Appendix D System Certification

Preview

This Appendix is aimed at all those personnel who will be involved in the certification process including top management and below.

In this Appendix we examine

- The reasons for seeking certification
- How to choose a certification body
- Factors to consider when preparing for certification
- How to deal with permitted exclusions from the requirements
- How to define the scope of registration
- How to handle the assessment
- How to deal with nonconformities
- How to use the certification to best advantage and avoid bad practices

Reasons for seeking certification

Being ISO 9001 certificated should make no difference to the way the organization is managed. If your organization operates in a sector in which it is well known, certification will add no value. But if your organization wants to win business from outside its community, from customers that have no knowledge of its capability, ISO 9001 certification might add significant value. It is therefore imperative that the approach you take to ISO 9001 is one that does not force you to do things that add no value.

If ISO 9001 is perceived as a requirement it is more than likely that it is your customers that demand certification in order that your organization may remain on an approved suppliers list or retain eligibility for receiving invitations to tender.

If ISO 9001 certification is not a customer requirement, there are perhaps a few benefits for some organizations

- The value of an independent audit of your management system

To the critics of ISO 9000

Until such time as every child leaving secondary education is equipped with the skills and knowledge to apply the principles of quality management, we have to make do with the crude tools we have and one of these is the ISO 9000 family of standards. They can help those people who don't have the time or the inclination to work out for themselves the right things to do by providing a prescription that experience has shown will reduce failure and improve quality when applied intelligently.

Every manager has the right to decline to do anything that cannot be shown to add value and it is the responsibility of consultants and auditors to behave professionally at all times by providing such justification.

There is no requirement in ISO 9001 that is mandatory. It is the complexity of an organization and the market in which it operates that will determine which requirements apply.

Where proven to apply, there will be few situations where an organization will not be applying or will not gain from applying the prescribed principles and practices to some extent.

The extent of application is at the discretion of the management. If they choose not to constrain the application of requirements it will more than likely result in an over bureaucratic system of documentation that stifles initiative and innovation. This is not the intent of the ISO 9000 family of standards and never has been. When used intelligently, it can help organizations towards sustained success.

- The pressure to formalise the management system
- The recognition that certification brings in the market place

There is no valid evidence that ISO 9001 certification provides a guarantee of product and service quality or that those organizations that obtain ISO 9001 certification produce better quality products and services than others. Therefore, if preparing a case for certification and the consequential costs without a customer mandate, the arguments are weak but it rather depends on the type of organization and its management style. Some organizations won't make any progress without external pressure.

Choosing a certification body

An issue of concern to organizations choosing certification to ISO 9001:2008 is the variability of the certification process and the validity of the resultant certificate. There are certification bodies that are not accredited by a recognized accreditation body. There is a wide variation in the competence of certification body auditors meaning that there is no guarantee that an auditor from an accredited certification body will be any better than one from an unaccredited certification body. The only difference is that one can show evidence of nationally recognized independent review and the other can't. Therefore, if you choose an accredited certification body and have problems they are unwilling to resolve you can appeal to the accreditation body. You have no redress with an unaccredited certification body except for litigation.

Unfortunately, auditors are more likely to certify ineffective systems than fail robust systems and most managers will accept minor corrective actions rather than create a fuss. But you need to believe you are getting value for money.

Questions addressed to the certification body might include:

1. What experience have the auditors in our business?
2. Which organisations of our type have you registered?
3. What continuity will be maintained between auditors chosen for the initial audit and the surveillance visits?
4. What criteria will be employed to judge the effectiveness of our QMS?
5. What are the conditions for issuing a certificate?
6. How soon after the assessment will we receive the written report and what will it contain?
7. What approach will the auditor take to the audit - will he/she be checking element by element or process by process or department by department?
8. Will the auditor wish to visit every site?
9. How much notice do we have to give for the initial assessment?
10. When will the auditor want to review the documentation?
11. Which documents will the auditor wish to examine in the documentation review?
12. Will the auditor want to review the documentation on or off site?
13. How will the results of the documentation review be conveyed?
14. Will the auditor require objective evidence of compliance with every requirement at the

time of the audit or can some requirements be checked at a later stage?

15. Will you permit us to vet any new auditors before their assignment?

16. What guidance will be provided to help us improve the system?

17. Should we wish to lodge a complaint about the audit what is the procedure?

Some of these questions may already be addressed by the literature you are sent, but a discussion to clarify them is often useful for both parties.

Preparing for certification

In order that you are properly prepared for the external assessment you need to be fully aware of how your system meets the requirements of ISO 9001:2015. Although the auditors will seek evidence to demonstrate conformity to the requirements, it is also necessary that you be able to show the auditor how your system meets the requirements. The more skilled you are at predicting what auditors will look at and what they are looking for when they find it, the more successful you will be. But if you know the system is noncompliant don't try to bluff as it only makes things worse when you are found out. It is better to declare you don't know the answer than pretend you do.

Everyone should know where the ISO 9001 compliance table (see Chapter 30) is located and have access to it during the external assessment. In addition, all personnel should be able to explain

- The objectives of what they are doing
- The process they are using to achieve these objectives
- How they know they are achieving these objectives
- How they know they are doing this in the best way
- How they know these are the right objectives

Personnel should also be informed to only answer the questions asked but if the auditor looks as though they are going down the wrong path through ignorance of the system, personnel should know the system well enough to offer redirections.

Dealing with exclusions

See Chapter 14 of the ISO 9000 Quality Systems Handbook 7th Edition.

Scope of registration

The scope describes the products and service for which you require your QMS to be certified. In assessing the QMS, auditors are looking to see that the system is capable of ensuring you have the capability of supplying the products and services specified in the "scope". For example, if you register your system for the manufacture of washing machines then add to your business the manufacture of electronic components, you cannot claim that you are certificated to ISO 9001:2015 for the manufacture of electronic components. The registration is limited only to the scope. When selecting suppliers, you cannot rely on the fact that they are registered to ISO 9001:2015. You need to know for what products and

services they are registered. You also need to know which accreditation body issued the certificate since not all are registered with the national accreditation agency.

The scope of registration is not the same as the scope of your QMS (see Chapter 14). You may include many functions and processes in the QMS that are not addressed by ISO 9001 or which do not affect product or service quality directly. If you choose to design a management system which reflects how you conduct your business then you may include, legal, medical, catering, personnel, health and safety, environmental and other management processes. If you do not intend to sell or supply these services to your customer then you don't have to include them in the scope of registration. However, if you do, they will be assessed. This scoping effect is illustrated in Figure 14-1

Handling the assessment

The Assessment process

It is important to commence a dialogue with your certification body early in the programme so as to obtain their interpretation of the standard to your business. The assessment itself is only as good as the auditor who conducts the assessment. Auditors are subject to annual appraisal by an independent council but the process in no way guarantees that high standards are maintained. You need to determine whether the auditors appointed will be fair and reasonable and that they have an adequate understanding of your business. Further information on how the assessment will be carried out is given in ISO 17021. The certification process is illustrated in ISO 17021. ISO 17021 requires the audit programmes to include a two-stage initial audit, surveillance audits in the first and second years and a re-certification audit in the third year prior to expiration of the certificate.

The Initial audit – stage 1

The purpose of the stage 1 audit is to establish both parties readiness for the stage 2 audit and will:

- Evaluate the locations and site-specific conditions and establish their level of preparedness for the stage 2 audit
- Establish the extent to which the organization understands the requirements of ISO 9001 particularly with respect to identifying objectives, processes and key performance parameters
- Verify the scope of system to be audited, the locations involved, to identify the customer specific, statutory and regulatory requirements that apply and to identify associated risk factors.
- Examine the management system documentation and establish the extent to which it reflects a system that conforms with the requirements of ISO 9001
- Determine the resources required for the stage 2 audit and agree the detail of the stage 2 audit

- Evaluate the internal audit and management review processes and establish that sufficient evidence exists to substantiate that the organization is ready for stage 2 audit.

It will be clear from this that it will be necessary for the third-party auditor to visit the site during the stage 1 audit. This used to be undertaken unofficially as part of an initial visit or preliminary assessment but ISO 17021 now rolls these into the formal audit.

The initial audit – stage 2

The purpose of that stage 2 audit is to verify the implementation and effectiveness of the organization's management system and will::

- Gather evidence of conformity with all requirements of ISO 9001
- Gather evidence that the organization is achieving the declared objectives and key performance targets
- Gather evidence that the organization's processes are being managed effectively
- Gather evidence of a clear alignment between the what the organization is under an obligation to achieve, what is being reported internally it is achieving and what actual performance data demonstrate it is achieving.

Documentation audit in stage 1

During stage 1 of the initial audit the QMS documentation will be examined to gather evidence that the requirements ISO 9001 have been addressed in one form or another.

As the auditor is now required to visit the site, there is no need to send a copy of your documentation to the certification body. In fact as many documented systems are now intranet based, it is probably more desirable that the auditor sees the documentation in the same form as the users. Many of the requirements in the standard cannot be addressed at the policy level. Some will be only be addressed in the process descriptions and others much lower down in the tiers of documentation, in operating procedures, instructions and forms. If the relationship between policies and procedures is vague then the auditor may well want to look at the detail. Writing the quality manual around the requirements of the standard makes the auditors job easier but may well not provide a system which reflects the way you conduct your business. A manual written around the standard is often not user friendly and hence is likely to been seen as only serving the needs of the auditor. It is also not what the auditor either wants or needs. A better approach is for your Quality Manual to describe your system and for a Compliance Table to show the relationship between your manual and the requirements of the ISO 9001. (see Chapter 30)

In assessing the documentation, the auditor is looking for conformance, although some auditors may appear to be only concerned with nonconformity. It is therefore of no interest that you may have included aspects outside the scope of the standard. The documentation should reflect a system with elements which fit together. The outputs from one process should be inputs to other processes. There should be no loose ends, conflict, gaps, unnecessary overlaps and ambiguities. The Auditor should therefore look for coherence. The Auditor may well request further information in order to gain an adequate

understanding of your system. Should an element of the standard have not be addressed the Auditor will proceed no further until it has been resolved. Should a clause of the standard# have not been addressed this may be resolved by providing documented procedures for review. Should a requirement of a clause have not been addressed the Auditor may add this to the check list and establish whether the practice is compliant during the implementation audit.

Table 60-1 Determining validity of nonconformities

Condition	Requirement of ISO 9001	Provision of registration	Process documented	Process implemented	Example	Result
Activity outside scope of business	Yes	No	No	No	Design or servicing	No Nonconformity
Activity outside scope of quality system	No	No	No	Yes	Finance, Security, Medical	No Nonconformity
Activity outside scope of quality system	Yes	No	No	Yes	Design or servicing	No Nonconformity
Activity outside scope of registration	No	No	Yes	No	Advertising, Public relations	No Nonconformity
Activity outside scope of registration	Yes	No	Yes	No	Marine products	No Nonconformity
Pertinent activity	Yes	Yes	No	No		Nonconformity
Pertinent activity	Yes	Yes	No	Yes		Nonconformity
Pertinent activity	Yes	Yes	Yes	No		Nonconformity

Implementation audit in stage 2

In assessing the practice, the auditor is looking for evidence that you are implementing the system you have documented. If you are not implementing those parts of the system that are outside the scope of the standard or the scope of registration, the auditor may or may not regard this as a nonconformity by virtue of the requirements of ISO 9001:2015 clause 4.4.1. If your practices are compliant with the requirements of the standard but the practices are not addressed in your documented system, this is no longer deemed to be a minor nonconformity (see later). Table 60-1 should help to distinguish between valid and invalid nonconformities. The table clearly shows that the only nonconformities that are valid are those where the requirements of ISO 9001 and the scope of registration match.

Audit process

The site visit will take the following form:

There will be an opening meeting to introduce the assessment team, confirm the scope and timetable, outline the assessment process and reporting method and clarify any unclear aspects.

During the assessment, the auditors interview members of your staff to determine how work is carried out in certain areas, establish if it conforms with your documented processes, seek objective evidence of the facts and compare the facts with the requirements of the standard. Any observations will be documented and the auditor may seek confirmation of the facts and request you endorse the observation report before proceeding further.

At the end of the assessment the auditor will prepare a report detailing the observations and identifying those which are nonconformities with the requirements of the standard. The Lead Auditor will draw conclusions from the results and formulate the recommendations.

There will be a closing meeting to thank the participants, emphasise the good points, explain the nonconformities and observations and make recommendations as the whether or not the company will be recommended for registration. The auditor may leave the assessment report with you or it may be issued later following a review by the certification body.

If there is more than one auditor there will be a Lead Auditor who will manage the assessment. If the assessment takes more than one day the Lead Auditor may call a daily meeting with the company to convey the results thus far.

Dealing with nonconformities

Results

If the auditors use the Pass/Fail method to summarize the findings there are only three possible results of the assessment: Pass, Open or Fail.

- A pass verdict means that no major or minor nonconformities were detected
- An open verdict means that the auditors found no more than one major and several minor nonconformities and that you have 90 days in which to eliminate them.
- A fail verdict means that the auditors found two or more major nonconformities.

Should you fail the assessment or fail to correct the nonconformities to the auditors satisfaction within the 90 days, you will have to make a new application for registration and

go through the whole process again. With an open verdict, the auditors return to conduct a follow-up audit on the specific areas where nonconformities were detected. Certification is not granted until all outstanding nonconformities have been closed.

Nonconformities

The definitions of major and minor nonconformities rely on there being unified understanding on what a clause of the standard is and there is currently no ISO definition of this or of major and minor nonconformities. All nonconformities should be identified with the element and clause of the standard which has not been met. The nonconformity statement should be concise, accurate and supported with objective evidence. It should enable you to correct the problem to eliminate the nonconformity. Vague statements should be challenged. Nonconformity statements should therefore specify:

- The object of the nonconformity
- The location of the object
- The requirement of the standard which has not been met.

Here are some typical nonconformity statements:

- No measures had been taken with Avometer S/N 3568 located in the final test area to safeguard the measuring instrument from adjustments which would invalidate the measurement result as required by clause 7.1.5.2c) of ISO 9001:2015.
- No records could be found for latch mechanism JC 478 held in despatch area which provide evidence of conformity with acceptance criteria as required by clause 8.6a) of ISO 9001:2015.
- There was no evidence that the interfaces between latch mechanism JC 034 designed by the company and boom arm JC 021 had been communicated to the subcontractor of the boom arm as required by clause 7.4.3a) of ISO 9001:2015

You will note that in all these examples the exact wording from the standard has been used and this is to ensure objectivity.

As the detection of a major nonconformity can be cause for refusal to award certification, it is extremely important that there is agreement on the nature of such nonconformity. One instance of failing to meet one requirement or a clause of the standard is not a major nonconformity. To be a major there has to be no provision in place to meet a clause of the standard or the provisions in place are not working as intended. If the provisions in place have not been followed in one instance then the auditor should look for more objective evidence. If compliance is established in some cases but not others then a judgment needs to be made as to whether it signifies that the system has broken down. The auditor needs to establish whether the nonconformity is the result of random error or indicative of operations being out of control. In any case, the auditor should establish if the system is incapable of stopping the supply of nonconforming product or service

Existing nonconformities

If you know of nonconformities and have in fact put in place corrective action plans which have not yet been implemented, whether the nonconformities would be deemed sufficient cause for refusing certification will depend on their magnitude. Failure to address an

element or clause of the standard, regardless of your plans to remedy the situation, will be cause for refusal of certification, simply because your system is incomplete. You may however, have commenced a programme of change which is only partially complete. Providing there is evidence of conformance to the standard in some cases, then you will be deemed compliant. The Auditor will want to check progress at the subsequent surveillance visit. If no progress has been made, this may indicate that the system is not in place.

Challenging nonconformities

If you believe the nonconformity to be invalid, challenge the auditor to demonstrate its validity by showing you the requirement of the standard that has not been met and showing you the evidence of nonconformity. If you are still not satisfied, ask the auditor to explain how the nonconformity can affect quality. A useful question to put to external auditors when they report they have found nonconformity that you disagree with is

"How does confidence in the quality of the product become diminished if this requirement is not met?"

Remember you are paying for the assessment, although if you withdraw on the basis that you are dissatisfied, you may have to pay another certification body to repeat the assessment. It is prudent only to challenge the auditor when you are on firm ground and when the corrective measures may well be costly, and in your view, add no value. Minor nonconformities are best accepted if their correction is trivial. You do not want to give the impression that you are not committed to quality by dismissing errors in the paperwork. The smallest error in paperwork has been known to result in severe penalties. Auditors should note that "You are only taken as seriously as your most insignificant nonconformity"

Correcting nonconformities

The standard requires that you take corrective action without undue delay for nonconformities found during internal quality audits and the same is expected (but not required except in the contract with the Registrar) of external audits. The Auditor will request proposals from you concerning the action you intend to correct the problem and to prevent it recurring and the dates by which these actions will be completed. The Auditor will not normally agree to timescales in excess of three months to correct the nonconformities as it indicates that the assessment was premature. In some cases the nonconformity can be closed by letter or submission of changed pages to the system documentation. In other cases the new provisions need to be in place for several months before sufficient evidence has been generated to show that the system is effective.

Using and abusing certification status

There is some very useful guidance in the ISO publication; Publicizing your ISO 9001: 2000 or ISO 14001:2004 certification. The guidance will help you to apply good practice in publicizing, communicating and promoting your certification to all stakeholders. There are a number of issues to bear in mind

Scope

When you are awarded an ISO 9001 certificate it is for the organization's QMS and as such has a scope of registration that defines the extent to which the certificate applies. You should be accurate and precise about the scope of your organization's ISO 9001:2000

certification, as far as both the activities, the products and geographical locations covered by the certification are concerned

Logos

When you receive your certificate, you will be given instructions by your certification body on what you can and cannot do but these sometimes get mislaid. You should not use, adapt or modify ISO's logo. In fact ISO will take whatever actions it considers necessary to prevent the misuse of its logo. If you want to use a logo, ask your certification body for permission.

What you can and cannot claim

If your organization is certified to ISO 9001:2008, use the full designation (not just "ISO 9001") because your certificate is valid only for a specific version of ISO 9001. You should replace use of the generic term "ISO 9000 certification" by the specific term "ISO 9001 certification".

In the context of ISO 9001:2015, "certified" (and certificated) registered (and registration) are equivalent in meaning and you can use either term. However, you should not say your organization has been "accredited" or "ISO certified", or has "ISO certification ".You should use instead " ISO 9001 :2008 certified "or " ISO 9001:2015 certification ". Only certification bodies are accredited. This means they are authorised to conduct certification of conformity to prescribed standards and ISO 9001 certification does not authorise your organization to do this.

You cannot display ISO 9001:2015 certification marks of conformity on products, product labels, or product packaging, or in any way that may be interpreted as denoting product conformity. You should also not give the impression in any context that ISO 9001:2015 certification is a product certification or product guarantee.