

AS9101D Auditing for Process Performance

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AS9101D Auditing for Process Performance

Combining Conformance
and Effectiveness to Achieve
Customer Satisfaction

Chad Kymal

ASQ Quality Press
Milwaukee, Wisconsin

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Preface

The aerospace industry—unlike some other industries who have been badly hurt in the economic downturn—has not only survived, but all indications point toward a period of strong growth. Most organizations in the aerospace industry are already looking ahead to tremendous opportunities. The challenges are formidable, but the benefits are huge.

In the next two decades, the aerospace industry will undergo dramatic changes for three reasons: the need for improvement, marketplace growth, and awareness of major technological changes for energy efficiency in the aerospace and defense industries. The aerospace industry has few competitors, not only at the OEM (original equipment manufacturer) level, but also in aerospace subsystems such as engines, hydraulics, and/or wing composites. This lack of competition has resulted in an average ppm (parts per million) level of 30,000 ppm and an on-time delivery rate of 50% or less. The need for improvement will be precipitated by new competitors from organizations traditionally associated with the automotive industry in the United States seeking to diversify their operations at the tier I level, as well as competitors from India and China looking to enter the lucrative and high-growth aerospace industry at both the OEM and tier I and II levels.

The aerospace industry will be fueled by the economies of China and India, which are expected to emerge as the largest market, followed by North America and then Europe (see table). The need for localization of aerospace content and adherence to the governmental policies of China and India will lead to aerospace joint ventures (JVs) and industries that will steadily transform into competitors of the future.

Along with this expected market growth and a level of performance that would be considered less than world-class, there is huge rush of new technologies in the aerospace industry, including electronics, composites, and other lightweight technologies. The opportunities and growth in the

Aerospace industry demand by region—2010 to 2029.		
Region	New airplanes	Value (\$B)
Asia Pacific	10,320	1,320
North America	7,200	700
Europe	7,190	800
Middle East	2,340	390
Latin America	2,180	210
CIS*	960	90
Africa	710	80
Total	30,900	3,590
*Commonwealth of Independent States.		

market, coupled with inefficient companies, new technologies, and new or inexperienced competitors, bring large risks but great rewards.

Risks will be prevalent for those entrenched players who either are resistant to change or are not able to quickly adapt to the new realities of the marketplace. Opportunities abound for those newer and more nimble competitors who are able to embrace change in both technology and the supply chain.

This is the proper prism through which to view AS9100 Revision C. Many organizations in the industry have embraced these changes, and, to a large extent, the need for change is reflected in the AS9100C standard through the introduction of the concept of risk management. Process auditing and the idea of prioritizing the audit are key themes emerging out of the new AS9100 auditing standard. In fact, at Omnex we are bold enough to say that an aerospace quality management system (AS9100) implemented and audited using a customer and process focus will help organizations transform to a large degree. However, the focus of the implementation will need to change from “conformance” to “best-in-class.”

Key changes to the AS9100 auditing process include the following:

- Introduction of the PEAR (Process Effectiveness Assessment Report) tool
- Process orientation of the organization
- Customer metrics and measurements

- Project management with risk assessment built throughout the company (not only in design)
- Linkages of characteristics (special characteristics, critical characteristics, and key characteristics, including the flow-down of metrics)
- Importance of customer requirements (customer requirements via standards and contract)
- Configuration management

As author of this book, I aim to accomplish two overall goals: first, to help aerospace organizations improve through effective audit practices, and second, to help auditors improve their overall auditing skills.

NOTE TO THE READER

This book is focused on internal audits and internal quality system audits. As such, keep in mind the following:

- There are three common types of audits: system, process, and product audits. The focus of this book is on system audits. Product and process audits are important and will be the focus of future books and/or articles. At Omnex, we couple process audits with the manufacturing process flow, PFMEA, control plan, and work instructions of the process. In the coming years, we expect more and more aerospace organizations to adopt these risk management tools, making the process audit that much more important.
- Internal audits of the quality system need to be performed as stage 1 and stage 2 audits. The stage 1 audit is essential for planning and focusing the audit first on customer performance issues and then on process “performance.” The stage 2 audit has many purposes, including auditing leadership, customer satisfaction, effectiveness of the system, customer performance issues, and other important topics. Read this book with the idea that the internal audit process is focused on improving your overall organization. The outcomes of AS9100C and AS9101D process-focused audits are nonconformities that address fundamental issues within the organization. Therefore, nonconformities such as document control issues, document updates, and people “not trained” are not the outcomes expected for a properly executed audit as discussed in this book.

- Chapters 7 and 8 discuss the stage 1 and stage 2 audits. Both of these chapters are supported by audit checklists for the internal audit. The audit checklists in Appendixes A and B follow the same steps described for the audit process in Chapters 7 and 8.
- Appendix C includes an audit checklist that encompasses the Objective Evidence Report (OER, AS9101D). Though the checklist is clause-based, the audit should be process-based. Auditors auditing processes should cross-reference the clauses in the audit plan. *Note:* Internal auditors require guidance for conducting internal audits, and additional guidance is provided through the audit checklist in Appendix C.
- Internal quality system audits that drive performance and organizational improvement require the support of management for effective implementation. This support is key as the AS9101D audit for process performance is conducted in your organization.

Overall, this book is designed to be read progressively. The key chapters include Chapter 6 (Understanding Audit Trails), Chapter 7 (Stage 1 Audit), and Chapter 8 (Stage 2: On-Site Audit).

Chad Kymal
CTO and Founder, Omnex Inc.

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1

History of Aerospace Industry Standards

The aerospace industry standards as we know them today had their start in the mid-1990s when a team from AlliedSignal, Pratt & Whitney, Boeing, Rockwell Collins, GE Engines, Rolls-Royce Allison, Lockheed Martin, Sundstrand, McDonnell Douglas, and Northrop Grumman came together to create an aerospace industry standard under the auspices of the American Society for Quality (ASQ) and Society for Automotive Engineers (SAE). The resulting standard was the AS9000:1997 standard.

AS9000:1997

The 1997 version of the standard was designed using various standards from the participating companies, including D1-9000, ISO 9001, DOD, FAA, NASA, MIL-Q, MIL-I, and other standards prevalent in the aerospace and defense industries. The endeavor was primarily a U.S. effort resulting in the first AS9000 standard, which was released in 1997.

Almost immediately, an effort was made to create an international aerospace standard under the oversight of ISO Technical Committee 20—Aircraft and Space Vehicles. The United States convened the committee, which included members from Brazil, China, France, Germany, Japan, Mexico, the United Kingdom, and the United States. Three separate standards were merged to form the first version of the AS9100 standard structured around the ISO 9001 standard. This standard became the first aerospace world quality standard, AS9100:1999.

AS9100:1999 (REVISION A)

This is the first aerospace standard that was based on and built around ISO 9001, the international standard for quality management systems requirements. At the time of publication, AS9100:1999 added 83 additional requirements over and above ISO 9001, including 11 amplifications of some areas of the standard. The greatest emphasis was placed on design control, process control, purchasing, inspection and control, and control of nonconformances. The rationale of the writing committee was that ISO 9001 did not go far enough to capture regulatory requirements or the importance of safety, reliability, or maintainability. Second, it was necessary to capture aerospace supplemental requirements agreed to at an international level. This first standard was the predecessor to the current AS9100C standard, for all practical purposes.

At the same time as AS9100:1999 was released, the International Aerospace Quality Group (IAQG) was formed (see Figure 1.1). All responsibilities were transferred from the WG11, who authored the AS9100:1999 Revision A standard, to the newly formed IAQG. AS9100:1999 was published in the United States, Europe, and Japan with three different standard numbers—a practice that still prevails to this day.

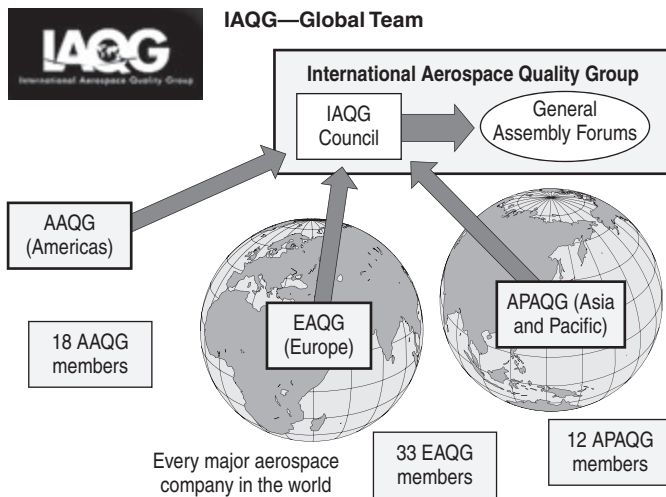


Figure 1.1 International Aerospace Quality Group (IAQG) global organization.

Source: IAQG website *AS9100 Changes*, page 3.

AS9100 REVISION B

Almost immediately, the IAQG started to work on revising AS9100 to be harmonized with the ISO 9001:2000 standard. ISO 9001:2000 was a major departure and a significant change from the older ISO 9001:1994 standard on which the AS9100:1999 standard was built. Since many of these standards were released in such tight time frames, AS9100 Rev A consisted of two separate sections so it could be integrated with either ISO 9001:2000 or ISO 9001:1994. This allowed organizations to work with the AS9100 standard regardless of their current ISO 9001 registration. It wasn't until 2003 that the IAQG released AS9100 Rev B, which simply removed the section on ISO 9001:1994 requirements.

AS9101—AUDIT CHECKLIST

In conjunction with AS9100 Rev B, the AS9101 audit checklist was released. This marked the inception of a common audit checklist for the aerospace industry. It was written to cover all requirements of both AS9100 and ISO 9001. Certification bodies were required to use this checklist when auditing to AS9100. The release of the checklist also coincided with the formation of a certification scheme developed by geographical area. The idea was to create a system that granted the ability to share audit results, hence reducing the multiple audits prevalent in the aerospace industry. The goal of the audit system was to conduct one audit that would provide confidence to the industry that multiple additional audits are not necessary. The OASIS database was also launched at this time.

AS9104

In order to standardize all requirements for auditors, registrars, and accreditation bodies, the IAQG developed a new standard titled AS9104. This standard was released in June of 2001 and included the following important considerations:

- Requirements for accreditation bodies (ABs) and certification bodies (CBs)
- Requirements for auditors
- Training requirements explicitly stated

- Requirements for reporting results of audits
- Minimum audit times and guidelines
- Industry involvement
- Requirement of suppliers to notify OEMs of status of registration and any changes thereto
- Requiring that problems must be reported to registrars
- Tracking suppliers versus registrars versus performance

FOUNDATION YEARS 2000 AND 2001

2000 and 2001 were important years for the AS9100 series of standards. In a short period of time the building blocks of the present-day standards were put in place, as was the IAQG and its three regional groups—the Americas Aerospace Quality Group (AAQG), the European Aerospace Quality Group (EAQG), and the Japan Aerospace Quality Group (JAQG). Many of the standards as we know them today had their start in 2001, including the AS9100 standard integrated with ISO 9001, the AS9101 audit checklist, and the first attempt to standardize requirements for auditors, registrars, and accreditation bodies with the AS9104 standard. Other related standards, such as *AS9102—Aerospace First Article Inspection Requirements* and *AS9103—Variation Management of Key Characteristics*, had already been in use by some companies in the aerospace community.

It was also at this time that a version of AS9100 for distributors was published in Europe as EN9120. EN9120 was accompanied by its own checklist, EN9121. At that time, the United States had a few competing distributor standards, including ASA-100 and AS7103. The standard for aviation maintenance organizations, AS9110, was not even being considered at this time. The foundation for the creation of the AS9100 standard can be seen in Figure 1.2.

AS9110 Requirements for Aviation Maintenance Organizations and *AS9120 Quality Management Systems—Requirements for Aviation, Space and Defense Distributors*, the most recent additions to the AS family, were published in January 2003 and November 2002 respectively. These two standards were based on ISO 9001:2000 and focused on the specific quality requirements of the maintenance and stockist distributor segments of the aerospace industry.

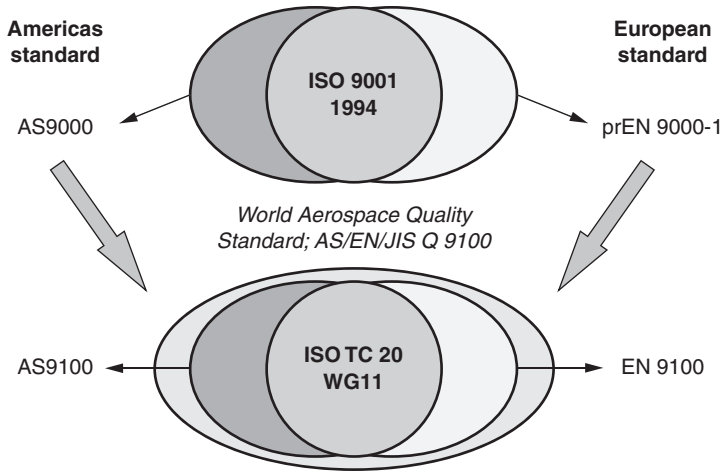


Figure 1.2 Foundation of the AS9100:1999 (revised) standard.

Source: The Koyoto AS9100 IAQG Meeting, presentation by Dale K. Gordon, March 14, 2002.

AS9100 REVISION C

The latest revision of AS9100 (Rev C) was released in January, 2009, approximately three months after the release of the ISO 9001:2008 standard. By the time AS9100C was released, IAQG had become a well-established aerospace industry group with wide acceptance in the international aerospace community. Most of the aerospace OEMs already required conformity to AS9100 for their prime contractors. Many tier 2 and tier 3 aerospace organizations had also adapted the standard to their own use.

Beyond the incorporation of ISO 9001:2008, the biggest change to AS9100C was the expansion of scope to include land- and sea-based systems for defense applications, as well as risk management, project management, configuration management and critical items, and special requirements. The argument can easily be made that the 2009 changes (Rev C)—along with the new AS9101 auditing standard (AS9101D)—are the biggest changes to the AS9100 series of standards in a long time.

The changes to AS9100 come from ISO 9001:2008 sections on risk management and critical/special requirements, and the AS9101 auditing standard. At the time Rev B was released in 2001, the impact of the process approach versus the procedural approach of ISO 9001:2000 and

ISO 9001:1994 was minimized for many reasons, due at least in part to the quick succession of the 1999 and 2001 versions. In AS9100C, the process approach and its effect on aerospace auditing as a whole is going to come to a head. The need for risk management in the aerospace industry, along with the process approach and the audit approach of AS9101, will be among the biggest changes to tackle from both an implementation and an auditing perspective. These and other changes will be covered in detail in the next chapter.

AS9100, AS9110, AND AS9120 STANDARDS

Aerospace, Defense, and Space Industries

The AS9100C standard was written with the assistance of 18 members representing the Americas, Europe, and Asia-Pacific IAQG sectors. The objectives of the revision included incorporating all ISO 9001:2008 changes, expanding the scope to include land- and sea-based systems for defense applications, ensuring alignment with the IAQG strategy of on-time and on-quality performance, and adopting new requirements based on stakeholder needs, as well as improving existing requirements where stakeholders identified a need for clarification, including instances where a documented procedure is needed.

The scope of the AS9100C standard is aerospace, defense, and space industries. With this revision, defense industries were added to the scope of the AS9100 standard. This revision includes six additions, eight revisions and relocations, and three deletions to AS9100, on top of the changes to ISO 9001:2008. This will be covered in the next chapter.

Maintenance Organizations

The AS9110 standard was written with the assistance of 12 members from the Americas and Europe IAQG sectors representing five different countries, eight different IAQG member companies, and three different CBs. The objectives of the 9110 revision included incorporating ISO 9001:2008 changes and 9100C changes as applicable to maintenance activities, providing clarity in order to resolve interpretation issues, addressing stakeholder needs, promoting an industry standard and ensuring that this standard is compatible for use by all stakeholders, and preparing for the forthcoming safety management system implementation requirements in accordance with International Civil Aviation Organization (ICAO) directives.

The intended application of AS9110 includes:

... use by maintenance organizations whose primary business is providing maintenance, repair, and overhaul services for aviation commercial and military products; and for Original Equipment Manufacturer (OEM) organizations with maintenance, repair, and overhaul operated autonomously or that are substantially different from their manufacturing/production operations.

[It] is tailored for organizations with National Airworthiness Authority (NAA) repair station certification and those that provide maintenance, repair, and overhaul services for military aviation products; but the standard could significantly benefit non-certificated maintenance organizations that choose to adopt it. (AS9110A, 1.2—*Application*)

AS9110 includes nine additions and one revision. This book will cover the AS9110 changes in Chapter 3. See Table 1.1 for a comparison between AS9100, AS9110, and AS9120.

Distributors to Aviation, Space, and Defense

AS9120 was written with eight members representing the Americas, Europe, and Asia-Pacific IAQG sectors including distributors, OEMs, and associations from both production and aftermarket. The objectives of the 9120 revision included incorporating ISO 9001:2008 changes, alignment with the IAQG strategy (on-time, on-quality performance), alignment with AS9100C changes, and adopting new requirements based on stakeholder needs, as well as improving existing requirements where stakeholders identified a need for clarification, including instances where a documented procedure is needed.

The scope of AS9120 applies to distributors to the aviation, space, and defense industries. Similarly to AS9100, defense industries were added to the scope of AS9120. The standard includes six additions, five revisions/relocations, and two deletions. This book will cover the AS9120 changes in Chapter 3. See Table 1.1 for a comparison between AS9100, AS9110, and AS9120.

Common Aerospace Auditing Standard

AS9101, which was released in March, 2010, was written by 13 members, representing the Americas, Europe, and Asia-Pacific IAQG sectors, from six different countries, including eight IAQG member companies and four certification bodies.

The objectives of the 9101D revision included alignment with the IAQG strategy (on-time, on-quality performance, improved control of other party

Table 1.1 Comparison of ISO 9001:2008 to AS9100, AS9110, and AS9120.

	ISO 9001:2008	AS9100 compared to ISO 9001:2008	AS9110 compared to AS9100	AS9120 compared to AS9100
1.0	Scope	1.0 Scope General Reference that the standard includes ISO 9001:2008 requirements	1.0 1.1 Scope General References baseline maintenance requirements	1.0 Scope Same
			1.2 Application References baseline maintenance requirements	
2.0	Normative references	2.0 Normative References—Same	2.0 Normative references—Same	Normative references—Same
3.0	Terms and definitions	3.0 Terms and definitions—Additional definitions	3.0 Terms and definitions—Additional definitions	Terms and definitions—Additional definitions
4.0	Quality management system	4.0 Quality management system—References to statutory and regulatory requirements	4.0 Quality management system—References baseline maintenance requirements	Quality management system
		4.2 4.2.1 Documentation requirements General—Organization's personnel aware and have access to QM documentation and changes	4.2.2 Quality manual—Additional requirements specific to maintenance personnel under "d"	

Continued

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Table 1.1 Continued.

ISO 9001:2008	AS9100 compared to ISO 9001:2008	AS9110 compared to AS9100	AS9120 compared to AS9100
	4.2.4	4.2.4	Control of records— Added additional records
5.0 Management responsibility	5.0	Management responsibility	Management responsibility—Same
	5.2	Management commitment— Adds safety and safety objectives	
	5.5.2	Safety objectives— Added	
		5.5.1.1	Accountable executive manager—Added
		5.5.1.2	Maintenance managers— Added
		5.6.2	Review input—Added h, i, j
		5.7	Safety policy—Added

Continued

Table 1.1 Continued.

	ISO 9001:2008	AS9100 compared to ISO 9001:2008	AS9110 compared to AS9100	AS9120 compared to AS9100
6.0	Resource management	6.0	6.0	6.0
		Resource management—Same	Resource management—References baseline maintenance requirements	Resource management—Same
			Human resources	
			6.2	
			6.2.2	
			Competence training and awareness—Added f, g, h	
			6.3	
			Infrastructure—Added d	
7.0	Product realization	7	7.0	7.0
		7.1	Product realization—Minor additions related to special product requirements	Product realization
		7.1.2		
		Risk management—Added		
		7.1.3		7.5.2
		Configuration management—Added		Validation of processes for production and service provision—Delete
		7.1.4		7.1.1
		Control of work transfers—Added		Design and development—Added
		7.1.1		7.1.2
		Project management—Added		Risk management—Deleted

Continued

Table 1.1 Continued.

ISO 9001:2008	AS9100 compared to ISO 9001:2008	AS9110 compared to AS9100	AS9120 compared to AS9100
	7.2.2		7.2.2
	7.3.1		7.3
	7.3.3		
	7.3.3		
	7.3.6.1		
	7.3.6.2		

Continued

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Table 1.1 Continued.

ISO 9001:2008	AS9100 compared to ISO 9001:2008	AS9110 compared to AS9100	AS9120 compared to AS9100
7.4 7.4.1	Purchasing Purchasing process— Major revisions	7.4.1	Purchasing process— Added g. Implement controls to prevent the purchase of counterfeit and suspected unapproved parts
7.4.2	Purchasing information— Major revisions		
7.4.3	Verification of purchased product—Major revisions		
7.5	Product and service provision—Major revisions		
7.5.1.1	Product and process verification—Added		
7.5.1.2	Control of production process changes—Added		
7.5.1.3	Control of production equipment, tools, and software programs— Added		
7.5.1.4	Post delivery support— Added		

Continued

Table 1.1 Continued.

	ISO 9001:2008	AS9100 compared to ISO 9001:2008	AS9110 compared to AS9100	AS9120 compared to AS9100
	7.5.5	Preservation of product—Major Changes		
	7.6	Control of monitoring and measuring equipment—Notes added		
8.0	8.0	Measurement analysis and improvement	8.0	Measurement analysis and improvement
	8.1	General—Added notes		Deleted section after 8.1c
	8.2.1	Customer satisfaction—Added note		
	8.2.2	Internal audit—Added note		
	8.2.3	Monitoring and measurement of processes—Added a, b, c, d		
	8.2.4	Monitoring and measurement of product—Major additions		

Continued

Table 1.1 Continued.						
	ISO 9001:2008	AS9100 compared to ISO 9001:2008	AS9110 compared to AS9100	AS9120 compared to AS9100		
					8.2.5	Evidence of conformity—Added
		Control of nonconforming product—Major additions			8.3	Control of nonconforming product—Distributor has no authority to rework or repair
		Continual improvement—Note added				
		Corrective action—Added g, h, i				
		Preventive action—Added note				

certification), incorporating the AS9100C changes and aligning with ISO 17021 content, supporting the process approach for quality management systems as described in the 9100-series standards, incorporating the ICOP (Industry Controlled Other Party) resolutions and improving the value of third-party auditing, defining the requirements for all activities of the audit program, and providing an adequate audit report to stakeholders on the performance of organizational processes.

AS9101 defines the common auditing requirements for the AS9100, AS9110, and AS9120 standards. The AS9101 audit standard is a complete rewrite of the previous version it replaces, making AS9101 a process-focused and performance-based standard. In many ways, Figure 1.3 represents a summary of the changes the standard represents. The AS9101 standard and its changes will be covered in detail in Chapter 3.

SUMMARY

The aerospace standards had their start in 1997 with the advent of the AS9000:1997 standard. This represented the first effort at standardization by the aerospace industry. The next big step toward standardization was the foundation of the IAQG and the release of AS9100 Rev B.

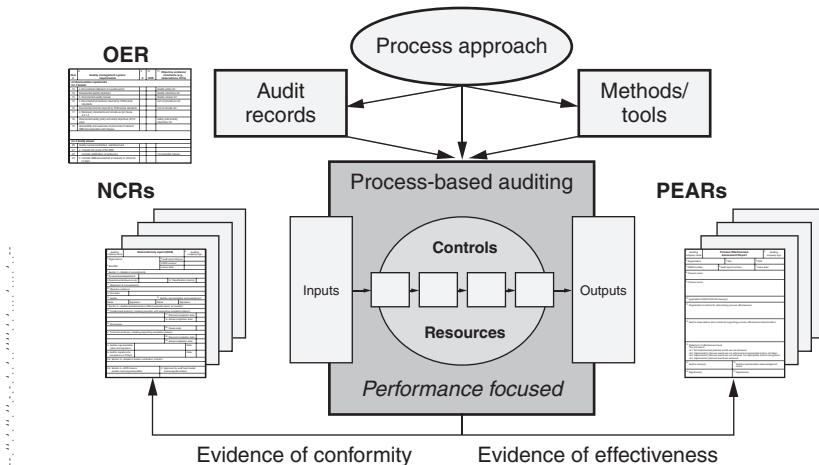


Figure 1.3 Model for process-based auditing.

Source: AS9101 model for process-based auditing, IAQG 9101:2009 change overview presentation, April 2010.

With the release of AS9100 Rev C and the common AS9101D audit standard, the push to unify the aerospace industry under a common set of standards is hitting its stride. The AS9100 series of standards and the IAQG have reached their maturity, and their influence and impact will be felt by the industry for the next 10 years. The advent of AS9100C will push customer-focused performance of “on-time and quality” and overall customer satisfaction. There will be another improvement surge in third-party auditing as well. All these changes bode well for the aerospace industry.

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2

AS9100C Key Changes and the Impact to the Quality Management Systems

An AS9100-compliant quality management system (QMS) is impacted not only by the AS9100 standard, but also by the AS9101 standard. Though the AS9101D requirements are mandatory for third-party auditors and registrars, the expectations of the auditor will dictate the requirements that the organization's QMS needs to meet. This chapter will cover the key changes to the QMS and will also list a number of QMS requirements that are influenced by the AS9101D auditing standard. These and other AS9101D changes will be covered in greater detail in the next chapter.

Overall, three groups of changes impact an AS9100 quality management system: AS9100C changes, AS9101D changes, and ISO 9001:2008 changes. All three of these need to be considered by organizations implementing and auditing to AS9100C.

AS9100 CHANGES

The IAQG identifies six additions, eight revisions/relocations, and three deletions to AS9100 on top of the changes to ISO 9001:2008. The six additions they refer to are:

1. Risk (3.1): undesirable situation or circumstance
2. Special Requirements (3.2): requirements that have high risk
3. Critical Items (3.3): items (such as functions, parts, software, characteristics, processes, and so on) that have a significant effect on product realization and use of the product (including safety, performance, fit, function, producibility, service life, and so on) that require specific actions to ensure they are adequately managed

4. Customer Focus and Customer Satisfaction (5.2 and 8.2.1): focus on product conformity and on-time delivery performance
5. Project Management (7.1.1): planning and managing product realization (new product development) with acceptable risk
6. Risk Management (7.1.2): process for the management of risk in product realization

Risk, special requirements, critical items, project management, and risk management are all linked together. They are a part of the overall risk management process in an aerospace, space, or defense organization. Figure 2.1 demonstrates the interrelationship of these new additions.

Impact of Key Characteristics and Risk Management Process on the QMS

Auditors should expect a comprehensive risk management process implemented at the organizations they audit. The management of risk starts at sales for suppliers (7.2 Customer-Related Processes) or in the planning phase (7.1 Planning of Product Realization) for OEMs. See Figure 2.2 for the product realization process.

The risk management process needs to be embedded in sales or contract review, planning, product design, manufacturing and delivery, and post-delivery processes. It should include the definition of all special requirements, critical items, and key characteristics. Though key characteristics are not new to AS9100C, they act as an important designation for controlling variation on the shop floor. When auditing an organization, the auditor should look for evidence of a risk management process embedded within the product realization process that includes special requirements, critical items, and key characteristics. If the risk management process is implemented as a stand-alone process, the linkages between the risk management process and planning, sales, design, manufacturing, and first article inspection (FAI) processes must be clearly defined.

During the IAQG-sanctioned auditor transition training, examples of risk management were demonstrated through the use of design failure mode and effects analysis (DFMEA), process failure mode and effects analysis (PFMEA), control plans, and statistical studies both during FAI and after FAI for process control. Many aerospace organizations are embracing the FMEA methodology along with a structured new product development phase gate approach for the launch of new products. In fact, Omnex is currently working with some large aerospace manufacturers and their suppliers—including Bombardier and Pratt & Whitney—to introduce these tools into their new-product launch processes.

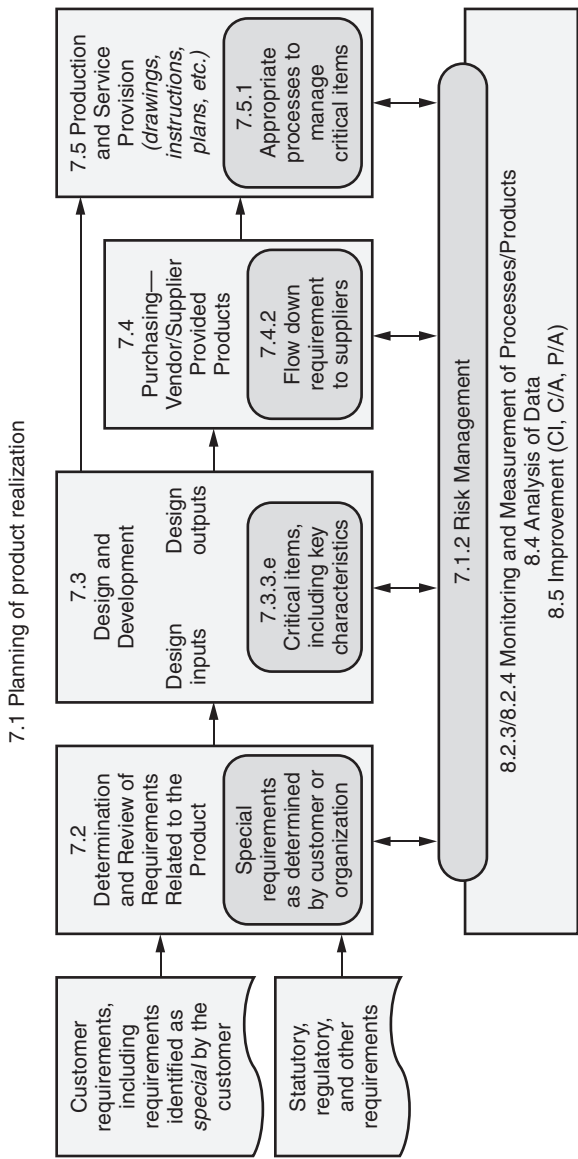


Figure 2.1 Interrelationship between special requirements, critical items, key characteristics, and risk management process.
Source: IAQG AS9100 deployment materials.

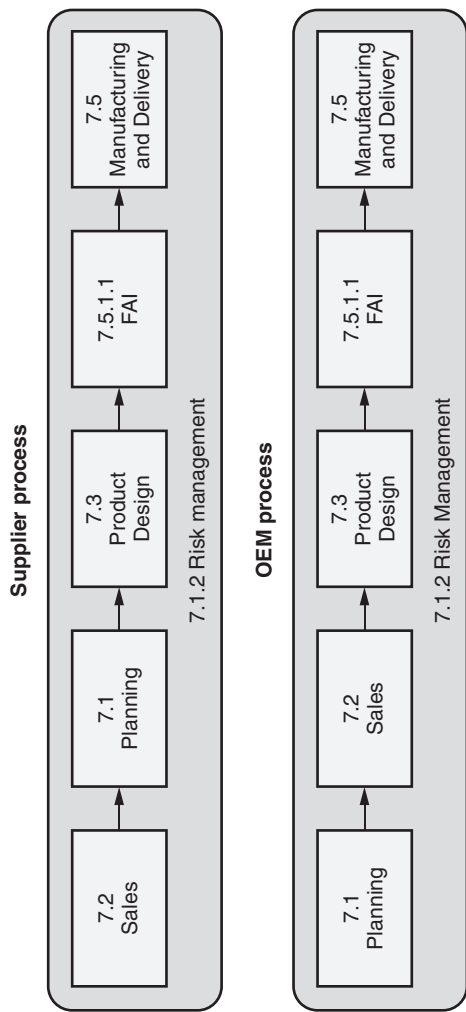


Figure 2.2 Embedding risk within the product realization process.

In case you didn't know, the FMEA methodology was originally initiated at NASA to understand the risk of launching space vehicles, and then became popular in many other industries including automotive, electronics/semiconductors, and medical devices. Only now is it once again gaining popularity within the aerospace industry.

Here are definitions of the terminology that may be common when auditing risk management:

- *Team feasibility commitment.* A commitment by the organization's product quality planning team that the design can be manufactured, assembled, tested, packaged, and shipped in sufficient quantity at an acceptable cost and on schedule. [APQP, 2nd edition]
- *Project management.* Planning and managing product realization in order to meet requirements at acceptable risk while adhering to any and all resource and/or schedule constraints.
- *Special requirements.* Those requirements identified by the customer, or determined by the organization, that have high risks to being achieved, thus requiring their inclusion in the risk management process. Factors used in the determination of special requirements include product or process complexity, past experience, and product or process maturity. Examples of special requirements include performance requirements imposed by the customer that are at the limit of the industry's capability, or requirements determined by the organization to be at the limit of its technical or process capabilities. [AS9100C]
- *Critical items.* Those items (for example, functions, parts, software, characteristics, processes) having significant effect on the product realization and use of the product, including safety, performance, form, fit, function, producibility, service life, and so on, that require specific actions to ensure they are adequately managed. Examples of critical items include safety-critical items, fracture-critical items, mission-critical items, key characteristics, and so on. [AS9100C]
- *Key characteristics.* An attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life, or producibility that requires specific actions for the purpose of controlling variation. [AS9100C]
- *Design failure mode and effects analysis (DFMEA).* An analytical technique used by a design-responsible organization as a means

to assure, to the extent possible, that potential failure modes and their associated causes/mechanisms have been considered and addressed. [APQP 2nd edition]

- *(Design) verification*. Confirmation through objective evidence that specified requirements have been fulfilled. Testing to ensure that all design outputs meet requirements may include activities such as: design review, performing alternate calculations, understanding tests and demonstrations, or review of design stage documents before release. [APQP 2nd edition]
- *DVP&R*. Design verification plan and report.
- *Process flow*. The manufacturing process flow depicts the entire process, from receiving to shipping and the manufacturing processes. There are many formats of process flow used within the industry. Overall, the manufacturing process flow should be able to show the entire process from start to finish, including alternative flows. The FAI/production part approval process (PPAP) is typically based on the flow depicted in the process plan, PFMEA, and control plan of the process.
- *Process failure mode and effects analysis (PFMEA)*. An analytical technique used by a manufacturing-responsible engineer/team as a means to assure that, to the extent possible, potential failure modes and their associated causes/mechanisms have been considered and addressed. [APQP 2nd edition]
- *Control plan*. Written descriptions of the system for controlling production parts or bulk materials and processes. They are written by organizations to address the important characteristics and engineering requirements of the product. Each part must have a control plan, but in many cases “family” control plans can apply to a number of parts produced using a common process. [PPAP 4th edition]
- *Enhanced FAI or PPAP*. Standardized method for use by organizations to submit approvals for new or changed parts to their customers prior to shipping mass quantities for production.

The overall integration of risk management and high-risk characteristics and their control is one of the major changes in AS9100C. There are other major and minor changes as this chapter and the next will show.

Customer Focus and Customer Satisfaction

Customer focus and customer satisfaction go hand in hand with one of the core principles of AS9101, which requires the organization to be “customer driven.” According to an IAQG presentation on the changes in AS9100C, organizations need to measure and evaluate product conformity, on-time delivery performance, customer complaints, and corrective action requests. Also, the organization should develop and implement plans for improving these metrics or measurables, including customer satisfaction improvement.

Customer satisfaction is not just measuring quality or conducting customer surveys. As clause 8.2.1, Customer Satisfaction, of AS9100 states:

Information to be monitored and used for evaluation of customer satisfaction shall include, but is not limited to, product conformity, on-time delivery performance, customer complaints, and corrective action requests. Organizations shall develop and implement plans for customer satisfaction and improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

Also, changes made to ISO 9001:2008 suggest that customer satisfaction needs to have multiple inputs.

Customer focus and customer satisfaction are both closely related. Customer focus is often thought of as the input into the organization while customer satisfaction is the output of how the customer feels about the organization. This relationship can be seen in Figure 2.3. Customer focus entails not just quality or delivery, but also requires understanding all the “customer needs and expectations” and implementing them within the organization. Various models can be used; see Figure 2.4 for a model

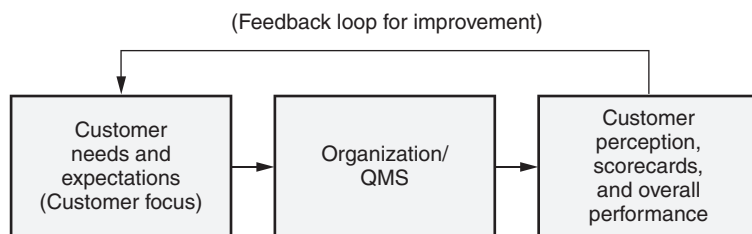


Figure 2.3 Customer focus and customer satisfaction.

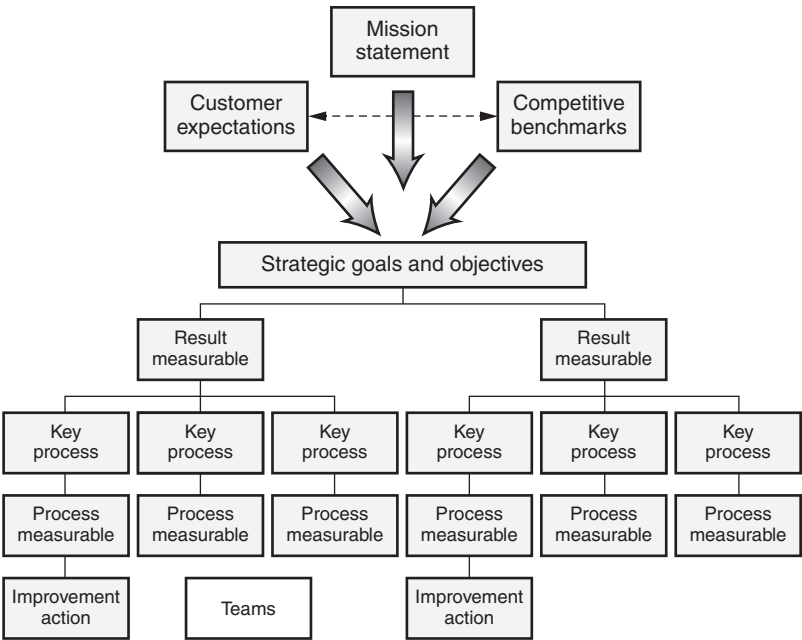


Figure 2.4 QOS/BOS model.

called QOS/BOS (quality/business operating system) that Omnex developed for Ford Motor Company and has since implemented at many organizations worldwide.

This model comprises a seven-step action-oriented model used by many organizations worldwide, from Magna to Bosch to TRW. Also, service organizations from Ryder to Kelly Services, and architectural firms such as Loaring Construction and Giffels, use this model to ensure they are customer focused and practicing continual improvement. In fact, QOS/BOS is a requirement for all Ford manufacturing and service suppliers.

AS9101 CHANGES

As mentioned earlier, the second driving force impacting the QMS is the changes to the AS9101 auditing standard. This chapter will only focus on those changes to AS9101D that affect a QMS. Auditing changes will be covered in the next chapter. AS9101 is built upon the following six core principles:

1. Customer driven—impacts the QMS
2. Process-based approach—impacts the QMS
3. Organization performance focus—impacts the QMS
4. Audit methodology—impacts the QMS
5. Quality management system effectiveness (in addition to conformity)
6. Improved reporting of audit results

Customer Core Principle 1 (CP1)—Customer Driven

This first core principle (CP1) of AS9101 requires the following:

- Customer focus (4.1.2.1): evaluation of customer satisfaction based on performance information and feedback
- Customer QMS requirements that must be audited
- Audit focused on processes that directly impact the customer
- Customer importance that must be reflected at the planned audit time
- Information and review of customer satisfaction and complaint status and processing

The key change affecting a QMS from CP1 is customer focus, as pointed out in AS9100. Both the third-party and internal audits should focus on customer focus and customer satisfaction; thus, an AS9100 QMS must have robust processes for handling customer requirements and customer satisfaction (that is, 5.2 and 8.2.1).

Though it may not be evident to the reader, the “Audit focus on the processes that directly impact the customer” is a process called *customer oriented process* (or COP), a term originating in the automotive industry. A COP is defined as a process that has an input from a customer with an output going back to the customer. Figures 2.5 and 2.6 show examples of COPs and Figure 2.7 shows an example of a Turtle diagram, terms used in automotive ISO/TS 16949:2009 auditing. The Turtle diagram is introduced as an auditing approach, but is also used by those implementing robust processes.

The next chapter will discuss these items in greater depth.

Typical implementation practices in the automotive industry include identifying the COPs and the Turtle diagrams for processes within an

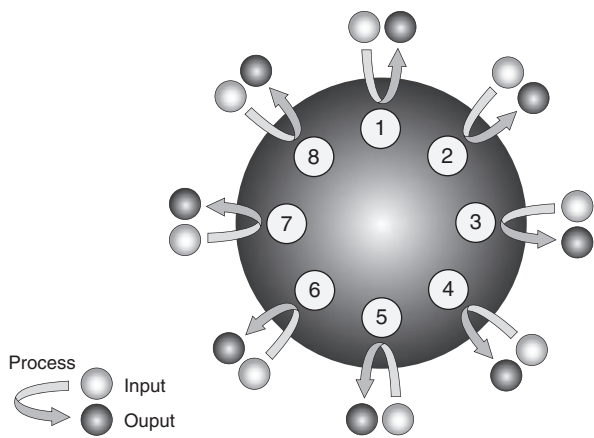


Figure 2.5 Customer oriented process example.

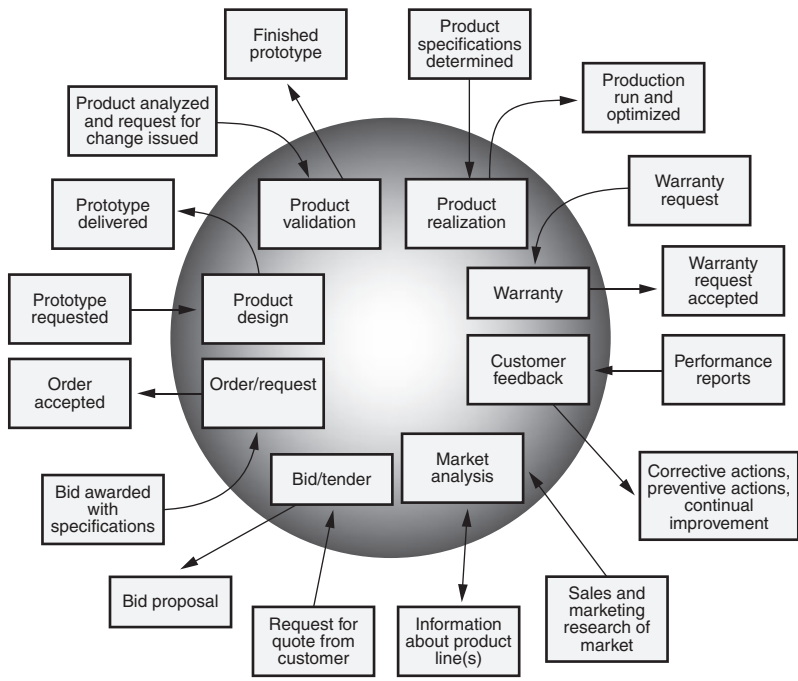


Figure 2.6 Multiple COPs in an organization, termed an octopus diagram by the automotive industry standards.

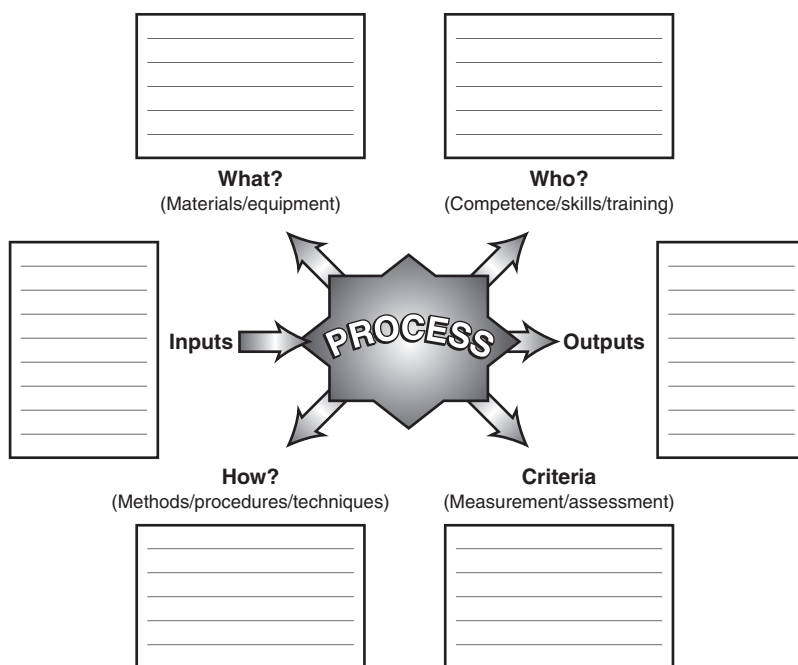


Figure 2.7 Turtle diagram example.

organization. This is an implementation practice Omnex recommends for organizations in the aerospace industry to develop their process approach.

Customer Core Principle 2 (CP2)—Process-Based Approach

The process-based approach requires the auditor to examine and audit the process used by the organization and discern whether they are following an elemental or clause approach versus a process approach. Figure 2.8 illustrates the process approach.

Many organizations in the aerospace industry have process maps that utilize a clause approach, and procedures that simply regurgitate the standard. For this reason, the process approach is viewed as a big change within the AS9100 QMS auditing and implementation scheme. The clause approach of an organization is evident in the process description, that is, process map, procedures or processes, and process measurements.

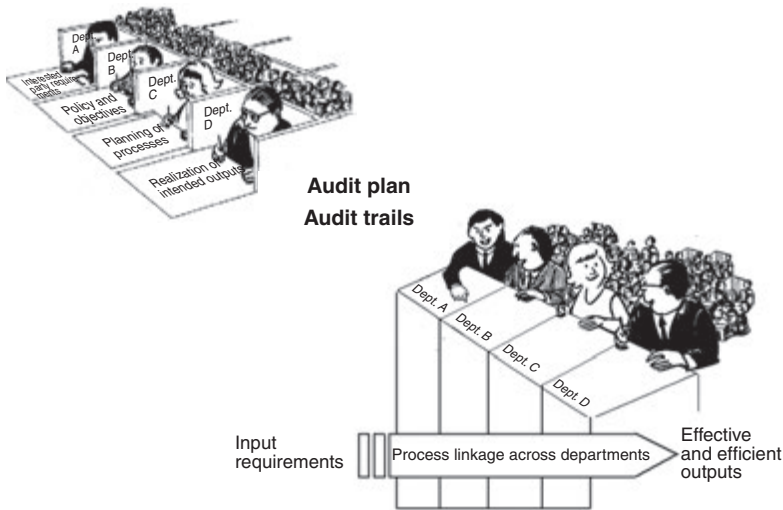


Figure 2.8 Organization process approach.

Source: *Guidance on the Concept and Use of the Process Approach for Management Systems*, ISO/TC 176/SC 2/N-544R3.

The process focus and customer focus can be examined/audited during the readiness review of the organization, thus allowing CP1 and CP2 to be audited/reviewed at that time.

Customer Core Principle 3 (CP3)—Organizational Performance Focus

The auditor will focus on organizational process performance, continual improvement, and customer satisfaction to determine if the process is performing effectively. Organizations preparing for this type of audit should determine process measurements and improvement goals for their primary or key processes. Omnex typically plans process performance using a business management system (BMS) control plan, which is displayed in Figure 2.9. Similarly, organizations that have conducted planning will be in a better position to answer the question, “are the processes performing satisfactorily?”

An auditor should study customer data (satisfaction, complaints, and so on), including organizational reviews, to determine how to prioritize the audit. This is conducted in the stage 1 audit.

Business Management System Control Plan									
Organization _____		Product description _____							
General manager _____		Issue/rev date _____							
Process activity	Customer requirement/expectation	Key process/COP	Measurement	Responsibility	Acceptance criteria 2002	Review frequency	Control methods	Comments/reaction	
					Q1, Q2, Q3, Q4				
Examples									
Business fulfillment	On-time delivery	K	% on-time in operations	Logistics	94, 95, 96, 96%	4/yr	Monthly management meeting	Corrective action after 3 consecutive	
			% on-time to customer	Production control	100%	4/yr	Trend chart	C/A is more than 15% off target	
Customer complaint	Provide timely response	C	Complaint response	Quality	10 days	4/yr	Production control department	Continue to monitor	
Design and development	Meet timing requirement		Time to market	Design/development	52 weeks	Weekly	Quality department	R, Y, G reaction	
Business creation	Innovation		Patents filed	Design	20 per year	Monthly	Design meeting	Continue to monitor	

Figure 2.9 BMS control plan example.

Customer Core Principle 4 (CP4)—Audit Methodology

One of the audit methodologies describes process performance and effectiveness as an evaluation of process definition—including sequence and interaction, assigned responsibilities, process controls, resource availability, monitoring, measuring, and analysis—against planned results.

This description is really about the use of the Turtle diagram for auditing the process. See Figure 2.7 presented earlier. Auditors will use this tool or something similar to determine process performance and effectiveness along with process prioritization.

The use of Turtle diagrams (as taught in the IAQG Aerospace Auditor Transition Training) in turn affects QMS implementations. Typically, Omnex develops and uses certain tools to develop processes in organizations.

Customer Core Principles CP5 and CP6

The remaining customer principles, CP5, QMS effectiveness, and CP6, improved reporting of audit results, are changes to the auditing process rather than changes affecting the QMS, and hence will be covered in the next chapter.

ISO 9001:2008 CHANGES

The third major factor affecting the AS9100 QMS is the changes in ISO 9001:2008. Though these changes were introduced to the community as simply clarifications to interpretations of ISO 9001:2000, there are some changes of which auditors and those conducting implementations need to be aware.

The interpretations for this section originate from the International Register of Certified Auditors (IRCA), registrars, and other respected sources. The key changes that impact a QMS are:

- *Outsourced processes.* “‘Outsourced process’ is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.” Most organizations will need to evaluate those processes that they have defined as outsourced processes. Control of outsourced processes will need to be defined in the organization’s QMS.
- *Inclusion of information systems in clause 6.3, Infrastructure Requirements.* AS9100C has specifically included information systems as a part of an organization’s infrastructure. Organizations