

**THE
BIGGEST
MISTAKES
PEOPLE**

**MAKE WITH
ISO 9001**



1. Arguing with auditors

Auditors, don't you just love them!

You have to understand that a lot of auditors coming to see you and your organization can cause you a little bit of concern; they may also be under pressure themselves.

Potential characteristics of a negative / unprofessional auditor are as follows

- Aggressive in manner
- Rude
- Late for no good reason
- Testing a person and putting them under sustained pressure, silences etc
- Not listening and uninterested
- Showing superior and 'know it all' characteristics
- Ignorance of others
- Picky and pedantic - always looking for a non conformity to quench a thirst for negativity

Undesirable qualities can severely affect an audit and the person on the receiving end.

The potential characteristics of a good auditor are as follows;

- Good communicator
- Fair and polite
- Firm when appropriate
- Logical tendency
- Diplomatic
- Open minded and willing to listen
- Uses manners
- Punctual

When you feel that you are being subjected to a negative audit, you should not carry on in the audit if you feel that the pressure is making you answer incorrectly.

Take time to answer.

To combat a negative auditor and therefore a negative situation, you have to fully understand the auditor's questions. If you feel that you are being put under pressure as a result of awkward questioning you should combat the auditor's approach with something similar to the following:

"I am not sure why you are asking me this question in the manner in which you present it and I would like you to fully explain the reasoning behind your question, as I feel that you are placing me under an unnecessary tension."

This will do two things for you: number one - this will break the auditor out of his or her programme and force them to evaluate the manner of their questioning and number two this will give you the confidence to get the audit under some form of (your) control.

If you feel that the audit is making you feel ill, politely say to the auditor 'I would like to take a break as I don't feel very well at all.' Or 'Please may we break off as I need a moment'.

When you return you may find that the auditor's question technique has altered somewhat?

I am not suggesting you use this technique if you are not under pressure but if you feel that you have been placed under unnecessary tension and pressure, it is right for you to take a quick break unless operationally, this is not possible.

It is right to feel some pressure on audit, but not to the point where you feel helpless or too stressed.

2. Internal audits are not completed by the right person

Auditing can be carried out by anyone in your organization, or a mixture of people, preferably impartial from the process or implementation task - preferably someone in your organization who is experienced.

Training is very important to be able to complete this accurately.

You should also choose someone who gets on well with people - if you can!?

In our opinion, approach is probably the single most important factor in preparing, initiating, completing and reviewing an audit. Approach is the key to gaining information - and that approach should be a well mannered one, from whoever is carrying this out.

If you are new to auditing and you find non conformance, always proceed with caution, make sure that the non conformance is conclusive, or risk the non conformance being argued and being made to look silly.

When addressing non conformances they usually come from 4 areas:

- Incorrect company (written) procedure followed
- A contract potentially compromised
- Legislation / regulation potentially compromised
- The ISO 9001 Standard not being followed
- Health and Safety problems

We always recommend this regarding non conformance - 'if you cannot write the non conformity in one sentence or a few short sentences, there is more to argue about and therefore you are open to question.'

A good non conformance is written similar to these examples:

"3 personnel records could not be presented when requested"

"Purchase orders were not raised for 10 purchases when audited. The company procedure documents that Purchase Orders are raised for all purchases without exception"

"There is no quality policy available to audit"

"There are no measurable quality objectives"

Before you raise non conformance, make sure your base is solid or you'll risk ridicule if they are 'turned over'

Get the picture? Stick to these rules and you will have an easier time auditing. There is nothing worse when someone argues your non conformities!

3. Not using the ISO 9001 Standard to your own advantage when being audited

Do you know what the best defence is when being audited?

Quite simply it is the ISO 9001 Standard itself! Auditors use it to audit you, so you must use it for your protection.

Let us not forget that the auditor is there to audit you on facts, not on his or her emotional likes and dislikes.

Due diligence must be observed in the audit, or the auditor will potentially audit you against what they like and don't like. Due diligence is auditing against fact and knowing the difference between fact and opinion; a good auditor will display opinion but not use it against you.

The trouble with some auditors is that they feel superior in some way. This is not always the case of course, but can happen from time to time, most auditors we find are good people and good at their job.

When they are questioning you, they must have a valid reason to do so that supports their need to assess you for certification against ISO 9001.

So why do we say this?

When you are being audited and are being questioned about your procedures and processes you are eventually going to come up against a question that you do not fully understand and where it corresponds against the clauses of ISO 9001.

Sometimes an auditor is going to have difficulty explaining the line of questioning, because from an auditor's perspective he or she has to understand your procedures and processes within a relatively short space of time.

With that said it is important to note that when seeking clarification from an audit question you need to be able to reference back to the ISO 9001 standard.

Let me explain further...

When you are in the role as an auditee, occasionally you will come across questions which you do not understand. When this happens you are to politely request that the auditor shows you the reference to his question in the ISO 9001 standard or show its relevance to ISO 9001 and how the descriptions of the clauses back up the question.

By seeking clarification, using the standard in this way will do two things for you, one, the auditor will have to use ISO 9001 and show you where the standard supports the question and two, this will increase your own understanding of ISO 9001.

Use the standard as your shield to protect you, just as much as it is used to gauge whether you meet the clauses (or not).

4. Not getting proper Director ‘buy in’

How do you encourage management commitment?

- Discuss with senior management how important a QMS is to the business
- Have regular meetings to update on progression of audits
- Discuss how the QMS can assist with goals and company objectives
- Ask what actions the management would like to see
- Consistent management review meetings

Management review

First things first: management reviews are carried out when ***you*** specify. Most organizations write this into their system, in their quality manual for instance.

We believe that one review a year is sometimes not enough but is about the average.

But some organizations we go to do not even carry it out that frequently - and end up with a non-conformance because their procedure says that they do complete one every year! Management review is absolutely necessary.

5. Not assessing all costs of certification visits

Certification

Obviously, choosing a certification body is important. Who are these bodies? Some of the major ones to look out for are:

- WCS
- BSI
- NQA
- LRQA
- ISOQAR

Before you choose a body to certify your organization, it is wise to consider the following:

Is the certification body accredited by a National body or International body themselves? UKAS and ANAB are two of the more widely known accreditation bodies. UKAS is the single National Accreditation body for the UK and ANAB for the USA. They are also the sole national representatives to the ISO for their respective countries.

These two international bodies accredit certification bodies to ISO 17021; to ensure that good and proper certification of organizations (like your own) is upheld. They are usually connected to Government although not always. UKAS and ANAB both are. We will only use and recommend to you, UKAS and / or ANAB accredited organizations for certification.

Does the certification body have the scope to certificate you in our industry? An appropriately accredited certification body cannot just certificate you, it has to have the experience (the auditor from a suitable and relevant field / sector similar to yours) and the administration and assessment of risk in your sector, to back it up, to be able to prove auditing competency in a particular sector. Most sectors are covered by all certification bodies.

Are they competitive? Quite simply, how does the quote measure up to your expectations?

Do they charge expenses? Some do and some do not. Better to check before your auditor gets flown in, has a few nights in a 4 star hotel and you get the bill. We've seen this happen so many times; find out where the auditor is coming from **BEFORE YOUR AUDIT!!!**

Do your customers recognize them? In the case of certification, some of your overseas customers may request a particular body who are accredited by someone who they recognize as competent.

Are their auditors available or do you have to book months in advance to get an audit date? Certification bodies have their personnel issues, just like any of us. If you think you need to speak to them in April, phone them in February, most are very busy and auditor competency is a big issue, so get in touch earlier than you think, or you may be waiting longer than you anticipated for an audit.

What are their ongoing terms after certification? Most certification bodies' terms are 3 years which is acceptable, be careful though, some terms and conditions are not customer friendly and they may make it hard for you to leave that body and transfer? Find a body that will charge you once per year for your audits with their administration charges built in.

6. Not writing your system on what you do at present

We have seen this issue cost one particular business over £27,500 in lost time and resources. This one particular company spent 22 months generating procedures, policies and instructions that they barely needed.

Let us be clear, when you are setting out your procedures and work instructions, you write about what you do, nothing else - nothing less.

The key here is to set out your procedures in a way that you find agreeable, agreeable to you and agreeable to your customers if they require procedures being written in a certain manner.

If you write about what you'd like to do in the future, you'll possibly forget you have written it and it will be audited!

7. Not setting out procedures properly

This is your company, these are your procedures, and these procedures are written on what you do and with the exception of what you need to write in the future, you write in the present tense.

- Purpose - what is the procedure for?
- Scope - where is the procedure to be applied?
- Responsible - who is responsible for the procedure?
- Procedure - the writing or diagrammatical procedure of what you do.
- And finally, reference documents - what makes your procedure work in the form of records / documents / software etc?

Everybody has their own ways of writing procedures but if you set them out according to the previous five points, you will be 99% accurate.

The ISO 9001 standard does not tell you at present how to set out your procedures so you will find the information above highly valuable.

It is also really useful to have a document register, this document register is used to record and control your documentation i.e. procedures, policies, instructions etc.

8. Not understanding what the biggest benefits are

The system is for driving down risk (as well as making you ultra efficient - eventually!)

All in all your system (when proven) drives down the risk to the buyer of your products and services and when that happens, a bond of trust starts to form and enables your relationship to prosper.

As you become more dependent on your system, a system that works, you will find that your confidence grows, improvements are quickly implemented and errors reduced. That is why BIG corporations want their supply chain to have proven systems and standards in place.

Because they know that standards and companies who follow them work and it drives down the risk to the BUYER!

Just ask the Royal Air Force, NASA, and McDonalds etc about systems and if they work...

If you think you are exempt from standards implementation? Just ask why the above aren't.

The ISO 9001 Standard can be interpreted in many ways; and there are always more than a few avenues to your destination of achieving it.

Good luck.