

WHITEPAPER
JANUARY 2019

WHAT TO EXPECT
FROM AN ISO AUDIT

CONTENTS

Introduction: Why Audit?	Page 3
Part One: Benefits and Barriers	Page 4
Part Two: The Audit Process	Page 6
Part Three: After the Audit	Page 8
Conclusion	Page 9
Contact Us	Page 10

Introduction: Why Audit?

Whether your organisation is seeking ISO certification or has already achieved it, audits are a pre-requisite to ensuring your processes are working to the required standards. Audits are an integral component of all standards, from the most widely sought, such as ISO 9001 Quality, ISO 14001 Environmental and ISO 27001 Data Security, to specific industry frameworks ranging from ISO 13485 Medical Devices to the AS 9100 family of standards covering the aviation, defence and space sectors.

Internal and external audits can be conducted. Internal audits (instructed by an organisation to take place on the same organisation) can be carried out either by the organisation itself or by a paid consultant on their behalf. These audits are required to be carried out during the course of a year and cover all aspects of the business.

External audits (instructed by one organisation to take place on another organisation) usually take place because a customer wants to discover any gaps in capabilities and that the organisation they're buying from measures up to the high quality they expect. These audits can be conducted by the customer or an appointed consultant who will examine the supplying firm's procedures and report back. This allows the customer to seek answers to any questions arising from the audit.

External scrutiny varies in scope. Sometimes it covers specific areas such as quality control or staff training, but other customers may require a more thorough report. Customer audits aren't a pre-requisite of ISO practice but there's no harm in getting a fresh pair of eyes to run the rule over your business, and they may be a requirement by that customer to meet their own quality control checks.

A third type of audit is required to be conducted by the ISO certifying organisation on a regular, usually annual, basis to ensure the entire quality management system is operating correctly and in line with the requirements of the relevant standard(s). The certifier appoints third-party auditors and charges the company for completing the work.

All ISO standards follow a four-stage cycle: Plan-Do-Check-Act. The audit itself happens in the Check stage; stress-testing that your organisation is doing as it should be and if it isn't, offering the reasons why. Once completed, the findings from the audits (internal, external and certifier) all feed into the Planning stage to provide indication of what needs to be adapted and changed moving forwards.

Ultimately, audits are critical for businesses to understand how all their management systems are faring and uncover where improvements can be made – for the benefit of the organisation, its workforce and customers alike.

Part One: Benefits and Barriers

If audits didn't take place, organisations might continue in ignorance of the areas where improvements are needed. Whichever type of inspection your firm undergoes, it's a great opportunity to understand and change it for the better.

These positive changes don't always have to come from the top of your business. Wide-ranging audits absorb the views and ideas of staff, while also offering auditors the chance to discuss areas for improvement with team members.

Under ISO systems, there is a requirement that an organisation's processes are better than they were the previous year. Staff feedback, along with other inputs such as customer opinion, legislative changes, boardroom decisions and goals, should be regularly reviewed and fed into systems to ensure the procedures are optimised – thereby completing the improvements required.

Initially, in most companies, audits are viewed with suspicion. Individuals can think the business is trying to "catch them out", simply identifying what's deemed "incorrect" in the eyes of the management and auditors. We strongly advocate making the process overtly positive.

Firstly, [catch people doing things right](#) – it makes an often dull or tricky job easier and more fulfilling. Furthermore, this creates a culture of reward rather than blame.

Secondly, embrace the opportunity to improve internal communication by [allowing junior staff to pose questions to managers](#). New approaches in popular standards such as ISO 9001 quality management, ISO 45001 health & safety and ISO 14001 environment require more diligent internal auditing. A good way to achieve this is for managers to allow themselves to be questioned (appropriately) about the system procedures by a more junior employee acting as an auditor. Agreeing to this process can be far less contentious and much more beneficial for a business than it might, at first, appear.

Of course, audits only really make a difference if the discrepancies they discover in your procedures are fixed. There are lots of roadblocks to getting to that point – and, in fact, to kicking off an audit in the first place. But here are some ways to overcome these obstacles:

- "Not now"/ "Not ever" – book the audit in advance and make people aware as the date gets closer. If rebooking is needed, apply pressure on management to ensure it happens. Try to ensure stakeholders can't forget all about it. If it keeps getting pushed back, the chances are it will eventually be rushed and completed sloppily, which is pointless. Remember that is a requirement of ISO certification so cannot be ignored for ever. Some may be concerned that an audit that is "flagged" won't find any issues – but remember we want to catch people doing things right!

- Finding fault – it's too easy to use audits as a finger-pointing exercise. Instead, if someone isn't doing their job correctly, consider whether they really have the right tools for the job, if they truly understand what they have to do, or whether the tasks are viable in the given timeframes. In these circumstances, the blame must actually lie with those appointing the person to their role or tasked with supplying the equipment and knowledge required
- Failure to follow-up – when problems are identified but the business adopts an 'ostrich mentality' and ignores the issues and simply 'never gets round to doing them'. Assigning responsibility and a strict implementation timeframe to an overseer - and then holding that overseer to account - is the remedy
- Audit fatigue – it's easy to treat annual audits as a carbon copy of previous processes, if only for ease of completion. But they will quickly become meaningless, with the same answers from the same people leading to the same supposed solutions which don't then get enacted. The organisation will miss out on the chance to do the right thing.

Part Two: The Audit Process

Finding an internal auditor is fairly straightforward. We advocate appointing a team member who has been trained or already has auditing experience. We offer two days of training when we are hired to set up the audit systems, or can provide refresher or new auditor courses at any time. Each of the auditor's tasks, described overleaf, may take as little as ten minutes to an hour. Anything longer than this should be broken down to stop the process becoming unwieldy. Budgets for time and opportunity cost should be set aside accordingly. Training can be logged against each individual's personal training goals.

The internal audit process, if conducted by an external expert, is usually conducted in several 'batches'. This can take anything between a day and a week in total to complete, depending on the size of the business. Costs can either be settled internally or paid to outsiders. We happily give free advice on the choice of Certifier as part of our range of services.

As for customer audits, costs are split between the customer and supplier organisations and usually take a day or less, depending on the processes being checked and the scale of the organisation.

Auditors at certification bodies should have a range of experience in auditing and knowledge specific to your organisation's sector. Don't be afraid to check their accreditation. Certifier-led audits, meanwhile, last at least two days to cover all technical and industry-specific aspects. These usually carry the highest costs, often up to £1,500 + VAT per day.

Before any audit takes place, the auditor must understand what the processes under scrutiny are individually trying to achieve. For example, in order to audit a quality test on a new product component, the auditor should devise a list of questions that examines whether the relevant manufacturing systems operate as they should. It's important to vary the questions, and - if possible - the auditor, from process to process so that nothing is overlooked and any previous problems with the procedure are ironed out.

While there will always be a range of questions suggested by the needs of complying with the Standard(s), there should be others driven by the organisation's own goals over and above the Standard(s). Example questions include:

- Who carries out the task? Have they been appropriately trained?
- When does the task take place?
- Where is it conducted?
- Are sufficient resources in place to make it happen as required?
- What testing conditions are necessary?
- How are the results to be recorded?

- Are the results actually being recorded?
- Who does what with the results to ensure that they are being correctly used?
- What happens if a non-conformance is detected? etc

As in Part One, it may be the case that the auditor is junior to the person performing the task in question. It's important they don't feel intimidated when asking the questions. In effect, this is a prime opportunity for the more senior staff member to pass on their knowledge and demonstrate their expertise. Conversely, if the senior person makes life difficult - through constant postponements or simply being unhelpful - the auditor should be allowed to escalate the matter to someone more senior still.

It's fair to say that some firms are more prepared than others at the start of the audit process. Organisations often regard ISO systems as a "necessary evil" to join tender lists. They are not likely to use the systems daily, so, at best, actual procedures may not match those written down, and at worst they might not be recorded at all.

This scenario leaves the organisation that is due to be audited playing catch-up – a less than ideal situation. It's far better to match constant activity to written procedures that also must mirror the ISO guidelines from the outset. An audit will then run more smoothly – as well as the organisation gaining far more from its ISO systems overall. It's also necessary to record internal audit actions at each step of the way so that any external auditors can check suggestions are being implemented.

Specifically for Certification Audits:

These examination assessments are in two parts:

Stage One Assessment: The auditor reviews documentation and meets staff responsible for the procedure(s) being audited, ensuring processes, as they are written down, conform with the relevant ISO standard. This stage can take between one and several days, and can be completed on- or off-site.

Stage Two Assessment: Conducted on-site, this stage assesses whether the process that is written down is actually happening (and still matches the requirements of the standard). It also identifies issues to be addressed, along with recommendations, and checks whether previously identified problems are being, or have been, tackled.

Part Three: After the Audit

In all instances, the auditor will then make positive and negative recommendations in a report that should be reviewed by a senior manager. Once signed off, a timescale and overseer should be agreed, and staff member appointed with individual responsibility for ensuring improvements occur.

So, what can organisations expect to receive from the auditor once the audit is completed?

Internal auditors: The final step is for the next management meeting to include a full review of the report, the recommendations and their progress to date so that these findings are blended with other policies and requirements, ensuring systems are subsequently updated.

Customer audits: These result in similar documentation, though the actions will usually be focused on specific areas (rather than all-embracing). Recommendations become closer to being tactful “demands” for the supplier to change their systems to ensure that such issues do not re-occur.

Certification audits reveal a list of conformances and non-conformances to documented systems. The non-conformances are split between Major and Minor Non-Conformances. Minor Non-Conformances must usually be satisfied by the next annual audit. Major Non-Conformances may cause the certification to be removed, but usually the organisation gets up to three months to make the changes before potentially going through a re-audit to check this has been carried out appropriately.

Benefits Table

Audit Related Situation	Beneficial Impact
Regular Review	Drives structure and consistency
Staff interaction and involvement	Cross-silo conversations; cross-hierarchy conversations, cross-training opportunities
Auditor Rotation	New eyes to spot different issues previously unnoticed/suggest alternate solutions
Where procedures not followed	Opportunity for a new approach; opportunity to improve
Where procedures are followed	Opportunity to praise
3 rd party audits (customer or certifier)	Encourages the regimen of getting it right
Full audit process covered annually	Checks for attainability of included corporate goals
Audit (refresher) training	Opportunity for individuals to learn; to shine; to enhance overall training; to break from usual routine
Spotting problems/finding solutions	Long term cost benefits; productivity benefits; morale raising benefits

Conclusion

By now, you should have a better understanding of what to consider ahead of an ISO audit; how the process works, who will conduct it and the associated costs; and the outputs of an audit, which are all aimed at making your systems better for the good of your customers and employees.

It's important to note that, regardless of the stage your organisation has reached in its ISO certification journey, the audit process never really ends. Implementing the changes and improvements revealed by your most recent audit takes time, and as these actions are completed, the next annual audit – or ad hoc investigation if required by customers – will soon roll around again.

The key point, however, is that audits are one of the best way to identify where improvements can be made to your systems and processes that will make them more effective over time. Since audits involve interaction between staff and auditors, overseers and management, they already ensure that everyone is on board with the changes – which, in turn, means changes will more likely be easily adopted.

Our expert team of Qualitators is on hand to discuss our approach to ISO audits and advise you on the best way to implement an audit at your business. We'd be happy to help you make your organisation the best it can be.

CONTACT US

For more information, please contact us on:

enquiries@qualification.co.uk or call 0345 600 6975