

The 15 most impactful changes in the transition from AS9100:2009 “Rev C” to AS9100:2016 “Rev D”

1. **10 Elements** - The standard has been completely renumbered from an 8 element based system to a 10 element based system. You DO NOT have to renumber your Quality Management System, but if it doesn't put too much of a hardship on your company's resources, it is recommended to renumber your system in order to help your personnel be able to better relate to the new standard.
2. **Context of the Organization** – The new standard wants you to be able to demonstrate that management has a deep understanding of their company's internal and external issues, for example: strengths, weaknesses, opportunities and threats. Companies are expected to monitor these on an ongoing basis.
3. **Interests of External Parties** – Companies need to document a general description of who their external interested parties are. Examples would be Customers, Regulatory Authorities, Mother Corporations, Stock Holders, other.
4. **Objective Programs** – Now, instead of only having to have an action planned defined when you are not meeting an objective in order to correct it, you must have a plan for each objective which describes: what will be done; what resources will be required; who will be responsible; when it will be completed; how the results will be evaluated. We commonly refer to this as having a documented objective program.
5. **Risk Based Thinking** – In AS9100 Rev C, risk was only required to be assessed at contract review or quoting and then the results communicated throughout product realization, as applicable. Now, companies must also assess Process Risk, Corporate Risk and Opportunities.
6. **Product Safety** – Companies must determine what controls are necessary to assure the safety of the products and services they offer and they must train their personnel on these requirements.
7. **Ethics Training** – Personnel must be made aware of the importance of ethical behavior. It is a good idea to have an Ethics Policy for the company to train personnel on.
8. **Management Review** – Management Review has several new input requirements including: the performance of external providers; on-time delivery performance; the adequacy of resources; the effectiveness of actions taken to address risks and opportunities. One new output was added: Risks that have been identified. Also, action items from management review must be considered for inclusion in the continual improvement process.
9. **Organizational Knowledge** – The new wording lends itself towards having a Matrix or Database that shows a company has determined what knowledge/training is necessary for its personnel and also pushes companies further towards having Job Descriptions.
10. **Counterfeit Parts Prevention** – Companies must have a procedure for Counterfeit Parts Prevention which must include sampling and analysis of raw materials and parts. It would also be prudent for companies to join GIDEP (Government Industry Data Exchange Program) in order to meet the intent of the Note regarding the elements of Counterfeit Parts Prevention.

11. **Supplier Monitoring** - It is now required to measure both the OTD and Quality for suppliers.
12. **Purchasing** - Flow down requirements have been expanded including requirements for suppliers to make their employees aware of Product Safety and the importance of Ethical Behavior and their contribution to product or service conformity.
13. **Communication** – Companies must determine requirements for internal and external communication including a) on what it will communicate; b) when to communicate; c) with whom to communicate; d) how to communicate; e) who communicates.
14. **Change Management** – There is more of an emphasis throughout the standard on controlling changes to the QMS, its processes, planning, production, contracts, etc.
15. **Human Factors** – There is a note in the Work Environment section regarding Human Factors and then it is also added as a requirement in the production control and corrective action root cause analysis sections. Even though this may not seem like a “big deal”, AAQG (the American Aerospace Quality Group) has already put out a lengthy presentation on “Human Factors” which is being distributed amongst Aerospace Auditors. Here is a list of Human Factors to consider in your system:
 - a) *Ergonomics* - Machine and tool design, material flow, intuitive to use, at hand.
 - b) *Equipment* - Suitable tools, appropriate clothing, access equipment, raw materials.
 - c) *Culture* - Management attitude, Can / Can't Do, Pride, Values, Reward / Recognition, Pressures, Resources.
 - d) *Competence* - Knowledge, Skills, Experience, “Documented Information”, Training, Coaching, Support.
 - e) *Environmental* - Time of Day, Temperature, Lighting, Noise, Distractions, Safety Risks, Rest / Refreshment.
 - f) *Feelings* - Mental State, Physical Health, Perception of Worth, Ambition, View of Authority/Leadership, Confidence, Co-worker relationships.
 - g) *Lessons Learned* – Fatigue, Lack of Concentration, Complacency, Lack of Knowledge, Distraction, Lack of Teamwork, Lack of Resources, Pressure, Lack of Assertiveness, Stress, Lack of Awareness, Negative Norms (Incorrect Tribal knowledge).