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Your Guide to Assessment

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Introduction

This guide has been prepared to help you:

a Document your system

b Prepare your Documentation

c Understand the MQA Assessment Procedure

d Understand the MQA Surveillance Procedure

a Documenting the system

The requirements for a quality system are contained in part in Section 3.6 of the relevant Standard and in detail in ISO 9001:2008 Section 4.2 Quality System. The key points to note in preparing your Quality System are:

1 The system which you develop for managing the quality of activities needs to be properly documented, with a structured description of the system, supported by more detailed policies, procedures and work instructions. All these areas need to be under adequate control.

2 The system, and therefore the documented description, needs to be related to the "specified requirements", which are usually the Customer or Market requirements for the product or service.

3 The procedures and instructions which describe how your activities are controlled must be checked to ensure that they are up to date, relevant and complete and that they are being implemented correctly.

4 You should be able to audit the system throughout your organisation against a procedure or work instruction.

5 The notes detailed under section 4.2.3 of ISO 9001 are a separate section which is referred to as Quality Planning. This is no different to Planning in the normal sense and your Procedures should identify how this is to be achieved in your organisation.

Notice that section 4.2 calls for Quality Plans and a Quality Manual; the latter is a mandatory requirement of ISO 9001. Most companies find it convenient to group together the key Quality System documents into such a manual, i.e. descriptions of the processes by which Business Plans, Marketing and Sales Plans are produced etc.

6 The Documented System is what a third party assessor, such as MQA, and your customers will compare you against. In other words, "I've read your Documentation and Procedures, now show me!". A common enough phrase but one which can lead to success or failure during any assessment.

7 We would suggest that you should retain a degree of flexibility within your operations to allow for changing market or customer conditions. Too much documentation, in too much detail will only create an additional workload when the inevitable requirement to change is identified. However, too little documentation and you may not be able to demonstrate that you have met the requirements of the external standards as well as your own. So a balance is required.

8 How you produce the documentation is up to you, be it on paper or on machine readable data, produced by a computer system. The chances are that most of what you are doing is already described in some way, to meet your current business requirements. Indeed, you should not have to do anything especially for MQA. The objective should be, don't re-invent the wheel.

9 A definition of Quality is that it should meet the need or requirement, this is also true with regard to documentation and how detailed it should be. It is important that you describe what actually happens and not what you think MQA might like to believe is happening. In constructing your documented Quality System it is useful to use, as a check list, a list of the requirements in ISO 9001 and the MQA Specification. Once you have finalised your Quality System and documented it we suggest you:

- Decide the scope and relevant standard and/or specification for which you require certification. Talk to MQA who will help you decide.
- Start the training and awareness of it.
- Do trial audits.
- Regularly review progress.
- Build up a relationship with MQA – ask them to do a trial audit.
- Set a realistic target date for assessment and publicise it to your staff – you will be amazed how it focuses people on the goal!
- If you have any queries, contact MQA who will be happy to answer them.

b Preparing your Quality Manual

The pinnacle of your documented Quality System will usually be the Quality Manual. Points to note are as follows:

1 This is the document that overviews the organisation and identifies the key processes applicable to the Standards and your own business requirements.

2 It is the document that can be presented to your customers to demonstrate your organisation's capability towards meeting their requirements. "Yes, we can meet your requirements and this is the system we use. We have the processes in place t6o ensure that you, the customer, will receive the best possible service from us".

3 It is also the document that gives an external assessor, such as MQA, an entry point into your processes and therefore the procedures that support them. Usually, cross references to the procedures is a method of achieving this.

4 The manual should be kept readable and able to withstand a certain amount of operational changes without major updates.

5 Having produced the manual, it should be sent to MQA, who will analyse it and see if what you describe would, in fact, meet the objects of ISO 9001 and, if relevant, the MQA Specification.

6 MQA will produce a report on your documented system and identify areas where there is a query or where it is believed that the objectives are not being met. The objective is to give you confidence that the described system is likely to meet the requirements. You can submit the manual as often as you wish.

7 In summary then, the Quality Manual overviews your organisation and provides the entry point into the processes.

Each process and its individual supporting functions should be capable of withstanding an audit commencing with a review of the Quality Manual. You should audit every process at least once before the MQA assessment.

C The Assessment Procedure

1 Before the assessment visit takes place, MQA staff will have agreed with you the number of sites to be visited, and will have informed you who the members of the assessment team are and their background. You may object to any member of the assessment team if you wish, rather like a jury system. You will not be asked for the reason for your objection.

2 The MQA representatives will inform you of any special requirements for the assessment team. Such requirements include the provision of a guide and a small office with desk, chairs and a telephone. A plan for the assessment visit will have been agreed with you, defining the size of the team, the elapsed time and the date at which the assessment visit will take place.

3 Before the assessment, MQA will have appointed a lead assessor who will normally, during the assessment, be present at your Head Quarters. Other members of the team may be visiting outlying sites or offices.

4 At the commencement of the assessment visit the MQA lead assessor will hold an opening meeting during which he will explain the purposes of the assessment, what is to be covered, answer any queries, confirm facilities are available, and establish target time scales for breaks, the duration of the assessment each day and the people the assessors would like to visit and speak to.

5 At this stage, he will offer you a final chance to object to any member of the assessment team. If you object, the assessor would be replaced without any question.

6 After the opening meeting, the assessors may request a brief tour of your office or facility if they have not visited it already.

7 After that the assessment will begin. Each assessor will be armed with the MQA Specification, ISO 9001 and, if relevant, assessment guidelines for your sector of business and should be given a copy of your documented Quality System (i.e, Quality Manual). Each assessor should be accompanied by a member of your staff who acts as a guide and observer.

8 The assessor's task is then two-fold. First to establish that you and your staff do what the documented system says that they do, and secondly that the methods, processes and techniques which are used relate to achievement of the objectives defined in ISO 9001 and the MQA Specification if it applies.

9 The assessment team will cover all aspects of your organisation and operation, covering everything from the management philosophy and systems through to detailed operations, including administration which relate to the scope of registration.

10 If the assessor find a difference between what is actually happening and what should be happening he will raise a discrepancy form. The discrepancy form will be completed, in the following manner. First the appropriate section of the standard or specification will be defined and a set of factual statements will be made which describe the differences between what should happen and what is happening. The guide who accompanies the assessor at all times should check hat what is written is factually correct, and if so, should indicate his agreement by signing the section of the discrepancy form which the assessor has filled in. The assessor may also make formal observations which will be written down.

11 At agreed times during each day the assessment team will hold a meeting with your representatives to review progress. The discrepancy forms which are raised by the assessors will be presented as proposed discrepancies. Your representatives will be invited to confirm that what is written on the form is factually true and secondly that it is indeed a discrepancy.

12 Once this agreement has taken place the discrepancy will be categorised into Major and Minor. A minor discrepancy is one where an isolated incident f a difference between what should happen and what is actually happening has occurred. A major discrepancy is one where the system which is designed to meet one of the objectives, in either the ISO 9001 Standard or the MQA Specification, is non-existent or has broken down, such that the objective is not being met.

13 Your system should be cost effective, therefore it is expected that there will be some minor discrepancies found, so you and your staff should not be concerned about this.

14 There is no score for minor discrepancies, with one exception. If a significant number of minor discrepancies are all reported against a particular section, then there may be prima facie evidence that the system which is designed to meet that objective is not working. A thorough investigation would take place to ensure that there was, or was not, in fact a major discrepancy in this area. If a major discrepancy is realised, then this of course means that registration would not be awarded.

15 The assessors will also present their formal observations which are intended to be helpful and not directly related to either ISO 9001 or the MQA Specification. They tend to come in three categories.

- The first is that there is something which is not a discrepancy now, but it may become one. An example of this is that of a small group of people working together very closely, and an informal method of operation involving verbal communication is in place. However, the business is likely to expand and such informal methods may not be applicable within the expanding unit.

- The second category of observation is one where another Standard may be the subject of scrutiny. Such Standards may include safety and regulation requirements.

- The third category is one which is intended to counter the rather critical nature of the identification of discrepancies. That is if a group or an individual appear to be doing a good job then the assessor may say so. It is often a morale booster for your staff to be informed that an outsider who has no axe to grind has commented favourably about them.

16 Once the discrepancies have been agreed then you are required to fill in the bottom half of the discrepancy form stating what actions you intend to take to clear the discrepancy in the timescale you set yourself. The timescale should not be too short, it should be sufficient to clear the discrepancy and ensure that it does not happen again.

17 During the assessment, team, who invariably have a background in commerce or industry, are sensitive to the possibility that people may be nervous and not be at their best. The objective is to observe your operation as it normally is, not under a period of great stress.

18 At the end of the assessment there will be a final meeting at which the assessment team present their finding. The team leader will sum up and announce the result. The result could be, if there was a major discrepancy, that registration will not be awarded. If minor discrepancies occurred then registration would be recommended, the qualification being that you would clear the discrepancies in the timescale you have set yourselves and agreed with the assessment team. A copy of the report of the assessment, signed by the assessment team leader and a representative of your company, will be presented to you by the lead assessor.

19 Having announced the result the assessment team will leave your premises and allow you to celebrate.

20 Within 10 working days, MQA will, if registration has resulted, send you a copy of the certificate of registration. A 'ceremonial' certificate is also available of which you may have any number of copies on request.

21 MQA will be pleased to help you publicise your success and this will be discussed after the assessment has been completed.

d After Successful Assessment and Registration

At the end of the assessment, the MQA assessor will agree with you the number of surveillance visits your organisation will receive during the year, with costing guidelines.

There may have been some minor discrepancies given during the original assessment. If so, you will be allowed an agreed period of time to make corrections. Shortly after this period has elapsed there will be another visit from one or more MQA assessors to ensure that the discrepancies have been cleared satisfactorily.

The surveillance visits by MQA are an independent audit of your organisation. Procedures, work practices etc, will be tested and a report will be given to your Company's representative. Any discrepancies will be recorded and agreed, as will the period of time allowed for correction.

As with the assessment itself, MQA surveillance visits, although testing, are an aid to keeping your business efficient and maintaining a quality system that conforms to the relevant Standard.

If you disagree on the validity of a discrepancy which at any time prevents registration, then you have a right to appeal to the Secretary of the Appeal Panel at MQA. Details are contained in the MQA Regulations brochure MQA B10.