AS 9100, Rev. D, 2016

Key Changes

(Review ISO 9001:2015 changes in conjunction with this presentation)

This presentation is for companies who are upgrading to the new revision.

Refer to iaqg.org for additional materials

RAMP ENTERPRISES

* Standard structural and terminology changes
* Risk-based thinking through-out
* Change management
* Knowledge Management
* Context of the Organization
* Align QMS with Strategy of the organization
* Greater flexibility with documentation
* More compatibility with service

* ISO 9001 changes – see ISO powerpoints

Terminology

- Products is now Products and Services
- Exclusions is now Non-applicability
- Documentation is now Documented Information
- (record control is not retained information)
- Purchasing is now Externally provided products and services
- Supplier is now External provider

AS 9100 Changes

- Product Safety
- Counterfeit parts prevention
- Awareness
- Human Factors
- Configuration Management
- Independent testing

Common Threads

- Counterfeit parts
- Product Obsolescence
- Product Safety

- Consider these aspects throughout Context, Planning (Risks), Support, Operation and Actions taken.

New Definitions

* Product Safety – The state in which a product is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.

* Counterfeit Part – An unauthorized copy, imitation, substitute, or modified part (e.g., material, part, component), which is knowingly misrepresented as a specified genuine part or an original or authorized manufacturer.

Training implications and new notes:

- Clarity with metrics
- Get better at metrics unique to the process, rather than using the same metrics for multiple processes.
- Data (associated with metrics) can include information on product and service reported by external sources (government/industry alerts, advisories)

*Metrics and Data

Product Safety

- Consideration throughout the product lifecycle
- Look for clauses:
- **8.1.3**, 7.3, 8.1, 8.4.3, 8.5.4
- The organization shall plan, implement, and control the processes needed to assure product safety during the entire product life cycle, as appropriate.
- Examples: hazards, safety critical items, analysis and reporting, communication and incorporation into risk management

Counterfeit parts prevention

- Consideration through-out QMS
- Mitigate effects of growing counterfeit/fraudulent product
- Look for clauses: **8.1.4**, 8.3.3, 8.4.2, 8.4.3, 8.7
- The organization shall plan, implement, and control processes, appropriate to the organization and the product, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in products(s) delivered to the customer.
- Next slide

Counterfeit parts prevention

- Considerations:
- Training and awareness
- Parts obsolescence monitoring program (design and purchasing)
- Controls for acquiring externally provided product from original or authorized manufacturers, authorized distributors, or other approved sources
- Assuring traceability of parts and components to their original or authorized manufacturers (OCM, OEM, PMA)
- Verification and test methodologies to detect counterfeit parts (Parts identification/marking, test or chemical analysis)
- Monitoring of counterfeit parts reporting from external sources (GIDEP)
- Quarantine and reporting of suspect or detected counterfeit parts.

More on Counterfeit Parts

- Examples: False identification of marking or labeling, grade, serial number, date code, documentation or performance characteristics.
- Reporting: Monitoring reporting from external sources. Quarantine and reporting of internal incidences in appropriate government and industry reporting systems. What is the escalation?
- Segregate and control: Ensure products are not re-introduced into the supply chain.

Additions to Awareness 7.3

- AS 9100:2016: Employees must be aware of:
  - Relevant QMS documented information and changes
  - Their contribution to product or service conformity
  - Their contribution to product safety
  - The importance of ethical behavior
- Ethical Behavior?
- Organization defines and look for contractual flowdown
- Consider: laws, regulations, internal policies, conflicts of interest, intellectual property agreements, invitations/favors, communication requirements, etc.

Human Factors

- Requirement to include human factors considerations in the root cause and corrective action.
- Consider: people, psychological affects, personality, stress, fatigue, distraction, as well as, interaction with other persons, equipment, facilities, procedures, and data.
- Look at clauses: 7.1.4, 8.5.1.g

* Identify risks associated with suppliers of products and services.
* Include inspection and periodic testing, for mitigation, when there is a high risk of nonconformities and/or counterfeit.
* When supplier test reports are utilized the organization shall implement a process to evaluate the data in the test reports. When raw material is a significant operational risk, a process to validate the accuracy of the test reports needs to be in place.

* Verification of purchased products and services

Other Subtle changes

- There are many other subtle changes. We will perform an academic gap assessment at the beginning of the implementation process or as part of our internal audit process.
- Don’t skimp at this stage, do your homework!
- Look for a clause-by-clause powerpoint.

* See attached High Level Summary from IAQG.

* Conclusion