



26th Annual ASQ Audit Conference
Blueprint for a Successful Audit

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Lessons Learned from an ISO 9001:2015 Transition

Tamara Hueston
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Agenda:

- What initial steps were taken
- What plans were created
- How associates were prepared
- What were the certification audit characteristics
- Results and reflection on what worked best



Initial Steps:

Comprehensive comparison of ISO 9001:2008 standards to ISO 9001:2015 standards

- Identified new requirements
- Identified removed requirements
- Reviewed terminology changes

ISO 9001:2008	ISO 9001:2015
0. Introduction	0. Introduction
1. Scope	1. Scope
2. Normative References	2. Normative References
3. Terms and Definitions	3. Terms and Definitions
4. Quality Management System	4. Context of the Organization
5. Management Responsibility	5. Leadership
6. Resource Management	6. Planning
7. Product Realization	7. Support
8. Measurement, Analysis and Improvement	8. Operations
	9. Performance Evaluations
	10.Improvement

Comparing the requirements

ISO 9001:2015

2008
5. Management Responsibility
5.1 Management Commitment
5.2 Customer Focus
5.3 Quality Policy
5.4 Planning

2015
5. Leadership
5.1 Leadership and Commitment
5.1.2 Customer Focus
5.2 Quality Policy
6. Planning
6.1 Action to Address Risk and Opportunities
6.2 Quality Objectives and Planning to Achieve them
6.3 Planning of Changes



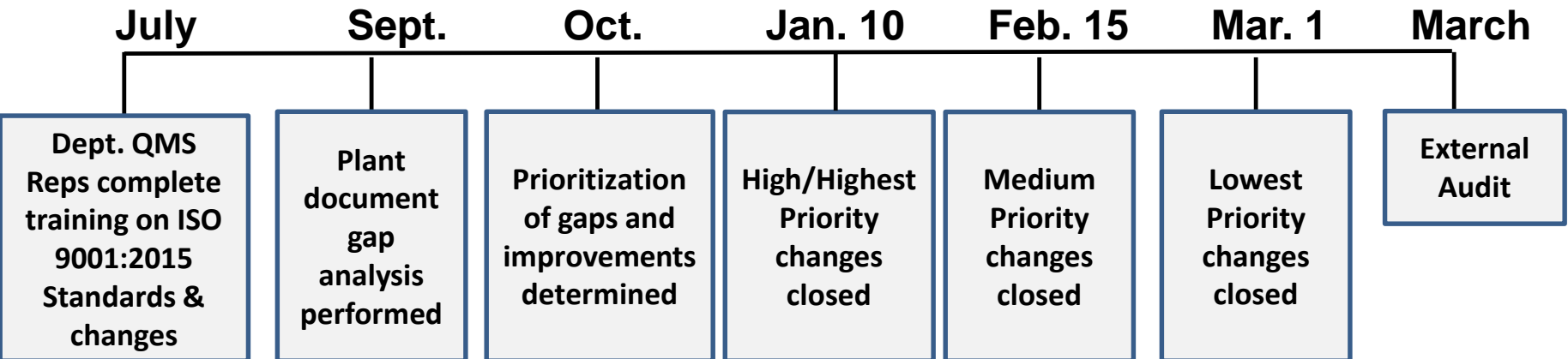
ISO 9001:2008 Clause Number	9001:2015 Clause Number	Changes/Differences
5.3 Quality Policy	5.2 Quality Policy	<i>Establish & review quality objectives</i> <i>Satisfy applicable requirements</i> <i>Ensure Quality Policy is documented information and available</i>
5.4.1 Quality Objectives	6.2 Quality Objectives and Planning to Achieve Them	<i>Retain documented information on planning quality objectives: what to be done, resources, responsibility, completion, and results</i> <i>(Measurable and consistent with Quality Policy)</i>
5.4.2 Quality Management System Planning	6.2 Quality Objectives and Planning to Achieve them 6.3 Planning of Changes	<i>Identify risks and opportunities and reviewing the potential consequences of change</i>

RED indicates change/new 2015

ISO 9001:2008 Clause Number	ISO 9001:2015 Clause Number
4 Quality Management System (Section Title)	4 Context of the Organization (Section Title)
4.1 General Requirements	4.4 Quality Management Systems and its processes
4.2.2 Quality Manual	None- (A Quality Manual is no longer specifically required, however the content previously found in the quality manual is now specified under clauses 4.3 Determining the Scope of the Quality Management System, 7.5.1 General, and 4.4 Quality Management System and it's processes)
4.2.3 Control of Documents	7.5 Documented Information, 7.5.1 General, 7.5.3 Control of Documented Information, 8.5.6 Control of Changes
4.2.4 Control of Records	7.5 Documented Information, 7.5.1 General, 7.5.3 Control of Documented Information, 8.5.6 Control of Changes



Timeline to achieve completion....



Start to perform internal audits to 2015 standards

Plant level SWOT analysis conducted to prioritize risks

QMS System Risk Analysis

Area	Strengths	Weaknesses	Opportunities	Threats	External Influences	Impact	Risk Judgement
Training					ISO 2015 Revision Regulations		
Calibration							
Record Retention/ Document Control							
Preventative & Corrective Action (PTC, QIS, NCPD, NCR's)					ISO 2015 Revision		
Equipment Acceptance					ISO 2015 Revision Regulations		
Equipment Maintenance					ISO 2015 Revision Regulations		
Process Control					Regulatory Requirements ISO 2015 Revision		
Design Change					ISO 2015 Revision Regulations		

After conducting a SWOT analysis, the identified areas were prioritized based upon risk. Areas were ranked as: very high, high, medium or low.

Rating Category	Description
Very High	The risk is totally unacceptable. Immediate measures must be taken to reduce these risks and mitigate hazards.
High	The risk is unacceptable. Measures to reduce risk and mitigation hazards should be implemented as soon as possible.
Medium	The risk may be acceptable over the short term. Plans to reduce risk and mitigate hazards should be included in future plans and budgets.
Low	The risks are acceptable. Measures to further reduce risk or mitigate hazards should be implemented in conjunction with other security and mitigation upgrades.

Determined 2008 Opportunities For Improvement That Still Existed & Compounded in 2015

Clause	ISO 9001:2008 Items
Production & Service Control	<ul style="list-style-type: none"> • Equipment Acceptance • Maintaining Required Records • Monitoring & Measuring activities
Corrective Action	<ul style="list-style-type: none"> • Countermeasures not implemented • Countermeasure not effective • 5P's not robust
Management Commitment	<ul style="list-style-type: none"> • Provide evidence of commitment to QMS & continual improvement
Training	<ul style="list-style-type: none"> • Records not maintained, available, or completed properly

Clause	ISO 9001:2015 Items
Production & Service Control	<ul style="list-style-type: none"> • Ensure externally provided products conform to requirements • Equipment Acceptance
Corrective Action	<ul style="list-style-type: none"> • Document evidence of nonconformity & corrective action taken • Review effectiveness of Corrective Action taken • 5P's more robust
Management Commitment	<ul style="list-style-type: none"> • Demonstrate Leadership & commitment to QMS & Customer Focus
Training	<ul style="list-style-type: none"> • Competency captured • Org. Knowledge • Succession Planning

Requirement

Auditing Risk Identified **1**
 Risk to Organization of Conforming **2**
 Benefit of Conforming **3**

ISO Analysis

1. Auditing risk identified
2. Risk to organization of not conforming
3. Benefit of conforming

4. Evidence of Conformance
5. Potential Problems
6. Identified Gaps
7. Related Procedures

Requirement: When planning for the QMS, the organization shall consider the issues referred to in 4.1 and requirements referred to in 4.2 to determine the risks and opportunities that need to be addressed to:

6.1.1

a) give assurance that the QMS can achieve the intended results
 b) enhance desirable effects
 c) prevent, ore reduce, undesired effects
 d) achieve improvement

6.1.2

The Organization shall plan:
 a) actions to address these risks and opportunities;
 b) how to:
 1) integrate and implement the actions into its QMS processes (see 4.4)
 2) evaluate the effectiveness of these actions

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

NOTE 1: Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

- Opinion on actions taken to increase desirable effect and reduce undesired results
- Set expectation before audit begins
- Not have a clear understanding of what actions taken might look like.

- Missed opportunities
- Unforeseen Risks
- Under/over reacting to risks and opportunities
- Missed uncontrolled processes/ systems
- Failure to improve
- Loss of certification
- + External Audit NCRs
- - Morale
- - Market share

- Adverse of risk
- Improved systems and processes
- - Failure Cost of Quality
- Associate involvement
- + Innovation

NOTE 2: Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customer' needs.

Inputs	Process	Outputs
<ul style="list-style-type: none"> • 4.1 • 4.2 • 4.4 	<ul style="list-style-type: none"> • Determine risk and opportunities when planning for QMS • Plan actions to address risk and opportunities • Plan how to implement and integrate actions • Plan to evaluate these actions 	<ul style="list-style-type: none"> • Assurance QMS works • Increase desirable effects • prevent, reduce, undesired affects • Achieve improvement • Actions taken shall be proportionate to the potential impact on conformity of product

Evidence of Conformance:	4	•	•
Potential Problems:	5	•	•
Identified Gaps:	6	•	•
Related Plant Procedures	7		

Process Maps

Materials

Measures

Manpower

Method

Suppliers

Inputs

Process

Outputs

Customers

Interested Parties

Process Approach

Interested Parties

Machine

Environment

Risk

Risks

Context of the Organization Matrix

Context of the Organization

External Issues	Indiana Culture	Social	Political	Legal	Economic Environment (local)	Financial	Market	Competitive	Technological	Internal Issues	Indiana Culture	Social	Financial	Technological
Work Force	Available competent work force	Education level	N/A	Diversity	N/A	Wage Increases	Job Market	Competitors	Education level	Work Force	Maintaining work force	Negative & positive publicity	Maintaining work force	Training Availability
Utilities	Green Community	N/A	N/A	N/A	Environmental Impact	Natural Gas Prices	N/A	N/A	N/A	Utilities	N/A	Green plant with minimal usage of resources	Costs	N/A
Part Suppliers	N/A	Director	N/A	Future exports	Increase in the need of parts Supply/Demand	Price Increases	N/A	Bids	N/A	Process Knowledge	Education Level	Different Levels	Training Costs	Training Availability
Raw Material Suppliers	N/A	Director	N/A	Future exports	Increase in the need of parts Supply/Demand	Price Increases	N/A	Bids	N/A	Products and Services	N/A	Protect company nameplate	Cost of Quality	Innovation
Transportation	Bad Drivers	Dock Striker	N/A	Changing regulations/export models	Road Conditions Traffic Patterns	Cost of Fuel Increase in amount of product/deliveries	N/A	Bids	N/A	Process Activities	N/A	N/A	Improvement Costs	Continual Improvement
MAP	N/A	N/A	N/A							Company Strategic Direction	N/A	Societal Impact	Improvement Costs	Innovation
ELP	N/A	N/A	N/A											
HCM	N/A	N/A	N/A											
HTM	N/A	N/A	N/A											

Considerations for External & Internal issues:

Culture	Social	Political
Legal	Environmental	Financial
Market	Competitive	Technological

Interested Parties Matrix:

Interested Parties												
External Parties	Relevant to QMS	Examples	Requirements	Risks	Opportunities	How Met or Demonstrated	Internal Parties	Relevant to QMS	Requirements	Risks	Opportunities	
County	No	Area Planning Assessor/Commissioners Council Emergency Management Health Dept. Highway Dept. Recorder Sheriff Dept. Soil & Water Solid Waste	Environmental Aspects	N/A	N/A	N/A	Associates	Yes	Clean / Safe Work Environment (7.1.4) Correct Tools for the Job (7.1.5.1) Training (7.2)	Mismatch in competency levels leads to a lower standard Higher cost of retraining Lower morale Non-conformances	Attain resources for continual improvement Capture organizational knowledge	Do
City	No	Mayor City Council Engineering, Planning & Zoning Street Dept. Police Fire Waste Water Treatment Plant	Environmental Aspects	N/A	N/A	N/A	On-site Contractors	Yes	Ensure that persons doing work under the organization's control are aware of: Quality Policy Relevant quality objectives Implications of not conforming with the QMS requirements	No accountability for actions	Higher conformity within the QMS	
State	No	Dept. of Transportation Economic Development Corporation Dept. of Labor Workers Compensation Board IEDC Skills Enhancement Training	Environmental Aspects	N/A	N/A	N/A	Departments	Yes	Internal communications relevant to the QMS: what, when, whom, how, who	Lost communication Important communication lost Confidentiality breach Wrong information	Strengthen communication Look at which means of communication are most productive for all depts	
Federal Agencies	No	HAZMAT OSHA	Safety Regulations	N/A	N/A	N/A	Top Management	Yes	Demonstrate leadership & commitment to QMS	Ineffective Quality Systems Overtime Additional Manpower Misplaced Priorities Inefficient Processes	QMS Implemented at all levels of the organization Increase in quality Investment in improvement Reduce costs	Suit Res ass under Parti Score

**When considering your internal and external parties:
 Are they relevant to your QMS?
 Can you give examples?
 What are the RISKS/Opportunities for them?
 How do you demonstrate that you conform to this requirement?**

Transition Timeline Approvals

Activity	P/A	December/January																				Status	
		1	2	5	6	7	8	9	1	1	1	1	1	1	2	2	2	2	2	3	4		5
Division Manager Meeting- Presentation	P				★																		
	A																						
Department Manager Kick Off Presentation	P						★																
	A																						
Interested Parties Matrix Created (Master List)	P	▲									▲												
Approval from Upper Management	A																						
Approval from Top Management and CIE, work with Depts. to establish path forward	P																						
	A																						

Transition activity started in 2015 with awareness campaigns to the COC and top management.

Preparing Associates for the Transition:

- Information communicated to associates via:
 - Company Wide Broadcasting
 - Communication Boards
 - Ask Me Table

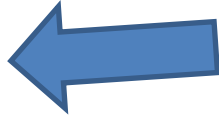


- Division, Dept. and Team Managers received presentations
- Dept. QMS Reps. received training
- Top management received training internally & externally

Trainings for the Dept. QMS Reps

6.1 Actions to Address Risks & Opportunities

Teach the requirement and then understand how it applies to your organization.



Requirement:

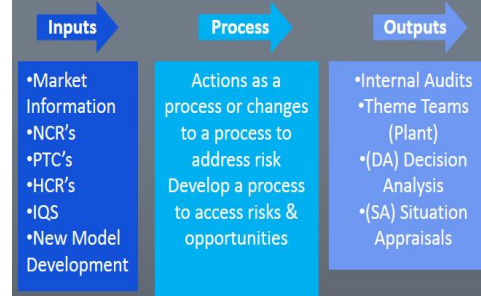
6.1.2 The organization shall plan:

- a) Actions to address these risks and opportunities
- b) How to:
 - a) Integrate and implement the actions into it's QMS process
 - b) Evaluate the effectiveness of these actions

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of the product

6.1 Actions to Address Risks & Opportunities

Evidence of Conformance



ISO 9001:2015 Transition training occurred between January and July.

It was an entire training and not just change points.

This allowed for an opportunity to strengthen foundation training.

Takeaways from trainings....

- Each Dept. QMS Rep was given a binder to put their Quick Reference Cards and other materials into.

ISO 9001:2015 Element 7 Support

Documented information replaces "Documents" and "Records"

7.3 Awareness

Expansion of "personnel" to "persons doing work under the organization's control"

7.3.3 Control of Documented Information

Control Documented Information

Personnel must not only be aware of Quality Policy but must understand how they contribute and implications for not conforming

ISO 9001:2015 Element 8 Operations

7.2 Competence

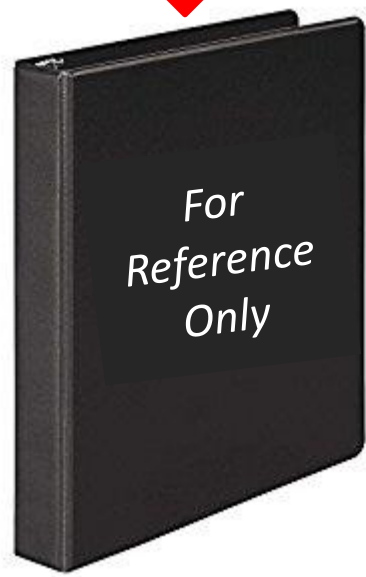
7.3 Awareness

Documented information is required to be kept to demonstrate conformity of product & service to requirements and that processes can be carried out as planned

Terminology Changes:

Products and Services replaces products

Operations replace Product Realization



ISO 9001:2015 Element 4 Context of the Organization

External and Internal issues are the relevant issues, both inside and out, that have an impact on what the organization does, and that would affect its ability to achieve the intended outcomes of its management system.

Internal Context: Anything within the organization that may influence the way in which the organization manages its internal risks.

External Context: Any external factors that influence selection of its objectives (goals & targets) or its ability to meet its goals.

Interested parties are those that could affect or potentially be affected by the organization's products and services that meet customer and regulatory requirements.

Plan-Do-Check-Act

Risk Assessment Tools: SWOT, FMEA, Risk Matrix, KT-Potential Problem Analysis, etc.

Audit planning....

- **Begin process approach auditing**
- **Determine support (resources) needed for auditing the remaining 7 audits scheduled**
- **Push process approach audits to second half of the year**



Analyze	Implement	Check
<p>Identify gaps in the Departments.</p> <p>Process Mapping Key processes.</p> <p>Identify systematic weaknesses across the plant.</p>	<p>Update documented procedures.</p> <p>Work to implement Countermeasures for identified gaps.</p> <p>Help Departments implement training to new standards.</p>	<p>Use gap analysis to develop improvement plans for departmental QMS.</p> <p>Develop Intra-departmental checks.</p> <p>Help develop BP Metrics to ensure planned changes are monitored.</p>

Approved plan

- **QMS Team members were assigned Departments to support**
- **Weekly reporting from theme leader ensured monitoring of targets as identified in the schedule**
- **Team members helped support activities**

Reporting Targets

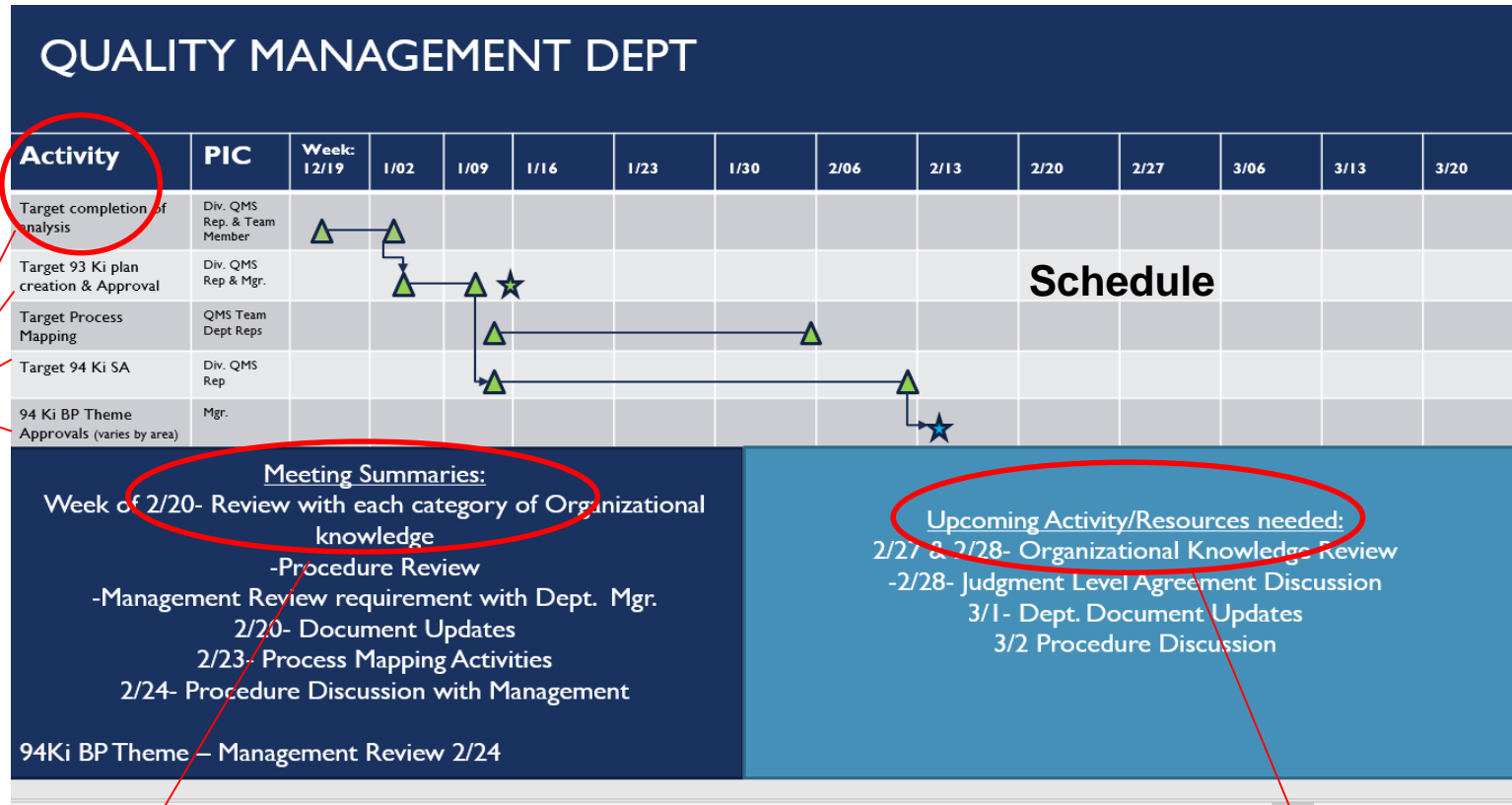
WEEKLY

- **Significant road blocks**
- **Key work Items**
 - **Scheduled activity**
 - **Gaps/concerns**
 - **Countermeasure progress**
 - **Systematic concerns**

MONTHLY

- **High Level scorecard (all Dept.)**
- **Detailed information on delayed or stalled items**
- **Countermeasure activity progress**
- **Systematic concerns (plant level)**

Weekly Plant Reporting



List of activities

Meeting Summaries

Resources needed, upcoming activities

What was the certification audit like?

- Auditing questions...

4 Context of the Orga	Requirement:	Audit Question	External Auditor Question
4.1 Understanding the organization and your context	Organization shall determine external and internal issues that are relevant to it's purpose and its strategic direction and that affect the ability to achieve the intended results of the QMS.	How has the organization determined ext./int issues relevant it's purpose and strategic direction?	<div style="border: 2px solid red; padding: 10px; text-align: center;"> External Auditor Questions </div>
	The organization shall monitor and review information about these external	How do these affect the ability to achieve the intended result of the QMS?	
	Note 1: I	How do you monitor and review information about these internal and external issues?	
	Note 2: U		
	<div style="border: 2px solid red; padding: 10px; text-align: center;"> Requirement </div>	<div style="border: 2px solid red; padding: 10px; text-align: center;"> Possible Audit Question </div>	
4.2 Understanding the needs and expectations of interested parties	Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet the customer and applicable statutory and regulatory requirements, the organization shall determine:	How have you determined what interested parties are relevant to the QMS?	<p>How are you identifying what is covered and what is not included? What is excluded and why?</p> <p>Can you show me where you have identified a risk?</p> <p>Can you show me where you have rolled a risk up to North America?</p> <p>Can you show me the outcome of that risk?</p>
	a) the interested parties that are relevant to the QMS	How have you determined what requirements those parties have that are relevant to the QMS?	What is going to be our evidence that we are reviewing risks with top management before we roll up items to North America?
	b) the requirements of interested parties that are relevant to the QMS	How have impact or potential impact been determined?	Can you show me in the last management review where you covered risks & opportunities, including customer satisfaction?
	The organization shall monitor and review information about these interested parties and their relevant requirements.	How do you monitor and review the information about interested parties and their relevant requirements?	
4.3 Determining the scope of the QMS	Organization shall determine the boundaries and applicability of the QMS t	How have the boundaries and applicability of the QMS been used to establish the scope of the organization?	
	When determining this scope, the organization shall consider:		
	a) the internal and external issues referred to in 4.1	How has the external and internal issues been considered when developing the scope?	
	b) the requirements of relevant interested parties referred to in 4.2	How has the requirements of interested parties been considered when developing the scope?	

Reference Tool that lists the requirement, possible audit question, and what the external auditors question was like.

Audit reflection....

What worked best:

- Interested parties matrix
- SWOT analysis for plants and depts.
- Process mapping
- Trainings for associates

What could have been more robust:

- Performing process audits to all requirements (External Auditor preference)
- Understanding the scope of externally provided services



ISO 9001:2015



WE DID IT!



October 12 - 13, 2017

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**ANY
QUESTIONS?**



Tamara Hueston
812-560-9118

Tamara.Hueston@hmin.honda.com