

## **AN INTRODUCTION TO QUALITY ASSURANCE AND A GUIDE TO THE IMPLEMENTATION OF BS 5750**

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This paper introduces the philosophy of Quality Assurance and traces the development of the British Standard for Quality Systems - BS 5750. The key components of the Quality System are covered and there is a discussion on how to choose a Quality System which is most appropriate to the needs of the particular organisation. A comprehensive guide (including flowcharts) is also given which addresses the nature and scope of tasks which must be undertaken in implementing a Quality System commensurate with the requirements of a recognised international standard such as BS 5750.

### **QUALITY ASSURANCE - AN INTRODUCTION**

The concept of seeking a guarantee in return for goods or items exchanged is not new. In fact, the well-known phrase 'my word is my bond', still in use today, is a form of guarantee or assurance that an agreement reached or an obligation undertaken will be honoured. Guarantees in respect of items purchased (in exchange for money) are usually not verbal agreements but take the form of signed receipts, which imply that items bought will be fit for the purpose for which they were advertised or intended and that someone is accountable if they fail to live up to those expectations.

Of course not all items which we purchase come with a guarantee - we regularly buy food items for example from the local supermarket which come with no such guarantees. In this case we trust that the appropriate food manufacturer has been inspected by the relevant authority to a standard which ensures that we as the consumers do not suffer any ill effects as a result of consuming the items. On the other hand, electrical items where there is an element of safety involved usually come with a guarantee which not only assures the working life of the item but also states that it was manufactured to a specific standard.

#### **The Evolution of National Standards**

Naturally, there is no merit in claiming that an item meets a specific standard unless those standards are recognised by all as being adequate measures of quality. In response to the need for nationally recognised measures of quality and performance, so-called National Standards Organisations were established and charged with the responsibility of developing just such agreed national standards. There are in existence today many such national bodies and literally hundreds of products for which recognised standards have been set.

The familiar 'Kite Mark' of the British Standards Institution was in fact introduced as a form of consumer protection signifying (to members of the public) that items have been manufactured to an appropriate British Standard. In essence the Kite Mark is a form of product certification.

However consumers were not the only driving force behind the introduction of national standards. As early as Victorian times it was recognised that some form of standardisation was required for the survival of British industry and industry 'norms' or standards were set for criteria such as for screw threads, pipe diameters and so on. Commensurate with the development of these standards came the concept of 'inspection' and specialist organisations such as the Institute of Engineering Inspectors (incorporated in 1922) now renamed The Institute of Quality Assurance, were established to fulfil this role and check that products were being manufactured to agreed norms and standards.

### **The Rise of Quality Assurance Standards**

As the complexity of industrially manufactured products grew, so did the requirements for inspection and certification. The situation became particularly unwieldy with the passing of two world wars and with the increasing sophisticating of military and aerospace products. In the United States, in particular, where a large number of complex engineering projects were underway (with components being obtained from many different suppliers), there were problems of late supply, incompatibility and component failure.

As a result, it was recognised that some form of overall management control and co-ordination was required and a number of Military Standards (MIL Standards) and in the UK subsequently Defence Standards (DEF STAN 05-21/1 - 'Quality Control System Requirements for Industry') were drawn-up specifically for this purpose. These initial military specifications were in reality the forerunners of the modern Quality Assurance Standards. They were significant in that they enabled an important distinction to be made between the previous Quality Control / inspection environment and a new concept for ensuring overall quality and control - Quality Assurance.

It was not only in the military and aerospace industries that there was a recognition that the old inspection-based systems were no longer totally adequate. In Great Britain, the large nationalised industries at that time (e.g. British Gas, British Rail, The Coal Board, British Steel etc.) were seeking a system whereby they could be assured *up-front* that any goods or services that they bought would be delivered on-time, within budget and to a pre-defined level of Quality. As large consumers, these purchasers recognised that a system of Quality Assurance could provide them with the guarantee they needed (prior to committing funds) and they were to a considerable extent instrumental in the introduction of Quality Assurance to British industry.

### **British Standard 5750**

Following the production of a Government White Paper on the subject, a British Standard for Quality Assurance (BS 5750 'Quality Systems') was published in 1979. It contained a description of the controls which it prescribed were required to be instituted in order for a supplier to claim that it was a 'Quality Assured' Organisation. In the same way as with the registration of products to a particular standard, an organisation could not be accredited to BS 5750 unless it had been inspected (and formally accredited) by an independent authority (such as the British Standards Institute) against the standard.

In contrast to the Kite Mark (which is a method of product certification), BS 5750 is a form of company certification. The standard specifies all those 'elements' of the management system which are seen to be critical to the quality of the final product and describes how these elements are to be controlled.

Although its initial adoption by industry was quite slow, a number of organisations have now implemented Quality Systems commensurate with the requirements of BS 5750, although its predominance in the engineering sector remains. In fact, BS 5750 has been increasingly criticised for its continued focus on the engineering / manufacturing environments - which a quick glance at the index of the standard will show. In more recent years, in particular, a number of non-engineering and service sector organisations have recognised that the philosophy of Quality assurance is in fact applicable to every organisation and have sought a more broadly based guideline or standard.

In an effort to accommodate the views of these other industry sectors, a number of QAS (Quality Assurance Schedules) have been produced to augment / amplify the standard. Schedule no. 8 for example, is written specifically for the Service Sector industries and contains some additional requirements and guidance on the interpretation of the standard's requirements for these organisations. In 1987 the entire standard was revised and republished and its format was significantly amended. The text is now identical with that of its equivalent International and European Standards - ISO 9000 and EN 29000.

BS 5750 is due for another major renewal in 1996 and there *is* currently some interesting discussion underway as to its most desirable format and scope. It should be noted that the Nuclear Industry has for some time had its own Quality System Standard. In the UK this is BS 5882 ('Specification for a Total Quality Assurance Programme for Nuclear Power Plants'), which is similar in philosophy to BS 5750.

### **The Philosophy of Quality Assurance**

There are a number of ways in which the concept or philosophy of Quality Assurance could be described. The term 'Quality' is defined in British Standard 4778 ('Quality Vocabulary') as "*The totality of features and characteristics of a product or service which bear upon its ability to satisfy a given need*". As we have seen, 'Quality' in today's terms is also synonymous with meeting customer needs and expectations, that is the concept of 'fitness for purpose'.

The term 'Quality Assurance' might then best be described as a philosophy or concept whereby all those activities and functions which have an impact on the quality of the final product are controlled and managed, i.e. "*All those planned and systematic actions necessary to ensure that a product or service will satisfy a given need*" (BS 4778). To enable the concept of Quality Assurance to work in an organisation therefore requires translating this philosophy into a practical system or framework of management control.

In the first instance, the level of quality that is to be achieved must be defined. In cases where products (such as manufactured items) have a British Standard specifying appropriate levels of quality, this may be a fairly straightforward exercise. In the case of a service-sector industry such as 'consultancy' or 'health care' it will be more difficult. Secondly, there must be a practical and achievable plan for attaining the desired level of Quality. This is sometimes referred to as the Quality Assurance Programme. Finally, there must be a system for ensuring the maintenance of that initial level of quality - a Quality Management System. The Quality Management System must be demonstrable (so that potential customers can see how the company plans to maintain the level of Quality) and therefore it must be documented and published.

The term Quality Assurance is often confused with the term Quality Control. The two are actually quite different. In contrast to a Quality Control System, where the quality of the product is measured or inspected as the production process progresses, a Quality Assurance System seeks to define *in advance* those management controls which must be applied and continually adjust these to ensure the adequacy of the *System* and thereby the fitness for purpose of the final product.

## **Basic Principles of Quality Assurance**

There are perhaps three basic principals of Quality Assurance that underline its overall philosophy. These are:

**1) Quality is everybody's business** (each person has a specific quality-related responsibility).

**2) Get it right first time** (on the assumption that 'prevention is better than cure' - a properly designed Quality System will have identified and anticipated all the likely problem in advance).

**3) Communicate and plan** (the real benefits of Quality Assurance come from operating in an organised and controlled environment - each person must be made aware of their specific quality related responsibilities and plan for these within their daily activities).

These principles have been described in the past as no more than 'common sense'. Any organisation which is successfully providing a product which is fit for purpose and a hospitable working environment for its employees should be paying some attention to these issues. Equally, one would expect some sort of formalised controls in place over quality or (at least) safety critical activities. However it is surprising how many organisations lack such a formalised structure of control. Often, in large organisations, it is not so much the fact that no one is paying attention to such issues, but more that everyone is doing it in a different way and the problem becomes one of overall co-ordination and integration.

In considering the scope of 'critical activities' which should be addressed by the Quality System, there is a lot of room for confusion. An organisation may choose only to control those activities pre-prescribed by a recognised standard (such as BS 5750). However, if the organisation is in a service sector industry, there are few (or no) such guidelines to follow, what then? What is the scope and breadth of the critical activities upon which the organisation should focus? At this point it is wise to consider the true purpose or motivation for introducing the philosophy of Quality Assurance to the organisation.

From a purely market-driven standpoint, one could argue that the organisation should only seek to control those activities which are dictated by the relevant Quality System Standard. However, taking this route will mean that not all activities within the organisation will be addressed, for example, 'marketing' which many would agree is an essential or critical activity, is not covered within BS 5750. Therefore a decision may be taken to use the standard as the guiding force but include a number of other (company dictated) activities. By introducing the requirements of the standard alone there will of course be a number of benefits - not least of which is registration, giving the company a significant marketing edge over its 'non-assured' competitors. There will also be a number of 'spin-off benefits from introducing BS 5750, for example, various anomalies or gaps in the management system will be identified and areas where significant improvements can be made will be highlighted.

However, it has been argued that a truly integrated Quality Management System should embody a wider brief than those aspects dictated by a specific standard alone. In this context, the exponents of TQM (Total Quality Management) are leading the way. They advocate that in order to realise the whole scope of improvements which may result from the introduction of Quality Assurance, it is vital to consider the whole organisation and not just those processes dictated by an external standard. Re-engineering of processes is a frequent outcome of TQM and this philosophy is already gaining a significant reputation for not only improving the quality of processes but reducing the unnecessary costs of inefficient practices.

In the final analysis, it is entirely at the discretion of the organisation itself to choose which route to take. The former may not involve such a large initial capital outlay but the rewards may be limited when compared to the second TQM-type approach.<sup>1</sup>

### **'Products' of the Quality System - Quality Manuals and Procedures**

The Quality Assurance System must be documented (and published) in order to achieve its objectives. Quality System Documentation must be distributed internally to staff (so that they are aware of their responsibilities) and certain items (i.e. The Quality Manual) are additionally distributed externally to customers. The Quality Manual is an important document and is one of the first items which an auditor or assessor will require if the organisation is to be formerly accredited (i.e. audited against a recognised Quality System standard).

The Quality Manual The Quality Manual is a documented statement or description of the organisation's Quality Programme and is officially defined in BS 4778 as "*A document setting out the general quality policies, procedures and practices of an organisation*". The contents of the Quality Manual will typically include:

- A signed policy statement from the Company Chairman or Managing Director outlining the organisation's commitment to Quality
- A list of responsibilities with respect to maintaining the Quality Programme
- A description of the mechanism in place to control those activities which potentially impact the quality of the final product.

The 'mechanism' for controlling the critical activities is an interesting point of discussion. It may take a number of different forms but the most usual is a series of written procedures.

Procedures The usual way of controlling activities within an organisation is through a system of formalised procedures. Procedures are the documented controls over critical activities and describe how an activity is to be performed and by whom. They should be written according to a standard format but there are a number of different ways in which they may be published. The particular style chosen is at the discretion of the company but must obviously be geared to the particular 'culture' of the organisation. For example, a number of companies choose to include flowcharts (of various types) within their procedures as these can be a useful way of drawing attention to the important activities while keeping the number of textual pages to a minimum.

Procedures are not the only way of controlling activities - training courses, company notices and signs, on-the-job training and supervision and of course - auditing are just some of the other methods of instituting control. Computer systems can even be thought of as a form of automated procedural control although it is unwise to entirely substitute the normal (manual) methods of control with these systems. Computers should be thought of as 'tools' -

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<sup>1</sup> It should be noted that BS 5750 is comprised of 6 individual parts, with 2 Introductory sections. The 6 principal sections are comprised of 3 'pairs' of specific requirements and accompanying 'guidance notes'. The 3 specific requirements are similar but are geared towards the differing complexities of activities that may be undertaken by a company. Part 1 is applicable to the most complex type of organisation and includes requirements for those companies engaged in 'design' activities for example. Part 3 is targeted at organisations who do not have a design function and therefore the standards requirements in this respect are not applicable.

they are useful ways of enhancing various processes but are not a substitute for manual control or adequate training.

### **Auditing the Quality System**

One of the most important ways of maintaining control of the Quality System is through the process of audit, the purpose and value of which can be summarised as follows:

- 1) Auditing provides objective evidence of the effectiveness of the Quality System.
- 2) Deficiencies and deviations in the Quality System (and its component parts e.g. procedures) can be identified and addressed before they become significant.
- 3) The audit process provides an opportunity to review the effectiveness of the current controls.
- 4) Auditing ensures the maintenance of any internal or external standards to which products and services are being delivered.

Formal Quality System documents (i.e. procedures) are fundamental to the auditing process because it is against the processes described in these documents that the Quality System will be audited. Any discrepancies will be highlighted and documented in the form of 'Corrective Actions' - which must be 'closed out' prior to the next audit being undertaken.

The introduction of a programme of internal audits is a requirement of BS 5750 and is fundamental to the philosophy of Quality Assurance since it is the method of ensuring that the Quality System is continuing to meet its objectives. It is also a requirement that auditors (personnel with stated auditing responsibilities) be specifically appointed by the organisation and trained so that they are suitably qualified to carry out their task. Training should be carried out in compliance with a recognised national scheme such as that administered by the IQA - The Registered Assessor Scheme.

### **preparing for the Implementation of BS 5750**

Before implementing BS 5750, there are a number of issues to consider. These will influence the nature and scope of the Quality System and include such issues as:

- What is the purpose of implementing a Quality Management System (e.g. to gain competitive edge, to cut the costs of inefficient practices, to tighten-up management control and so on)?
- What standard is to be used to define the scope of the Quality System and are there any accompanying schedules which need to be considered?
- Is the Quality Standard to be used for internal guidance only or is it a stated requirement of our customers.
- How will the Quality System be maintained, what scale of resources are to be apportioned to it?

Once these issues have been addressed, the actual process of implementing the Quality System can begin. The following section of this paper considers briefly some of the main activities (referred to as tasks) which must be undertaken.

## **BS 5750 - A GUIDE TO IMPLEMENTATION**

It is impossible within the scope of this paper to describe in detail every potential task or activity which may be required in implementing a Quality System. Naturally the precise sequence and scale of these tasks differs according to the particular organisation. The *main* tasks however are described below and depicted in flowchart form in Figures 1,2 and 3 which should be referenced by the reader in conjunction with the text.

Figure 1 (Quality Assurance Programme Implementation - An Overview) gives a complete overview of the major activities which are required in the implementation of the Quality Assurance Programme. It assumes that some form of formal accreditation is being sought (i.e. to a National Quality System Standard such as BS 5750). Each major task on the flowchart has been numbered and for ease of reference these numbers are referred to within the task headings.

### **Task 1 - Defining the Scope of the Quality Programme and Preparing a Costed Action Plan**

A detailed breakdown of the activities which require to be undertaken within the scope of this task are given in Figure 2 (Defining the Scope of the Quality System and Preparing a Costed Action Plan). The implementation of a Quality System costs money and in business terms, it is essential to make some estimate of the scale of resources which will be required to achieve this so that management can commit and plan for the necessary funds and resources.

The definition of what constitutes a 'critical activity' has already been discussed.<sup>2</sup> Taking the 'simplest' case (i.e. that the organisation wishes only to address those activities as dictated by the relevant standard) the requirement headings within the standard will still need to be interpreted into the activities actually undertaken by the organisation. Typically the activities undertaken by the company do not 'sub-divide' into the exact divisions (as specified by the requirement headings in the standard) and some form of cross-reference matrix may need to be drawn up.

When it has been established where activities representative of the standard's requirements are occurring within the organisation (and who is responsible), it is necessary to conduct a structured review of them. This is almost a pre-implementation audit, the purpose of which is to establish just how adequately these activities are *currently* being controlled. The judgement will, to a certain extent, be subjective and will also depend on the experience (and even the staff position) of the reviewer. The review should address such questions as:

- Are there any documented controls on the activity in question, what form do they take and are they adequate?
- Are the personnel responsible for this activity in possession of the relevant instructions and do they fully understand their responsibilities?
- Are there any problems associated with performing this activity and of what nature are they (ad-hoc or recurring)?

and so on.....

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<sup>2</sup> Note the remarks made in footnote number 1. The decision as to which Quality System Standard is to be used includes deciding which Part of that Standard is applicable.

Eventually a picture will emerge of where current controls on processes are inadequate and need to be improved. An estimate must then be made of the resources necessary to correct them. In some cases new or improved procedures may be necessary, the lack of adequate training may be a problem or there may be wider and more subtle issues to consider such as staff motivation and morale.

A checklist of necessary improvements will need to be drawn-up and a decision made as to how the necessary resources are to be provided. Questions which will have an impact on the budget for the Programme include:

- Do we have adequate expertise in house to correct the situation (e.g. to write the necessary procedures)?
- How will the exercise effect our production / cash flow?
- Are there any grants available which might help and what are the rules of applying for these? (e.g the DTI Enterprise Scheme)
- What form of external (consultancy) help might be appropriate?
- Should this external help be provided in the form of training' or tasks' ?

Finally, some form of costed action plan will need to be prepared for submission to management.

### **Task 2 - Obtain Management Approval / Commitment of Senior Staff**

Strong leadership and the commitment of management personnel are essential if the new Quality System is to succeed. Management approval is usually 'crystallised' in the production of an official Quality Policy Statement (signed by the Chairman or Senior Executive) which describes the intention of the organisation to adopt a Quality Assurance Programme and commit the necessary funds. A signed policy statement of this type is a necessary inclusion in the company's Quality Manual.

### **Task 3 - Implement the Quality Programme**

A detailed breakdown of activities to be undertaken in implementing the Quality Programme is given in Figure 3 (Implementing the Quality programme). The production of a statement of responsibilities and the appointment of an Action Team to lead the initiative are the first important tasks.

The statement of responsibilities should indicate those personnel who are specifically responsible for the assurance of quality within the organisation. There may be a dedicated Quality Manager, Lead Auditor, Assistant Auditors, Quality Control personnel and so on. In a small organisation, these responsibilities may not translate to dedicated individuals but at least the quality management and auditing responsibilities must be nominated to specific personnel and specified within specific Position or Job Descriptions and shown on accompanying organisation charts.

The Action Team may comprise those individuals actually charged with developing new procedures, writing job descriptions etc., or may be made up of personnel of a senior nature who have a steering committee function and are responsible for overseeing the status of the programme overall. The steering committee can perform a useful role by adjudicating on the scope and format of the necessary procedures which are to be developed.



Procedures should be prepared in a standard format and they must additionally be authorised by an appropriate signatory. The first issue of a procedure (and their ongoing amendment and distribution) must be strictly controlled. The Action Team will need to make a ruling (if there is no precedent from existing documents) on the format and content of such procedures and the authorisation process to be adopted.

Once the necessary procedures have been drafted, they must be issued to the staff and after allowing for a period to settle in, activities must be audited against them. A series of internal audits must be conducted, corrective actions identified and closed out. Throughout the implementation process, training is an important activity and may be necessary in the following topics:

- Quality Assurance • General Introduction
- Procedure Writing
- Auditing

Once there is a high degree of confidence that the relevant controls are in place, it is then necessary to consider which Certifying Authority to approach for formal accreditation - see Figure 1.

#### **Tasks 4.0 and 5.0 - Selection of the Certifying Authority**

There are a number of bodies who are certified to accredit organisations to BS 5750 and any relevant accompanying schedules. Organisations such as the British Standards Institute and Lloyds Register are accredited to assess companies in a wide range of different industry sectors, while other accreditation bodies have a more limited remit. The process of formal accreditation is quite involved and can be costly - depending upon the size and nature of the organisation. It is usually a good policy to prepare an Invitation to Tender (I.T.T.) for accreditation services. A firm estimate of the costs of the accreditation process should be gained and it is also useful to meet the various certification bodies to gain an insight into their methods.

After the initial assessment, the process of accreditation is in fact ongoing and a series of annual or biannual visits will be conducted as long as the company wishes to retain its accredited status. The scope of each individual assessment may be slightly different. In large organisations, it is usual for the certifying authority to focus on a sample of activities and rotate their focus of attention over the years. Certificates are issued at each assessment and provide 'accreditation cover' for the next immediate period.

#### **Task 6.0 - Conduct Programme of Internal Audits and Final 'Dress Rehearsal'**

Once the certifying authority has been chosen, a date will be given for formal assessment. One of the first items that the Certifying Authority will ask for is the Quality Manual and a list (or even copies) of the organisation's procedures. It is a requirement of the certifying authorities that the organisation has had a Quality System implemented for a minimum of two years before a formal assessment can be undertaken and accreditation granted. Naturally, one of the principal items of evidence of this fact is the record of all the internal audits undertaken and any corrective actions closed out.

Not surprisingly, it is one of the requirements of BS 5750 that there be a formal method (i.e. a procedure) for carrying out such internal audits. Most organisations have

supplemented this with a procedure to be followed in respect of external assessment or audit. It is usual to put this to the test in a 'dress rehearsal' so that any potential problems can be ironed out before the official accreditation takes place.

### **Tasks 7.0 and 8.0 - Undergo Formal Assessment and Obtain Accreditation**

The formal accreditation process may last 2 to 5 days and depends upon the size and complexity of the organisation seeking accreditation. If accreditation is awarded a suitable certificate will be prepared and issued. The certificate will clearly state to which part of BS 5750 the organisation has been accredited (i.e. Part 1,2 or 3). The organisation may obtain accreditation with conditions, in which case the certifying authority will need to revisit to ensure that these conditions or recommendations for amendment have been implemented or closed-out before unconditional accreditation is granted.

### **Task 9.0 - Publicise and Communicate**

When a company has achieved accreditation to a recognised standard, it is usual to publicise the fact. Where a particularly innovative Quality System has been designed or accreditation gained in a new sector of industry it may also be appropriate to apply for a British Quality Award. In a similar manner to the product Kite Mark (see earlier in this paper), there is a similar recognised symbol for accreditation to BS 5750. It could be thought of as a 'kite mark' for the company's management (or Quality) system and conveys a similar degree of confidence or understanding to potential customers.

Figure 1: Quality Assurance Programme Implementation  
An Overview

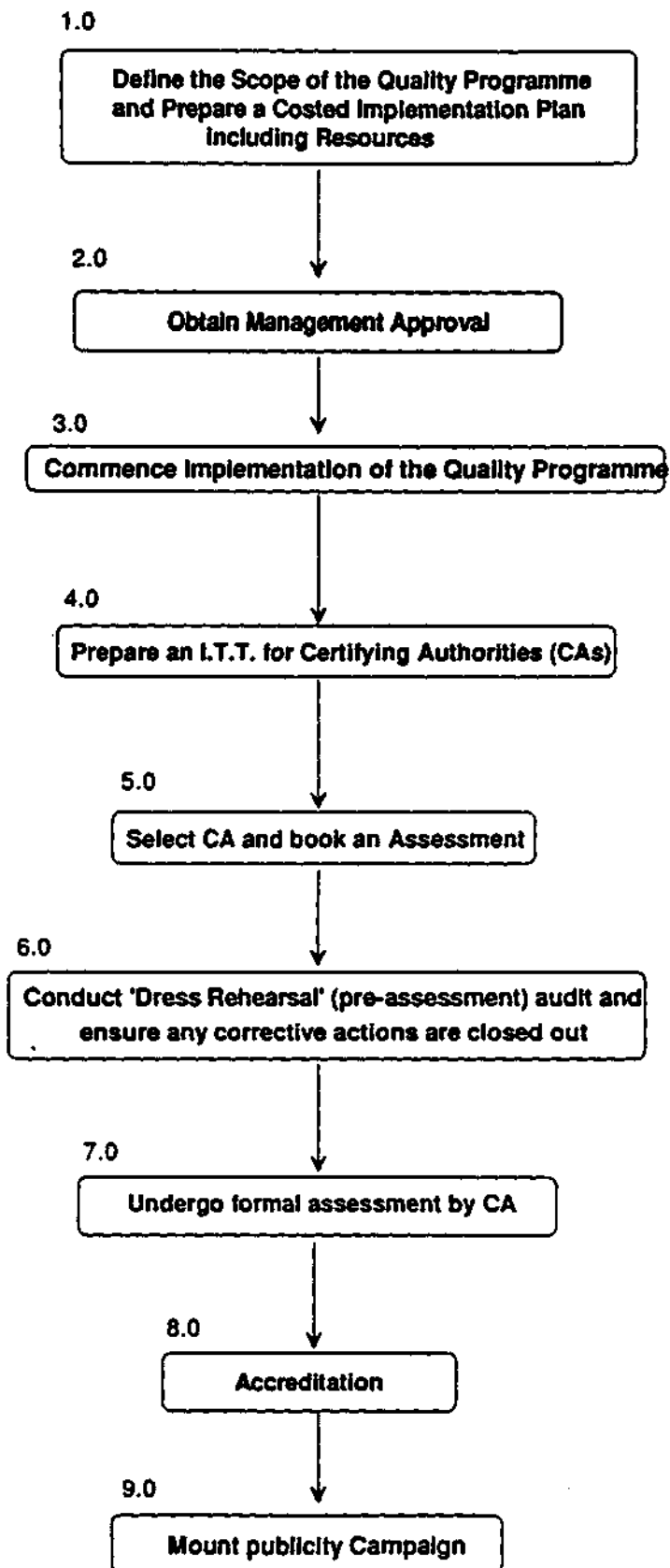


Figure 2: Defining the Scope of the Quality System  
and Preparing a Costed Action Plan

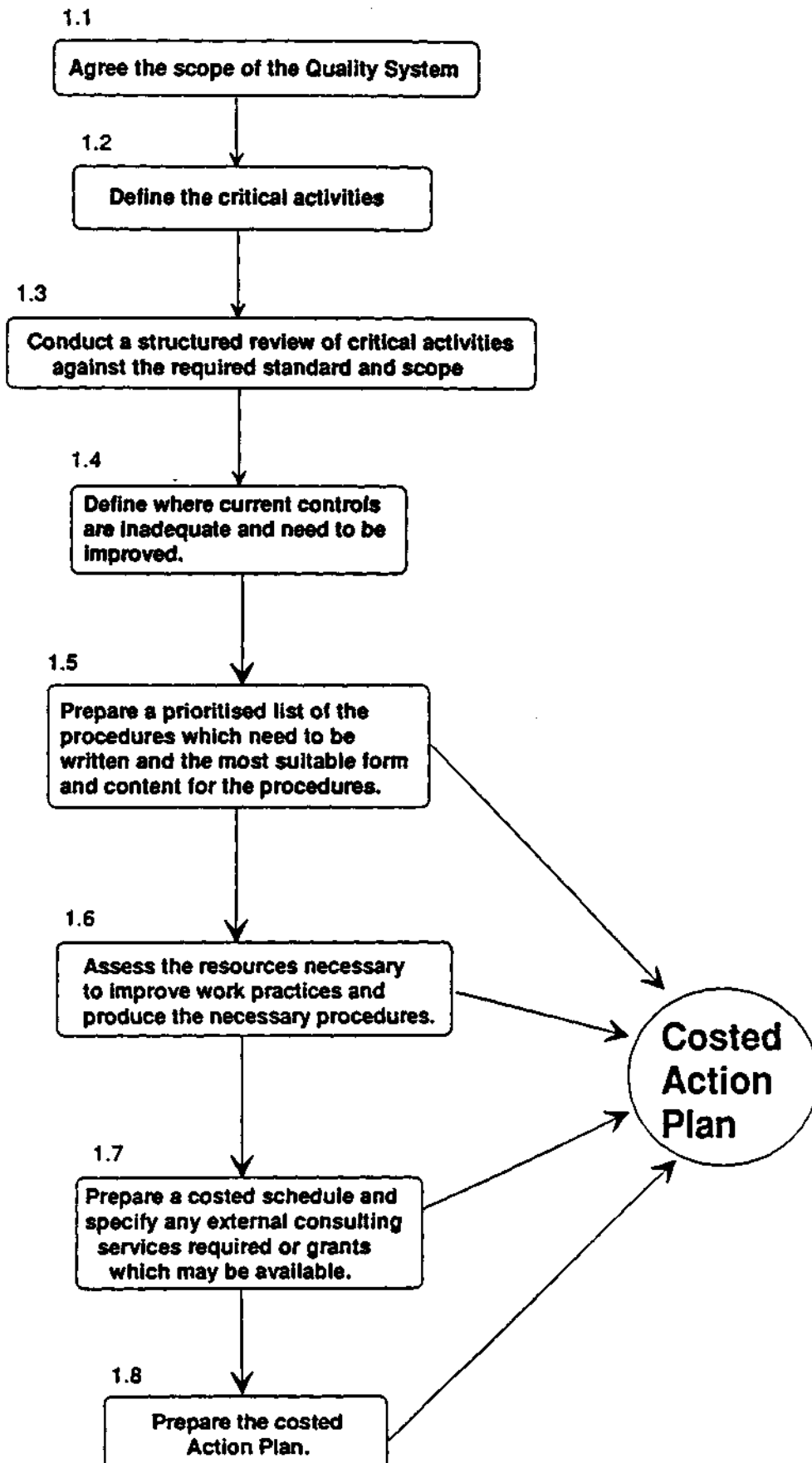


Figure 3: Implementing the Quality System - Typical Activities

