

## 18<sup>th</sup> Annual North American Supplier Conference

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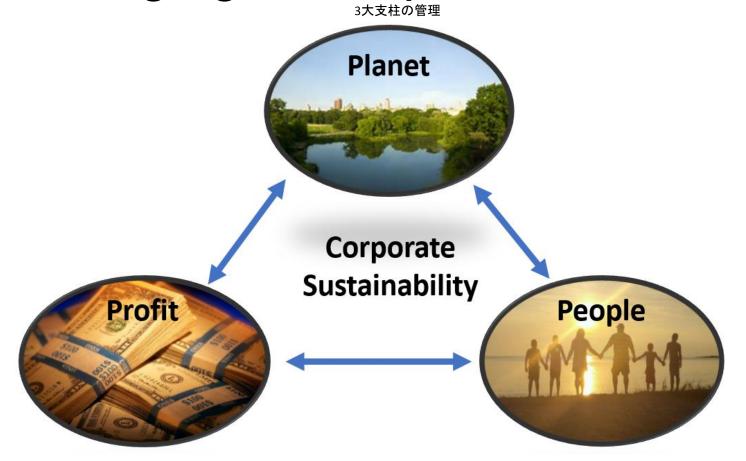
"Growth Through the Pursuit of Quality"

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# Corporate Sustainability American MITSUBA Corp.

企業の持続性

Managing the Triple Bottom Line



### **IATF Update**



## Risk Based Thinking!

## Risk management at a high level

- The organization shall determine the risks and opportunities that need to be addressed to give assurance that the quality management system can achieve its intended result and shall evaluate the effectiveness of these actions.
- Coordinated set of activities and methods that organizations use to manage and control the many risks that affect their ability to achieve objectives.

ISO/TS 16949 Clauses	IATF 16949 Clauses		
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. Operation		
	9. Performance evaluation		
	10. Improvement		

The organization shall demonstrate leadership and commitment with respect to quality management system by promoting the use of process approach and risk-based thinking.

## MITSUBA American MITSUBA Corporation

# Risk Based Thinking! Effectiveness vs Efficiency

The degree to which objectives are achieved and the extent to which targeted problems are solved. In contrast to efficiency, effectiveness is determined without reference to costs and, whereas efficiency means "doing the thing right", effectiveness means "doing the right thing".

Understanding this difference

Evaluation of **Effectiveness** is through the eyes of the customer (doing the right thing)

Evaluation of **Efficiency** is through the eyes of your organization (doing the thing right)

- > At a minimum, the following supplier performance indicators shall be monitored:
  - a) Delivered product conformity to requirements
  - b) Customer disruptions at receiving plant
  - c) Delivery schedule performance
  - d) Number of occurrences of premium freight



## Risk Based Thinking! Second-party audits

- ➤ The organization shall require their suppliers of automotive products and services to develop, implement, and improve a quality management system certified to ISO 9001 unless authorized by the customer...
- The organization shall include second-party audit process in their supplier management approach. Second-party audits may be used for:
  - a) Supplier risk
  - b) Supplier monitoring
  - c) Supplier QMS development
  - d) Product audits
  - e) Process audits
- <u>Based on a risk analysis</u>, including product safety/regulatory requirements, performance of the supplier, and QMS certification level, at a minimum <u>shall</u> document the criteria for determining the need, type, frequency, and scope of second-party audits.

## **IATF Update**



## **Management Reviews!**

#### Required Inputs (ISO 9001)

- ✓ Status of actions taken from previous management reviews
- ✓ Changes in external and internal issues
- ✓ Information on performance
- √ Adequacy of resources
- ✓ Effectiveness of actions taken to address risk/opportunity
- ✓ Opportunities for improvement

#### **Required Inputs (IATF 16949)**

- ✓ Cost of poor quality
- ✓ Process effectiveness
- ✓ Process efficiency
- ✓ Product conformance
- ✓ Manufacturing feasibility
- ✓ Customer satisfaction
- ✓ Maintenance objectives
- √ Field failures

#### **Required Outputs**

- ✓ Opportunities for improvement
- ✓ Any need for changes to QMS
- ✓ Resource needs
- ✓ Document and implement an action plan

$$Y = f(x)$$

### **IATF Update**



### RISK Based Audit Days Model (2018)

#### Assess the risk at the site based on five Risk Drivers

- New Product Launch Activity
- Safety / Regulatory Products
- Business KPI's
- TS Certificate History
- Product Quality and Delivery Performance





Risk-based thinking requires companies to evaluate risk when establishing processes, controls and improvements in a Quality Management System.



#### American Mitsuba Website <a href="http://www.americanmitsuba.com">http://www.americanmitsuba.com</a>



#### AMC Purchasing

By recognizing our reliance on each other for success, American Mitsuba and its suppliers have the unique opportunity to create a competitive advantage in the marketplace for our customers. Not only do we recognize the often competing objectives that our customers challenge us with, but embrace them as a source of creativity and strength. We recognize the value in growing a community of suppliers that understand American Milsuba's emphasis on quality and interest in developing supply chain relationships that additionally embrace timeliness, cost and efficiency.

#### Supplier Manual

#### Supplier Requirements

Advanced Process and Quality Planning Control of Nonconforming Product Customer Specific Requirements IPP System Control Labeling Requirements PO Terms and Conditions

#### 5 P B I

Supplier Development
Business Systems Overview
Business Systems Overview 2
Crisis Management
C-TPAT
Customs Compliance Overview
Environmental Management System
MMOG / LE
Quality Management System
RoHS Overview

#### Supplier Assessment

Supplier Performance Evaluation Supplier Audit Procedure Annual Supplier Survev

#### Blank Forms

Acceptance for Mass Production
APQP Status Report
Capability Study Worksheet
Coating System Assessment CQI-12
Heat Treat System Assessment CQI-9
IPP Tag
Nonconformance Report (8D, 5P)
Packaging Approval Form
Plating System Assessment CQI-11
Process and Material Change Request
Request for Deviation
Potential Supplier Assessment
Supplier Audit Checklist
Gage RR Study Worksheet
Sustainability Supplier Self Assessment
Nonconforming Product Sorting Notice
VA/VE Proposal Form

### **Gap Analysis Tool**

Standard	Element	Is this a new requirement?	ISO 9001:2015 / IATF 16949:2016 Requirements	Correlation	Commentary	Level of current implementation
		New/Modified/ Carryover	Bolded text indicates new to ISO 9001:2015 and IATF 16949:2016	ISO/TS 16949:2009		1 = Fully implemente 5 = Nothing in place
I.O Context of th	he organization					
.1 Understandi	ng the organizat	ion and its context				
			The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and	No equivalent	This was not specifically mentioned in the previous standard land is now an explicit requirement.	
			that affect its ability to achieve the intended result(s) of its quality management system.  The organization shall monitor and review information about these external and internal issues.	ciause	and is now an expricit requirement.	
			NOTE 1: Issues can include positive and negative factors or conditions for consideration.	1	The organization must now be able to demonstrate they have	
ISO 9001	4.1	New	NOTE 2: Understanding the external context can be facilitated by considering issues arising from legal, technological,	1	identified, monitored and reviewed all external and internal	
			competitive, market, cultural, social and economic environments, whether international, national, regional or local.		issues.	
			NOTE 3: Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and	1		
			performance of the organization.			
1.2 Understandi	ng the needs an	d expectations of in	terested parties			
			Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet	No equivalent	The intent of this requirement is to ensure that the organization	
			customer and applicable statutory and regulatory requirements, the organization	clause	considers the requirements of relevant interested parties	
			shall determine:		beyond just those of the customer.	
ISO 9001	4.2	New	a) the interested parties that are relevant to the quality management system;			
			b) the requirements of these interested parties that are relevant to the quality management system. The organization shall	1	The intention is to focus on the interested parties which are	
			monitor and review information about these interested parties and their relevant requirements.		relevant to the Quality Management System (QMS).	
			The organization shall monitor and review information about these interested parties and their relevant requirements.			
1.3 Determining	the scope of th	e quality manageme	ent system			
			The organization shall determine the boundaries and applicability of the quality management system to establish its scope.	Sec. 1.2	The new revision to the standard now explicitly requires that	
			When determining this scope, the organization shall consider:		before you set the scope of the QMS, you must have previously	
			the external and internal issues referred to in 4.1;		considered and demonstrated that the issues within 4.1 and	
			the requirements of relevant interested parties referred to in 4.2;		interested parties within 4.2 are completed, prior to setting the	
			the products and services of the organization.		scope and boundaries of the QMS.	
ISO 9001	4.3	Modified	The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.		It is important to note that ISO 9001:2015 requires that all	
			The scope of the organization's quality management system shall be available and be maintained as documented information.	1	requirements within the standard are to be met unless they do	
			The scope shall state the types of products and services covered, and provide justification for any requirement of this		not apply. This scope must be documented and include the	
			International Standard that the organization determines is not applicable to the scope of its quality management system.		products and services provided as well as any justification for	
			Conformity to this International Standard may only be claimed if the requirements determined as not being	1	any requirements that the organization has determined do not	
			applicable do not affect the organization's ability or responsibility to ensure the conformity of its		apply.	
			products and services and the enhancement of customer satisfaction.			
.3.1 Determini	ng the scope of t	the quality manager	nent system - supplemental			
			Supporting functions, whether on-site or remote (such as design centers, corporate headquarters, and distribution	Sec. 1.1, 1.2	Originally included in ISO/TS 16949:2009, Sec. 1.1 and 1.2. The first	
			centers) shall be included in the scope of the quality management system (QMS).		requirement relating to supprting functions was revised to not	
			The only permitted exclusion for this Automotive QMS Standard relates to the product design and development		only address the need to include them in the audit, but also to	
IATF 16949	4.3.1	Modified	requirements within ISO 9001, Section 8.3. The exclusion shall be justified and maintained as documented information (see		ensure that they are included in the scope fo the QMS.	



## **MITSUBA VISION 2024**

Enter a New Stage with a New Global Viewpoint

