Risk Management
A Hands on Approach & Transition Experiences

16 May 2017

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OUR PURPOSE

TO SAFEGUARD LIFE, PROPERTY AND THE ENVIRONMENT
DNV GL - Global reach – local competence

150+ years
300+ offices
100 countries
14,000 employees
Tomorrow’s successful companies will create value by meeting the world’s **social, economic** and **environmental** needs.

We help you build **Sustainable Business Performance** through our global certification, verification, assessment and training services.

**SUSTAINABLE VALUE** and **STAKEHOLDER TRUST**
A Shared Ambition

- **DNV GL:**
  - Sustainability in everything we do. Partnering with our customers to build sustainable business performance and stakeholder trust, contributing to a safe and sustainable future.

- **ISO:**
  - Their vision is for the ISO standards to contribute to innovation and sustainable development

“In the longer term, we can expect sustainability to become a fundamental principle for ISO standards in just the same way as market relevance.”
DNV GL Business Assurance services

- Management system certifications
- Product assurance
- Supply chain management and assurance
- Training
- Sustainability Services (strategy and reporting)
- Food & beverage certification and assessment
- Healthcare accreditation and assessments

www.dnvglcert.com
Business Management Systems Certification

More than 80 national accreditations and over 80,000 certificates issued worldwide

Broad service portfolio

- Quality - ISO 9001
- Aerospace - AS9100, AS9110 & AS9120
- Information Security - ISO/IEC 27001
- Environment - ISO 14001, RC14001
- Occupational Health and Safety - OHSAS 18001
- Automotive - ISO/TS 16949 → IATF 16949
- Medical Devices – ISO 13485 & MDD
- Food safety - ISO 22000, BRC, IFS, SQF & Supplier Audits
- Telecommunications – TL9000
- Social Accountability – SA-8000
- Etc.
Step by Step Transition

1. Identify Key Changes
   - Understand the new requirements
   - Training

2. Perform Gap Analysis
   - Gap Assessment

3. Plan and Do
   - Planning for critical activities
   - Implementation strategies
   - Management commitment

4. Check
   - Internal audits
   - Management Review
   - External audit (if certified)

5. Act
   - Improvement Strategies
Transition Requirements

*DNVGL Target Deadline for Transition Audit:*
15 June 2018

- **Important Dates**
  - 15 March 2017
  - All new certifications or re-certifications will be issued against ISO 9001:2015
  - 15 September 2018
    - ISO 9001:2008 mandatory expiration date, which is the withdrawal date of both standards
    - Certificate is issued after an upgrade surveillance or recertification audit against ISO 9001:2015 has been performed
Additional Resources

- DNV GL Resources:
  - Live and OnDemand Webinars
    https://www.dnvgl.us/assurance/webinars/index.html
  - Interpretive guidelines to ISO 9001:2015
  - Training (Public and Private)
    https://www.dnvgl.us/assurance/Training/qualitytraining.html
  - Certification Resource Center
Bio/Background

- Jason Teliszczak - CPP® | LEED Green Associate | CSDS | ZWBA | CES | CSMP | ASHM | CFDC I & II | CGPM | Safefood 360 Partner | HACCP Manager | eGCC | QPSWPPP | QCIS | CET | CESCO | GPCP level TM Faculty Member | Green-Star Auditor | CHSO | GCP | STP | FCRA – Advanced

- Jason Teliszczak founded JT Environmental Consulting, Inc. over 15 years ago. JT Env. Now assists non-for-profits up to Fortune 500 clients and has certified and qualified consultants located throughout the USA, South America, Asia, Australia, as well as within the UK.
Industries

- Aerospace
- Automotive
- e-Waste
- Food
- Manufacturing
- Medical Devices
- Non-for-profits
- Watercraft
- Etc.
Quality

Corrective Action or Preventative Action – The new risk based methodology for ISO 9001:2015

- ISO 9001:2015 was published at the end of September 2015

- “With over 1.1 million certificates issued worldwide, ISO 9001 helps organizations demonstrate to customers that they can offer products and services of consistently good quality. It also acts as a tool to streamline their processes and make them more efficient at what they do.” – www.iso.org
Quality

Corrective Action or Preventative Action – The new risk based methodology for ISO 9001:2015

- Corrective Action – Action to eliminate the cause of a detected nonconformity or other undesirable situation.

- Preventative Action – Action to eliminate the cause of a potential nonconformity or other undesirable potential situation.
Corrective Action or Preventative Action – The new risk based methodology for ISO 9001:2015

- Corrective Action – Action to eliminate the cause of a detected nonconformity or other undesirable situation.

- Preventative Action – Action to eliminate the cause of a potential nonconformity or other undesirable potential situation.

- Risk Based Thinking – 0.3.3 – An organization needs to plan and implement actions to address risks and opportunities. 6.1.2 – Actions taken to address risk and opportunities shall be proportionate to the potential impact on the conformity of products and services.
Corrective Action or Preventative Action – The new risk based methodology for ISO 9001:2015

- Three main areas that are different/updated:
  - Process approach – Consistent results, align the standard with the direction of the organization.
  - PDCA – Individual processes, as well as the system as a whole.
  - Risk Based Thinking – Preventing undesirable outcomes (non-conforming products and services, etc.).
Quality

- Process Approach

“...involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle (see 0.3.2) with an overall focus on risk-based thinking (see 0.3.3) aimed at taking advantage of opportunities and preventing undesirable results.” – ISO 9001:2015 - NEW
Quality

Process Approach

- “The application of the process approach in a quality management system enables:
  - a) understanding and consistency in meeting requirements;
  - b) the consideration of processes in terms of added value;
  - c) the achievement of effective process performance;
  - d) improvement of processes based on evaluation of data and information” – *ISO 9001:2015 - NEW*
Quality

PDCA

- **Plan**: establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers’ requirements and the organization’s policies, and identify and address risks and opportunities;
- **Do**: implement what was planned;
- **Check**: monitor and (where applicable) measure processes and the resulting products and services against policies, objectives, requirements and planned activities, and report the results;
- **Act**: take actions to improve performance, as necessary.”

– ISO 9001:2015 - **NEW**
Quality - PDCA

- Planning (6)
- Leadership (5)
- Performance evaluation (9)
- Improvement (10)
- Support (7), Operation (8)
- Customer satisfaction
- Products and services

Organization and its context (4)
Customer requirements
Needs and expectations of relevant interested parties (4)
Quality

Risk Based Methodology

- Risk based thinking -
- “...enables an organization to determine the factors that could cause its processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise...” – ISO 9001:2015 - NEW
Quality

Risk Based Methodology

- “Risk-based thinking (see Clause A.4) is essential for achieving an effective quality management system. The concept of risk-based thinking has been implicit in previous editions of this International Standard including, for example, carrying out preventive action to eliminate potential nonconformities, analyzing any nonconformities that do occur, and taking action to prevent recurrence that is appropriate for the effects of the nonconformity.”

  – ISO 9001:2015 - **NEW**
Quality

Risk Based Methodology

 “To conform to the requirements of this International Standard, an organization needs to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the quality management system, achieving improved results and preventing negative effects.”

– *ISO 9001:2015 - NEW*
Quality

Risk Based Methodology

 “Opportunities can arise as a result of a situation favourable to achieving an intended result, for example, a set of circumstances that allow the organization to attract customers, develop new products and services, reduce waste or improve productivity. Actions to address opportunities can also include consideration of associated risks. Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects. A positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities.”

– ISO 9001:2015 - NEW
Quality

Risk Based Methodology

- Risk – “is potential of losing something of value. Values (such as physical health, social status, emotional well being or financial wealth) can be gained or lost when taking risk resulting from a given action, activity and/or inaction, foreseen or unforeseen. Risk can also be defined as the intentional interaction with uncertainty. Uncertainty is a potential, unpredictable, unmeasurable and uncontrollable outcome, risk is a consequence of action taken in spite of uncertainty” – Wiki
Quality

Risk Based Methodology

- Risk – “the possibility that something bad or unpleasant (such as an injury or a loss) will happen
  : someone or something that may cause something bad or unpleasant to happen
  : a person or thing that someone judges to be a good or bad choice for insurance, a loan, etc.” - Webster
Quality

Risk Based Methodology

- Risk –
  - “1 - possibility of loss or injury : PERIL
  - 2 - someone or something that creates or suggests a hazard
  - 3 - the chance of loss or the perils to the subject matter of an insurance contract; also :
    - a: the degree of probability of such loss
    - b: a person or thing that is a specified hazard to an insurer
    - c: an insurance hazard from a specified cause or source <war risk>
  - 4 - the chance that an investment (as a stock or commodity) will lose value” - Webster
Quality

Risk Based Methodology

- Risk – “effect of uncertainty” – *ISO 9000:2015 NEW*
- “Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.” - *ISO 9001:2015 NEW*
Quality

Risk Based Methodology

- So what is the potential impact?
  - What is the severity?
    - How much will it impact the organization’s products and/or services?
  - What is the probability or likelihood?
    - How often will it potentially occur?
# Modified Risk Assessment Matrix

<table>
<thead>
<tr>
<th>SEVERITY</th>
<th>Frequency</th>
<th>Likely</th>
<th>Occasional</th>
<th>Seldom</th>
<th>Unlikely</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catastrophic</td>
<td>I</td>
<td>1</td>
<td>2</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Critical</td>
<td>II</td>
<td>3</td>
<td>4</td>
<td>7</td>
<td>11</td>
</tr>
<tr>
<td>Moderate</td>
<td>III</td>
<td>5</td>
<td>9</td>
<td>10</td>
<td>14</td>
</tr>
<tr>
<td>Negligible</td>
<td>IV</td>
<td>13</td>
<td>17</td>
<td>18</td>
<td>19</td>
</tr>
</tbody>
</table>

**Risk Levels**

**Quality**

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16 May 2017
Quality

Risk Based Methodology

- Risk analysis process –
  - Risk Management
  - Risk Analysis
  - Risk Communication
Quality

- Risk Based Methodology
- Risk Management –
  - Identification
  - Measurement
  - Management of events – Which could adversely impact the organization
Quality

Risk Based Methodology

- Risk Management – IDENTIFICATION

  - Protection of the brand
  - Financial and non-financial perspectives
  - Organizational factors
  - Operational factors
  - External factors
  - Staffing issues – such as capacity and/or skill levels
Quality

Risk Based Methodology

- Risk Analysis process –
  - Process to eliminated the risk
  - OR
  - Reduce the risk to an acceptable level
Quality

Risk Based Methodology

- Risk Analysis process – MITIGATIONS PLANS
  - None - No plans currently in place
  - Planning
  - Implementing
  - Completing
  - Refining
Quality

Risk Based Methodology

- Risk Analysis process – MITIGATIONS PLANS
  - Define Responsibilities
  - Action plans
  - Timeframes
  - Expected outcomes
  - Review, reporting, and controlling mechanisms
  - Evaluate the effectiveness of the actions taken
Quality

Risk Based Methodology

- Risk Communication –
  - Linked with all interested and affected groups
  - Takes place throughout the risk analysis process
  - Provides guidance on how the risk should be managed
  - Provides information on the states and bases for decisions
  - Two way exchange of information
  - Enhances the understanding of the risk
Quality

Severity or Impact

- Overall Product
- Reputation
- Financial
- Health and Safety
- Natural environment
- Social or affect on the community
- Media involvement
- Legal
# Quality

## Modified Risk Assessment Matrix

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<th>Severity</th>
<th>Probability</th>
<th>Risk Levels</th>
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<tr>
<td></td>
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Quality

Define the Chart – Severity

- Catastrophic / Critical – Death of a person, very significant financial loss, ...
- High – Extensive injuries to people, ...
- Moderate / Medium - some injuries that required medical treatment, significant financial loss, ...
- Low – minor injuries, minor financial loss, ...
- Very low / negligible – No injuries, no embarrassment, zero media coverages, ...
Quality

Define the Chart – Probability

- Frequently – Daily, hourly, ...
- Likely – Daily, once a week, ...
- Occasionally – Monthly, quarterly, ....
- Seldom – Annually, every 1-5 years, ...
- Unlikely – Once every 10-50 years, ...
Sources

- ISO – [www.iso.org](http://www.iso.org)

- JT Environmental Consulting – [www.jtenv.com](http://www.jtenv.com)
Polling Question

What type of guidance do you feel you need?
Question & Answer
Contact Us

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