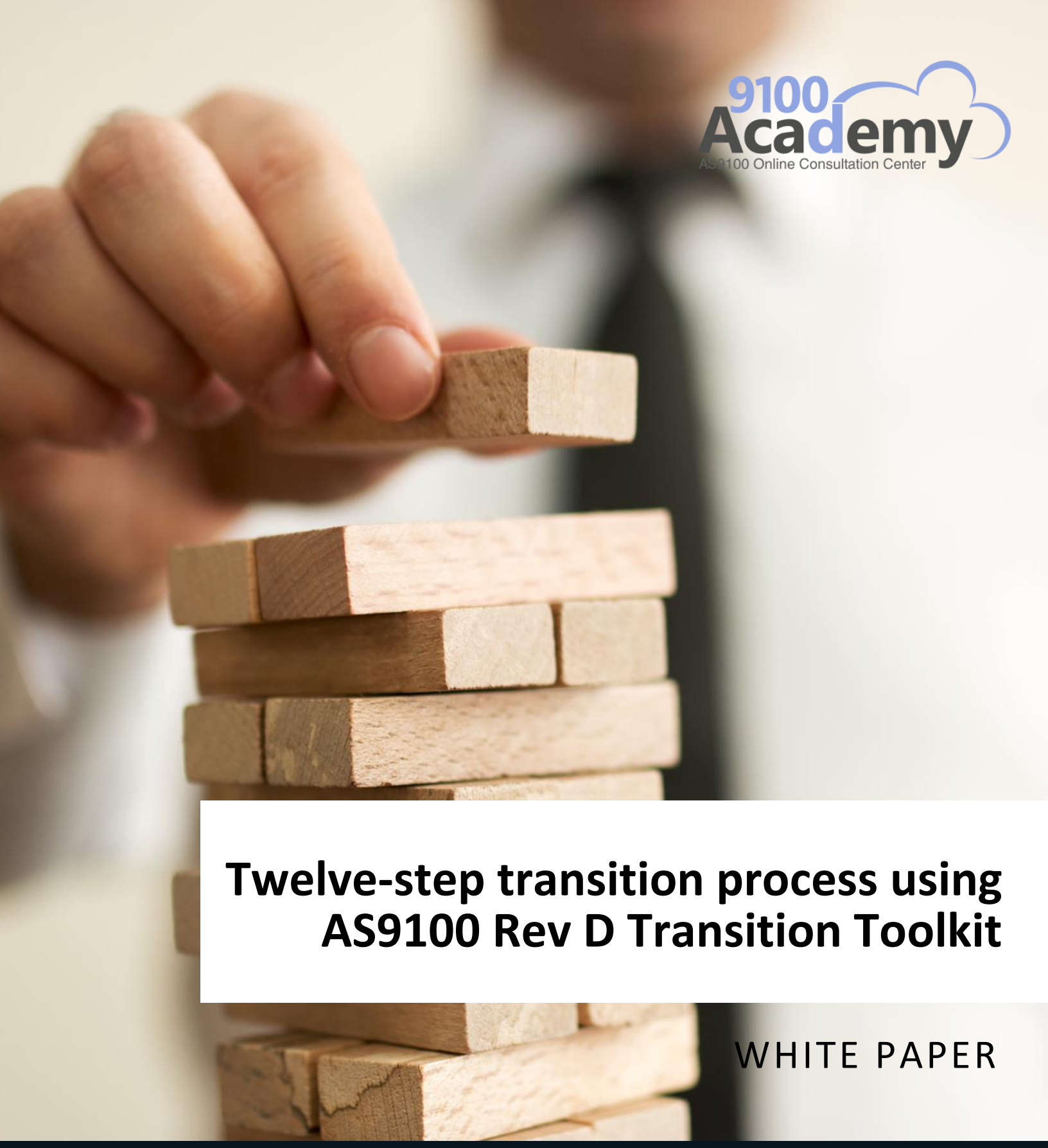

9100 Academy
AS9100 Online Consultation Center

# Twelve-step transition process using AS9100 Rev D Transition Toolkit

WHITE PAPER

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# 1. Purpose

This whitepaper is intended for user of the AS9100 Rev D Transition Toolkit, to help the organization make necessary changes in their QMS documentation and processes.

# 2. Other useful resources

For some more information on AS9100 Rev D see these articles and tools:

- Infographic: AS9100 Rev D vs Rev C – What has changed?
- Clause by clause explanation of AS9100 Rev D
- AS9100 Online Gap Analysis Tool
- The future of the quality manual in AS9100
- New approach to document and record control in AS9100
- 5 key elements of risk management in AS9100 Rev D
- Understanding configuration management in AS9100 Rev D
- Is the management representative still required in AS9100 Rev D
- Five special aerospace terms in AS9100 Rev D

# 3. Timing of the transition

AS9100 Rev D was released in September 2016, and is based on ISO 9001:2015 requirements that were released 12 months earlier. As an organization, you have a limited time to transition from the older version of the standard to the new requirements once the final release is made. After this time, any older versions of the standard, and certifications that are compliant with the older version, become obsolete and no further certifications will be granted against the previous revision. So, for ISO 9001:2015, this transition needs to happen by September 2018, and the transition period for AS9100 Rev D has been aligned to the ISO 9001:2015 period, so you must perform this process by September 2018 as well. It is important to note that some certification bodies have announced that they will not issue new certificates against the old standard well before this time, so it is important to find out from your certification body what deadline pertains to you.

# 4. Twelve-step transition process

The easiest way to make the upgrade to As9100 Rev D is by following these steps:

## Before you start

The transition is not just about implementing new requirements, it is about revising your entire system, and is a great opportunity for QMS improvement. Before you start your transition, those involved need to understand AS9100 Rev D, and the new requirements within the standard. Then they can assess your existing system to see what gaps exist that need to be filled in order to be fully compliant to AS9100 Rev D. For that reason, we have included the updated Internal Audit Checklist in the toolkit that contains all requirements of AS9100 Rev D in the form of "yes" and "no" questions. When you have a negative answer, you will require additional actions that must be included in the transition project.

## 1) Define the context of the organization

In AS9100 Rev D there is a new requirement for defining the context of the organization. This is a critical change in the standard that requires an organization to identify all of the factors that can influence the QMS, thereby forming the basis of the QMS. What factors exist that will influence the organizations purpose, objectives and sustainability with respect to providing products and services? For this, you need to consider both external issues and internal issues, as well as factors that may be cultural, social, economic, legal or technological – basically, any factors that could affect your QMS. It is advisable that the outcome of this process be demonstrated in your organizational Quality Policy, or another document.

Although AS9100 Rev D does not require a procedure for defining context of the organization it is advisable since this is a totally new concept within the QMS.

In folder 01 Determining context of the organization, you will find the Procedure for Determining Context of the Organization and Interested Parties, with comments that will help you address this requirement.

Read more about this here: AS9100: Understanding the requirements of context of the organization

## 2) List all interested parties

Also new to AS9100 Rev D is the requirement to understand the interested parties of your QMS; those who may be affected by the decisions of your company with regards to providing your products and services. This could include customers, government agencies, suppliers, shareholders, employees, unions, and even community groups who may have an interest in your organizational activities. For example, if

you have decided to start performing a hazardous test at your facility (such as radiation testing) rather than sending it out to an external provider, then any local residents who may be affected by this increased risk could be considered interested parties. It is necessary to identify these interested parties, determine their needs and expectations, and then decide which needs and expectations will become compliance obligations in your QMS.

In folder 02 List of all interested parties, you will find the record named List of Interested Parties, which contains examples and comment that will help to meet this requirement.

Find out more here: Identifying interested parties and their requirements according to AS9100 Rev D.

# 3) Scope of the QMS

If you are transitioning form AS9100 Rev C to Rev D, you will already have a QMS scope in place, but now is the right time to review this scope and determine if it needs to be amended. Now that you have gone through the process of defining your organizational context and interested parties does this change the scope of your QMS at all? Properly defining the scope of the QMS is necessary to make the Quality Management System effective, so review this for changes during your transition.

In folder 03 Determine the scope of the QMS, you will find the document called Scope of the QMS, which contains comments that will help you to meet this requirement.

# 4) Demonstrate leadership

Every QMS needs leadership to make it successful, and this is realized in the updated requirements of AS9100 Rev D. In the previous version of the standard, it could be interpreted that leadership could take a passive role in the QMS, but this is now defined as a much more active and responsible role. The organization's leadership has responsibilities in AS9100 Rev D for the QMS scope and results, aligning quality objectives with company strategy, policies and processes, company culture, communication, ensuring a commitment to quality, and providing resource and training opportunities. It is clear that "top management" involvement in every aspect of your QMS is required to make the management system work. It will become almost impossible to make decisions regarding topics like risk assessment without the strategic involvement of leadership.

The leadership requirements of AS9100 Rev D are not met in one single document, but rather through providing resources, taking accountability for QMS effectiveness, promoting the process approach and risk-based thinking and finally through formulating a quality policy.

While the requirements for the quality policy have not changed significantly, in folder 04 Demonstrate Leadership, you will find the quality policy document that will help you to meet these requirements of the standard.

# 5) Align QMS objectives with the company's strategy

While the top management of a company knows in which direction they want the company to go, not every management team has written this down. With the new requirements in AS9100 Rev D to ensure that the quality objectives are aligned with the strategic direction of the company, this process may need to be better defined and recorded. You will also need to ensure that plans are created to achieve the quality objectives that you have defined, so that you can track the progress. Your business strategy and quality objectives will be reliant on each other more than ever before.

In folder 05 Align QMS objectives with the company's strategy, you will find the record for Quality Objectives, which contains examples and comments to help you meet this requirement.

For a better understanding see: How to define quality objectives in AS9100

# 6) Identify risks and opportunities

With the inclusion of risk-based thinking into the AS9100 Rev D standard, there is a new requirement to consider what risks and opportunities are present for all aspects of the QMS. After identifying all risks and opportunities that exist, you will need a documented plan on how you will address each risk: planning to remove the risk, mitigating the risk, planning actions to react to the risk, or just accepting the risk. This is intended to become an integral part of all major QMS planning and decision-making processes. This is an important addition to the responsibilities of top management, as well as a benefit to the overall business planning process, and maintaining a "risk log" is a good way to maintain this activity within your top management. In addition, any operational risks will need to be managed even further, with routine review of the status of actions to address operational risk.

Although clause 6.1 Risks and opportunities does not require a documented procedure for the application of a risk management methodology, this is recommended, since it will provide a systematic approach within your QMS. This procedure also covers the Operational Risk Management necessary to meet clause 8.1.1 of the standard.

In folder 06 Assess risks and opportunities, you will find a procedure that will help you implement risk-based thinking together with a registry of key risks and opportunities.

For more on operational risk management see: 5 key elements of risk management in AS9100 Rev D

# 7) Documented information control

The term "documented information" has been introduced in place of the previous terms "documents" and "records". While it is not necessary to change how you refer to your own information (if documents and records is what your employees understand, then keep those titles), this is still a good chance to

review what you have created to see if you can reduce some of your reliance on documented information. If you could get the same process results by replace a wordy procedure with a flow chart, why not take this opportunity to do just that? Improving your documentation can be a good way to show continual improvement, but make sure that you still have all of the documented information required by AS9100 Rev D when you do.

AS9100 Rev D has combined the requirements for documents and records into a single clause, treating them in the same way. This clause covers rules for each phase in document and record control: creating and updating, storage, preservation, retention, and disposition.

While your previous procedure for document and record control will address most of the requirements, in folder 07 Control documented information, you will find the updated procedure with comments explaining the requirements and how they are met within this procedure. You will also find the records needed to make the procedure work.

Find out more here: New approach to document and record control in AS9100

# 8) Operational Control

One of the goals of AS9100 Rev D is to improve operational control versus the stated criteria. You must define the criteria for your products and services to be effectively delivered, and then ensure that the resources and documentation are in place to meet these criteria. It is important that you ensure that your process documentation has the accuracy and operational controls necessary to produce the targeted results and outcomes in your criteria. In addition, operational control includes the important aerospace requirements for operational risk management, configuration management, product safety and prevention of counterfeit parts, so these controls also need to be included in your operational controls.

As9100 Rev D has many more specific requirements regarding the provision of products and services, and these need to be implemented in all processes of the organization. These requirements include necessary documented information, resources, responsibilities, product safety and counterfeit parts, and release, delivery and post-delivery activities.

In folder 08 Operational control, you will find the Procedure for Production and Service Provision, with clearly marked changes that need to be made along with records needed for full compliance with AS9100 Rev D Clause 8.5.

To better understand these aerospace terms, see: Five special aerospace terms in AS9100 Rev D

# 9) Review your design and development process

There is a change in the level of design and development control required by AS9100 Rev D, and these updates may change your design and development processes. Some factors that now require specific

consideration include; inputs and outputs, design responsibilities, change control and authorization, and actions to prevent adverse impacts. It is also critical to ensure proper documentation of these factors. Can you provide the evidence showing not only who approved design changes, but also how that person is deemed "qualified" to make those changes? This detail is necessary to ensure that products and services retain their integrity to meet the needs of your customers.

In folder 09 Review design and development process, you will find the procedure with track changes and comments explaining what needs to be done in order to align your design and development process with AS9100 Rev D.

## 10) Review control of external providers

The requirements that used to be "purchasing" in the previous standard are now concerned with "control of externally provided processes, products and services." How do you ensure that any externally provided process, product or service fulfills your stated requirements, and therefore, how do you determine the level of control to place on each of your external providers? As9100 Rev D requires that you to be able to illustrate the exact specification, timeline, quality and cost expectations for your outsourced processes, products, and services so that the external providers know exactly what you require.

The new version of AS9100 now prescribes rules for control of not only suppliers, but also outsourcing partners. By widening the scope of the purchasing procedure to include controls for outsourcing partners you can achieve compliance with the new requirements of AS9100 Rev D.

In folder 10 Control of external providers you will find the procedure along with the records needed to make it work.

## 11) Performance evaluation

How do you evaluate that your QMS processes are adequately implemented and effective? You will need to keep documented results of your performance evaluations to demonstrate QMS effectiveness, which can also help you develop continual improvement initiatives in your QMS.

In folder 11 Performance evaluation, you will find the Matrix of Key Performance Indicators that will help you monitor your process's performance, as well as the Data Analysis Report that will help you formulate the additional data necessary for management review.

## 12) Monitoring and measuring

The requirements for monitoring, measuring and reporting across several clauses in AS9100 Rev D have become more specific, so a check to ensure that you measure all aspects in the requirements is essential.

For instance, measurement within the processes for internal audit and management review needs to be aligned in AS9100 Rev D. The techniques for these processes stay the same, but the process inputs have changed slightly to include different review elements. The standard is tries to make these two processes "measurable," where this was not necessarily a requirement before. By being measurable, these processes are now open to finding improvements.

In folder 12 Measuring and reporting, you will find the Procedure for Management Review that contain all the necessary inputs and outputs required by AS9100 Rev D, with helpful comments to help you meet the requirements. Since the internal audit process has remained unchanged, with only the standard requirements to be audited changing, you will find the Internal Audit Checklist in the folder Before You Start.

Once you have conducted your internal audit and all nonconformities have been identified, you will need to initiate corrective actions. In this same folder, you find the Procedure for Management of Nonconformities and Corrective Actions together with the records needed for effective management of nonconformities and corrective actions.

## Wrap up the project

Although the Quality Manual is no longer a mandatory document according to AS9100 Rev D, many organizations will find it useful to keep this as part of their Quality Management System. For that reason, we decided to include the Quality Manual in our transition toolkit. In folder Wrap Up The Project you will find a completely revised Quality Manual, aligned with AS9100 Rev D with comments on each clause and an explanation of changes compared to the previous version of AS9100.

Read more at: The future of the quality manual in AS9100

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