Are You Auditing 21st Century Requirements?

Welcome

Thank you for downloading our 'Auditing' white paper which will help you get the most out of your audit process.

Here's my personal Top Ten, plus lots of supplementary questions. The first 9 questions are the main points that Certification Body auditors will focus on. Question 10 deals with the new issues of auditing processes and auditing without procedures.

It is important for internal auditors to ask these high-level questions (rather than merely focusing on procedures as was usually the case under ISO 9001:1994) especially in the run up to Certification and periodically thereafter.

Most Certification Bodies require at least three months history between the implementation of the quality system and the Certification Audit. Typically, they require that at least one internal audit covering all elements of the quality system has been completed and followed by a management review before the Certification Audit. This enables the company to identify any problems for itself and to resolve them prior to assessment by the Certification Body.

To your success!

Stephanie Keen

Managing Partner, ISO Navigator Management Systems

info@iso9001help.co.uk
www.iso9001help.co.uk

Introduction

In our opinion, auditing can often appear to be an end in itself. The role appears to be one whereby the auditor is there to verify that the procedure is being followed rather than trying to determine whether the activity is being performed in a way that is beneficial to the organisation and, as a by-product, that it meets the procedure.

This was particularly the case for ISO 9001:1994 internal audits. They were often performed in a robotic way, where the auditor followed a pre-defined checklist which was designed to ask a question against each paragraph, just to put "a tick in the box".

What's New?

Audits should assess the effectiveness of the QMS and an organisation's overall performance. ISO 9001:2008 Para 8.2.2 now requires that your internal audits demonstrate compliance with your "planned arrangements" (e.g. quality manual, procedures or process-maps) and that the planned arrangements are effectively implemented and maintained.

An audit of your key quality management activities will always be more relevant and produce more meaningful results than a simple procedural audit. Most of the following high-level questions can also used to supplement your own checklists as part of your routine internal audits. You may well want to refine this list based on special concerns and risks faced by your company. Decide what matters most to your organisation and focus your audit process on those aspects.

Are You Auditing 21st Century Requirements?

Ten Powerful Audit Questions

1. Are Personnel Aware of the Quality Policy & Quality Objectives?

ISO 9001:2008 requires that organisations establish measurable objectives at relevant functions and levels (Para. 5.4.1) and that the quality policy is communicated and understood (Para. 5.3 d)

Perhaps an even more significant requirement is that personnel understand how they contribute to achieving these objectives (Para. 6.2.1). These requirements don't just apply to SOME employees; they apply to EVERYONE. All personnel must be able to explain how they help achieve objectives.

Not all objectives apply to everyone. Auditors can only expect that personnel understand the quality objectives that apply to them. Interviews with personnel allow the auditor to verify if they have appropriate awareness, understanding and knowledge of the way the organisation's quality policy and objectives relate to their own activity, regardless of the terms used to express their understanding.

This question directly reflects on an organisation's ability to communicate what matters most to its success. Truly comprehending objectives means that people understand specifically what they can do to improve the organisation. They appreciate the significance of their roles and are prepared to carry them out. This knowledge creates strategic focus throughout the organisation. Instead of having a limited view of activities and tasks, personnel begin to understand how their jobs link to the organisation's larger mission.

Auditors should keep in mind that the objectives can be measured in a quantitative (e.g. hard numbers: counts or physical measurements) or qualitative manner (e.g. soft numbers: surveys, opinions, etc). Quality objectives are not static and need to be updated in the light of the current business climate and the quest for continual improvement. Also remember that there is a clear link between the dynamic aspect of revising the quality policy and the quality objectives and the commitment of the organisation to continual improvement.

When auditing objectives, remember that you are looking at a work-in-progress and are unlikely to see the final result. For example: The objective is to reduce scrap by 5% over a 12 month period and the audit is carried out at the start of Month Four.

Month	One	Two	Three
% Improvement	0.1	0.4	0.7

TOTAL 1.2% improvement overall

Would you say:

1. They are on target?
2. They are behind schedule?
3. They've made a good (but slow) start?
4. Any improvement is better than none?

Old style auditors would immediately answer No. 2 and reach for the non-conformance report and de-motivate everyone. We might instead answer No. 3 and would then want some assurance that following a slow start the trend will continue and that Month Three is not a freak.

Closely related questions include:

- How are objectives determined?

- How employees are made aware of the quality policy and objectives?
- How is progress towards objectives measured and communicated?
- What processes and/or tools are in place to help achieve objectives?
- Is there evidence of progress?

2. What Happens to Non-conforming Product?

This question reflects on the organisation's ability to deal with product problems in a systematic way. Controlling non-conforming products is a basic discipline (Para. 8.3) and one that smart auditors always probe. The answer to this question can be compared to the documented procedure and, more importantly, to the auditor's observations.

Few other processes require as rigid adherence to procedures as controlling non-conforming products. There can be no room for deviation.

It's worth mentioning that controlling non-conforming products applies to services just as much as it does to tangible goods. Reports, data, test results and intellectual property, to name just a few service outputs, can all be potentially non-conforming, in which case all the disciplines of this process apply.

Problems relating to controlling non-conforming products almost always pose significant risks to the organisation e.g. additional costs, wasted time, aggravated employees, angry customers and loss of business.

During an audit, find some examples of non-conforming products (if there are any) and follow-up with these questions:

- How are nonconforming products identified?
- Where are they located?
- What are the responsibilities and authorities related to dealing with non-conforming products?
- How is disposal determined and implemented?
- Where are the records of non-conforming products and actions taken on them?
- Are there trends in non-conforming products and what's being done about it?
- How is the procedure linked to the corrective action process?

It's worth mentioning that controlling non-conforming products applies to services and software just as much as it does to tangible goods. Reports, data, test results and intellectual property, to name just a few service outputs, can all be potentially non-conforming, in which case all the disciplines of this process apply.

3. How are Customer Requirements Assessed and Communicated?

All organisations have a "product". It might go to an external customer or simply to the next process inside the organisation. In all cases, though, personnel must understand the product requirements. ISO 9001:2008 Para. 7.2 specifically requires that organisations identify product requirements in four ways:

- As stated by the customer
- Not stated by the customer but necessary for intended use
- As statutory and legal regulations related to the product
- As any additional requirements determined by the organisation

The standard additionally requires that information describing the product be available (i.e., documented). Asking how personnel access product requirements is an important audit question because when requirements aren't accessible, big problems often result. Employees

don't need to know product requirements by heart, but they should certainly be able to find the current versions of requirements and describe how they carry them out.
Follow up questions could include:

- Are product requirements complete?
- How does the organisation ensure that only the correct versions are available?
- How are requirements reviewed prior to acceptance?
- How do you ensure that product meets the stated requirements?
- What happens when changes are made to product requirements?

4. How are Problems Prevented?

Problem correction is relatively simple: Define the problem, identify the cause and take action to remove it. Problem prevention is rather more complex. Preventive action is specifically required by ISO 9001:2008 (Para. 8.5.3), and it provides one of the most valuable links to continual improvement.

The most obvious way to generate preventive action is by analyzing data (Para. 8.4). Data analysis is a primary job of top management, but it can happen at other levels of the organisation too. When an organisation openly shares data and encourages its analysis on a broad scale, then preventive action becomes easy.

Employee creativity and innovation can also be a valuable starting point for preventive action. Forward thinking organisations look for ways to solicit improvement ideas from their employees and provide feedback on the viability of the ideas. Another source of preventive action is feedback from customers. Often, customers will provide ideas for improving the product in subtle yet significant ways.

Additional questions could include:

- How do data trends get analyzed?
- How do employees communicate their improvement ideas?
- How do preventive actions get recorded?
- Are statistical techniques (e.g. FMEA) used?
- How are customer perceptions captured?
- How are critical pieces of plant and equipment maintained?
- Is there a disaster recovery procedure?
- Is the work environment appropriate? (Ref Para 6.4)

5. How is Customer Satisfaction Data Collected and Used?

This question probably won't apply to all personnel but it's especially relevant to top management and employees responsible for gauging customer perceptions. The question is significant because most organisations manage fairly well to capture perceptions but usually fall short of actually doing something with the information.

ISO 9001:2008 (Para. 8.2.1) specifically requires that organisations define methods for obtaining and using customer satisfaction data. Customer feedback is a process. It needs to be audited as a process, not as a “clause of the standard”. The audit also needs to be performed on the way in which the process is managed (Para. 4.1.c), and its ability to provide meaningful information with which to judge the overall effectiveness of the QMS.

The way in which the organisation obtains this feedback (“the method”) is up to the organisation to define. This is another reason for relying on simple methods for capturing customer perceptions: Experience suggests that the more complex and resource-intensive your customer satisfaction methods are, the less likely you'll take action on what you learn. It's a curious

paradox. Many organisations run out of gas before they get to the action phase, and the valuable opportunities afforded by customer feedback are ignored as other problems arise.
The auditor should recognize that many factors can affect the organisation's approach, and that there is no fixed "recipe". Consideration should be given to factors such as:

- The organisation's size and complexity
- The level of sophistication of products and customers
- The risks associated with the product
- The diversity of the customer base

Here are some supplementary questions:

- How is customer satisfaction data analyzed?
- How are opportunities identified, prioritised and actioned?
- What's the connection to the corrective and preventive action systems?
- What are the organisation's long-term trends in customer satisfaction?
- How are resources for customer satisfaction identified and provided?
- What connections exist between customer satisfaction and the organisation's objectives?

6. How are Customer Complaints Handled?

Despite everyone's best efforts, customers will occasionally complain. Customer complaints represent both a huge risk and a valuable opportunity to the organisation-it all depends on how they're handled. This question is especially relevant to salespeople, customer service representatives, technical personnel and top management.

The auditor is looking for proof of a systematic approach to dealing with complaints. This will typically include defined responsibilities for logging and tracking complaints, clear problem statements with all relevant facts included, determination of problem causes and actions that address the causes. Specific examples of complaints must be sampled, of course. The link between the complaint process and corrective action also requires special scrutiny (Para. 8.5.2).

Here are some follow up questions:

- What's the largest complaint category?
- What's being done about it?
- Has the number of complaints changed over time?
- How are personnel trained in their roles in preventing complaints?
- How are customers made aware of actions on their complaints?
- What tools are used to identify the causes of complaints?

7. How does Top Management Demonstrate Commitment?

An auditor with limited experience should NEVER be assigned to interview top management. One of top management's most important responsibilities is reviewing the organisation's performance. I'm not talking about employee performance but the organisation's success as a whole.

Is our organisation becoming more efficient, more competitive, better at serving customers, or is it moving in the opposite direction?

Top management should regularly analyse the data that provide the answers to these questions. ISO 9001:2008 (Para. 5.6) specifically requires management review with defined inputs and outputs. And there's no sense in conducting an ISO 9001 management review, then

conducting a separate review of the organisation's performance - they should be one and the same.

Some of the best approaches to reviewing organisational performance are the most creative. Many organisations conduct their management reviews in a number of different forums and time frames, which is a practical and realistic way to approach the process. Regardless of how the review is conducted, the three key points are data analysis, identifying opportunities and taking action on them. Smart organisations treat these three activities as inseparable.

Here are some related questions:

- Are policies and objectives available and relevant?
- Is there a clear link between the policies and objectives?
- Who's involved in reviewing the organisation's performance?
- What actions have resulted from these reviews?
- How are records of the reviews generated?
- Are all required inputs and outputs addressed by records?
- How does the rest of the organisation learn of actions arising from reviews?

8. How is Continual Improvement Demonstrated? (Para. 8.5.1)

This question can be asked of everyone, especially top management. In organisations that have developed improvement tools and provided opportunities for their application, this is an easy question. In organisations where improvement efforts are very narrowly applied, it becomes a much harder question. There should certainly be some evidence of continual improvement within the scope of most, if not all, audits.

Large-scale improvements are impressive, of course, but all improvements have value. This question actually summarizes many of the earlier questions into a single point of inquiry. The ultimate purpose of a management system is to provide a means for improvement.

Just because one or two people aren't able to provide evidence of improvement isn't necessarily a problem. It may indicate weak improvement efforts, though, and further investigation would certainly be needed. In a mature QMS, all personnel are involved in making improvements, and proof of this happening is abundant.

Look for evidence that the organisation is analysing data from process monitoring, and is then taking the results forward for evaluating process efficiency and/or improving process output. One point that should be specifically examined is the consistency of the way in which the improvement of any one process contributes to meeting the overall objectives, so as to ensure that this will not conflict with the achievement of other objectives.

The type of information that an auditor needs is evidence of how the company objectives are translated into specific QMS objectives. For example: the organisation has set an objective to reduce customer complains by 20%. Analysis shows that 50% of those complaints are because of overdue deliveries.

The auditor should then look for evidence that the organisation is monitoring and analysing key aspects of its scheduling and planning activities to reduce delays.

These are some additional points to investigate:

- Who's involved in improvement efforts?
- What tools are used to pursue continual improvement?
- How are personnel trained to use improvement tools?
- How are ideas for improvement prioritised?
- How employees are made aware of improvement efforts and successes?

Are You Auditing 21st Century Requirements?

9. How are Training Needs Determined?

Developing human resources is one of the keys to organisational success (Para. 6.2). This audit question attempts to probe the degree of planning that goes into developing these resources. Is training performed as a knee-jerk activity with no real objectives? Or is it geared toward empowering each employee with the skills and knowledge needed to move the organisation forward?

During the audit, make sure to probe the training needs that have been determined for all levels of personnel: hourly, salaried, contract, technicians, line-managers and top management. Training is an activity that applies to all personnel, not just a narrow slice of the organisation.

The auditor should determine whether there is a systematic approach in place to identify skills and e competencies and to verify that the approach is effective. The outcome of the process may be a list, register, database, human resources plan, competencies development plan, contract, project or product plan, etc

Verify that some form of evaluation process is in place to ensure that the competencies are appropriate to the organisation's activities, and that the personnel are demonstrating those competencies.

Here are some additional questions:

- What kind of training is given to new employees? (including those on short-term contracts)
- How are personnel made aware of the organisation's mission, values and measurable objectives?
- How is the effectiveness of training evaluated?
- What happens when training is determined to have been ineffective?
- What records of training are maintained?

10. Auditing Processes & Auditing without Procedures

A significant new challenge for the auditor in ISO 9001:2008 is that there may be no documented procedure defining the process against which the audit is be carried out. We know that there are only 6 mandatory documented procedures required and the organisation may have chosen an alternative method of controlling the process.

If the alternative is a flowchart or process map there is still something tangible to follow, but if there is no documentation and the process depends on a competent person to control it, auditing is no longer straightforward.

Nonetheless, it can still be audited. Perhaps the principles behind this method of auditing should be used to audit all processes, whether there is a documented procedure or not.

10a how do I audit a process?

If you have been involved in a certification body audit you have probably noticed that the professional auditors often use this method to perform the audit:

They will start at either the beginning or the end of the organisation's workflow and follow a sample of orders, contracts, projects, products, etc. through the organisation. This is a process audit. On an internal audit you may not have time to do the entire process in one audit - in which case break the process into manageable chunks and use that as your audit schedule.

The first task for the auditor is to establish what the process is there to achieve. If it is a sales department, it could be that its primary function is to provide an effective interface between the organisation and its customers, and to enter clear, accurate customer orders onto the computer system in a timely manner. (These may turn out to be the 'quality objectives' for that process as required by Para 5.4.1).

If these are the most important objectives of that process, then the audit must concentrate on verifying whether or not they are being achieved.

Performance is often best proven by looking at how well output of Process A satisfies the input requirements of Process B. For example: how often does Process B have problems with the data entered, how many customer complaints have arisen due to inaccurate or late information being entered?

If there is a documented procedure in place it should define the process and the steps to be taken to ensure that the objectives are achieved.

Consider these points:

- Is there continuity between the various processes in the organisation?
- Is the task done consistently on a person-to-person, day-to-day basis?
- Do the interfaces between the departments operate smoothly?
- Does product and information flow freely?
- Is the procedure right?
- Does it meet the Standard?
- Is it helping the organisation effectively?

There is clearly no advantage in verifying that the procedure is being followed if the result is not beneficial to the organisation, and consequently, the customers.

10b how do I audit without procedures?

In cases where the organisation has chosen not to have a documented procedure to control a process, the first step must be to establish what method it has chosen, whether by a competent person, software or any other appropriate means.

From there the auditor can evaluate the effectiveness of the process by testing to ensure that it is being performed consistently, and by comparing it to the appropriate clauses of ISO 9001.

Some requirements are general and apply to most areas of the organisation e.g. controlled documents (4.2.3), records (4.2.4), responsibility, authority & communication (5.5), competence and training (6.2.2), identification & traceability (7.5.3).

Others are 'area specific' e.g. 7.2 is mostly about the sales activities, 7.4 for purchasing.

Select the 'predominant' clause for the process being audited plus the more general ones, and you should be able to verify both the effectiveness of the process (see 10a) and also its compliance to the Standard.

This can prove to be particularly useful when performing internal audits, as it helps the organisation to satisfy the requirement in clause 8.2.2 which requires us to "determine whether the quality management system conforms to planned arrangements, to the requirements of this International Standard and to the quality management system requirements established by the organisation".

Consider these points:

Are You Auditing 21st Century Requirements?

- Is there continuity between the various processes in the organisation?
- Is the task done consistently on a person-to-person, day-to-day basis?
- Do the interfaces between the departments operate smoothly?
- Does product and information flow freely?
- Does it meet ISO 9001?
- Is it helping the organisation effectively?

Summary

All these questions are based on specific ISO 9001 requirements and in light of ISO 9001:2008 Para. 8.2.2, the unavoidable implication is that internal auditors must now have an understanding of ISO 9001, rather than solely focusing on procedures.

An audit of your key quality management activities will always be more relevant and produce more meaningful results than a simple procedural audit. Most of these high-level questions can also used to supplement your own checklists as part of your routine internal audits. You may well want to refine this list based on special concerns and risks faced by your company. Decide what matters most to your organisation and focus your audit process on those aspects.

Follow this link to the ISO 9001 Audit Practices Group and learn more about modern audit techniques. The leading UK Certification Bodies NQA and Lloyds Register Quality Assurance both provide free, and useful information on 21st Century quality thinking.