APPLYING AS9100 REV D

THE HASSLE-FREE APPROACH TO IMPLEMENTING AN

AEROSPACE QMS

FOR SMALL BUSINESSES

MARK HAMMAR

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The Hassle-Free Approach to Implementing an Aerospace QMS for Small Businesses

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Click here to see his LinkedIn profile.

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PREFACE

I have felt great pride as many people have viewed and commented on my articles in the AS9100Academy Blog and ISO 9001Academy Blog, and although many people have said that they have found these articles useful, there is a bit of a problem – they are not collected in a nice way so as to make it easy to use them when implementing the standards. Indeed, there are many articles published about implementing a Quality Management System (QMS) in both of these blogs, so it can be very hard to use all of this knowledge in a systematic way.

That is why this book has been written – to provide a comprehensive, step-by-step guide for AS9100 implementation, written in plain language, that can be understood by beginners with no prior knowledge of the standard. The book is also structured so that you know where to begin and how to end your AS9100 implementation successfully.

Yes, it is true that a lot of the content in this book is taken from the most important articles and materials on the website, because I thought it would be valuable to present all of these materials in a structured way.

However, what I think you'll find most helpful in this book is the practical examples and answers to real-life questions that come up when implementing AS9100. These bits of advice come from my experience both implementing AS9100, and from questions that I have been asked on a daily basis.

Therefore, after reading this book, you'll be able to implement the standard yourself, since it will provide you with enough knowledge and tips to implement the requirements in a small or mid-sized company.

I hope you succeed in this endeavor. Enjoy your book!

ACKNOWLEDGEMENTS

Special thanks goes to Dejan Kosutic, who convinced me to write this book and gave great inspiration for the content and style. He also gave me much of the common management system information from his book: "Secure & Simple: A Small-Business Guide to Implementing ISO 27001 On Your Own."

1. INTRODUCTION

Why design a QMS specifically for the aerospace industry? What makes AS9100 Rev D particularly useful if you are in the aviation, space or defense industry? Is this book the right choice for you?

1.1 Why is AS9100 Rev D important within aerospace?

Companies that don't meet the needs of their customers when providing their products and services don't last long, that is just a fact. In order to be a profitable company you need to give your customers what they want, while still balancing the overall cost to provide your product or service.

However, there is more to running a business than just making and delivering products. Many different processes need to come together to make this happen, from the identification of requirements through to the delivery and post-delivery of the product or service. These processes ensure that your customer is satisfied with what you have delivered. With so many balls in the air at one time, it can be difficult to manage the juggling without dropping any, so it is best to have some sort of system in place to ensure that everyone knows what needs to happen – what balls need to be juggled – and how the balls are supposed to interact.

Take, for instance, the identification of requirements for your products and services. This may sound like an easy task – so easy that you could have anyone assigned to it, but is it really? Not only will you get requirements from your customer contracts, but there will also be legal requirements that you will have to meet. You may also have aerospace industry standards as well

as internal limitations that need to be considered, not to mention the needs of other stakeholders. Looking at it in this way, this is a bigger job than at first glance.

In order to ensure that all of these different processes and tasks are managed in a consistent way companies have taken to implementing a QMS. When implemented properly, the QMS will ensure that all of the interrelated processes of the business are controlled so that no problems occur when the output of one process leads to the next. In many cases, this structure becomes more of a business management system as it identifies and controls all of the processes in your business.

This is where AS9100 comes into play. If you are to design a business management system to control your processes, you will want a structure that is proven to work. AS9100 provides this structure for aerospace organizations. As you will see later in this book, AS9100 is a standard set of requirements for implementing the process of a QMS. It is based on best practices that are recognized world-wide, and tailored to the aerospace industry. This gives you a framework that can be tailored to your company's unique needs, and promotes continual internal improvement of your processes to help ensure your company remains viable into the future.

So, the point is: AS9100 implementation should not be just another bureaucratic piece of overhead. If implemented properly, it can be a beneficial tool to not only help you to maintain control over what you do now, but to also find improvements and gain some business benefits.

1.2 How is aerospace different?

"That's all well and good," I hear you say, "but what's so special about aerospace? Why can't we use the same QMS as everyone else?"

While it is true that many of the processes of a QMS are the same for an aerospace company as they are for any other company, there are some additions that are needed.

Or course, the reason for the additions is that the product and service requirements of aerospace are much more stringent than many other industries. The reason behind this is the usage of the products in question. The aerospace industry is comprised of companies that supply products and services for the aviation, space and defense sector. For these products and services, reliability and safety is of the utmost importance. If a problem happens in an aircraft, there could be a fatal crash; if a satellite fails after launch, there is no way to get it back for repairs; if a defense warning system fails, lives could be in danger.

Because of the above factors, the standard requirements for a QMS, although very good, are not enough. As I will explain in section 2.2, AS9100 uses internationally recognized QMS (ISO 9001:2015) requirements, and adds components specific to, and determined by the aerospace industry. That is why, on top of the standard requirements for quality management processes, there are requirements for such important factors as product safety, operational risk management and the prevention of counterfeit parts.

In effect, what AS9100 does is to take the world-class best practices for managing quality and adds the additional requirements that are important to the aerospace industry. In this way, you have everything you need in one place to demonstrate your ability to consistently provide aerospace products and services that meet all the applicable requirements.

1.3 AS9100 puts it all together

One of the best things about AS9100 is that it has a comprehensive, yet balanced approach to building up an aerospace QMS. It not only strikes a perfect balance between the quality management and business sides of the organization, but it also requires the direct involvement of top management in the quality management implementation. This helps to ensure that the project has all the required resources while still supporting the strategic objectives of the company.

AS9100 explains how to structure the quality management documentation and how to apply only those controls and safeguards that are really necessary for the company. It gives you the tools to regularly review the whole system and improve it whenever it is possible, it provides you with a system to train your employees and make them aware of the importance of quality principles, and it includes the requirements for resource planning, including financial resources.

As I will explain in detail later on, it gives a perfect implementation path. It is written in such a sequential way that you just have to follow the structure of the standard to implement your QMS in the most logical way.

Finally, it provides a management framework to evaluate whether quality management has achieved some business value. This is achieved by setting objectives and measuring whether these objectives are fulfilled. You may be surprised, but I like this part very much because, if the management sees concrete benefits from their quality management investment, it is the best way to ensure a long and successful life for the QMS in your company.

1.4 Who should read this book?

This book is written primarily for beginners in the field of QMSs, and for people with moderate knowledge about AS9100. It is structured in such a way that someone with no prior experience or knowledge in the implementation of an aerospace QMS can quickly understand what it is about, and how to implement the whole project. If you do have experience with the standard but feel that you still have gaps in your knowledge, you'll also find this book very helpful.

This book provides implementation examples in small- and medium-sized organizations (i.e. companies with up to 500 employees). All the principles described here, however, are also applicable to larger organizations. That means, if you work for a larger company, you might also find this book useful. Please be aware that, in some cases, the solutions will have to be more complex than the ones described in this book – for example, you might have the need for more complex production and service controls than is described in chapter 9.

So, if you are a quality manager, quality management professional, head of the quality department or a project manager who is tasked with implementing AS9100 Rev D in a small- or mid-sized company, this book is perfect for you. This book will also be quite useful for consultants, as I have made an effort to present information in the most logical way to implement an aerospace QMS. By carefully reading this book you will gain the know-how for your future consulting engagements.

One thing this book is not, is an audit guide. This book is not written as a guide for performing the audits, but it might be useful for internal auditors, because it will help them to understand all the requirements of AS9100 Rev D. It will also

present the best practice for implementation, which can be helpful when the auditor needs to provide some recommendation in his or her audit report.

Finally, this book can be used as a kind of checklist for experienced aerospace quality management practitioners. As with training courses, even if you do not learn anything especially new, it is always helpful to get a comprehensive and structured view of how AS9100 Rev D should be implemented.

This is exactly how this book is written – it gives a systematic picture of what AS9100 Rev D is all about, and how to make sure you didn't forget something in your implementation. This book will explain how to use AS9100 Rev D as a framework, and to become fully compliant with this standard.

1.5 How to read this book

This book is written as a step-by-step implementation guide. Chapters 3 to 12 should be read in the exact order they are presented, as this sequence represents the optimal way of implementing the standard.

Here are some other features of this book that will make it easier for you to read and use it in practice:

- When a section of this book is related to a particular clause in the standard, then the standard's clause is written in the title of that section.
- Since Chapters 5 to 11 describe the implementation of particular clauses of the standard, each section has these elements:
    - Purpose – briefly describes why such a clause exists, and how it can be used for your QMS.

  - Inputs – which inputs you need to have in order to implement the requirement
  - Options – which options you should consider when implementing the requirement.
  - Decisions – which decisions you need to make to move forward.
  - Documentation – describes how to document the requirements of AS9100 Rev D.
  - Example or Case Study – A short example to help you to understand how the requirements would be implemented in an organization.
  - Documentation tip (Sometimes) – briefly summarizes the documents you need for each requirement.

- Some sections contain tips about free tools that will enable you to implement the standard in an easier way – for example, in section 4.3, regarding use of a gap analysis, you'll find a link to a quick online gap analysis tool.
- At the end of the most important chapters, you'll see a section called "Success Factors," which will emphasize what you need to focus on.
- Throughout the book you will see some short case studies which explain how particular elements of AS9100 Rev D are implemented in real situations.
- You'll find lots of useful information in the appendices – glossary, implementation diagram, checklist of mandatory documentation, special terms in AS9100 Rev D, etc.

1.6 What this book is not

This book is focused on quality management, project management, documentation, how to get the support for your project, etc., but it is not focused on technology. However, this book will give you a methodology on how to get all the inputs to make the important decisions about what needs to happen in your QMS, what documented information needs to be maintained, what information would be necessary in a QMS software tool (if desired), etc.

This book won't give you finished templates for all your policies, procedures, and plans, but it will explain how to structure every document required by AS9100 Rev D, which options you have for writing such documents, who should be involved in writing and decision-making related to each document, where to find the inputs, etc.

This book is not a copy of the AS9100 standard – you cannot replace reading the standard by reading this book. This book is intended to explain how to interpret the standard (since the standard is written in a such a way that it can be rather difficult to understand). It shows you how to implement every element of the standard using best practices based on experience, but it is not a replacement for AS9100 Rev D itself.

So, please don't make the mistake of starting an implementation of the standard without actually reading it – I think you'll find the AS9100 Rev D standard and this book to be the perfect combination for your future work. You can purchase the standard at the SAE International Webpage or Techstreet Standards website.

1.7 Additional resources

Here are some resources that will help you, together with this book, to learn about AS9100 and how to implement it:

- AS9100 Knowledge base & AS9100 Blog – free online information that will teach you the basics of AS9100 Rev D, how to perform an audit, etc.
- AS9100 free downloads – collection of white papers, checklists, diagrams, templates, etc.
- Conformio – cloud-based document management system (DMS) and project management tool focused on ISO standards.
- AS9100D Documentation Toolkit – set of all the documentation templates that are required by AS9100 Rev D, with included expert support for the implementation.
- Official SAE International webpage about AS9100 Rev D – here you can purchase an official version of the AS9100 Rev D standard.

Are you interested now? Excellent!

Let's look more closely at what AS9100 Rev D is all about.

2. WHAT EXACTLY IS AS9100?

As you will see later on, there are many myths about AS9100 Rev D, and at least half of these myths have persisted because many people talk about the standard without ever reading and understanding it. The other half of these myths are based on the fear of being overwhelmed with policies and procedures in the workplace.

So, what is AS9100 Rev D, and what is it not?

2.1 What is a Quality Management System (QMS)?

A QMS is a set of internal rules which are defined by a collection of policies, processes, documented procedures and records. This system defines how a company will achieve the creation and delivery of the product or service they provide to their customers. When implemented in your company, the QMS needs to be specific to the product or service you provide, so it is important to tailor it to your needs. However, in order to ensure you do not miss elements of a good system, some general guidelines exist in the form of AS9100 (QMS – Requirements for Aviation, Space, and Defense Organizations), which is intended to help standardize how a QMS is designed for aerospace organizations.

QMS processes start with the initial management planning stages of a company. These stages define the goals of the company, including what products and services the company will be offering. The system then deals with all processes needed from sales of the product or service through creation and finally delivery of the product or service to the customer.

Additionally, the support processes required to make this happen are controlled as part of the system. This will include managing resources like people and equipment, procedures to control documents and records, and documents defining how to control products or services which do not meet requirements.

Finally, there are processes as part of the QMS which are designed to monitor the processes within the system and lead to improvement. These processes will include a method of auditing the system processes, applying corrective actions for process problems and a way for management to review the system to ensure requirements are met and plans are made for improvements.

One of the best ways to ensure that your system has included all applicable processes is to refer to a standard set of requirements for the QMS. The AS9100 standard is one such set of requirements which define and outline all the typical policies, processes, documented procedures and records that are needed for a successful aerospace QMS. It can be used and tailored for the specific needs of any aerospace organization.

QMS development can have some challenging times. One of the first of those times is overcoming the misconception of thinking a QMS only refers to the processes necessary to deal with inspection and disposition of non-conforming products. Such a system only manages the inspection of a product without managing the inputs that help compliance in the first place, effectively trying to inspect quality into the product or service.

Once this is overcome, the biggest challenges are in demonstrating management commitment by having the policies defined and communicated to all levels of the organization. Once this happens, the QMS can be made to work as a method of ensuring that all necessary requirements are defined and met, and improvements made.

2.2 Based on ISO 9001: Internationally recognized QMS requirements

Both AS9100 and ISO 9001 are standards which include requirements for implementing a QMS in your organization. The format of the AS9100 standard is based on the 2015 update of the ISO 9001 requirements (as detailed below), so it is best to understand the ISO 9001:2015 standard first.

ISO 9001 is an internationally recognized standard for QMSs published by ISO (the International Organization for Standardization). Its requirements are recognized worldwide as an acceptable basis for implementing a QMS. Since it was last updated in 2015, it is referred to as ISO 9001:2015.

While the ISO 9001 standard is generally accepted by any industry around the world, AS9100 is specifically aimed at aerospace companies. The International Aerospace Quality Group (IAQG) has taken the ISO 9001:2015 requirements, in their entirety, and added to them to create a set of specific aerospace QMS requirements: AS9100 Rev D. This is done by adding to the ISO 9001:2015 requirements, without removing any existing requirements, thus creating the AS9100 Revision D standard. These additions appear in bold and italics in the IAQG document. As of March, 2017, there are over 17,000 companies certified with AS9100 around the world.

2.3 How does AS9100 work?

When speaking with someone new to AS9100, or management system standards in general, I often encounter the same problem: this person thinks the standard will describe, in detail, everything they need to do – for example, how often they will need to perform process measurements, how their test

measurements should be done or, even worse, which kind of technology they must use for quality management processes.

The fact is that AS9100 does not prescribe these things; it works in a completely different way.

Why is AS9100 not prescriptive? Let's imagine that the standard prescribes that you need to measure the dimensions of every part 100% of the time. Is this the right thing for you to do? It might be, but this is really a decision to be made based on your product, your customer requirements, and your internal requirements. In fact, services would not have this as a requirement at all, since there would be no part to measure.

The point is that for this standard to fit any type of company, then a prescriptive approach is not possible. It is simply impractical to define the physical measurement requirements, which technology to use, and how to report to the customer, etc.

By the way, this belief that AS9100 will prescribe everything is the biggest generator of myths about AS9100 – you'll find these myths in the next section.

"So," you might wonder, "why would I need a standard that doesn't tell me anything concrete?"

The answer is: because AS9100 gives you a framework for you to decide on appropriate process application. It's the same reason that, for example, you cannot copy a marketing campaign of another company to your own. You need to tailor it to your specific needs. This same principle applies to quality management.

Risk management is a central idea of AS9100. The way AS9100 tells you to achieve this tailor-made QMS is to perform risk assessment and risk treatment for both your QMS risks and

operational risks. This is nothing but a systematic overview of the bad things that can happen to you (assessing the risks), and then deciding which actions to take to prevent those bad things from happening (treating the risks). This is true for QMS risks (as discussed in section 7.5 and 7.6), however, further risk management is required for operational risks (as discussed in 9.1)

Requirements of interested parties. These requirements are a second crucial input when selecting the safeguards. As you'll see later on in section 5.2, interested parties could be government agencies, your customers, partners, etc. All of them probably expect you to meet the requirements of your products and services, and this is reflected in the laws and contracts you have with them. Therefore, your processes must comply with all these requirements as well.

The whole idea here is that you should implement only those process controls that are required by the risks and the requirements of interested parties, not those that someone thinks are fancy. This logic also means that you should implement *all* the process controls that are required and you cannot exclude some simply because you don't like them.

The quality department alone is not enough to provide products and services. If you work in the quality department, you are probably aware that most of the incidents are happening not because the inspection was done incorrectly, but because the original process was insufficient to prevent an error.

Such wrongdoings cannot be prevented with inspection only; clear policies and procedures are also needed, along with training and awareness, legal protection, discipline measures, etc. Real-life experience has proven that applying more diverse process controls results in a higher the level of product and service quality.

This fact that the quality department is not enough for providing products and services that meet requirements is recognized in AS9100. This standard tells you how to run the QMS implementation as a company-wide project where not only the quality department, but also the business side of the organization, must take part.

2.4 What AS9100 is not – 6 Common myths

There are many misconceptions about AS9100 that often do not allow this standard to become a serious candidate for consideration, let alone implementation. Actually, we could call these myths the biggest enemy of AS9100.

Below are 6 common misconceptions about AS9100 Rev D with one partial truth included; don't let these misunderstandings hinder you in your implementation of AS9100 Rev D:

1) AS9100 Rev D is only for big aerospace suppliers – This is where a partial truth can be found. AS9100 Rev D is intended to be used only by aerospace companies, also known as aviation, space and defense organizations. However, the standard is not intended only for large organizations. The standard is purpose-written to be descriptive but non-prescriptive; which means the requirements say what needs to be done but not how to do it. For instance, the standard will tell you that you need to have a method of controlling the prevention of counterfeit products, but how you do this is up to you. In this way the requirements of the standard give "best practices" for your QMS to be effective; no matter if you are a small, medium or large sized aerospace organization.

2) We need to document everything – Some documentation will be necessary to ensure that the processes of your QMS are properly implemented and that you have records to show that the planned results have been met. It is not true, however, that absolutely everything needs to be documented. If you can ensure that your process will be adequate to meet your needs, and you have the records to demonstrate this, you have enough documentation for that process. Detailed and in-depth procedures are not necessarily required for everything.

3) AS9100 Rev D tells us how we need to do things – As has been mentioned above, the requirements say what needs to be done but not how to do it. So, when AS9100 Rev D states that you need to plan, implement and control the processes that you need to ensure the safety of your product during its entire life-cycle, it is up to you to determine how these processes will work. The standard notes that these processes may include such things as risk management and safety critical items, but this is only a suggestion regarding what you may include.

4) The quality department "owns" the QMS – While many of the processes within the QMS, such as internal audit, are typically performed by the quality department, this does not mean that the quality department owns the entire QMS. The QMS is intended to cover every aspect of the business, from planning through delivery of your products and services, and in doing so is owned by every process owner in the organization. The QMS works best when it is the way you do business, not an add on system solely to satisfy someone else.

5) The QMS needs to be perfect right away – One of the main principles behind the QMS is that a company needs to continually improve over time, so this means that the QMS is not intended to be perfect right away. The processes need to be adequately monitored and stable, so that you can find any problems and provide a correction and corrective action to these problems. This is not, however, the same as being perfect. You first need to put in place the processes necessary to meet your customer needs and expectations, then work to find ways to improve over time to improve your customer satisfaction and overall business success. This is where your QMS will show benefits over time.

6) AS9100 Rev D costs a lot to implement and maintain - There is no doubt that there is some cost associated with implementing your AS9100 Rev D QMS, but the long term benefits should outweigh this initial expense. If you are implementing AS9100 Rev D as a way for you to drive improvement in your company and to work towards increasing your customer satisfaction, you will find that your return on investment is high and you will continually find cost and time savings in your organization. If, on the other hand, you choose to only pay lip service to your QMS and do nothing about improvement then you may be right… this will be a big expense.

The point here is: read AS9100 Rev D before you form your opinion about it or, if it's too boring for you to read it (which I admit it is), consult with this book to see what is and what isn't true.

2.5 For which type and size of company is AS9100 intended?

As is indicated by the title of the standard, AS9100 Rev D is intended for use by aviation, space and defense organizations, with the additional aerospace requirements defined by the International Aerospace Quality Group (IAQG).

The type or size of the company is not important. Big or small, local or international – it doesn't really matter which kind of company you work in, AS9100 can be implemented in any aerospace company. Geographically speaking, the standard is applicable in any country around the globe, and the requirements are applicable to any company providing products and services in the aerospace community.

So, which industries within the aerospace community are typically implementing this standard?

Mechanical manufacturers. Companies that provide machined components, especially for aircraft, will find that implementing AS9100 is vital for meeting their customer needs. This is especially important since many customers expect processes for controlling critical items, key characteristics and special requirements for their mechanical parts. AS9100 includes the best practices for these elements.

Electronics manufacturers. With problems in the recent past concerning the use of counterfeit parts in the defense industry, many companies have scrambled to find a way to not only identify these components, but to ensure they are not used within their products. AS9100 includes this in the QMS requirements for aerospace companies.

Test equipment manufacturers. When it is critical to ensure that the test results are accurate, you need to ensure that the equipment used to test an aerospace product is built as well as the products themselves. To this end, manufacturers of test equipment are required to have a QMS in place using the requirements of AS9100.

However, two types of organizations within the aerospace community will find that AS9100 is not for them. They have other QMS requirements which are applicable specifically to them. These two organizations are Aviation Maintenance Organizations which use AS9110 (see section 14.4) and Aerospace Distributors which use AS9120 (see section 14.5).

2.6 A short history of AS9100

Standards for creating and managing QMSs have been around for a long time. The first standard appeared in 1959 in the form of the United States Department of Defense standard MIL-Q-9858. Later, in 1987, the ISO organization published their first QMS standard that was intended to be applicable to all organizations. In 1997, the first aerospace specific standard, AS9000, was issued to address aerospace specific additions to the ISO 9001:1994 standard. You can see a short history of QMS standards in the figure below.

AS9100 Rev D. After ISO 9001 was revised in 2013 the AS9100 standard was updated to Rev D in 2016. The most important changes in revision D are related to the structure of the main part of the standard, interested parties, objectives, monitoring and measurement. Some requirements were deleted from the 2013 revision, such as preventive actions and the requirement to document certain procedures.

You'll read about all these elements in chapters 5 to 11 while, in Appendix C, you'll find an infographic that shows the differences between the Rev C and Rev D revisions of the standard.

All these changes in revision D did not greatly alter the standard as a whole. Its main philosophy is still based on ensuring customer satisfaction, and the same phases in the Plan-Do-Check-Act cycle still remain. This new revision of the standard is easier to read and understand, and it is easier to integrate with other management standards like ISO 14001, ISO 22301, ISO 27001, among others.

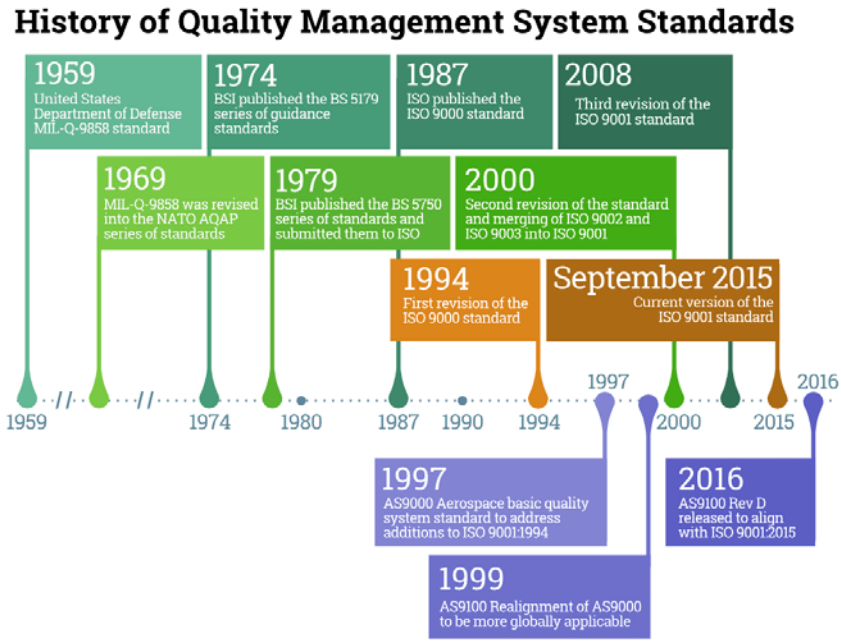

Figure 1: History of QMS Standards

2.7 What does the standard look like? The structure and main clauses

When you purchase AS9100 Rev D, you'll notice that it is a PDF document, about 54 pages long. It is split into 12 sections, plus Annex A through D. Sections 0 to 3, and section 11 are introductory and explanatory (and are not mandatory for implementation), while sections 4 to 10 are mandatory – meaning that all their requirements must be implemented in an organization if it wants to be compliant with the standard. Annex A through D are also explanatory and give more information about the AS9100 Rev D requirements.

According to Annex SL of the International Organization for Standardization ISO/IEC Directives, the section titles in AS9100 Rev D are the same as in ISO 9001:2015, and other management standards, enabling easier integration of these standards.

- Section 0: Introduction – Explains the purpose of AS9100, some foundation principles of the standard, and its compatibility with other management standards.
- Section 1: Scope – Explains that this standard is applicable to any type of aerospace organization that aims to enhance customer satisfaction.
- Section 2: Normative references – Refers to ISO 9000:2015 as a standard where fundamentals and vocabulary are given, as well as referencing ISO 9001:2015 on which AS9100 Rev D is based.
- Section 3: Terms and definitions – Again, refers to ISO 9000:2015, and defines the additional terms "counterfeit

part," "critical items," "key characteristics," "product safety and special requirements."

- Section 4: Context of the organization – This section is part of the Plan phase in the PDCA cycle and defines requirements for understanding internal and external issues, interested parties and their requirements, and defining the scope of the QMS .

- Section 5: Leadership – This section is part of the Plan phase in the PDCA cycle and defines top management responsibilities, setting the roles and responsibilities, and contents of the top-level Quality Policy.

- Section 6: Planning – This section is part of the Plan phase in the PDCA cycle and defines requirements for addressing risks and opportunities of the QMS, setting the quality objectives and planning of changes.

- Section 7: Support – This section is part of the Plan phase in the PDCA cycle and defines requirements for availability of resources, competencies, awareness, communication, and control of documents and records.

- Section 8: Operation – This section is part of the Do phase in the PDCA cycle and defines the implementation of all processes to plan, define, design, procure, create and deliver the products and services of the organization.

- Section 9: Performance evaluation – This section is part of the Check phase in the PDCA cycle and defines requirements for monitoring, measurement, analysis, evaluation, internal audit, and management review.

- Section 10: Improvement – This section is part of the Act phase in the PDCA cycle and defines requirements for

process nonconformities, corrections, corrective actions, and continual improvement.

- Section 11: Notes – Information on how the revision indicator works in the AS9100 Rev D document.
- Annex A – This annex provides clarification of the new structure, terminology and concepts used in AS9100 Rev D.
- Annex B – This annex provides linkages to other international standards of quality management and QMSs, including a relationship table.
- Annex C – This annex provides linkages to other aerospace standards of quality management and QMSs, including a relationship table.
- Annex D – This annex provides a bibliography of documents related to ISO 9001:2015.
- Annex E – This annex provides a bibliography of aviation, space and defense documents related to AS9100 Rev D.

As you may conclude from this structure, in order to make your QMS work, it is not enough to implement only the required processes. You first have to know what you want to achieve, you have to create an environment in which such a project is possible, and once you have implemented the processes and controls, you have to take care that they are maintained and improved.

In other words, if you leave any of the requirements out, you will have quality management that doesn't work. For instance, can you imagine maintaining the quality of your products and services without real support from your management? What would have happened if you didn't have clear rules on who can

approve which document, how each document is distributed and protected, and how it is maintained? What if your employees don't really care about your quality policies and procedures? If not chaos, you would certainly have a bunch of documents that only get in your way instead of helping you.

This is why the standard requires you to implement the requirements from clauses 4 to 10 if you want to pass certification, and only exclude requirements when they are not actually applicable to your organization.

I will cover the implementation of clauses 4 to 10 in detail in this book, however now would be a good occasion for you to start reading the standard itself. As we move forward in this book with the implementation of each clause, you should read the appropriate clause of the standard first, and then the corresponding section of this book.

Throughout this book you will find that I have used the word nonconformity. The definition of nonconformity is "non-fulfillment of a requirement." You will find that this can be used for products and services, when a requirement for that product or service is not met, or for processes. For processes, this basically means that a nonconformity is when you did not fulfill what is required by the standard, required by your own documentation, or required by a third party.

2.8 Introduction to the QMS

AS9100 Rev D basically describes how to develop the QMS, which you can consider to be a systematic approach for managing the processes within your company. These processes are required to consistently provide your products and services that meet all applicable requirements. The QMS represents a set of policies, procedures, and other controls which set the quality

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APPENDIX A – CHECKLIST OF MANDATORY DOCUMENTATION REQUIRED BY AS9100 REV D

Introduction

When implementing a QMS (QMS), especially in the aerospace industry, it is easy to find yourself unnecessarily documenting everything in the belief that this will improve your QMS, or that it is a requirement of the AS9100 standard. In fact, AS9100 Rev D has become even more lenient when it comes to the number of documented procedures required by the standard. It leaves many of the decisions regarding what is important for you to document in the hands of your company. AS9100 uses the term "documented information," but it is helpful to separate this into two categories: mandatory documents, and mandatory records. Below is a listing of each of these mandatory pieces of information, and where it is identified in the AS9100 Rev D standard.

What are the required documents and records?

Mandatory documents

Mandatory Documents	AS9100 Rev D Clause
Scope of the QMS	4.3
List of relevant interested parties (Can be included in the quality manual)	4.4.2

QMS scope including boundaries and applicability (Can be included in the quality manual)	4.4.2
Description of QMS processes and application (Can be included in the quality manual)	4.4.2
Sequence and interaction of QMS processes (Can be included in the quality manual)	4.4.2
Responsibilities and authorities for QMS processes (Can be included in the quality manual)	4.4.2
Quality Policy	5.2
Quality Objectives and Plans to achieve them	6.2
Procedures for control of Externally Provided Processes, Products and Services (outsourced processes)	8.4.1
Process for control of nonconforming products and services	8.7.1
Process for Nonconformity and Corrective Action Management	10.2.1, 10.2.2

Mandatory records

Mandatory Records	AS9100 Rev D Clause
Evidence that QMS Processes are carried out as planned	4.4.2
Records of Maintenance and Calibration of Monitoring and Measuring Equipment	7.1.5.2
Competence Records	7.2

Product/Service Requirements Review Records	8.2.3.2
Record of New Requirements for Products and Services	8.2.2, 8.2.3
Design and Development Inputs Records	8.3.3
Records of Design and Development Controls	8.3.4
Design and Development Output Records	8.3.5
Record of Design and Development Changes	8.3.6
Records of Product/Service Characteristics	8.5.1
Record of results of Production Process Validation	8.5.1
Record necessary to enable traceability (when required)	8.5.2
Records of activities for Lost, Damaged or Unusable Customer Property	8.5.3
Record of Changes in Production and Service Provision	8.5.6
Evidence of Product and Service Conformity & Release	8.6
Record of Nonconformity	8.7 & 10.2.2
Monitoring Performance Information	9.1.3
Internal Audit Program and Records	9.2.2
Management Review Records	9.3
Nonconformities and Corrective Action Records	10.2.2

While these are the documents and records that AS9100 Rev D has identified as mandatory documented information, it is important for the proper function of your QMS to also maintain

any documents and records that you have identified as necessary to enable you to implement, function, maintain, and improve your QMS over time.

Commonly found documents that are not mandatory in AS9100

Non-Mandatory Documents	AS9100 Rev D Clause
Process for determining Context of the Organization and Interested Parties	4.1 & 4.2
Quality Manual	4.4.2
Procedure for Addressing Risks and Opportunities	6.1
Competence, Training and Awareness Procedure	7.2 & 7.3
Procedure for Control of Documents and Records	7.5
Operational Risk Management Procedure	8.1.1
Configuration Management Procedure	8.1.2
Sales Procedure	8.2
Procedure for Design and Development	8.3
Procedure for Production and Service Provision	8.5
Warehousing Procedure	8.5.4
Procedure for Measuring Customer Satisfaction	9.1.2
Procedure for Internal Audit	9.2
Procedure for Management Review	9.3

AS9100 does not require that you document all procedures; but, as stated above, you need to identify what documented procedures and records you need for your QMS to be adequately implemented, functioning, maintained, and improved over time. The purpose of documentation within a QMS is to ensure that the planned arrangements of your processes are understood well enough to make sure that they are followed, and to demonstrate in the form of records that the planned arrangement are what took place. Remember: If, by not having documents and records, you could have a nonconforming product or service, then you should have a document; this can be the best way to ensure your QMS is properly implemented.

What is the best structure for documents and records?

While there is no perfect or preferred solution on documentation for a QMS, because you need to ensure that your QMS meets the unique needs of your company, below are some important elements that you should understand and consider including within your documentation:

Determining Context of the Organization and Interested Parties

While the concept of improving customer satisfaction has been deeply ingrained in AS9100, there are new requirements that ensure you will identify the context that your organization works in, as well as identifying the interested parties for your QMS, listing their needs, and determining which needs you will comply with. For this new requirement, it would be a good idea to document the process you are using and make sure that it contains all of the internal and external issues that you need to consider, as well as how you identified your interested parties and determined their needs, because this will be of interest during your certification audit.

Scope of the QMS

While this is quite short, the QMS scope statement provides the explanation of the extent of your QMS: what is included, and therefore relevant to your QMS. This can be kept as a stand-alone document, or it can be included within a quality manual, which is mentioned in AS9100 Rev D as an optional document to store many different pieces of documented information within the QMS.

Quality Manual

While a quality manual is not strictly required, even AS9100 Rev D notes that this is a convenient single source document in which to compile the description of your QMS. As such your quality manual can include the following mandatory information; description of interested parties, QMS scope including boundaries and applicability, description of QMS processes and their application, the sequence and interaction of your QMS processes and the assignment of responsibilities and authorities for the QMS processes. If you choose not to have a document called a quality manual remember that you need to find a place to document this information.

Quality Policy

This required statement provides everyone within your organization with a focused vision of what you intend to accomplish with your QMS. The quality policy is the company's documented intention to comply with appropriate requirements, enhance customer satisfaction, and work toward continual improvement. This statement is often written into the quality manual along with the QMS scope.

Addressing Risks and Opportunities in the QMS

This is another new requirement that changes the QMS drastically, obliging you to identify the risks and opportunities that are applicable to your QMS and address them, but there is not a requirement for a procedure or specific methodology to do so. Because you need to have a process that considers all of the internal and external issues that are relevant to your QMS, who the interested parties are, and what your scope is - having a procedure in place that identifies how you will perform this important task, as well as records of the results, can be very helpful, especially given that AS9100 includes requirements for operational risk management that may end up being closely related to your QMS risks.

Setting and planning to achieve Quality Objectives

One of the key quality management principles behind AS9100 is continual improvement, and your quality objectives are one of the main ways that you control and monitor your improvement activities. As with the previous version of AS9100, these objectives still need to be measurable and timely, but new requirements now include creating plans to achieve the stated objectives. One of the easiest ways to maintain these objectives is within a document that can control any changes you make.

Competence, Training and Awareness

Within any organization, you need to identify what competencies are required for your operations and determine how best to address these competencies within your workforce. You want to know that you have a good understanding of where training is needed, how training will be delivered, and methods to ensure training effectiveness. In addition, you need to identify and control the processes you have in place for communicating important QMS information to all necessary

individuals. Although it is not a requirement, having a procedure for competence, training, and awareness can be very useful to help ensure that this important process happens as planned.

Document and record Control Procedure

There are many requirements governing the creation, approval, dissemination, control, updating, and obsolescence of documented information within clause 7.5 in AS9100. The goal of documented information is to ensure that the right information is with the right person at the right time and place to be sure that the process is carried out as planned and adequate information is kept to prove that this happened. Having a documented procedure to control all aspects of document and record control is often seen as a necessity to ensure nothing is missed.

Risk Management Procedure

For many years, the aerospace industry has been concerned with managing risks throughout the provision of products and services - tracking the risks to conformity and delivery, while simultaneously taking action to mitigate harmful outcomes. As this is a task often shared with the customer, many companies have found it beneficial to have a procedure to control how this process happens for consistency throughout the company.

Configuration Management Procedure

Maintaining adequate configuration control over the documents and drawings that control the requirements of your products and services has been of high priority within the aerospace industry for many years, and many companies find it beneficial to have a procedure to control these processes in a manner that is acceptable to the industry and their customer needs.

Sales Procedure

While a procedure is not required in AS9100, there are requirements that define the review and appropriate approval of requirements for your products and services. One of the best practices that companies do is to have a procedure to ensure that these product and service requirements are properly reviewed and approved before the organization chooses to accept the task of delivering on the products and services. By doing so, it is less likely that important requirements are overlooked or prove to be unreasonably challenging for the company.

Procedure for Design and Development

There are numerous requirements within the AS9100 standard regarding the design and development of products and services, and these are some of the most demanding requirements in the standard. Every step in the process - from inputs, through controls and changes, to outputs - needs to be managed and documented with a record to demonstrate that requirements are met in the design. To ensure that everything happens in the correct sequence and is authorized, many companies that perform design processes find it beneficial to have a procedure to control the design and development processes.

Procedure to control externally provided processes, products and services

Managing and controlling the processes, products, and services that you have chosen to procure from another company can be complex, and many companies find it helpful to have a procedure to standardize the controls in place, even though AS9100 does not require this. This is often a procedure for purchasing and evaluation of suppliers, as it is these processes that normally benefit from having documented criteria and procedures.

Procedure for production and service provision

While it is only the requirement of AS9100 that provision of products and services to be done under controlled conditions, including the availability of documented information about product and service characteristics and desired results, this can be a complicated process and it is difficult to ensure the desired results without a documented procedure, or procedures, to clearly define all of the criteria necessary to provide your products and services.

Warehousing procedure

Maintaining the preservation of products and services to ensure that they remain conformant can be complicated by concerns of cleaning, special handling procedures, or shelf life control. When the criteria for storage of products can greatly affect the product quality, it can be useful to document the rules and practices required in a warehousing procedure.

Control of nonconforming products and services

With AS9100, you need to be able to provide documented information on your process for controlling nonconforming products and services, and for all intents and purposes, this means having a procedure. By documenting your procedure for what you will do with nonconformance in your products and services, it becomes easy to show your customers the process you will follow when something goes wrong during your creation and delivery of the products and services.

Monitoring performance indicators and customer satisfaction

In order for a QMS to be effective and efficient, management needs to monitor the performance of the QMS, including customer satisfaction indicators. While your criteria of what to monitor, how to monitor it, and when and how to evaluate the

data do not need to be in one procedure, it can be beneficial to have an overview of these key performance indicators in one easy-to-review location, such as a matrix of key performance indicators.

Internal audit

The intent of auditing your QMS processes is to ensure that the planned arrangements are being met, and there are many different aspects of the internal audit that need control. How will you schedule your audit program? Who will perform the audits? How will auditors be deemed competent? How will audit reports be disseminated, and to whom? How are audit corrective actions followed up on? While it is only required that records be kept of these activities, a procedure to control internal audits is often necessary to ensure consistency in auditing and reporting.

Management review

The process of management review in AS9100 is an important element of the standard, as it is the time when management does a full review of the QMS and determines that it is adequately implemented, maintained, efficient, and improving. As a systematic process, taking a certain list of inputs and creating a certain list of outputs, the best way to keep track of what needs to be discussed and decided is to have a procedure for management review to ensure nothing is missed.

Nonconformity and corrective action

The need for corrective action in the QMS is unchanged in the newest version of AS9100, and there are many steps to make sure that this process is effective and efficient. From identification of the problem, root cause analysis, planning for change, assessing the risk of change, and ensuring that the change has been effective, there are many steps to take for

good corrective action to be in place. Having a procedure for corrective actions is not only a good idea, but is also a requirement within AS9100 to easily demonstrate to your customers how you will address the correction of problems within your QMS

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