equipment and parts
DD 14 Guide on specification of reliability for engineering equipment and parts
DD 15* Guide on the collection and flow of reliability data for engineering equipment
DD 16* Guide on the presentation and interpretation of reliability data

*In course of preparation

7.6 Development. Although tests to destruction are neither possible nor feasible with certain products, one of the more successful ways of ensuring the quality and in particular the reliability of systems, equipment and parts is by the application of development engineering (research and test work), where attempts are made to simulate actual operational and environmental conditions on test specimens representative of the envisaged or actual product.

7.6.1 Particularly when used in the preventative rather than the assessment sense (where simple models and test rigs may be utilized) development can be most rewarding especially where the quality assurance function is working in conjunction with design, development and perhaps value engineering functions to monitor and feed-back the necessary data as a basis for future modifications.

7.6.2 Value analysis, value engineering and quality engineering are all concerned with the application of appropriate scientific and technological skills to achieve the desired quality at an acceptable cost. Once a product has been designed and tested for production, a considerable amount of capital has already been spent and consequently savings made by the application of value *analysis*, devoted essentially to reducing the intrinsic value of existing designs, can prove insignificant especially if the reliability of the product is sacrificed to this end. Quality and value *engineering* derive additional benefit and economy from co-operation with all related functions at an early stage.

7.7 Design/specification review procedures. Design/specification review procedures can take many forms and additional information in this respect is given in Appendix B. In small organizations it is perhaps only feasible to appoint a design assessor or checker who should analyse the design on the following lines:

(1) Does the design/specification include all customer requirements?

(2) Does the design meet functional and operational requirements?

(3) Is the design satisfactory for all expected environmental conditions?

(4) Has data on similar designs been reviewed?

(5) Have standard parts been utilized wherever possible?

(6) Are drawing and specification tolerances achievable in production?

(7) Does the design minimize installation problems?

(8) Does the design minimize maintenance problems?

(9) Has value analysis been utilized sufficiently?

(10) Have necessary safety precautions been included?

(11) Has aesthetic image or appearance of the product been considered?

8. Purchasing control

8.1 General. It is rarely sufficient for a supplier to control only the work done at his own plant as very few manufacturing businesses are self-contained to the extent that their products are made at a single location from basic materials through to end products. The supplier (or purchaser in this case) is responsible for ensuring that all supplies and services procured from his suppliers and sub-contractors conform to the specified requirements. Consequently, he must ensure that effective controls are exercised and this responsibility may include monitoring or surveillance by his staff at the suppliers' and/or sub-contractors' plant.

8.2 Purchasing data. The purchaser has the right to receive that which he has specified, but he in turn must make clear to his supplier/vendor/sub-contractor, precisely what is required:

(1) the type, class, style, grade or other precise identification; or

(2) the title or other positive identification and the issue date or number, where applicable, of specifications*, drawings, process requirements, inspection requirements or other relevant technical data.

*Attention is drawn to PD 6112, 'Guide to the preparation of specifications'

8.3 Supplier/vendor appraisal. As the quality of products can be more easily controlled at the point of manufacture or assembly, purchasers should assess potential suppliers before orders are placed and wherever possible, measure their performance in complying with the requirements of specification(s). This grading or assessment of the suppliers quality control procedures and performance should be done on a continuous basis, so that the resultant vendor assessment will give a rating for comparison purposes and assist the buying office in performing its function.

NOTE. An established standardized scheme of supplier/vendor appraisal is a part of the BS 9000 scheme for electronic components of assessed quality. A summary of the requirements of this scheme is given in PD 6436, 'A guide to the BS 9000 scheme'.

8.3.2 There is, in many fields, a trend away from placing sole reliance on incoming inspection towards a more rigorous assessment of the supplier's ability to satisfy the purchaser's needs. This cannot be derived solely from the check inspection of a small sample from a product batch, but involves also continuing surveillance of the supplier's quality organization and procedures. Alternatively, such evaluation and surveillance might be carried out by an independent third party in the form of certification schemes which can be particularly advantageous where standardized products (both in the national and international sense) are involved. For organizations which may not be able to build up elaborate vendor/vendee relationships, third party certification can provide the purchaser with an assurance of conformity to specification of ex-stock items that might be required at short notice from several different sources. The impartiality provided by such schemes can be mutually beneficial especially where equipment subject to safety legislation is involved; however, such schemes do not replace the need for management to review and evaluate continuously its own system for the assurance of quality although it can provide a useful assessment and confirmation in certain respects.

NOTE. The Kitemark certification scheme operated by BSI is an example of such a scheme which gives an assurance of compliance with a British Standard. It involves surveillance of production under a system of supervision, control and testing, including periodical inspection of the manufacturer's works.

8.4 Receiving (incoming)inspection. . In determining the amount and nature of inspection applied to delivered products, consideration should be given to the controls exercised at source and the objective evidence provided. If a supplier or vendor has an effective quality control system, the purchaser may reduce his goods-inward inspection. It should be apparent, however, that the purchaser's knowledge of a supplier's or vendor's quality stems primarily from proven performance, the records the supplier/vendor furnishes and any previous assessment. Receiving inspection should thus complement and supplement source quality control, rather than ignore it, or duplicate it unnecessarily.

9. Manufacturing/production control

9.1 General. The manufacturing/production function is responsible for producing goods in accordance with the production specification which should have all acceptance/rejection criteria adequately defined.

9.1.1 Management should ensure that manufacturing operations are carried out under controlled conditions. The omission of any particular operation or process from the scope of such control invites inferior quality. Ineffective, incomplete or intermittent control can lead to costly and unnecessary defects. For this purpose adequate communication is indispensable. Accordingly, manufacturing operations should be defined to the greatest practical extent by appropriate work instructions and work should be accomplished as specified in these instructions.

9.2 Process/material control. Process quality controls should be applied to all materials, production processes and equipment being used in the manufacture of products in order to attain specified requirements. Procedures should be provided to ensure that all materials to be used in manufacturing processes conform to the requirements of the specification.

9.2.1 The manufacturer should establish and maintain a system for the identification, preservation, segregation and handling of all material from the time of receipt through the entire production process. The system should include methods of handling that prevent abuse, misuse and deterioration.

9.2.2 Secure storage areas or stockrooms should be provided to isolate and protect material pending use. To detect and prevent deterioration, material in stock should be inspected periodically for condition and also to ensure that the shelf life has not been exceeded.

9.2.3 The supplier should arrange for the protection of the quality of his product during transit. As far as is practicable he should ensure the safe arrival and ready identification of his product at its destination. This includes the requirement for sub-contractors to exercise equivalent control on materials they use and the protection of items they supply.

9.3 Process capability. Every operator, machine or process has inherent variability and the extent of this variation is referred to as its process capability. Consequently, there is a need for management to:

(1) Establish the process capability of work methods in order to ascertain whether a job can be accomplished satisfactorily.

(2) Establish the process capability of existing plant and where necessary the need to bring it up to specified requirements.

(3) Control and monitor process capability on a continuous basis to detect and eliminate potential causes of non-conformance.

NOTE. Apart from satisfying quality requirements process capability data is of importance to other departments such as design, work study (industrial engineering) and rate-fixing.

9.4 Production tooling, gauging and test equipment. Management should recognize the influence that jig and tool design can have on the cost, design and feasibility of production. All production jigs, fixtures, tooling, templates, patterns, gauges and test equipment should be proved for accuracy prior to release and thereafter should be adequately stored between use and checked at stated regular intervals to ensure their continuing accuracy.

9.4.1 The accuracy of measuring instruments and gauges must be verified at appropriate intervals by comparison with certified reference standards. Information about this may be obtained from either the National Physical Laboratory or the British Calibration Service.

9.5 Inspection. The manufacturer should provide a system of inspection to ensure that specified requirements are satisfied. Many inspections are normally performed throughout a manufacturing process either for the purposes of process control or to ensure the acceptability of quality characteristics that cannot be observed or measured at a later point in the process. In addition, it is customary to perform a final inspection and a test of the completed item to obtain an overall measure of its conformance with requirements stipulated in terms of item performance.

NOTE. For general guidance see PD 6452, 'Guide to inspection procedures'.

9.5.1 *Type of inspection.* This may be accomplished in a number of ways, such as by machine operator (i.e. operator control), automatic inspection gauges, production line inspection stations, patrol inspection or by any combination of the above. Two basic methods may be utilized, namely:

(1) *Inspection by attributes.* Each unit of product inspected is classified as 'acceptable' or 'defective', e.g. GO or NO-GO gauging. The degree of 'acceptability' or 'defectiveness' is not taken into account, whereas

(2) *Inspection by variables* takes the *degree* of 'acceptability' or 'defectiveness' into account and operates by considering the measurements made.

9.5.2 *Indication of inspection status.* The manufacturer should establish and maintain a system for identifying the inspection status of material during all stages of manufacture. The manufacturer should be able to distinguish between inspected and uninspected material by using some suitable identification media such as stamps, tags, routing cards, or other control devices. There should be a positive way of knowing at all times whether a product has:

(1) not been inspected;

(2) been inspected and accepted; or

(3) been inspected and rejected.

9.6 Sampling procedures. Sampling procedures, when properly employed, provide a set of useful and economical tools for objectively estimating the level of quality or achieved control of a process with a minimum of effort. Where safety is of critical importance (e.g. aircraft structural components), 100 per cent inspection of certain items may be essential but this cannot ensure 100 per cent certainty due to possible equipment/personnel variability; consequently, factors of safety are applied in such cases. One hundred per cent inspection is not possible in many cases (e.g. functional tests on explosives) then some form of sampling inspection is essential.

9.6.1 Most sampling schemes relate sample sizes to batch size because of the prime need to ensure a representative sample, which becomes increasingly more difficult as the batch size increases. Accordingly, the penalty for rejecting a 'good' batch, or accepting a 'bad' batch, based perhaps on insufficient sample data also increases. These risks, due to sampling, which apply to both producers and consumers, *cannot* be completely eliminated although they can be accurately assessed by statistical techniques.

9.6.2 Statistical quality control, which may involve single, double, multiple, sequential or continuous sampling schemes, can be used to determine whether a process or manufacturing operation is 'in' or 'out of' control and thus enable appropriate action to be taken. It is advisable to have at least someone in an organization trained in the use of statistical methods.

NOTE. The following British Standards which relate to the more general application of statistical methods provide practical guidance on this subject.

BS 600 Application of statistical methods to industrial standardization and quality control
BS 1313 Fraction-defective charts for quality control
BS 2564 Control chart technique when manufacturing to a specification, with special reference to articles machined to dimensional tolerances
BS 2635 Drafting specifications based on limiting the number of defectives permitted in small samples
BS 2846 The reduction and presentation of experimental results
BS 6000 Guide to the use of BS 6001, sampling procedures and tables for inspection by attributes
BS 6001 Sampling procedures and tables for inspection by attributes

Further information on BSI publications concerning the application of statistical and sampling techniques in particular sectors of industry can be found in the BSI Yearbook.

10. Marketing/servicing

10.1 General. The marketing and servicing functions form the direct link with the customer and as such provide the main channel for the feedback of market reaction to goods and services supplied. Advantage should be taken of information available from these sources but care must be taken not to accumulate superfluous data and thus create analysis problems which can result from ill-conceived surveys and questionnaires. It is prudent to seek professional advice regarding the confidence expectations prior to submitting anything other than the simplest type of request for information to the market, otherwise much time and goodwill may be dissipated at considerable cost.

10.2 Marketing. Besides carrying out the prime function of selling a product or service in accordance with management objectives, the marketing function should also assist with the development of the quality programme by identifying market requirements at various quality levels (e.g. as seen in the automobile and clothing industries). Management should ensure that:

(1) Production/manufacturing expertise and related functions are fully consulted and their commitment obtained confirming their ability to satisfy any suggested quality level.

(2) Marketing is fully aware of the financial implications of offering to supply modified (non-standard) products.

(3) Market research takes account of user requirements such as environment, life expectation, wear and tear aspects, probable user abuse, government/legislation requirements, national and international standards, codes of behaviour and significant preferences.

(4) Cost estimates from all major functions engaged in a project are studied prior to pricing a product.

10.3 Servicing. Dependent upon the type of goods or services supplied, the programme may need to include:

(1) the provision of technical documentation and education for the user;

(2) planning and provisioning of adequate stocks of spare parts;

(3) preventative and/or corrective maintenance to keep equipment operable (e.g. cleaning, lubrication, repair etc.);

(4) the provision of skilled and prompt attention to all complaints.

11. Documentation

11.1 General. Although normally successful systems of administration and control are well documented it is important to remember that excessive paper work is counter-productive and simplicity plays an important part in the creation of efficient operational procedures. For example, rather than continually repeat details of practices commonly understood by skilled personnel in work instructions it is more economic to provide such details *solely* in a job description to which reference can be made.

11.1.1 Management should establish and maintain control of all appropriate documentation (including drawings) essential to the accomplishment of work at the design, production, inspection, delivery and post delivery phase.

11.2 Work instructions. Work instructions should be developed and maintained to prescribe the performance of all work that would adversely be affected by lack of such instructions. These written instructions should not only be created and brought to a satisfactory state and put into use, but should also be subject to continuing evaluation for effectiveness and adjusted as necessary. They provide a basis for control, evaluation and review and without them differences in policy and procedures can arise and variations in practice may occur resulting in confusion and uncertainty. Further to this, they provide means for delineating work to be done and for delegating authority and responsibility.

11.3 Modification control. All changes to documentation should be in writing and processed in a manner which would ensure prompt action at the specified effective point, indicating whether the modifications are (1) retrospective, (2) immediate or (3) to be carried out at some later point in time. Management should maintain a record of changes as they are made and ensure observance of the rule that notations written on *copy* documents do not authorize departure from the original. Documents (including drawings) should be re-issued after a practical number of changes have been made. Provision should be made for the prompt removal of obsolete documents from all points of issue and use.

11.4 Records. Management should develop and maintain records necessary to demonstrate the effective operation of the quality control system employed and to provide objective evidence of product or service quality.

11.5 Quality manuals. Quality manuals that set out the general quality policy and practices, or the rule book by which the organization for quality functions, can also provide useful aids for such purposes as training (e.g. complementary to works instructions), or marketing, especially if the *consequences* of modifications necessary to satisfy particular customer requirements are emphasized (e.g. costs of deviating from standards). Additionally they can provide:

(1) Information from which the purchaser may derive confidence in the supplier's organization (useful for supplier/vendor appraisal).

(2) An indication of the responsibilities and inter-related activities of personnel and functional groups.

(3) A vehicle for auditing, reviewing and evaluating the management and/or quality control system.

11.5.1 *Compilation of quality manuals.* Quality manuals should be so designed that provision is made for up-dating on a continuous basis, which is facilitated if the document is a concise statement of the basic quality assurance procedures without being too involved in more detailed aspects (e.g. general work instructions are normally included as examples only). Dependent on the type of functions involved this may necessitate:

(1) A part containing details of more permanent general policy, practices and organization – usually given wide circulation.

(2) A part giving a more detailed account of normal procedures for quality assurance, possibly containing specific examples and details of resource allocation (including personnel) – sometimes given a restricted circulation.

(3) A part containing particular quality plans setting out specific quality practices and activities relevant to a

particular contract or project – usually given a restricted circulation.

Irrespective of the type of basic structure, a quality manual should include:

(1) A section describing the whole range of communications, responsibilities and controls, with which every department must conform to achieve the quality objectives. This section should state in general terms the quality assurance functions and relevant responsibilities allocated to various managers and departmental heads. It is usual to illustrate these inter-relationships with organization and/or functional charts.

(2) Sections describing briefly the quality control procedures during design and development, with illustrations of how liaison with the design and research departments is maintained, including feedback of information of any corrective action which may be needed.

(3) Sections describing briefly the quality control procedures during production, together with a brief description of inspection procedures and statistical methods used (where applicable).

(4) A section dealing with customer liaison (where appropriate).

(5) Sections describing the organization and procedures for suppliers' quality assurance and vendor assessment.

(6) A section describing review and evaluation procedures.

The above is in no way intended to be exhaustive, e.g. sections might also be needed to deal with installation, servicing, maintenance etc.

12. Defect/failure analysis and remedial action

12.1 General. Poor work methods or non-compliance with work instructions are frequent causes of defects and failures in service. Often poor design or inadequate specifications are the cause. As the need indicates, remedial action requires:

(1) changing unsatisfactory designs, specifications and work methods; or

(2) enforcing compliance with satisfactory designs, specifications and work methods.

Prompt, effective, remedial action is essential to a sound quality programme and the segregation of unacceptable material from acceptable material is rarely sufficient.

12.2 Defects. Defects or defectives relate to items not conforming with the requirements of specifications, which are the responsibility of the supplier or the manufacturer. Sometimes they are classified for inspection purposes based on safety aspects, 'critical', 'major', 'minor' etc. (see BS 6001), or on costs.

12.3 Failures. The concept of 'failure' is primarily related to 'reliability' (the measure of quality in the time domain), which in general, concerns performance in service, normally under the control of a purchaser rather than a supplier or a manufacturer. Consequently, the classification of failures can be of particular importance not only for determining causes, but also for the allocation of responsibility for corrective action. In engineering, failures are sometimes classified under the following headings:

(1) cause (misuse, inherent weakness, primary, secondary, wear out failures);

(2) suddenness (whether or not it could have been anticipated by prior examination):

(3) degree (partial, complete, intermittent failures).

12.4 Analysis and remedial action. Classification of defects and failures can aid subsequent analysis of data accumulated and the allocation of total costs as appropriate. Management should:

(1) Establish a continuing analysis of rejected products or services to determine the cause, areas of responsibility and action required, e.g. scrapping, reworking, concessionary procedures etc.

(2) Establish a continuing analysis of service reports, customer complaints, or general product support/after sales service (maintenance) department data to ensure that the performance of the service is in line with market requirements, or alternatively, that quality standards are not in excess of such requirements.

(3) Ensure that those responsible for corrective actions accomplish their intended purpose at all levels and in all departments with the necessary authority and responsibility in this respect.

Appendix A

Economics of quality assurance

One of the basic management problems is to strike an optimum balance between the cost and value of quality assurance. Facts on certain costs of quality assurance are usually obtainable from accounts departments via data on scrap, defectives re-worked, and necessary replacements. Facts on the value of quality assurance as it affects the sales or competitiveness of a product or service are more difficult to evaluate since factors such as loss of goodwill caused by the marketing of defective or inadequate products can have a delayed reaction with disastrous consequences. Sometimes these costs are subdivided in terms of:

(1) appraisal costs;

(2) prevention costs;

(3) defect (non-conformance) costs;

(4) failure (in service) costs.

Fig. 2 illustrates the economics of quality assurance assuming a constant basic manufacturing cost. To the left of the optimum, opportunities to effect better quality have been missed such that the losses due to defectives, etc. are higher than the cost of the solution and in this region 'better' quality assurance costs less.

To the right of the optimum the costs are uneconomical due to 'perfectionism' and in this region the cure is perhaps worse than the disease so that 'better' quality assurance costs more.

When national security or prestige is involved, the intangibles are assigned enormous value and conventional economics play only a minor role. However, most industries are subject to the forces of conventional economics and an obsession with 'perfectionism' can lead to a mutual increase in costs, whether or not it is due to over-zealous quality specialists or some public authorities who may not be fully accountable for keeping costs within reasonable limits.

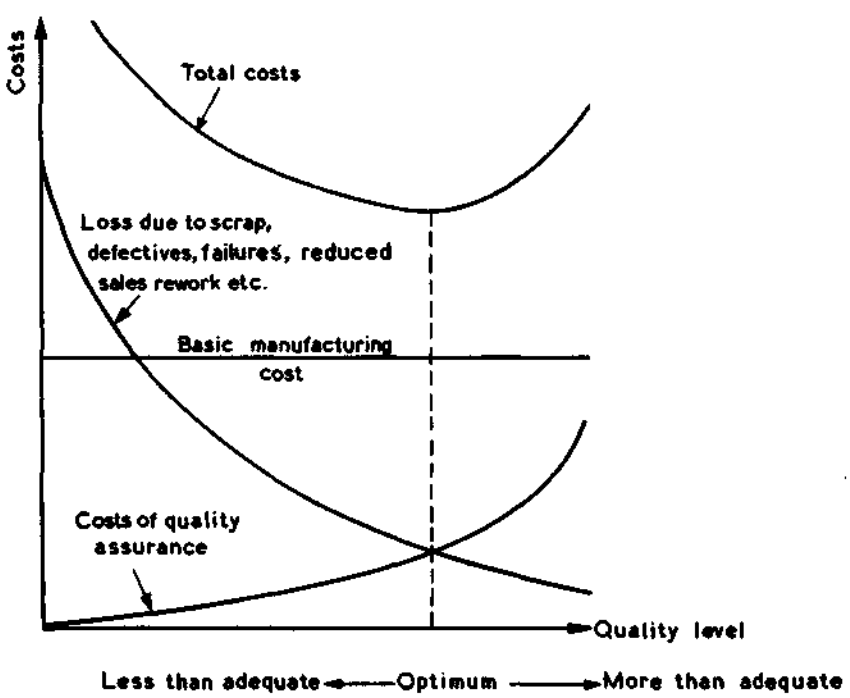

Fig. 2. Economics of quality assurance

Appendix B

Design/specification review procedures

Design/specification review procedures can prove advantageous both for the supplier and the purchaser, particularly on large scale projects where it may not be possible to prove the design by comprehensive development engineering or research work. Review procedures can differ significantly between different industries, companies or groups but one definition of this function accepted by many reads as follows: 'A design review is a formal, documented and systematic study of a design by specialists not directly associated with its development. It hastens the maturing, within cost limits, of all elements of a design – function, reliability, value and appearance.'

The prime objective of design/specification review procedures is to provide a *preventative* evaluation rather than a conformity (post-mortem or inquest type of inspection) or purely control function. Secondly, it can encourage constructive participation of an optimum design without usurping the responsibility of the design function.

Depending upon the type of organization and product under consideration, it may prove necessary to institute three stages in the design/development cycle from initial conception to the issuing of manufacturing instructions, specifications and drawings to a production department.

(1) *Preliminary reviews* held at the time of product concept and planning proposal, bid, or request for funds, and also when contract or authorization is received.

(2) *Intermediate reviews* held when the following are completed: block or function diagram; energy flow design; mechanical design; styling and development model tests.

(3) *Final reviews* held when material lists and drawings are complete or when pre-production units are tested and analysed.

The constitution of any design review panel should be limited to the minimum number able to discharge the objectives. Apart from the chairman (usually the engineering or technical manager), it is usual to have constant membership from the quality and/or reliability department, specialists on development engineering, value analysis and work study, as well as the design engineer(s) responsible for the product in question. Representatives from the purchasing, tooling, manufacturing, marketing and service departments might attend as appropriate and customer representatives would normally attend a final design review. As a corporate body it should be able to evaluate and constructively criticize a design. In this respect it is important that the responsibilities of each panel member be formally set out and thoroughly understood.

A review is normally initiated by the chairman who will generally wish to appoint a secretary from within the group to deal with procedural matters, such as the preparation and circulation of terms of reference, calling notices, agendas and minutes of the meetings indicating what actions needs to be taken, by whom and by what specified date.

Following completion of a review it is usual for a final summary report to be submitted to the engineering executive which should record the recommendations made and any modifications subsequently incorporated in a design. It should be emphasized, however, that final authority for design decisions rests with the design engineer and his design manager, although in cases of dispute it is not unusual for the general manager or managing director to act as a final arbiter.

Appendix C

Some organizational aspects related to quality assurance

There are many schools of thought concerning the basic types of organization necessary to achieve desired quality objectives, which in most cases cannot be divorced from the overall management objectives of an organization. Lessons can be learned from the instances of well established organizations being liquidated, primarily as a result of particular or singular failures in the quality sphere which in many cases were a combination of shortcomings in the programming, planning, design and development fields (e.g. optimistic forecasting and tendering based on insufficient development engineering and proving of a design), rather than in the production/manufacturing field.

Although case studies of similar organizations can provide useful information, it can be dangerous to imagine that 'success stories' are universally applicable, as operating conditions are rarely exactly comparable. Case studies also tend to suffer from obsolescence due to changes in market conditions and previous trends. In making use of these types of comparisons, management needs to fully appreciate the critical nature of some of the differing factors involved and to decide what reliance can be placed upon the assumptions made and the specialized techniques used.

Systems of organization are usually found to be made up of one or more combinations of the following:

(1) grouping of personnel according to occupational level (normal 'line' management);

(2) grouping of personnel according to subject of specialization;

(3) grouping of personnel according to project (each new product);

(4) grouping of personnel according to same phase of each project.

Such existing groupings are likely to be a governing factor as to whether or not a specialized quality department needs to be established. In this respect the interpretation of terminology can lead to difficulties. Where the term quality *control* department has been adopted, a tendency to place undue emphasis upon the word 'control' can lead to interdepartmental difficulties which may eventually guarantee non-co-operation if other departments suspect there is a move to usurp their function. It should be appreciated that:

(1) Responsibility for the design and specification of a product rests *primarily* with the design/engineering department.

(2) Responsibility for producing goods to specification rests *primarily* with the manufacturing/production department.

It is rarely sufficient just to change the name of an established inspection department to quality control or some similar title and assume that the quality objectives of an organization will be attained. This is not to say that the inspection function wherever it is operative within an organization is not important since it provides essential measurement parameters for use by both management and quality specialists (should they be appointed). Currently, there is some controversy as to whether the inspection function should be centralized or decentralized within an organization since certain approval organizations stipulate that, 'contractors' inspection departments shall in no way be under the control of the production/manufacturing executive.' The counter argument to this is that it implies that those responsible for production are not interested in the quality of the products they produce and ignores the fact that ultimately the inspection department and all others report eventually to the Chief Executive in an organization who is surely concerned with productive output.

Many recent investigations suggest that the main aim should be an integrated approach with the involvement of inspection or quality control departments with manufacturing wherever possible e.g. checking first off and machine setting or regulation of sampling procedures, which although dependent upon operator control should be checked by inspection or quality control departments. It is felt that this should lead to the realization that it is a production department's duty to manufacture goods to specification and to offer for approval only those that are conscientiously believed to be good. It is not the inspector's function to apply his own standards but to work to unambiguous specifications, and should such specifications be available and proper systems evolved, this can lead to increased operator control with the inspection or quality control department being mainly concerned with monitoring checks and maintaining metrology equipment.

It is extremely difficult to strike a correct balance between the more centralized or decentralized approaches, but before making any changes in an organization it is advisable to list the present functions and duties of existing departments and personnel to ensure that any shortcomings are not due to a lack of job definition or a problem of inadequate accountability (sometimes caused by divided responsibility).

Charts in the form of organization trees are readily available in most organizations. Such charts generally show *only* the division of work and delegation of authority and do *not* show the working relationships such as the flow of information, liaison co-ordination and integration of effort which are essential for the functioning of a successful enterprise. Over-emphasis of the principle of the 'division of labour' within an organization can lead to departmental isolation, the erection of hardly discernible internal barriers, lack of communication and organization efforts being dissipated in internal friction. Function charts (similar to Fig. 1) can provide details of the interaction necessary within an organization.

Much current theory suggests that management should provide for decisions to be taken at the lowest possible level in an organization, consistent with its objectives, enabling increased participation and involvement of personnel rather than the development of 'us' and 'them' attitudes. This does not absolve management from

needing to recognize apparently insignificant problems, sometimes dismissed as irrelevant details, the cumulative effect of which can be much greater than apparently important decisions taken at a higher level. Examples of this are defective minor components causing the breakdown of large expensive capital equipment or a commercial department being made *solely* responsible for the pricing of a product.

The increasing use of computers and mechanization in the design and management field seems unlikely to overcome the problems of organization. The opposite appears more likely as an even greater specialization in the use of knowledge is likely to be demanded and with this, more complexity of work to be co-ordinated. Managers and engineers are therefore likely to become more and more concerned about the position of the individual within the system and how to achieve effective systems.

The scope and intensity of the education and training given for quality assurance appears to be another governing factor as to the type of organization established, both in the national and corporate sense, but here again the need for balanced judgement of the centralized or decentralized approaches is obvious.

Where training has *not* been limited to specialists and has been extended to managers at all levels, supervisors and even non-supervisory staff, co-ordination of quality assurance activities is usually carried out by the line supervisors and managers in the regular chain of command. Accordingly, in this case, the role of any quality specialist is mainly in reviewing (auditing) and consulting and there is less of a tendency to establish numerous quality specialists or large (centralized) quality assurance or quality control departments.

Where intensive training in quality control methods has been largely restricted to specialists, e.g. quality control engineers etc., the dominant organization forms usually feature a strong (centralized) quality assurance or quality control department, well trained in its speciality, but sometimes difficult to co-ordinate with other departments because of the disparity in training. This is mainly because little has been done to train managers, supervisors or specialists in other functions and usually there has been no training of non-supervisory staff in quality control methods.

In the majority of countries, companies, and organizations, the training schemes adopted lie somewhere between these two extremes and usually no particular pattern is discernible. This is hardly surprising in view of the diversity in the size and type of existing organizations, the influence of which may change in particular locations depending on the standard of labour available. Where a centralized quality assurance or quality control department has been established it usually has authority for taking action or giving advice on quality matters in the following areas:

(1) marketing/servicing;

(2) design/specification/standardization;

(3) value analysis and reliability assessment;

(4) research and development engineering;

(5) documentation;

(6) purchasing and vendor assessment;

(7) incoming material and materials control;

(8) pre-production and production controls;

(9) metrology and test equipment calibration;

(10) quality control, inspection and production test procedures;

(11) feedback of service difficulties and complaints;

(12) defect analysis and remedial action;

(13) quality cost measurement;

(14) education and training for quality assurance;

(15) review and evaluation of management system for quality assurance.

The execution of the majority of the quality assurance functions listed above should remain the direct responsibility of the individual departmental managers concerned and these aspects have been emphasized in earlier parts of this document. Rather than attempt to usurp these responsibilities, a quality department manager should advise and assist on all quality tasks and monitor and co-ordinate them throughout an organization wherever possible. The following activities are likely to be the direct responsibility of a quality department manager:

(1) developing the quality assurance programme and quality manual;

(2) incoming and defective materials control;

(3) metrology and test equipment calibration;

(4) quality control system operation;

(5) defect/failure analysis;

(6) quality cost measurement.

In addition, a quality department manager might be required to carry out the training of staff throughout the company in matters relating to quality assurance, or to co-ordinate such training schemes.

BSI publications referred to in this standard

This standard makes reference to the following British Standards and special publications;

BS 600 Application of statistical methods to industrial standardization and quality control
BS 1313 Fraction-defective charts for quality control
BS 2564 Control chart technique when manufacturing to a specification, with special reference to articles machined to dimensional tolerances
BS 2635 Drafting specifications based on limiting the number of defectives permitted in small samples
BS 2846 The reduction and presentation of experimental results
BS 3138 Glossary of terms used in work study
BS 4335 Glossary of terms used in project network techniques
BS 4778 Glossary of general terms used in quality assurance
BS 6000 Guide to the use of BS 6001, sampling procedures and tables for inspection by attributes
BS 6001 Sampling procedures and tables for inspection by attributes
BS 9000 Electronic components of assessed quality
PD 3542 The operation of a company standards department
PD 6112 Guide to the preparation of specifications
PD 6452 Guide to inspection procedures
DD 10 Guide on the reliability of engineering equipment and parts. Introduction
DD 11* Guide on reliability programmes for engineering equipment and parts
DD12 Guide on the reliability of engineering equipment and parts
DD 13* Guide on assessment of reliability for engineering equipment and parts
DD 14 Guide on the specification of reliability of engineering equipment and parts
DD 15* Guide on the collection and flow of reliability data for engineering equipment
DD 16* Guide on the presentation and interpretation of reliability data.

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* In course of preparation

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