

# IATF 16949:2016 Transition Experiences

## Ismael Belmarez & Wendy Parr

**March 2017**  
**Business Assurance USA**

*DNV GL and Consultant are acting in cooperation to provide this Webinar purely as an informational session to attendees and no relationship should be implied between DNV GL and Consultant. Participation in this Webinar does not construe a request for auditing or certification services nor implies any relationship between DNV GL and Consultant. DNV GL remains impartial and does not recommend or endorse individual consulting companies or seek to influence clients in deciding whether to use a consulting company or which to select.*

# Transition Timing Requirements

- After 1 October 2017 no audits (initial, surveillance, recertification or transfer) shall be conducted to ISO/TS 16949:2009.
- Organizations certified to ISO/TS 16949:2009 shall transition to the new IATF 16949, through a transition audit in line with the current audit cycle for ISO/TS 16949:2009 (i.e. at a regularly scheduled recertification audit or surveillance audit), according to the allowable timing requirements defined in the IATF Rules, section 5.1.1.



# Transition Timing Requirements

- The timing requirements are as follows:
  - Failure to conduct a transition audit according to the timing in the IATF Rules, section 5.1.1 (or the timing of the decertification process in the IATF Rules, section 8.4) requires the organization to start over with an initial certification audit



# Transition Audit Requirements

- The transition audit shall be the duration of a recertification audit according to the IATF Rules, Table 5.2.
- The transition audit shall be a full systems audit equivalent to a recertification audit and shall comply with all requirements defined in the IATF Rules, section 6.8.
- A documentation review is required to be performed prior to the audit. If the information is not provided prior to the audit additional time will be added to the transition audit.



# Transition Audit Requirements

---

- The Transition audit will include all RSLs associated with the manufacturing location.
- The new certificate will be issued for 3 years once all NCs have been addressed.
- Note1: There is no requirement for auditor rotation at the Transition Audit
- Note2: Organizations are not allowed to transfer and transition at the same time.



## Additional Resources

---

- DNV Automotive Website
  - <https://www.dnvgl.us/assurance/automotive/index.html>
  - <https://www.dnvgl.us/assurance/automotive/16949changes.html>
- IATF Website
  - <http://www.iatfglobaloversight.org/>

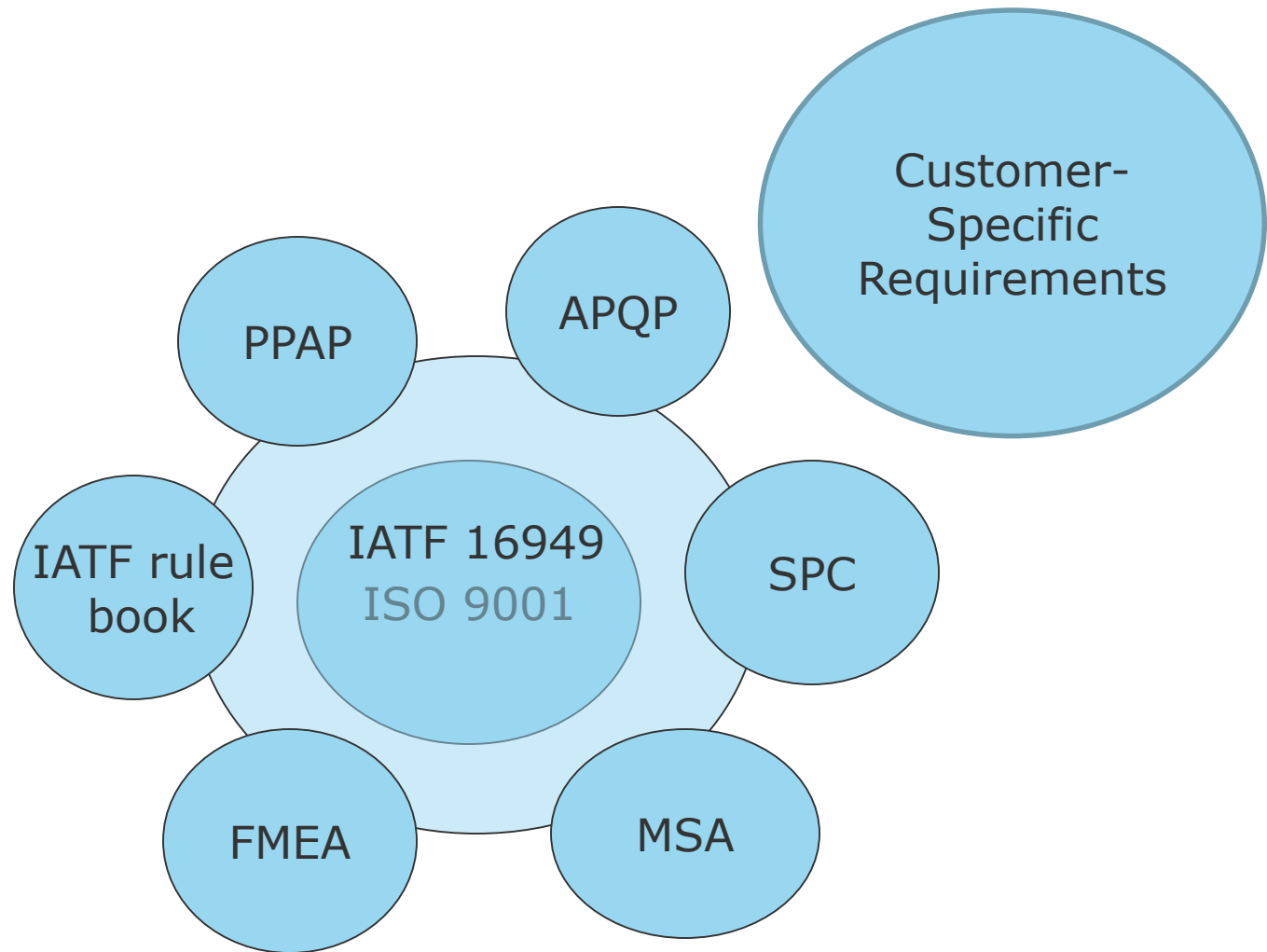
# IATF 16949:2016 Implementation Overview

Wendy Parr

Suggested implementation steps and key requirements



# ISO 9001:2015 & IATF 16949:2016





# IATF 16949 Implementation Overview - Agenda

---

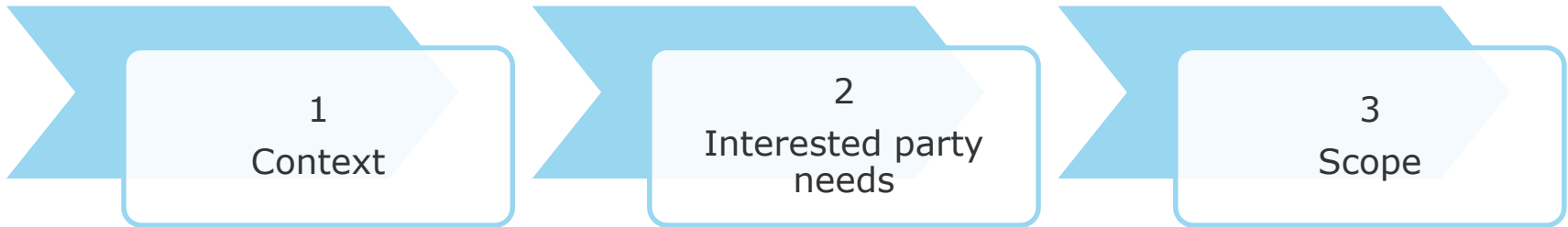
- ISO 9001:2015 Core Implementation Requirements
- Noted IATF sustainability requirements
- Other noteworthy additions

# ISO 9001:2015 Core Implementation Requirements

---

## Implementation Steps 1- 3

---



While many Quality Management Systems have been in place for some time, these steps must be taken as they are the foundation of the QMS.

## #1 Context (4.1)

---

“Combination of internal and external issues that can have an effect on an organization’s approach to developing and achieving its objectives.”

ISO 9000:2015

## #1 Context (4.1)

---

- Issues can include positive and negative factors or conditions for consideration
- Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local
- Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization

## #1 Context (4.1)

---

- Not required to be documented but must be monitored and reviewed
- Therefore, it is suggested that it be documented (e.g. Quality Manual)
- The registrar uses this information to ensure the scope is correct and overall risk factors are considered

## #1 Context – How to

---

- **SWOT**

- Strengths
  - Weaknesses
  - Opportunities
  - Threats
- Many organizations have most or all of a context statement already defined on their web sites

## Context Example

---

Master Machining Company was founded by Mike Master with a vision to provide customers with the finest in precision machined parts built with reliability and excellence without compromise. Located in Chicago, IL, MMC fabricates a comprehensive range of close tolerance component parts from steel, aluminum, stainless, titanium, brass, copper and plastic. MMC prides itself on its unparalleled precision machining techniques, quick turnaround times and the highest quality, complete-to-print parts.

MMC is proficient at producing low volume prototype to large volume runs on our state of the art multi-axis CNC machines for hydraulic, automotive, medical, and other industries.

Continued...



## Context Example

---

In the manufacturing industry there are many specialists with narrowly focused core competencies. MMC is confident that we have the best blend of skills and capabilities that this industry has to offer, in addition we have assembled the resources and expertise to offer the convenience of a one-stop, full service shop. We have an excellent relationship with top area businesses specializing in plating, grinding, honing, heat treating and a lot of other pre and post machining processes. We leverage our strengths and those of our partners, saving you missed deadlines, substandard quality, time and frustration.

end

## #2 Interested Parties (4.2)

---

“Person or organization that can affect, be affected by, or perceive themselves to be affected by a decision or activity”.

ISO 9000:2015

- Not required to be documented but must be monitored and reviewed
- Therefore, it is suggested that it be documented (e.g. Quality Manual)

## #2 Interested Parties (4.2)

---

- The registrar uses this information to ensure that processes and objectives consider all relevant interested parties

## #2 Interested Parties – Example

Interested Party	Needs & Expectations
Customers	<ul style="list-style-type: none"><li>• Product/Service meets specifications</li><li>• On-Time</li><li>• Billed correctly</li><li>• Supply of technical expertise</li><li>• Prompt resolution of problems</li></ul>
Owner	<ul style="list-style-type: none"><li>• Make money</li><li>• Image in marketplace</li></ul>
Employees	<ul style="list-style-type: none"><li>• Make money</li><li>• Desirable place to work</li><li>• Career advancement</li></ul>
External Providers	<ul style="list-style-type: none"><li>• Clear requirements</li><li>• On-time payment</li><li>• Required lead time</li></ul>

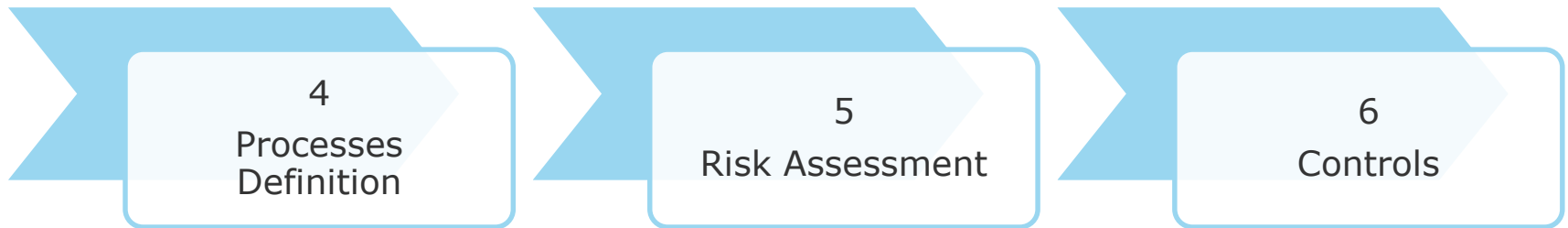
## #3 Scope (4.3)

---

- No significant changes in the requirement of the standard
- Confirm that it is correct as changes sometimes occur over time
  - Supporting functions
  - External locations
  - Products
  - Exclusions? i.e. product design
  - Customer-Specific Requirement
- Consult with your registrar if there are questions

## Implementation Steps 4 - 6

---



## # 4 Process Definition (4.4)

---

- a) determine the inputs required and the outputs expected from these processes;
- b) determine the sequence and interaction of these processes;
- c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
- d) determine the resources needed for these processes and ensure their availability;

## # 4 Process Definition (4.4)

---

- e) assign the responsibilities and authorities for these processes;
- f) address the risks and opportunities as determined in accordance with the requirements of 6.1;
- g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;
- h) improve the processes and the quality management system.

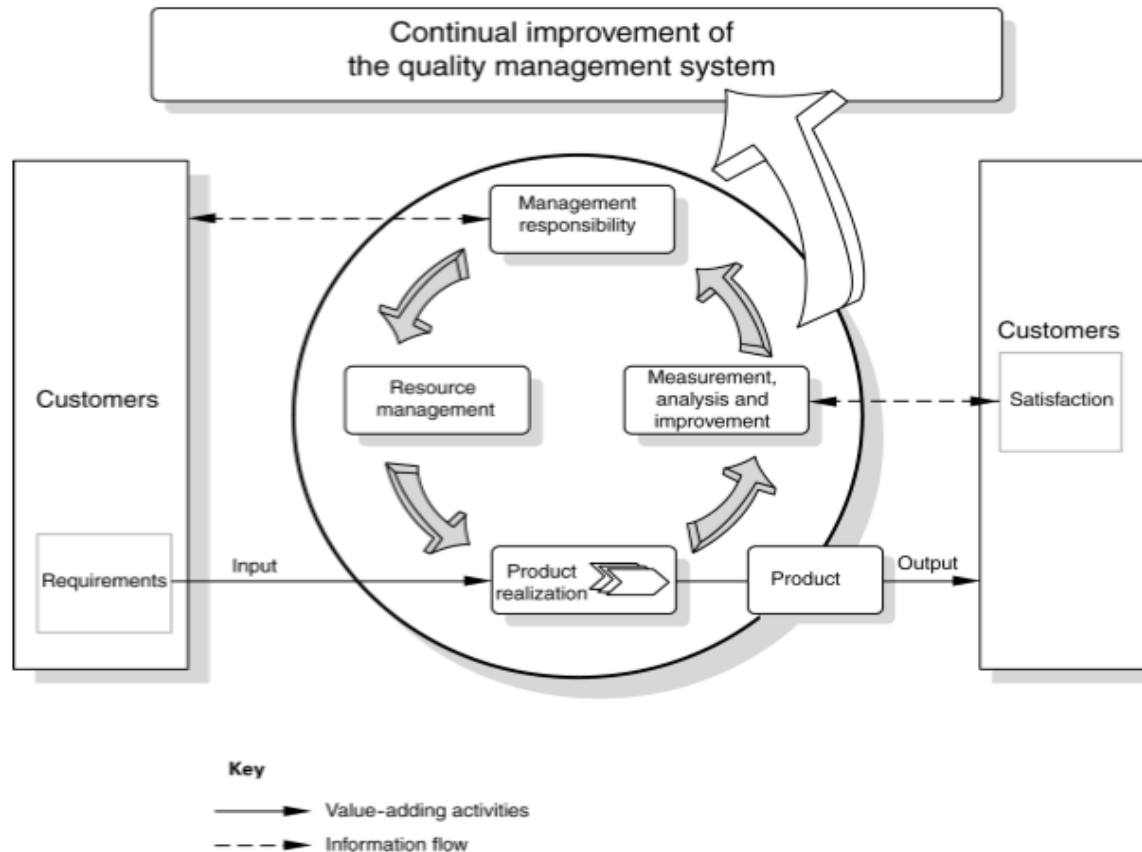


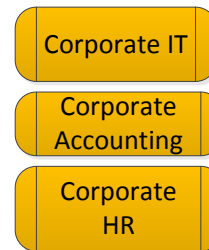
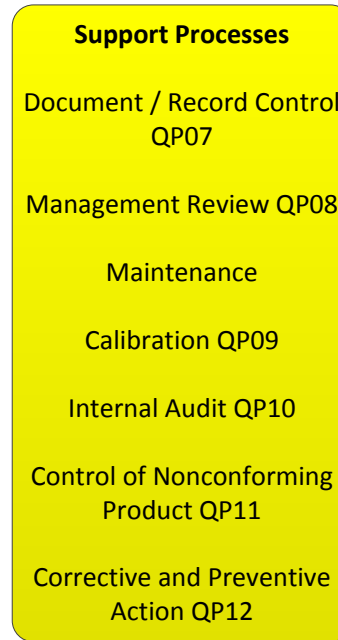
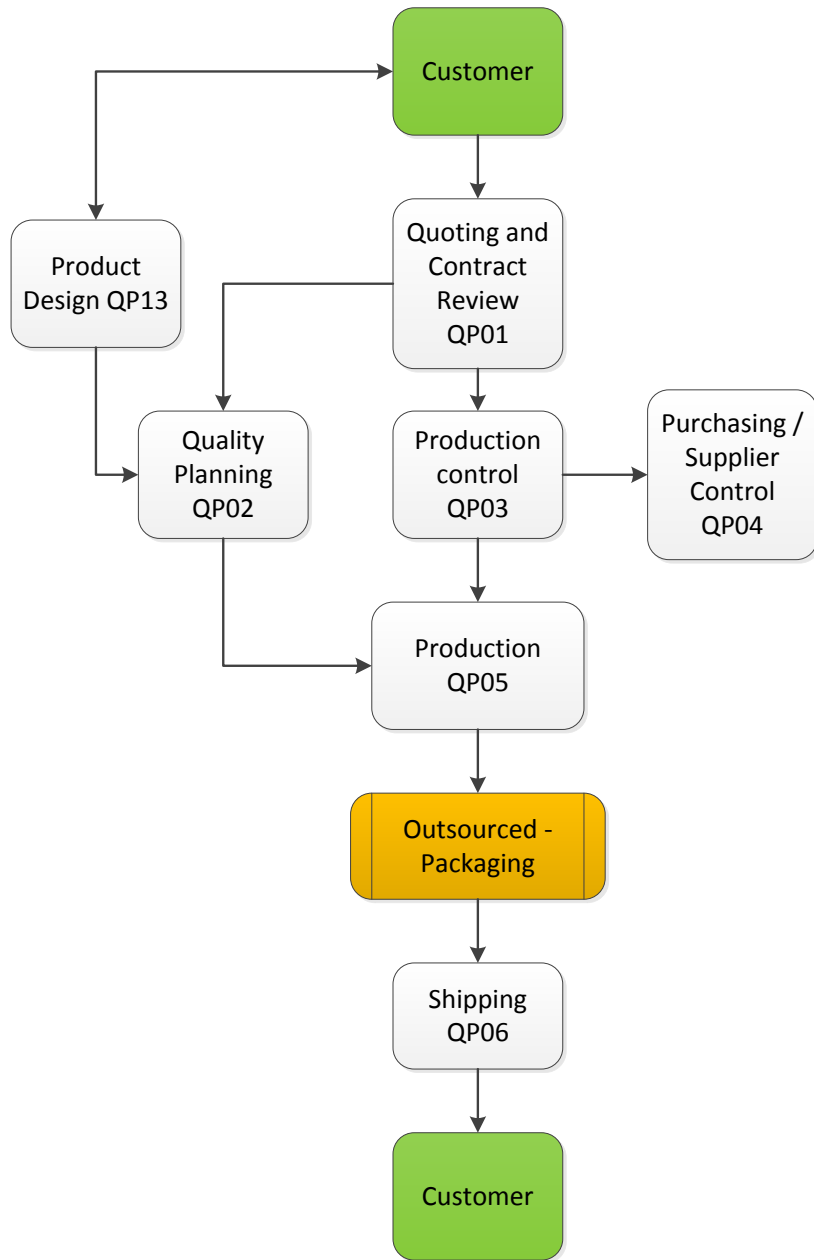
## # 4 Process Definition (4.4)

---

- Before you can perform a risk assessment, you must have good process definition
- Process Identification / Procedure template
  - Inputs/outputs
  - Sequence and interaction
  - Criteria and methods to ensure effective operation and control
  - Resources
  - Responsibilities
  - Risks and opportunities
  - Objectives

If your current process diagram looks something like this, you probably have not defined your processes adequately





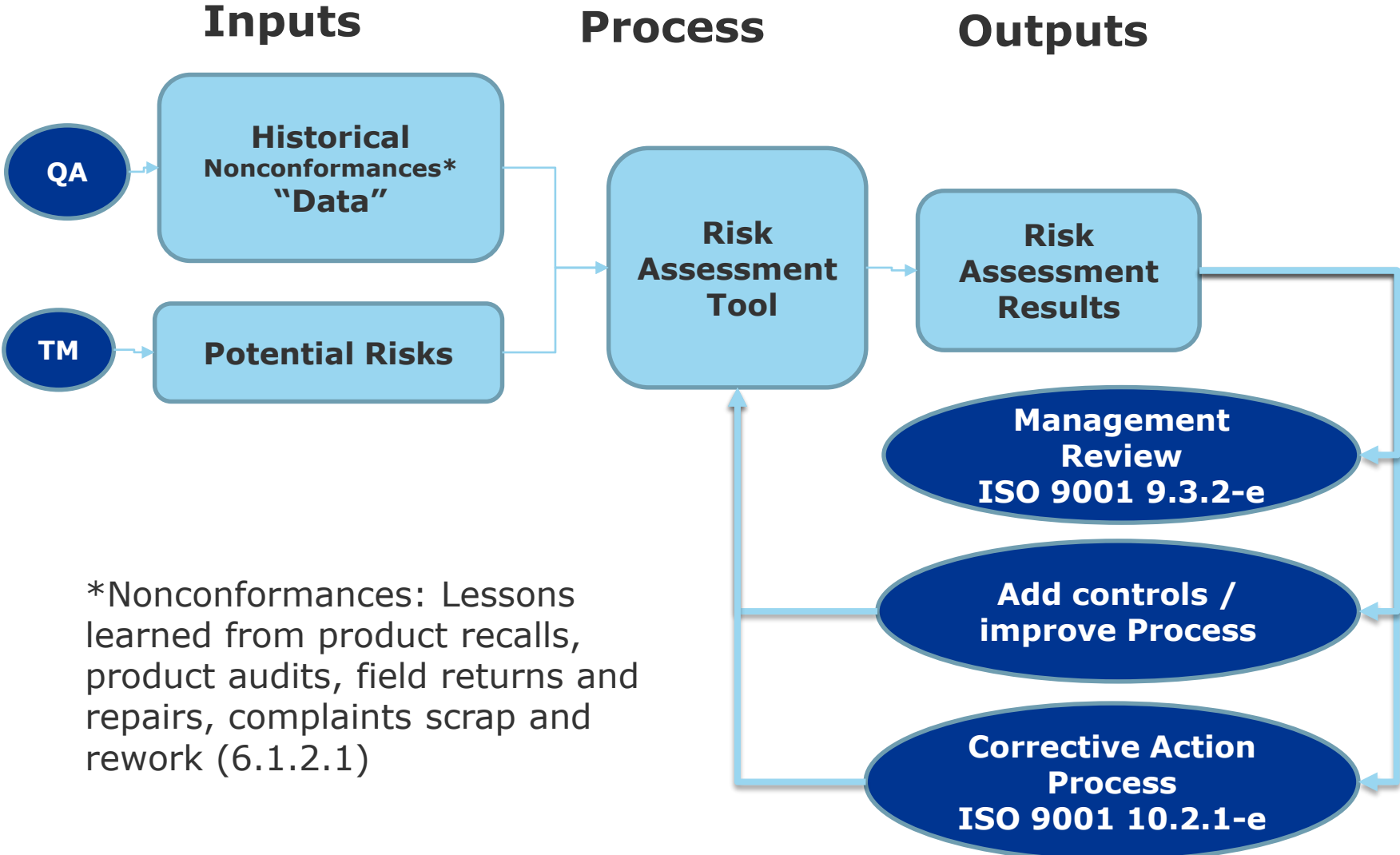
If your process diagram looks more like this, you likely have a good understanding of processes

## #5 Risk Assessment / Analysis

---

- IATF 16949 requires the risk analysis to be retained as documented information (6.1.2.1)
- Applies to all processes; not just PFMEA
- Options:
  - A – Risk assessment for all processes together
  - B – PFMEA + risk assessment for all other processes

# Risk Assessment Process



\*Nonconformances: Lessons learned from product recalls, product audits, field returns and repairs, complaints scrap and rework (6.1.2.1)

# Risk Assessment Tool

---

- Discussion

Risk Assessment Methodology								Version: 1		
Process #	Process Name	Potential Failures	Potential Consequence	Severity	Potential Cause of Failure	Likelihood	Current Prevention / controls	Current Detection Methods	Detection	RPN
SP1.1	Planning Contract Services - sampling	unacceptable sample	lost sale	3	Incomplete, inaccurate Sample Request	2	Completion of Sample Request Form prior to sample run	1st piece visual inspection, weight, & durometer	1	6
		unacceptable sample	lost sale	3	Personnel have insufficient training and/or knowledge	3	General Training and general procedure	1st piece visual inspection, weight, & durometer	1	9
SP1.2	Planning Contract Services - 1st time production order	nonconforming production parts	rework / additional labor / late shipment	2	Insufficient documentation of sample run / inadequate planning	2	Complete sample outputs: Approved Sample Report, notes, pictures, drawing changes	1st piece visual inspection, weight, & durometer	1	4
		parts not to customer specifications	customer dissatisfaction	3	Overlooking customer requirements	2	Quality Planning Review / release of Pre-production form	1st piece visual inspection, weight, & durometer	1	6
		parts not to customer specifications	customer dissatisfaction	3	Personnel have insufficient training and/or knowledge	3	General Training and general procedure	1st piece visual inspection, weight, & durometer	1	9
SP2.2	Quoting & Order Acceptance - <u>Quoting</u> (chemicals)	incorrect information to customer	customer dissatisfaction	3	Pricing Data inaccurate	1	documented quote required	President / Project Coordinator reviews/approves	1	3
		incorrect information to customer	customer dissatisfaction	3	Personnel have insufficient training and/or knowledge	1	System mistake-proofs process and procedure is detailed	President / Project Coordinator reviews/approves	1	3

### **Severity of failure ratings:**

- 1 - little impact on customer / company
- 2 - medium impact on operational efficiency and/or KPIs / little impact on customer
- 3 - customer satisfaction impacted

### **Likelihood of failure ratings:**

- 1 - has not happened in past and not very likely to happen in future
- 2 - has happened in past but not very likely to happen in future
- 3 - has occurred and has potential to occur in future

### **Detection of failure ratings:**

- 1 - detection of failure extremely likely, prior to customer impact
- 2 - detection of failure somewhat likely
- 3 - detection of failure unlikely

- This is NOT a FMEA; any scale and definition can be selected
- Do address loss of knowledge as a potential risk in each process (ISO 9001:2015, 7.1.6)



# Preventive Action (6.1.2.2)

## Risk Treatment

Process #	Recommended Action	Responsibility / Target Completion	Action taken	Severity	Occurrence	Detection	RPN
-----------	--------------------	------------------------------------	--------------	----------	------------	-----------	-----

SP1.1

SP1.2

**Controls**

**Documented procedures**

**Records**

**Process measures / objectives**

**Resources: personnel, system, tools, etc.**

**The Risk Assessment can be used as justification for the controls you have in place**

# Recap

---



## **Suggested next step: Self-assessment / gap analysis**

- Matrix on where each requirement is addressed in QMS (Note 7.5.1.1.d)
- Matrix on customer-specific requirements (7.5.1.1.d)

## Quality Manual (7.5.1.1)

---

- Step 1:
  - Step 2:
    - Context
    - Interested parties
    - Quality Policy
    - Scope \*
    - Reference to documented requirements \*
    - Process sequence and interactions (inputs & outputs) & extent of control of any outsourced processes \*
    - Matrix of where CSRs are addressed \*
    - Matrix of where IATF requirements are addressed
- \* required



# IATF Sustainability Requirements

---

- Product Safety 4.4.1.2
  - Documented process for management of product-safety related products and manufacturing processes.
  - Suggest logical groupings of products and a matrix to address a – m
  - Address those areas where needed e.g. matrix points to controls
- Corporate Responsibility 5.1.1.1
  - Anti-bribery, code of conduct, ethics escalation
  - Typically found in employee manual

## IATF Sustainability Requirements

---

- Contingency Plans 6.1.2.3
  - Defined according to risk and impact to customer
  - Annual reviews / document control
  - Specific potential failures to be addressed
  - Customer notification process
  
- end

## Management Of Change (6.3)

---

- When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner.
- The organization shall consider:
  - a) the purpose of the changes and their potential consequences;
  - b) the integrity of the quality management system;
  - c) the availability of resources;
  - d) the allocation or reallocation of responsibilities and authorities.

## Management Of Change (6.3)

---

- Determine scope of MOC process
  - Changes to facility, equipment
  - Vendors / supplied product
  - Personnel changes
  - Legal requirements
- Create process for ensuring that changes are effectively communicated and implemented across all processes
- Typically there would be a form and log which implies a resource to monitor
- Changes to the product realization process and temporary changes - additional verification / validation requirements (8.5.6.1) – typically ECN

## Competency (7.2)

---

- “appropriate training records” vs “records of competency”
  - Records of competency: Tests scores, certification where tests / evaluations were required, evaluations of supervisors / trainers
  
- Documented roles, responsibilities and authorities, process owners, awareness (5.3)
  - Suggest RACI Approach (Responsible, Accountable, Consulted, Informed)



## Embedded Software

---

- If the product has embedded software, there are multiple requirements, from product design through internal audit, which need to be addressed.

## Suppliers / Risk (8.4)

---

- This section has significantly enhanced requirements which suggests that the traditional methods used by organizations to select and control suppliers has not been especially effective
- Suggest a product/service risk assessment followed by an individual supplier assessment for higher risk external providers

## Suppliers / Risk (8.4)

---

- A risk methodology will help the organization focus on those products and services which need more attention
- And, focus on external providers who present the most risk to the organization, safety, interested parties, etc.
- Risk factors to consider are specified in 8.4.1.2

# Contact Us

**Ismael Belmarez, Accreditation Manager, NA**

**[contactus@dnvgl.com](mailto:contactus@dnvgl.com)**

**Wendy Parr, Global-Certified Lead Auditor, Parr Consulting, LLC**

**[isoparr@aol.com](mailto:isoparr@aol.com)**

**847-542-2128**

SECTOR SERVICES



## Automotive

Applying good management system practices is crucial to ensure safer vehicles.



## Certification Resource Center

Bridging the knowledge gap for transitions to the new standards

