SURECERT

Your ISO Compliance Partner

ISO Certified in 90 days or Less

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Your ISO Compliance Partner

ISO9001:2015 COMPLIANCE

Your Guide to Becoming Certified to ISO9001:2015

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Preface

Thanks for purchasing this eBook.

Mike Wilson trained as a quality auditor through International Certifications Limited and studied Business Management at the University of South Australia.

Mike has a Certificate IV in Training and Assessment and has qualifications and experience in web design and IT, sales and marketing and has managed and owned several successful businesses in the IT and training industries.

Over the years Mike has consulted with businesses of all sizes and shapes including local, state and federal government agencies in Australia and PNG; large corporate entities and small start-up companies in many different industries.

For the last three years Mike has assisted over 60 companies with Safety Management Plans, Environmental Management Plans, Quality, Safety and Environmental Management Systems, Risk Management Systems that comply with ISO and AS standards as well as Australian legislation. 100% of our clients have been certified on their first attempt.

How to get the most out of this eBook.

You are going to be presented with some new ideas in this eBook. It is recommended that you use it as a workbook. Watch for the icons below in the various paragraphs.

ICON KEY
Valuable information – A question might be asked at the end of the chapter.
Expand your knowledge – Carry out some Internet research.
Workbook review – Answer the questions

A wide margin has been provided for making notes as you go to enhance your learning.

"Tell me and I forget. Teach me and I remember. Involve me and I learn"
Benjamin Franklin

"Question Everything"
Albert Einstein

Busting the Myths

Most businesses are already 70 – 90% compliant when we are engaged to help.

To begin with, let's bust those myths that seem to put people off. Many of our clients come to us nervous about bad experiences they have had in the past.

Myth # 1: "This is going to require a lot of work."

You may be surprised to know that most businesses are already 70 – 90% compliant when we are engaged to help.

That doesn't mean there is no work to do. There are almost always processes that either don't exist or that are only partially compliant.

- The most important processes for certification are management of **Non-Conformances** and Continuous Improvement, **Internal Auditing**, **Document** Management and **Records** Management.

- You will also need a compliant **Quality Policy** and **SMART** (Specific, Measurable, Achievable, Realistic, Time limited) **Quality Objectives**.

Myth #2: "Start-up businesses can't get certified"

While it is true that you will need some history of having used the Non-Conformance and Continuous Improvement process, with an understanding auditor, after only three months of trading, you will have built up sufficient evidence of compliance.

- The trick is to shop around for an auditor. Ask questions of your potential auditor in the same way you would ask questions of a potential new employee.

  Remember, you are the customer.

Myth # 3: "Bigger is better"

ISO9001:2015 specifically states the level of documentation required is different for each organization.

- Clause 4.2.1 of ISO9001:2015 states that documentation is required for:
  - Quality Policy;
  - Quality Objectives;
  - Control of Documents;
  - Control of Records;
  - Internal Audit procedure;
  - Non-conformance management including corrective and preventative actions procedures.
- Apart from those few items, the only other requirement is that you **keep records** that provide evidence of quality assurance taking place.
- The extent of documentation can vary from one organization to another depending on:
  - The complexity of the processes;
  - The size of the organization and type of activities;
  - The competence of the personnel.
- Having said that, we normally recommend that you document all your operational processes because it is an easier way to show how you control quality outputs. In addition, the writing a process outline adds a further control mechanism in its own right.

Myth # 4: I am going to be tied in procedural knots"

I have had many occasions when customers have been fearful of getting bogged down in non-productive procedures that make it too difficult to make a profit.

It is gratifying to see the relief on the faces of the people we assist when they discover that there is very little or no changes required to existing procedures.

The formula for success is to use words like "if applicable", "where relevant" etc. when writing your procedures.

Myth # 5: "ISO9001 is too hard to understand"

There is no doubt that the standard has been written somewhat like a legal document.

The trick is to remember that there are basically three themes running throughout the ISO Standard.

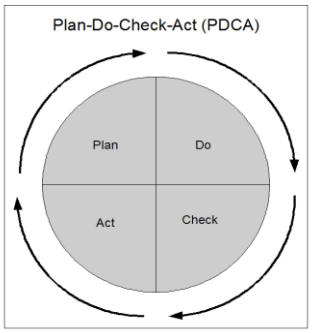
- **The three ISO themes are:**
  - **Direction**

    Direction is about policies and objectives as well as the plans you make to ensure that you are making progress toward the stated objectives.
  - **Control**

    Control is all about having documented processes, inspections, tests, calibration, quality assurance documentation like registers and checklists etc.
  - **Improvement**

    This involves identifying issues, fixing them, keeping records and analysing them for improvement i.e. corrective and preventative actions etc., a vital component of any quality management system.

- Virtually everything in ISO9001:2015 relates to this one thing:



- The Plan, Do, Check, Act management cycle developed by W. Edwards Deming.
- **Plan** means that we should have plans, policies, procedures, job sheets, drawings, specifications etc.
- **Do** is how those plans are implemented.
- **Check** relates to inspections, tests, audits, monitoring and supervision etc.

- **Act** stands for taking action based on the findings of the checking. That often means changing the plans or more often, changing the way the plans have been implemented.

Myth # 6: "Getting certified is best done one standard at a time."

Not necessarily. All business standards have the same basics i.e. the same six requirements for documentation mentioned in Myth # 3, in common. Therefore, why would you double up with each standard?

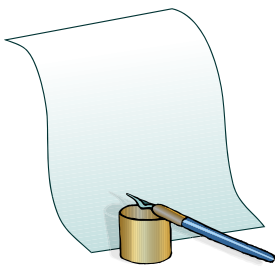
Let's look at what is different about AS4801:2001:

- You need a Safety Policy and associated Objectives (they can be integrated into Quality);
- Documents should be dated (last revision);
- You need to document your risk management processes including monitoring, measuring and emergency management;
- Statistical reports should be produced and reviewed regularly to measure performance against objectives;
- Staff should be consulted regarding safety;
- External documents e.g. legislation and standards etc. should always be the current version.

Everything else is the same as ISO 9001:2008.

Let's look at ISO14001:2004 differences:

- An Environmental Policy (it can be integrated in the Quality and Safety Policy) and Objectives are required;
- Community consultation and communication needs to be documented in your Environmental Policy.
- Consultation and Communication procedures need to be included.



Chapter 1 Review

Look up all items with the PC bullet 💻 on the Internet. There are a number of W Edwards Deming You Tube videos worth watching.

📖 **Name three items** that are required to be documented according to ISO9001:2015 clause 4.2.1

1._____
2._____
3._____

📖 AS4801 requires documents to be dated (last revision date)? ❒ **True** ❒ **False**

📖 The three ISO themes are: (Tick all that apply)

❒ Direction ❒ Connection ❒ Control

❒ Division ❒ Improvement ❒ Isolation

📖 According to the Myth # 1, businesses are usually: (pick one)

❒ Not well prepared

❒ 30-60 % compliant

❒ 70 – 90% compliant

❒ 50 - 80% compliant

📖 Start-up businesses can't be certified? ❒ **True** ❒ **False**

📖 It is best to tackle one standard at a time? ❒ **True** ❒ **False**

📖 All the business standards are basically the same? ❒ **True** ❒ **False**

Chapter 2

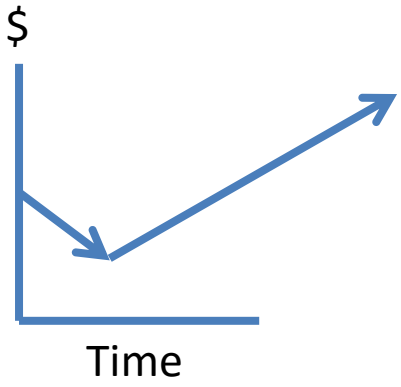
Steps to Certification

The first question should be "How much extra business will it take to for me to pay for the Quality Management System?" For many that we speak to, it is just one extra sale.

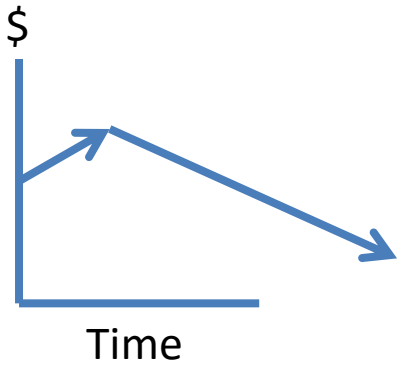
It is important to note that the authors of ISO9001:2015 never intended you to go broke trying to implement the perfect Quality Management System. Making a decision to become certified does mean there will be some cost, but the payback is always equal to or greater than the investment.

- The studies conducted by W Edwards Deming and others show clearly that companies who are focused on short term costs invariably pay more. While those who are focused on quality may pay more in the short term but over time costs go down as illustrated in Deming's A Vs B model below:

A - Focused on Cost



B - Focused on Quality



Requirements met =Satisfaction = Demand for service increases = $Profit

VS

Requirements not met= dissatisfaction = Demand for service decreases = business failure

The decision to become certified should be a strategic move based on the best economic and strategic interests of the company. In other words, it should not be about winning the next deal to the exclusion of all else.

Step 1. Determine the real cost

The first question should be "How much extra business will it take to for me to pay for the Quality Management System? For many that we speak to, it is just one extra sale.

The real cost of implementing ISO9001:2015 does not end at the initial certification audit.

Here are some potential costs.

Developing the Quality Manual / Management System.

- **Option 1 - Engaging a consultant** to write your QMS for you will cost $6,000 to $20,000 plus depending on the complexity and the size of the business. In the same way auditors vary, so do consultants and you don't want to engage someone who will needlessly make a rod for your back. Do your homework.

- **Option 2 - Training and workshops** $1,000 to $5,000 where you write your own manual after having been taught by experts. This option works well because not only will you be certified this year, but it will easier to maintain compliance in subsequent years when you understand the driving principles behind the standard.

- **Option 3 - A template or software** guided system may cost anywhere from $100 to $800. Some software systems provide online help and walk you through.

  This option can work for some, however in most cases the hidden costs of teaching yourself the standards, interpreting them correctly and writing your manual are much greater than anticipated and the enthusiasm dies along with the project. In other cases, the result is so generic, the manual has little or no meaning in real life making certification quite difficult.

Certification Audit

- Your initial certification audit: $4,000 to $10,000 plus. Your initial certification lasts for 3 years.

- You may have surveillance audits at 6 months and 12 months before the next full certification in 3 years' time. Surveillance audits can vary dramatically in price depending on the issues to be addressed. Allow approximately $2,000 to $3,000 plus per year.

- Your auditor will give you a better idea at the time he quotes you.

Consider the other standards

When working out your costs, don't forget to consider the other standards. The overall costs of implementation are far lower when all are done at the same time.

Step 2 – Organise Your Time.

Another cost factor is your time. What would you have been doing if you weren't implementing a Quality Management System?

There is a good chance that if your ISO Compliance project is not completed in a short time, enthusiasm and stamina will wane, the project will fade into oblivion and your investment will be wasted. That is where engaging a consultant really pays off. It keeps you within your planned time frame.

- If you engage a consultant or attend a workshop, you will need 2 or 3 days at the start to be trained and/or gather the raw data.

- Document writing should not take more than 2 weeks especially if you have engaged a consultant to write a manual for you.

Step 3 – Set the wheels in motion

By now you will have quotes and will investigate all your costs including the hidden cost of your time.

So this part is easy. Buy the template, engage the consultant or enroll in the workshop or training program.

Advance preparation for those meetings might include the following:

- Consider the wording you want for a Quality Policy;

- Start thinking about measurable Quality Objectives;

Step 4 - The Next 90 days

Your project should only take 90 days from commencement PROVIDED:

- You have engaged a third Party Consultant;
- You have backdated some historical records of corrective and preventative actions;
- You take the Good, Better, Best approach to implementation.

Implementation Plan

The 12 week Implementation Plan below is based on having 3rd Party assistance with ISO training and a Workshop. Going it alone with templates is likely to take longer or never be successful at all.

The implementation phase (yellow highlight) of the project incorporates the following milestones:

- Create a Pre-Audit Actions list and tick them off as you go (See Appendix A for an example);
- Build a history of dealing with Non-Conformances and Continuous Improvement issues;
- Organise documents and records;
- Conduct at least one Management Review Meeting.

12 Week ISO Compliance Implementation Plan

	W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
Initial compliance workshop												
Document writing												
Implementation of Management System												
Engage external auditor												
Internal Audit training												
Internal Audit												
Management Review Meeting												
External Audit												

Backdated records

It will be important for you to backdate reports that collect data for corrective or preventative actions. That does not mean you are cheating.

It means you are going to walk backward at least a few months and recall incidents or improvement opportunities that you have actually dealt with over the last three months and write reports about them and the actions taken.

You are then going to review these reports to determine if further corrective actions are required during the next Management Review Meeting.

- You will need at least one Management Review Meeting prior to your Certification Audit.
- We normally recommend that you delegate this task to your team so that each person is contributing where possible.

Good, Better, Best

In the wrap up of this chapter let's think about the big picture for a minute.

It is good idea at this point to ask some common sense questions.

- What is the purpose of having a Quality Management System?

  It is to provide a vehicle for continuous improvement.

- Does it mean you will be perfect?

  No. You will probably always have room to improve if you're staffed by human beings.

- So what is the point of delaying your certification audit until you are perfect?

  There is no point. You will probably never be perfect.

All that matters is that you have a system **GOOD** enough to become certified. Over time, you will get **BETTER**. The auditor may give some minor corrective actions which will need to rectify BUT that does not stop you from being certified.

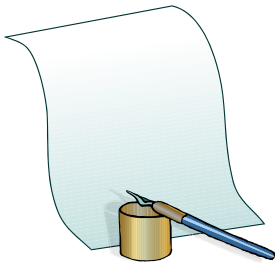
Let's say you receive some minor corrective actions during your certification audit.

- Are minor corrective actions are negative?

  No. They are positive. They simply mean you have room for improvement. Great! You are getting value from your Quality Management System.

Eventually you may get to the point where you have the **BEST** system in your industry but that does not need to be on day one.

In the next chapter we will explore audits and audit results. Read on and you will be able alleviate the fear of failure. Businesses do not fail audits.



Chapter 2 Review

Look up all items with the PC bullet 💻 on the Internet. There are a number of W Edwards Deming You Tube videos worth watching.

📖 Your initial consultation and data gathering should take: (pick one)

- ❒ 3 weeks
- ❒ 2 or 3 days
- ❒ 2 weeks
- ❒ It might never happen

📖 Advance preparation for a consultancy meeting requires you to prepare the Quality Manual outline? ❒ **True** ❒ **False**

📖 The implementation plan requires you to carry out the following: (Tick all that apply)

❒ Documents organised	❒ Write the Quality Manual	❒ Create a history
❒ Internal Audit	❒ Management Review Meeting	❒ Records organised

📖 **Name three options** that are available to help you become quality certified (see Step 1).

1._____
2._____
3._____

Auditors, Your Certification Audit

But is does mean that you don't have to be perfect either. Provided there is sufficient evidence that the compliance is being taken seriously some minors are OK.

Background

Who are ISO?

ISO is the International Organization for Standardization. Yes that's correct. You would think the acronym should be IOS wouldn't you? But it's not an acronym, it's an official abbreviation.

- It is like that because its name would have different abbreviations in different languages ("IOS" is English, "OIN" in French, etc.).
- The organization adopted "ISO", from the Greek word *isos* meaning *equal*), as its abbreviated name. We see the English prefix of ISO on words such as isometric, isotope etc.
- ISO was founded on 23 February 1947. Their purpose is to promote worldwide industrial and commercial standards. ISO9001:2015 is basically about Best Management Practices.

ISO make money from the sale of standards and accreditation of national accreditation bodies.

Who is JAS/ANZ?

- The **Joint Accreditation System of Australia and New Zealand** (JAS-ANZ) was established in 1991 by the Australian and New Zealand governments to strengthen the trading relationship between the two countries and with other countries.
- JAS-ANZ is a not for profit, self-funding international organisation. It is non-discriminatory in that it will accept applications from conformity assessment bodies (CABs) operating anywhere in the world.
- JAS-ANZ offers accreditation programs and work with regulatory bodies to create certification schemes in many areas including Quality Management Systems.

JAZ-ANZ gets paid by auditor companies (CABs) to provide accreditation for them to carry out conformity assessments on you, the customer. They also issue the conformity certificates for which another fee is charged to the CAB.

This explains why auditor companies need to charge you.

Who are CABs?

No they are not taxis. CABs (Conformity Assessment Bodies) are auditors. There are about 30 auditor companies in Australia and 70 in the USA all employing individual auditors.

CABs get paid by you, the customer. There is competition for your business so it's a good idea to get multiple quotes. The CAB should be friendly, helpful and interested in your business. A good auditor knows their standard, provides compliance advice and will even offer alternative methods of doing things.

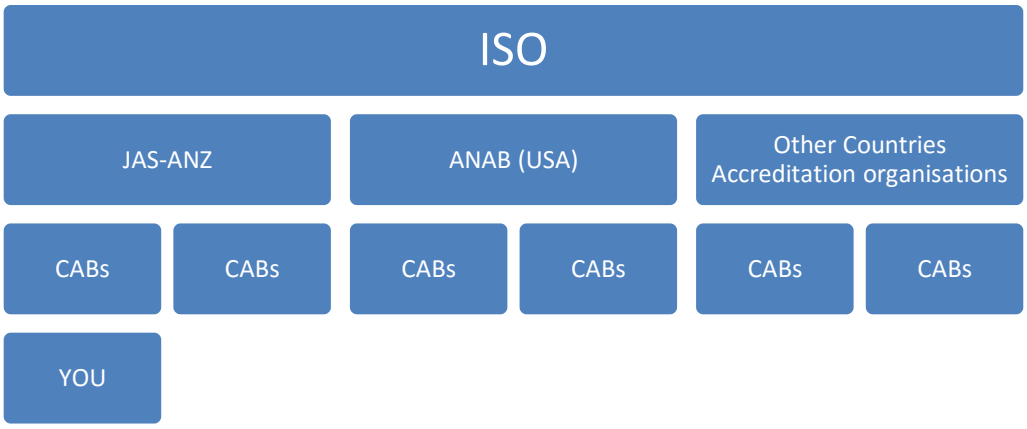
Your auditor wants to be with you as a customer for the long haul. They want you be prosperous.

If you disagree with an auditor you can go to his boss and discuss the matter if you believe an unfair interpretation of the standard has been applied.

If you don't satisfaction you can go to JAS-ANZ and lay out a case.

Lastly, and importantly, you can change auditors. YOU CANNOT CHANGE AUDITORS MID AUDIT.

The chart below gives you a better idea of who is who in the soup.



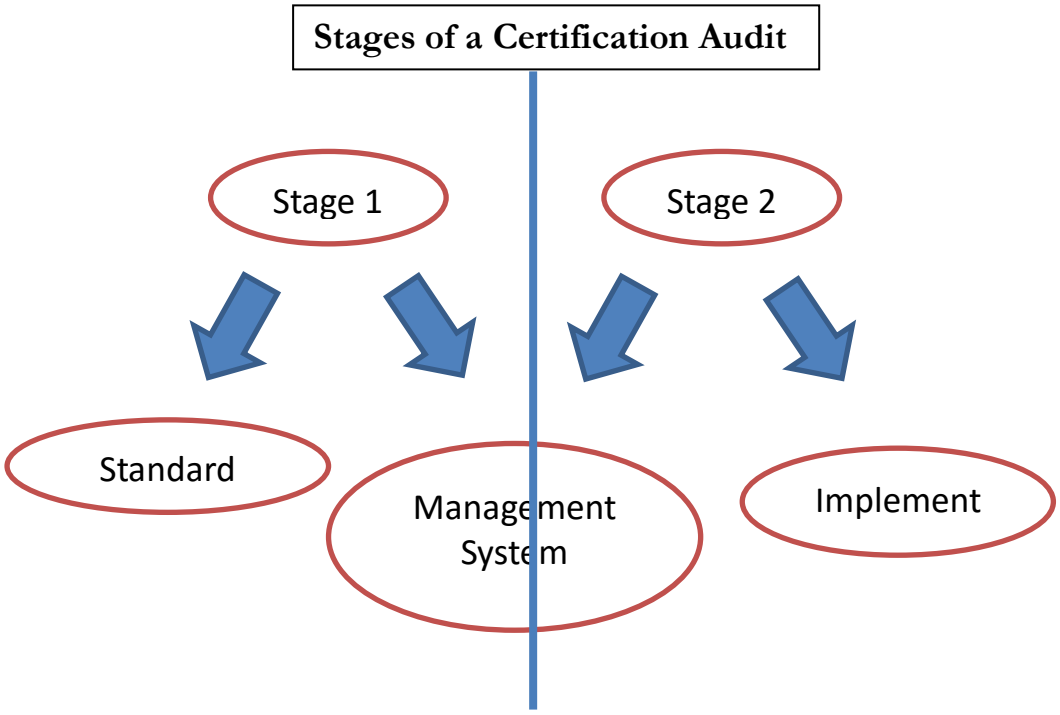
Audit Stages

There a two stages to a certification audit.

- Stage one is where the auditor compares your Management System manual to the ISO standard. If you have engaged a consultant to write your manual, it will have been checked for compliance prior to your having to submit it for auditing.

- You auditor may require a site a site visit in stage to get a good understanding of the business and how it operates.

- Stage Two will definitely require a visit to your site and perhaps building sites if you are in construction. During stage Two, the auditor is looking for how well what you have written in your Management System manual is being carried out in real life.



Audit Findings

There are four categories of audit findings:

- Significantly non-compliant;
- Almost compliant;
- Complying;
- Suggestion.

The names may change but they mean the same thing.

The only way would not get certified is you have a finding of significantly non-compliant and are given a major corrective action.

The chances of your getting a major corrective action are slim **PROVIDED**:

- You have a system in place for identifying issues and taking corrective and preventative actions. Here, again, you will need some history.
- You are keeping reasonable records, particularly in regard to anything quality assurance related. That includes archives.
- Your documents are looking good and you have evidence of managing your documents.
- You have not completed an Internal Audit nor have any evidence of your intentions or systems for an Internal Audit.

The table below outlines the effects of the various audit findings.

If you receive a suggestion it is exactly that. You can take it or leave it.

Finding	Auditor Action	Audit Result	Timeline to Resolve	Result if not Resolved
Significantly non-compliant	Major corrective action	No certification	3 month	Certification cancelled
Almost compliant	Minor corrective action	Certification achieved	Until next audit	Major corrective action
Complying	N/A	N/A	N/A	N/A
Suggestion	Observation	Certification achieved	N/A	N/A

So what does it all mean?

Well it doesn't mean that you get a large number minor corrective actions and it will be OK. You still have put in some effort. If an auditor sees a lot of minor corrective actions, the chances are you could still end up with a major corrective action because there is insufficient evidence that the standard is being implemented.

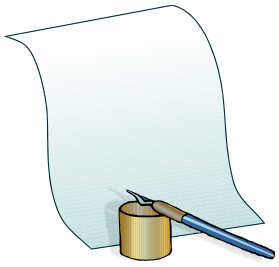
But is does mean that you don't have to be perfect either. Provided there is sufficient evidence that the compliance is being taken seriously some minors are OK.

Therefore, don't be a perfectionist or you will delay being audited forever.

It is best to in terms of Evolution not Revolution. Got some minor corrective actions? Don't sweat it. It is understood that you have to keep paying the bills.

Conclusion

Remember the areas of major importance outlined in chapter 2, think in terms of good, better, best (an ever evolving system), follow the ideas in this eBook and be certified in 90 days or less!



Chapter 3 Review

Look up all items with the PC bullet 💻 on the Internet. There are a number of W Edwards Deming You Tube videos worth watching.

📖 Your certification audit is: (pick one)

- ❒ 3 stages
- ❒ 2 or 3 days
- ❒ 2 Stages

📖 Your stage 2 audit involves comparing the management system manual to the standard? ❒ **True** ❒ **False** (pick one)

📖 How much time do you have make the correction if you receive a minor corrective action? (pick one)

- ❒ 3 months
- ❒ 12 months
- ❒ Indefinite

📖 Name three possible findings you might receive from your auditor:

1._____
2._____
3._____

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Appendix A

PRE-AUDIT ACTIONS.

Activity	Procedure Reference	Suggested Responsibility
Actions to be completed prior to the internal audit		