Everyone is muted.

We will start at 7pm EST.
Elizabeth Burns

As owner of E. Burns Consulting, Elizabeth has been successfully assisting manufacturing, service and not for profit industries in South Western Ontario in the implementation of ISO 9001 based management systems since 1990.

Elizabeth has been a Certified Quality Engineer since 1988 and an ASQ Fellow since 2009.

Elizabeth has been an active member of the Kitchener Section of ASQ since 1990, serving on the executive from that time until 1999. She has also served been personally involved in ASQ Milwaukee's Exam Development Process since 1996. She has serve as Chair of the ASQ Certification Board and the World Conference Technical Program Committee.
Over a two year period, Elizabeth Burns and Frank Battista integrated their business management system. The Integrated Management System now embraces these requirements into a comprehensive system which allows for standardization, metrics with meaning, and a seamless process approach. The integrated management system allows for being nimble to exceed customer expectations while maintaining business success.

“An Integrated Management System” presents how an integrated management system is created, by utilizing a structured process approach to understanding applicable standards. This webinar explains the activities used to define, deploy and implement such system.

It will be shown how the resulting integrated management system improved customer relationships through managing risk, building and sustaining a culture of quality.
INTEGRATED BUSINESS MANAGEMENT SYSTEMS

ELIZABETH BURNS, ASQ Fellow, CQE
E. Burns Consulting

ASQ Webinar Presentation
INTEGRATED BUSINESS MANAGEMENT SYSTEMS

- A. Berger Precision Ltd.
  - Located in Brampton, Ontario, Canada

- Facility Background:
  - Manufacture of high precision ferrous and non-ferrous screw machine parts.
  - Customers include aerospace, automotive industries
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The Background:

- Senior Management insisted on an integrated business management system
- Facility was transitioning between registrars.
- Customer scorecards and performance required overall improvement
- Implementation of integrated management systems would allow employees to do the “Right Thing”
- Achieve Organizational Alignment
  - There was a clear vision but implementation was weak
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Integration meant:

- TS 16949, AS 9100 and ISO 14001 standards be integrated into one business management system
- This meant one Tier 1 manual and one set of procedures wherever possible

Senior management’s expectation:

- Procedures which were “real” – not just the standards re-written with A. Berger Precision Ltd. inserted everywhere
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The starting point – May 2012
Reviewed current TS 16949 system
(automotive quality management standard)

- Implementation vs standard and customer requirements
- Identified gaps through aggressive internal audit program
- Planned activities to close the gaps
- Gaps were relatively large and serious
- Customer requirements were probably the only aspect which was consistently well done
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Please add AS 9100C – June 2012
(aerospace quality management standard)

• Request from Senior Management
  • Expectation was registration during TS re-registration audit
  • External audit (re-registration) was less than 3 months in future
  • New registrar – unknown aspect

• No experience with this standard
  • Lots and lots of learning
  • Used everything available from multiple sources
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Please add AS 9100C – June 2012

• Initial Assessment
  • “No way” - cannot be done
  • “Standard not read and complex”

• Outcome
  • “Failure is not an option”
  • “Do or Do Not – There is no Try”

• Research
  • AQS, business network, standard specific websites, white papers
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Consolidating the Tier 1 Manual

- Manual in May 2012 was primarily the TS standard re-worded
- Needed to revise the manual to reflect internal processes
- Needed to add AS 9100C requirements
- Needed to confirm ISO 14001 (environment management system) requirements had been met
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The reality of this activity – messy slide, messy process 😞

- Read the manual
- Read AS
- Re-Read the manual
- Re-Read TS
- Re-Revise the manual
- Ask Senior Management to read the revised manual
- Re-Re-Revise the manual
- Read TS
- Revise the manual
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- ISO 22301 Business Continuity
- AS 9100 FAI; flow-down to suppliers
- TS 16949 APQP
- OHSAS 18001 H&S Hazards
- ISO 14001 Enviro Aspects
- ISO 31010 Risk
- ISO 33001
- QMS System
  Management Responsibility
  Resource Management
  Product Realization
  Measurement, Analysis & Improvement

Slide 13
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- Cautions:
- Differences between NA and European interpretations
- Translate into everyday English
- Involve people who do the work being documented
- Need multiple people to review documents to ensure message is clear
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June 2012 - Perform Internal System Audits

- Audit organization based on checklists which covered individual aspects of TS and AS
  - i.e. word for word requirements
- Audit was based on current management system procedures and work instructions
- Classified audit results (nonconformance, observation, opportunity for improvement)
- Prioritized corrective action, preventive action and opportunities for improvement
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Conduct Weekly Management Meetings to Discuss Progress

- Members: Senior Management, Production Supervisors, Managers and Management Rep met at least weekly
- New experience for most – needed to implement good meeting practices without being too obvious
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- To get to finish line: “Motherhood and Apple Pie”
  - Clear, simple, every day language
- Worked through prioritized list
  - Kill, make sick, make uncomfortable
- Created “The September List”
  - “Things we have no hope of getting done before August but things which we don’t want to forget”
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Registration Audit(s)
- Timeframe: August 2012, 5 days.
- 5 Registrar Auditors; needed a well thought out schedule from the registrar
- TS 16949 – Re-registration – 2 automotive auditors
- AS 9100C – Stage 2 – 2 aerospace auditors
- ISO 14001 – annual assessment – 1 environmental auditor
- Even the auditors felt intimidated by the stress in the board room
- All aspects of the management system was being covered by the auditors
The Audit Results:

- 2 minor nonconformances under TS 16949
- 3 minor nonconformances under AS 9100C
- Lots and lots of opportunities for improvement identified by registrar auditors and guides
- The September List grew longer
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The Aftermath:

- Breathed a sigh of relief for a month
- Rewrote The September List into a prioritized list
- Improved the internal audit process and training of internal auditors
  - External training by registrar
  - More process orientated internal audits
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Maybe the integrated management system isn’t integrated enough...

- Senior Management would like to have risk management and business continuity integrated into our current system
- No experience with these standards
  - Didn’t even bother using this as an excuse.
  - Lots and lots of learning
  - Used everything available from multiple sources
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- Realized current Tier II procedures were not easy to audit and not well understood by most employees
- Rewrote the management system procedures into process flow format where possible
- Most process flows were two or three pages long
- Senior Management’s requirements:
  - Clear, simple, every day language
  - 2 or 3 pages per procedure
  - Critical aspects only
Customer Corrective Actions

**Purpose:**
To have a planned and systematic approach to problem solving through the Corrective Action process.

**Scope:**
This procedure covers all Customer, Internal, and supplier corrective actions requests.

---

**Customer**

- The customer will notify the Quality Department of a part quality concern that requires attention.

**Decision:**
- **Does the customer require a corrective action?**
  - **NO** → Treat the concern as an internal corrective action and follow the internal corrective action process flow as shown in this procedure.
  - **YES** → Continue to the next step.

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**Management Team**

**YES** → Continue to the next step.

---

**Quality**

- Contain parts as per MSP-022 (Control of Nonconforming Product) and report the results within 48 hours. Initiate a CCA-XXX 8D in the MQ1 system.
- Establish the root cause using “5 Why” or other Root cause analysis techniques as required by the customer during the weekly corrective action meeting.
- Complete all sections on the CCA-XXX in MQ1.
  - Copy Details onto the customer corrective action format when required by customer.
  - Finalize the CCA in MQ1 (and customer corrective action format) as applicable.
  - Update all applicable system documents such as Production Flow Charts, Control Plans, PFMEA, Work Instructions.
- Supply the finalized 8D to the customer; include updated documents, verification data and other evidence as applicable.

---

**Production**

Implement Corrective and Preventive actions.

---

**Review corrective actions issues during regular Management Review Meetings**

**END**
Internal Corrective Action

**Quality**
- The need for internal corrective action is identified from internal non-conformance or is the result of an informal customer concern.
- Contain parts as per MSP-022 (Control of Nonconforming Product), as applicable. An ICA-XXX internal corrective action is initiated in MQ1.
- Establish the root cause using “5 Why” or other Root cause analysis techniques as required during the weekly corrective action meeting.
- Complete all sections on the ICA-XXX in MQ1. Copy Details onto the customer corrective action format when required by customer.
- Finalize the ICA in MQ1 as applicable. Supply Verification data as applicable such as dimensional studies or capability studies MQ1.

**Production**
- Implement Corrective and Preventive actions.

**Management Review**

END
### Supplier Corrective Action

<table>
<thead>
<tr>
<th>Quality</th>
<th>Supplier</th>
<th>Management Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>The need for a supplier corrective action is can occur from an internal non-conformance of a supplier’s product or processing or can be the result of a customer complaint from a non-conforming supplied process or product to A. Berger.</td>
<td>Contain parts as per MSP-022 (Control of Nonconforming Product) as applicable. An SCA-XXX supplier corrective action request is initiated in MQ1.</td>
<td>Complete all sections on the SCA-XXX in MQ1. Copy Details onto the customer corrective action format when required by customer.</td>
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<tr>
<td></td>
<td>Send the SCA-XXX corrective action request with picture evidence of the non-conformance and the Supplier Corrective Action Request form (Ref. SYS-332).</td>
<td>The finalized corrective action with evidence an updated system documents received from the supplier, will be copied into the MQ1 system.</td>
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<tr>
<td></td>
<td>The supplier will respond in a timely manner as per the Supplier Quality Manual SQM-001 using the Supplier Corrective Action Request form (Ref. SYS-332).</td>
<td>Review corrective actions Issues during regular Management Review Meetings</td>
</tr>
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END
Related Documents:
Control of Nonconforming Product
Supplier Quality Manual
Supplier Corrective Action Request

<table>
<thead>
<tr>
<th>DATE</th>
<th>REVISION SUMMARY</th>
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<tbody>
<tr>
<td></td>
<td>Complete rewrite to process flow format</td>
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</table>
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- Rewrote the tier 1 manual to include risk management and business continuity
- Remember the reading standards, revising the manual, re-reading, re-revising – multiply that by 3 new standards
- ISO 22301 (business continuity), ISO 31010 (risk management), ISO 31001 (risk management)
- Head was swimming
Risk Management Assessment and Business Continuity

- Needed to develop a process to get this done with little (or no) knowledge
- Failure Mode and Effects Analysis (FMEAs) were well understood because of automotive customers, and provided for an easy path into understanding the RM/BC requirements
- FMEA’s provided the overall framework
Using FMEA framework, developed Matrix which covered all requirements of risk management

The Management Team, Production Supervisors, Managers and Management Rep met 6 times to complete matrix

The basic outline:

<table>
<thead>
<tr>
<th>THREAT TO BUSINESS</th>
<th>CRITICALITY RECOVERY TIME</th>
<th>VULNERABILITY</th>
<th>CONSEQUENCE OF RISK OCCURRING</th>
<th>CURRENT CONTROL</th>
<th>DETECTION</th>
</tr>
</thead>
</table>

RESULT = CRITICALITY X VULNERABILITY X DETECTION
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- Final version of matrix much more complex
- Addressed all requirements of:

  ISO 22301 (business continuity), ISO 31010 (risk management), ISO 31001 (risk management)
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Proceed with more Internal Audits and Gap Analysis

- Audited against the revised checklists and draft process flows
- Gaps were not as serious – things had definitely improved in the TS and AS requirements
- Performed internal audit against risk management and business continuity standards separately
Addressing Internal Audit Findings

- Senior Management, Production Supervisors, Managers and Management Rep met at least weekly
- Discussions became more concise, meetings were better run
- Cell phones were left at the door, policy instituted by Senior Management.
- Progress was made effectively
- Minutes with action items and timelines issued immediately after each meeting
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Addressing Internal Audit Findings

- Follow-up audits were performed
- Progress was made effectively
- Follow-up audits were performed
- Corrective and Preventive Actions were addressed and closed
- Reviewed content of current Work Instructions
  - Deleted / obsoleted many
  - Kept only what was relevant
  - Revised as necessary to reflect actual activities and tasks
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The Registration /Surveillance August Audit

- Annual assessment, not quite as many registrar auditors
- One TS automotive auditor
- One AS aerospace auditor
- One Risk Management / Business Continuity auditor
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Risk Management / Business Continuity

External Audit

- Was deemed an internal audit by the registrar
- Standards are not registrable
- Results from the audit:
  - No nonconformances
  - 1 observation
  - Number of opportunities for improvement
  - Letter of compliance to the standards was received
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Risk Management / Business Continuity
External Audit

- One of first companies, if not the first, to receive this recognition.
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The Final Result

- 37 page Tier 1 Manual meeting requirements of 6 management system standards
- 34 management system procedures
- 8 management system procedures specific to ISO 14001
- Risk Management / Business Continuity Matrix
- Reasonable amount of work instructions
- Business Management System Policy is one full page
  - Employees are trained on bullet points
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The Final Result

- Business Alignment
- Improved Risk Management
- Standardized Key Processes
- Metrics are cost and customer driven
- Streamlined documentation structure
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The “New” September List

- OHSAS 18001 – Occupational Health and Safety
- Continually improve the internal audit process (process measurables audited each time)
- Regular review of the risk management / business continuity matrix
- Prepare for forthcoming audit.
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Why it worked…

- Senior Management mandate and support
- Failure is not an option
- Motherhood and apple pie
- This makes sense for the business
### THE JOURNEY TIMELINE

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<tbody>
<tr>
<td>Start TS 16949 review</td>
<td>Aggressive internal audits Plan activities to close gaps</td>
<td>Request to integrate AS 9100C</td>
<td>Rewrite Tier 1 Manual Confirm ISO 14001 requirements</td>
<td>Internal audits based on TS / AS checklists and current internal documents</td>
<td>Plan activities to close gaps Prioritize corrective action, preventive action, opportunities for improvement</td>
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</tr>
<tr>
<td><strong>THE JOURNEY TIMELINE</strong></td>
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</thead>
<tbody>
<tr>
<td>Complete risk management matrix</td>
<td>Internal audits</td>
<td>Plan activities to close gaps Prioritize corrective action, preventive action, opportunities for improvement</td>
<td>Review and revise work instructions Delete / obsolete many</td>
<td>4 day annual assessment – TS, AS, RM/BC Implementation of OHSAS 18001 Request to registrar to schedule one week audit – all standards June each year</td>
</tr>
</tbody>
</table>
Questions? Comments?
Please type your questions in the panel box

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