A major focus shift in ISO 9001:2015 vs 2008 and associated industry specific standards is the emphasis on risk management. I will offer my insights into risk management to achieve sustained success in supply chain quality.
RISK

Risk comes from not knowing what you are doing.

-Warren Buffett

RISK DEFINED

- The probability of an undesirable event occurring and the impact of that event. (CSQP Primer).
- Effect (deviation of the expected) of uncertainty on objectives.
  - Effect = Deviation from the expected.
- Usually expresses in terms of sources, potential events, their consequences and their likelihood.
- ISO 31000.
RISK MANAGEMENT

- Coordinated activities to direct and control an organization with regard to risk.
- Taken to minimize probability and consequences of adverse effects to objectives.
- Risk examples
  - Product or activity does not meet expected performance levels.
  - Actual costs higher than budgeted costs.
  - Delivery or timing is late.
  - Technical performance
  - Environmental considerations.
  - Supplier selection/performance

RISK ASSESSMENT PHASES

- Risk Identification
- Risk Analysis
- Risk Treatment/control
- Risk monitoring & review
RISK IDENTIFICATION

- Documentation Reviews-project plans/assumptions/lessons learned.
- Information gathering techniques/Brainstorming.
- Interviewing SME / key experts
- Assumption analysis.

RISK RESPONSE PLANNING

- Avoidance—elimination of the adverse risk, schedule relaxation, scope change.
- Transferring risk—utilization of third party via insurance, warranties, contractors.
- Mitigation—reducing probability of occurrence or impact.
**RISK MANAGEMENT TOOLS**

- Basic Quality Tools (Flowcharts, check sheets)
- FMEA (Failure Modes and Effects Analysis)
- Hazard Analysis
- Risk ranking and filtering.
- Capacity planning?

**FMEA APPROACH**

- AIAG / MIL STD Format
  - Severity-Impact to end customer/user.
  - Occurrence-Likelihood of happening.
  - Detection-Likelihood of catching the adverse factor.
SUPPLIER RISK RANKING USING FMEA APPROACH

- Customer Impact (Severity)
  - How close is supplier to customer (direct ship, pass through, special process)

- Performance indices (Occurrence)
  - A measure of what is happening—OTD, PPM, SCAR.

- QMS Maturity (Detection)
  - Ability of a supplier to detect and prevent defects is related to strength of Quality Management System.

CUSTOMER IMPACT

- Higher Customer Impact Suppliers
  - Direct ship to customer after performance of value-add process.
  - Performance of special process (heat treatment, coating, NDT).

- Lower Customer Impact Suppliers
  - Raw material subject to several quality gates prior to use.
  - Providers of non-critical services (rough grinding, rough machining).
  - Providers of tooling?
SUPPLIER PERFORMANCE INDICES

- OTD
  - 100% is low risk
  - Less than 100% is higher risk depending on industry.
- PPM
  - Zero rejects over sustainable timeframe is low risk.
  - Define baseline acceptable level for med-high risk.
- SCAR Frequency
  - Zero SCAR over sustainable timeframe is low risk
  - Define baseline acceptable level for med-high risk
- Premium freight
  - Same as above.

QMS MATURITY

- High maturity/low risk—IATF 16949, AS9100, OEM Certified.
- Medium maturity/moderate risk—ISO 9001 with
  - Compliance to customer specific requirements through second party audit.
  - Compliance to aspects of IATF 16949/AS9100 through second party audit.
- Low maturity/higher risk—ISO 9001 only.
  - No ISO considered HIGH risk supplier.
### Supplier Risk - Definitions

<table>
<thead>
<tr>
<th>Severity / Customer Impact</th>
<th>Detection / QMS Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Ship 5</td>
<td>5 ISO 9001:2008 or new supplier.</td>
</tr>
<tr>
<td>Level A Assy 4</td>
<td>4 ISO 9001:2015 Registered</td>
</tr>
<tr>
<td>Level A 3</td>
<td>3 MAQMSR</td>
</tr>
<tr>
<td>Level B 1</td>
<td>2 ISO 9001:2015 + compliance to IATF 16949</td>
</tr>
<tr>
<td></td>
<td>1 IATF 16949 and/or ISO 17025 for test lab</td>
</tr>
</tbody>
</table>

### Occurrence / Perf. Indices

The rating will be the highest number based on scoring for SCAR, OTD, Premium Freight instances over a 4 Quarter period, as follows.

<table>
<thead>
<tr>
<th>SCAR</th>
<th>OTD</th>
<th>Premium Freight</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 or more</td>
<td>10</td>
<td>4 or more</td>
</tr>
<tr>
<td>5 to 6</td>
<td>7 85-88%</td>
<td>8 3 times</td>
</tr>
<tr>
<td>3 to 4</td>
<td>5 99%</td>
<td>4 1-2 times</td>
</tr>
<tr>
<td>1 to 2</td>
<td>3 100%</td>
<td>0 instances</td>
</tr>
<tr>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

### Supplier Risk Matrix

<table>
<thead>
<tr>
<th>Supplier</th>
<th>Type</th>
<th>Severity / Customer Impact</th>
<th>Occurrence / Perf. Indices</th>
<th>Detection / QMS Maturity</th>
<th>Prioritization</th>
<th>Main Issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supplier A</td>
<td>Direct Ship</td>
<td>5</td>
<td>1</td>
<td>1</td>
<td>5</td>
<td>N/A</td>
</tr>
<tr>
<td>Supplier B</td>
<td>Direct Ship</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>125</td>
<td>SCARs</td>
</tr>
<tr>
<td>Supplier X</td>
<td>Raw Material</td>
<td>3</td>
<td>5</td>
<td>3</td>
<td>45</td>
<td>OTD</td>
</tr>
<tr>
<td>Supplier C</td>
<td>Special Process</td>
<td>5</td>
<td>3</td>
<td>5</td>
<td>75</td>
<td>QMS Status</td>
</tr>
<tr>
<td>Supplier Z</td>
<td>Widgets</td>
<td>1</td>
<td>5</td>
<td>5</td>
<td>25</td>
<td>OTD, QMS Status</td>
</tr>
</tbody>
</table>
SUPPLIER AUDIT STRATEGY

- Audit frequency is determined by:
  - Supplier Impact
  - Compliance status / regulatory history.
  - Results of previous audits.
  - Major changes since last audit (new process, key personnel changes, turnover).

SUPPLIER AUDIT-OTHER CONSIDERATIONS

- Target QMS Level
- Supplier performance
  - SCAR increase
  - OTD
- Cost reduction activities
- Customer specific protocols
FMEA-NOT JUST FOR MANUFACTURING

- Can be applied to all aspects of organization
  - Customer service
  - Order entry
  - Engineering
  - Marketing
  - Product development.

FMEA-ORDER ENTRY

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Order placement</td>
<td>Customer service, SAP</td>
<td>Wrong product entered</td>
<td>9</td>
<td>Customer orders</td>
<td>3</td>
<td>5</td>
<td>125</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Shipping prints daily</td>
<td>Customer service, SAP</td>
<td>Wrong product entered</td>
<td>9</td>
<td>Customer orders</td>
<td>3</td>
<td>5</td>
<td>125</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Order entry</td>
<td>Customer service, SAP</td>
<td>Wrong product entered</td>
<td>9</td>
<td>Customer orders</td>
<td>3</td>
<td>3</td>
<td>Review of SAP</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>Pickups with carrier</td>
<td>Customer service, SAP</td>
<td>Wrong product entered</td>
<td>9</td>
<td>Customer orders</td>
<td>3</td>
<td>3</td>
<td>Review of SAP</td>
<td>18</td>
</tr>
</tbody>
</table>
SUPPLIER CORRECTIVE ACTION PROCESS

- Formal problem solving process
- Minimum steps should include
  - Correction of issue (replacement or approved rework/repair).
  - RCA
  - Corrective Action Implementation

- 8D or other formal mechanisms are best

8 D (DISCIPLINES)

- Problem Symptom
- Define Team
- Implement Containment
- Root Cause Analysis
- Verify Root Cause
- Implement PCA
- Prevent Recurrence / Organizational Memory
- Congratulate Team
ROOT CAUSE ANALYSIS

- Fishbone diagram w/ CFT Brainstorming
- 5 Why
  - 3x5 Why-How Made/How Shipped/System
- Is/Is-Not Diagram

CORPORATE SOCIAL RESPONSIBILITY / SUSTAINABILITY

[Diagram showing the quality triple bottom line with Management (ISO 9000/ISO 9001), Societal (ISO 26000), and Environment (ISO 14001).]
SOCIAL RESPONSIBILITY CORE SUBJECTS

1. Organizational governance
2. Human rights
3. Labor Practices
4. The environment.
5. Fair operating practices
6. Consumer issues.
7. Community involvement & development.

SOCIAL RESPONSIBILITY KEY PRINCIPLES

1. Accountability
2. Transparency
3. Ethical behavior
4. Respect for stakeholder interests
5. Respect for the rule of law
6. Respect for international norms of behavior
7. Respect for human rights
**SUPPLIER SOCIAL RESPONSIBILITY STRATEGY**

- Increasing number of customers require social responsibility to be verified within the supply chain.
- ISO 26000 Guidance on Social Responsibility
- Jennifer Stepnioski-ASQ Member, LinkedIn—excellent presentation on fundamentals.

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**SOCIAL RESPONSIBILITY SAMPLE AUDIT**

1. Supplier Information

<table>
<thead>
<tr>
<th>Supplier Name</th>
<th>Supplier Code</th>
<th>Location</th>
<th>Product/Service Supplied</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Subcontractors

2.1 Does your company own suppliers/service providers?

Yes ☐ No ☐

2.2 Are there specifications for environmental protection, for suppliers/service providers?

Yes ☐ No ☐

2.3 Are there requirements to the working conditions, for suppliers/service providers?

Yes ☐ No ☐
PRODUCT QUALIFICATION

- Assures that all customer engineering design and specification requirements are properly understood and verified.
- The manufacturing process has the potential to produce product consistently meeting these requirements.
- Actual production run at the quoted production rate

QUALIFICATION FUNDAMENTALS

- Significant production run.
  - Automotive requires 300 consecutive parts.
  - Should be negotiated with customer for low volume.
  - Bulk material—no industry requirements other than steady state.
- Design record/Material composition (IMDS if applicable).
- EC/Customer Eng Approval
- DFMEA/PFD/PFMEA/PCP
- MSA (Gage R&R)
- Dimensional / Material Performance Results
- Process studies
QUALIFICATION FUNDAMENTALS

- Qualified laboratory documents (17025 more commonly required).
- Appearance approval/Sample Parts/Master Sample/Checking Aids
- Customer Specific Requirements
  - Capacity studies—highly recommended if not required.
  - Change management documentation.
- Part Submission Warrant/Customer Approval Document

TAKEAWAYS

- Supplier Risk Ranking Matrix
- Supplier audit strategy
- FMEA—not just for manufacturing processes.
- Supplier Corrective Action Process
- Sustainability/Corporate Ethics strategy.
- Product Qualification Strategy
REFERENCES

- ASQ CSQP Primer 2016
- AIAG FMEA Manual
- AIAG PPAP
- ASQ Website-Social Responsibility