ISO 9001:2015

What’s it all About?

SUSTAINING EDGE SOLUTIONS Inc.
Creating Lasting Change For Your Business™
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Delivering Manufacturing and Service Organizations Solutions for Improved Business Performance

APICS Tucson Chapter

Tucson-Old Pueblo Section
The Global Voice of Quality™
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What We Deliver - Our Services

**Business Performance Improvement Systems**

- ISO 9001:2015 Management System
- AS 9100/10/20 Aviation, Space and Defense Management System
- ISO 13485 Medical Devices Management System
- ISO 14001 Environmental Management System
- ISO 27001 Information Security Management System
- ISO/TS 16949 Automotive Management System
- National Aerospace and Defense Accreditation – NADCAP
- Lean Manufacturing, Kaizen Events and Six Sigma
- Value Stream Mapping, 5S and Performance Measurement
- Training: Onsite, E-Learning and Classroom
- Baldrige Performance Excellence Assessments
- Market Research
- Business Development
- Project Management and Social Media

**Systems & Processes Lead to Success**
Agenda

• Why the Change?
• ISO 9001:2015 Standard Changes
• Annex SL
• Terms and Definitions
• Context of the Organization
• Documented Information
• Risk-Based Thinking and Requirements
• Auditing Risk
• Leadership
• Business and Quality Importance
ISO 9001 Journey

- International standard for a Quality Management System (QMS)
- Originally published in 1987 – Inspection Based
- Underwent major revision in Year 2000. 2008 revision included no new requirements - Process Based
- ISO 9001:2015 – Risk Based Approach
- Applies to any organization regardless of size or industry
- Implemented by more than 1.3 million organizations in over 170 countries
ISO TC/176: Technical Committee oversight leading revision

**June 2013**: Committee Draft (CD)

**May 2014**: Publication of Draft International Standard (DIS)

**July 2015**: Expected publication of Final Draft International Standard (FDIS)

**Sept 23, 2015**: Publication of Standard as ISO 9001:2015

**Sept 2018**: All 2008 standard certifications will be under the new standard. All initial certifications from *March 2017* will be under the new standard.
Why the Change?

- Increased organizational complexity
- Technical advances in business
- Growth of global business and services
- Multiple standards held in many organizations
- Fifteen years since the ISO 9001 standard has changed!

*Impact of Change:* over 1 million globally certified companies, OEMs, customers, supply chain, certification bodies, third party auditors, end users, consultants and regulatory agencies.
ISO 9001:2015 Main Changes

- The adoption of the high level structure
- Risk-based thinking to improve process approach application
- Fewer prescribed requirements
- Less emphasis on documents
- Improved applicability for services
- Requirement to define the QMS boundaries
- Increased leadership requirements
There is now 10 Sections (*instead of 8*) in the Standard. The requirements themselves are set out in Clauses 4 - 10.

<table>
<thead>
<tr>
<th>Clause</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Scope</td>
</tr>
<tr>
<td>2</td>
<td>Normative references</td>
</tr>
<tr>
<td>3</td>
<td>Terms and Definitions</td>
</tr>
<tr>
<td>4</td>
<td>Context of the organization – New Clause</td>
</tr>
<tr>
<td>5</td>
<td>Leadership</td>
</tr>
<tr>
<td>6</td>
<td>Planning for the quality management system</td>
</tr>
<tr>
<td>7</td>
<td>Support</td>
</tr>
<tr>
<td>8</td>
<td>Operation</td>
</tr>
<tr>
<td>9</td>
<td>Performance evaluation</td>
</tr>
<tr>
<td>10</td>
<td>Improvement</td>
</tr>
</tbody>
</table>
The new standard adopts the high-level structure and terminology of Annex SL (used for the development of all new ISO standards).

High level structure, identical core text and common terms, including core definitions for use in all Management System Standards.

Enhance the consistency and alignment of different management system standards.

Organizations that implement a single system addressing multiple standards (e.g. QMS, EMS, ISMS) will see the most potential benefit.

There is no requirement for the structure of an organization's quality management system documentation to mirror the Standard.
### Terms and Definitions

<table>
<thead>
<tr>
<th>ISO 9001:2008 - was</th>
<th>ISO 9001:2015 – now is</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exclusions</td>
<td>As applicable…</td>
</tr>
<tr>
<td>Products</td>
<td>Products and Services</td>
</tr>
<tr>
<td>Quality Manual / Procedures</td>
<td>[Maintain] Documented Information</td>
</tr>
<tr>
<td>Records</td>
<td>[Retain] Documented Information</td>
</tr>
<tr>
<td>Work Environment</td>
<td>Environment for the Operations of Processes</td>
</tr>
<tr>
<td>Purchased Products</td>
<td>Externally Provided Products and Services</td>
</tr>
<tr>
<td>Supplier</td>
<td>External Provider</td>
</tr>
</tbody>
</table>

There is no requirement for the terms used by an organization to be replaced by the terms used in this International Standard to specify quality management system requirements. Organizations can choose to use terms which suit their operations (e.g. using “records”, “documentation” or “protocols” rather than “documented information”; or “supplier”, “partner” or “vendor” rather than “external provider”).
4.1 Understanding the Organization and its Context

“The organization will determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system (QMS). The organization will monitor and review the information about these external and internal issues.”

External – Performance of competitive analysis, assessment of existing and emerging technology, impact on environment.

Internal – Values, culture, knowledge and performance of the organization
“Determine external and internal issues” What to consider and how far to go?

**Purpose & Strategic Direction**

**Examples of Internal Issues**
- Self-assessment results
- Organizational performance
- Internal audit results
- Competitive analysis
- Customer reviews/complaints
- Employee satisfaction data
- Best practices and industry benchmark comparisons

**Examples of External Issues**
- Economic environment & trends
- Competitive products and services
- Technology trends
- Opportunities for outsourcing
- Material availability and pricing
- International trade
- Benchmarking best-in-class performers in and outside your current market
4.2 Understand 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 customer and applicable statutory and regulatory requirements, the organization will determine:

- the interested parties that are relevant to the QMS;
- the requirements of the interested parties that are relevant to the QMS.

The organization will monitor and review information about these interested parties and their relevant requirements.

<table>
<thead>
<tr>
<th>Internal Interested Parties</th>
<th>External Interested Parties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Owners</td>
<td>Customers</td>
</tr>
<tr>
<td>Employees</td>
<td>Suppliers/Vendors</td>
</tr>
<tr>
<td>Company Divisions</td>
<td>End users of your products/services</td>
</tr>
<tr>
<td>External Departments outside of QMS?</td>
<td>Public</td>
</tr>
<tr>
<td></td>
<td>Regulators</td>
</tr>
<tr>
<td></td>
<td>Competitors</td>
</tr>
</tbody>
</table>
NEW  Clause 4: Context of the Organization

4.3 Determining the Scope of the Quality Management System

“The organization will determine the boundaries and applicability of the QMS to establish its scope.” When determining this scope, the organization will consider:

- the internal and external issues referred to in 4.1;
- the requirements of relevant interested parties referred to in 4.2; and
- the products and services of the organization.

The organization will apply all the requirements of this International Standard if they are applicable within the determined scope.

The scope of the QMS will be available and be maintained as documented information.

The scope will state the types of products and services covered, and provide justification for any requirement determined not to be applicable to the scope of the QMS.

Conformity to this standard can only be claimed if the requirements determined as not being applicable do not affect the organizations ability or responsibility to ensure conformity of its products and services and the enhancement of customer satisfaction.
Your organization needs a formal process – Conduct An Internal and External Self-Assessment.

- 4.1 Understanding the Organization and its Context
- 4.2 Understanding the needs and expectations of interested parties
- 4.3 Determining the scope of the quality management system
- 4.4 Quality management system and its processes

Reasons:

- It formalizes the process to ensure process evidence.
- It avoids going overboard on determining pertinent external and internal issues.
- It prevents disputes with external auditors regarding compliance.
Where Are We Now?

- A better understanding of the company has been gained. It’s stakeholders, internal and external issues of concern, information monitoring and measurement, and other factors which will build the framework for your thinking about risk (RBT).
- These results will be different for many companies, the risks can also be different.

**Risk Based Thinking (RBT) Kick-off**

*Risk is mentioned 8 times in the new standard*

**Risk Requirements**

<table>
<thead>
<tr>
<th>4.4.1</th>
<th>6.1.2</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1.1</td>
<td>9.1.3</td>
</tr>
<tr>
<td>5.1.2</td>
<td>9.3.2</td>
</tr>
<tr>
<td>6.1.1</td>
<td>10.2.1</td>
</tr>
</tbody>
</table>
“ISO 9001 Quality management systems—Fundamentals and vocabulary

“Risk is defined as the “effect of uncertainty.” Notes in the definition further describe risk as a “deviation from the expected,” either positive or negative.

The term “uncertainty” is clarified as a lack of information or knowledge about an event that can be expressed in terms of consequences—the likelihood of occurrence.

Lastly, ISO 9000 states that risk is related to potential events, and that it’s typically expressed as a result of the likelihood and consequence of such an event.

There is no requirement for formal risk management or a documented risk management process
• Risk - “effect of uncertainty on objectives” (ISO 31000:2009 Risk management—Principles and Guidelines)

• NOTE 1 An effect is a deviation from the expected — positive and/or negative.

• NOTE 2 Objectives can have different aspects (such as financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, organization-wide, project, product and process).

• NOTE 3 Risk is often characterized (i.e. named, e.g. credit risk) by reference to potential events (2.17) and consequences (2.18), or a combination of these.

Risk is the negative effect of uncertainty, and opportunity is the positive effect of uncertainty.
Examples of Risk Management Criteria

**Project** – ensuring project risks are evaluated before beginning

**Employees** – organizations need to ensure the safety, training, and qualifications of employees

**Process** – managing process variation

**Design** – building quality into the product design from the start, including its affect on planning

**Manufacturing** – ensuring that manufacturing is more efficient with streamlined quality planning

**Equipment** – ensuring that equipment can meet capabilities, current and future
4.4.1 QMS System and its processes
Address the risks and opportunities as determined with the requirements of 6.1 Actions to address risks and opportunities (next slide)

5.1.1 Leadership and Commitment
Top management will demonstrate leadership and commitment with the QMS by promoting the use of the process approach and risk-based thinking.

5.1.2 Customer focus
Top management will demonstrate leadership and commitment by ensuring that: “the risks and opportunities that affect conformity of products and services and the ability to achieve customer satisfaction are determined and addressed.”
6.1.1 Actions to address risks and opportunities

When planning for the quality management system, the organization will consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

a) give assure the quality management system can achieve its intended result(s)

b) enhance desirable effects (Opportunities)

c) prevent, or reduce, undesired effects (Risks) and

d) achieve continual improvement.

<table>
<thead>
<tr>
<th>External Issue</th>
<th>Type</th>
<th>Internal Interested Party</th>
<th>External Interested Party</th>
<th>Issue of Concern</th>
<th>Bias + / -</th>
<th>Process' Affected</th>
<th>Priority</th>
<th>Treatment Method</th>
<th>Reference Record</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material Availability</td>
<td>Supply Chain</td>
<td>Purchasing Mgr</td>
<td>Suppliers</td>
<td>Raw materials quality and critical services are not addressed when using sole source or limited source supplier</td>
<td>Negative</td>
<td>???</td>
<td>- High</td>
<td>-FMEA -PFMEA -RCA -Checklist -Fault Tree -Bowtie Analysis</td>
<td>-Record of Evidence related to the Risk Treatment</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>- Med</td>
<td>-</td>
<td>-FMEA# -CAR# -??</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Low</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
6.1.2 The organization will *plan actions to address* these risks and opportunities; and how to:

1. *Integrate and implement the actions into its QMS processes*
2. *Evaluate the effectiveness of these actions*

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

*Note:* Options to address risk can include avoiding the risk, taking risk to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

*Note:* Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new clients, building partnerships, using new technology and other desirable and viable possibilities to address the organization’s or its customer’s needs.
There is no requirement for formal risk management or a documented risk management process.

Formal risk assessment and risk treatment is not required, but you have to do something.

Failure Mode and Effects Analysis (FMEA) = Risk assessment and treatment

Be sure your process:

(1) identifies the risk, (2) evaluates the risk, (3) defines a risk action and (4) evaluates the actions taken.
### Example of a Risk Register

<table>
<thead>
<tr>
<th>Process</th>
<th>Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ln #</strong></td>
<td><strong>Process</strong></td>
</tr>
<tr>
<td><strong>Probability (of risk occurring)</strong></td>
<td><strong>Consequence (if risk is encountered)</strong></td>
</tr>
<tr>
<td>Likelihood</td>
<td>Potential Loss of Contracts</td>
</tr>
<tr>
<td>Previous Occurrences</td>
<td></td>
</tr>
</tbody>
</table>

**Mitigation Plan**

*(required for risk factors > 8.0)*

May reference external plan document

**Risk Factor after Mitigation**
Examples of Risk Management Tools

- Failure Mode and Effects Analysis (FMEA)
- Fault Tree Analysis (FTA)
- Probabilistic Risk Assessment (PRA)
- Event Tree Analysis (ETA)
- Event Sequence Diagram (ESD)
- Reliability Block Diagram (RBD)

Familiarize yourself with the various Risk Management Tools
ISO 9001:2015 Risk Requirements

9.1.3 Analysis and Evaluation (prior 8.4 Analysis of Data)

The organization will analyze and evaluate appropriate data and information arising from monitoring and measurement. The results of analysis will be used to evaluate:

– the effectiveness of actions taken to address risks and opportunities.

a) conformity of products and services;
b) the degree of customer satisfaction;
c) the performance and effectiveness of the quality management system;
d) if planning has been implemented effectively;
e) the effectiveness of actions taken to address risks and opportunities;
f) the performance of external providers;
g) the need for improvements to the quality management system.

NOTE: Methods to analyze data can include statistical techniques.
Where is Risk Addressed in ISO/DIS 9001?

9.3.2 Management Review Inputs

Top management will review the quality management system, at planned intervals, to ensure its continuing suitability, adequacy.

The management review will be planned and carried out with:

- Changes in external and internal issues that are relevant to the QMS
- the effectiveness of actions taken to address risks and opportunities (see 6.1)

10.2.1 Nonconformity and Corrective Action

When a nonconformity occurs, including any arising from customer complaints, the organization will evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: update risks and opportunities determined during planning, if necessary.
5.1 Leadership and Commitment

- Requires leaders to take accountability for the effectiveness of the quality management system.
- Requires leaders to establish a quality policy and objectives compatible with the context and strategic direction of the organization.
- Ensure the integration of the QMS requirements into the organization’s business processes.
- Engaging, directing, and supporting persons to contribute to the effectiveness of the QMS.
- Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

6.3 Planning of Changes and 8.1 Operational Planning and Control-New

When the organization determines the need for changes to the QMS, the changes will be carried out in a planned manner (see. 4.4)

“We need to establish a planned and systematic “management of change” process that evaluates the effect / consequences of any changes to the management system prior to implementation of the change.”
7.1 Organizational Knowledge

NEW: The organization will determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

- This knowledge shall be maintained, and made available to the extent necessary.
- When addressing changing needs and trends there is a need to consider current knowledge and determine how to acquire or access the necessary additional knowledge and required updates.

NOTES:
- Organizational knowledge can include information such as intellectual property and lessons learned.
- To obtain the knowledge required, the organization can consider:
  - Internal sources (e.g. learning from failures and successful projects, capturing undocumented knowledge and experience of topical experts within the organization)
  - External sources (e.g. standards, academia, conferences, gathering knowledge with customers or providers).

*Consider Management Review Meetings for effectiveness
Auditing Risk – Questions vs. Evidence

Auditors must be flexible when auditing a QMS for conformity to ISO 9001:2015’s risk-based thinking. There are no requirements in the standard for a risk management process or methodology, so auditors have been concerned that auditing a QMS will be difficult.

The following are some of questions auditors will ask when auditing your QMS:

1. **Does the organization identify internal and external issues as they relate to the context of the business?** (Clause 4.1)

2. **Has the organization identified relevant interested parties as they relate to the context of the business? Has the organization understood the interested-party expectations?** (Clause 4.2)

3. **Has the organization used the issues developed in the context and in the needs and expectations of the interested parties when planning for the organization?** (Clause 4.3)

4. **Has the organization identified the risks and opportunities as they relate to the organization achieving its intended results, i.e., goal and objectives?** (Clause 6)

5. **Has the organization identified the actions to address the risks and opportunities?**

6. **Is the organization meeting its goals and objectives, i.e., is it improving?**
Next Steps for Success

• Identify the gaps needing to be addressed with the new requirements
  ➢ Conduct a comprehensive internal and external assessment process. Now is the time to push quality out of the quality department!

• Develop an implementation plan
  ➢ Project Management: Utilize proven and effective methods. Get your senior management team to develop and drive the implementation plan with you.

• Provide appropriate training and awareness for all parties that have an impact on the new requirements and organizational effectiveness
  ➢ Identify responsible parties: Management and Leadership is a priority!
  ➢ Train internal audit team in the new requirements and objective evidence interpretation

• Update your existing management system and documentation to meet the revised requirements and provide verification of effectiveness
  ➢ Question your current system and its effectiveness! Get leadership involved. Ensure new requirements implementation are resulting in conformance and business improvement. Audit the system repeatedly for personnel understanding and effectiveness.

• When necessary, communicate with your CB for transition arrangements
  ➢ Plan now for a successful 2016 transition.
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Our Services Include:

• **Training – Onsite and Classroom.**
  – ISO 9001:2015 Transition Training (For ISO 9001:2008 certified companies)
  – ISO 9001:2015 Process Based Internal Auditor

• **Gap Assessment**

• **Onsite and Offsite Consulting**

• **Pre-Assessment internal audit**

• **AND MORE!**

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