Introduction

- Dan O’Leary
  - Dan has more than 30 years experience in quality, operations, and program management in regulated industries including aviation, defense, medical devices, and clinical labs. He has a Masters Degree in Mathematics; is an ASQ certified Quality Engineer, Reliability Engineer, and Six Sigma Black Belt; and is certified by APICS in Resource Management.

- Ombu Enterprises, LLC
  - Ombu works with small manufacturing companies, offering training and execution in Operational Excellence. Focusing on the analytic skills and systems approach of operations management, Ombu helps companies achieve efficient, effective process and regulatory compliance.
Participant Introduction

- Your Name
- Your company
- Your job title
- Something about ISO 9001 you would like to discuss
The Workshop

- Our approach is casual
- Ask lots of questions when they occur to you – don’t wait for the end!
- Turn off your cell phones
- Bring examples from your experience
- Participate
- Have fun!
The Material

- I didn’t print copies of the slides
  - If you would like an electronic copy, go to my website OmbuEnterprises.com
  - Check under Library.
- I did provide printed copies of some reference material
  - If you would like an electronic copy, please give me a business card
Outline

Our Perspective
The Topics We Will Cover
Perspective

- ISO 9001 defines requirements for a Quality Management System
- Purchasing professionals need to know about their supplier’s QMS
- They also need to understand their own company’s implementation
Outline

• ISO 9001:2008 – What changed (and when)?
• How did we get here – a little history
• Purchasing Requirements
• Supply Chain
• Outsourced Processes
• Data Analysis
• Customer Satisfaction
ISO 9001:2008

What Changed?
When do my suppliers need to recertify?
Guidance on transition

• ISO (International Organization for Standardization) and the IAF (International Accreditation Forum)
  – Issued a joint communique on the implementation strategy.
  – Provides a timeline for accredited registrations
• We provide a reformatted copy of the guidance in your participant's package.
What Changed?

• The good news
  – ISO 9001:2008 does not contain any new requirements
  – It only introduces clarifications to the existing requirements
  – It also introduces changes to improve consistency with ISO14001:2004
What Changed?

- The bad news
  - One year after publication of ISO 9001:2008 all accredited certifications issued (new certifications or re-certifications) shall be to ISO 9001:2008.
The Timeline

- ISO 9001:2008 was issued on Nov. 15, 2008
  - All certs & re-certs to ISO 9001:2008: Nov. 15, 2009
  - ISO 9001:2000 certifications not valid: Nov. 15, 2010

- You should know when your suppliers are due for re-certification
Tracking Suppliers

• Your suppliers will probably upgrade at their next surveillance audit
• The registrars generally won’t wait until the current certificate expires
• If you maintain copies of your supplier’s ISO 9001 certificate, you will need to update your collection
Quick Summary of Changes

• ISO 9001:2008 has a table that shows all the changes from the 2000 version to the 2008 version.
  – In the table, additions are underlined, while deletions are in a strikethrough.
  – This method makes it very easy to know what changed.
Changed Clauses Related to Purchasing

- Clause 7.4 Purchasing
  - No additions or deletions
- Clause 4.1 General
  - Two new notes discussing the relationship of purchasing to outsourced processes.
- Clause 8.2.1 Customer satisfaction
  - A new note about monitoring customer perception
- Clause 8.4 Analysis of data
  - The requirements for supplier data analysis now refers to Clause 7.4
- There is a copy of the changes to these clauses in your participant’s package.
A Little History

Who is ISO?
A brief review of the versions
Specific applications & supporting documents
Who is ISO?

• ISO is the International Organization for Standardization
  – Founded in Feb. 1947
  – Headquarters in Geneva, Switzerland
  – ISO has 158 members countries

• ISO publishes many types of documents:
  – International Standards,
  – Technical Reports,
  – Technical Specifications,
  – Publicly Available Specifications,
  – Technical Corrigenda, and
  – Guides
ISO Standards

• ISO has developed more than 17,500 International Standards
  – ISO publishes about 1,100 new standards every year.

• ISO is organized into Technical Committees and Subcommittees
  – TC 176 Quality management and quality assurance
    • TC 176/SC 1 Concepts and terminology
    • TC 176/SC 2 Quality systems
    • TC 176/SC 3 Supporting technologies
The ISO 9000 Family

• ISO 9000 is both a standard and the name of a family of standards
  – The principal family members today are:
    • ISO 9000:2005 Quality management systems – Fundamentals and vocabulary
    • ISO 9001:2008 Quality management systems – Requirements
    • ISO 9004:2000 Quality management systems – Guidelines for performance improvements
The 1987 Versions

- Initially, there were five standards in the immediate family
  - ISO 9000:1987 *Quality management and quality assurance standards - Guidelines for selection and use*
  - ISO 9001:1987 *Model for quality assurance in design, development, production, installation, and servicing*
  - ISO 9002:1987 *Model for quality assurance in production, installation, and servicing*
  - ISO 9003:1987 *Model for quality assurance in final inspection and test*
  - ISO 9004:1987 *Quality management and quality system elements - Guidelines*
The 1987 Concept

• Three standards of varying complexity:
  – ISO 9001: design, development, production, installation, and servicing
  – ISO 9002: production, installation, and servicing
  – ISO 9003: final inspection and test

• The customer would invoke the appropriate standard
  – The supplier could register the QMS with a notified body
  – The customer wouldn’t have to perform QMS audits on a supplier with a registered system
The 1994 Versions

• The standards were updated, but retained the same basic approach
  – ISO 9001:1994 Quality systems – Model for quality assurance in design, development, production, installation and servicing
  – ISO 9002:1994 Quality systems – Model for quality assurance in production, installation and servicing
  – ISO 9003:1994 Quality systems – Model for quality assurance in final inspection and test
The 2000 Versions

• These versions introduced major changes:
  – Developed the “process approach”
  – Consolidated ISO 9001, ISO 9002, & ISO 9003 into a new ISO 9001

• The immediate family became:
Process Approach

• “The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the ‘process approach’”.

• The process approach links requirements of clauses 4 to 8 with a Plan – Do – Check – Act (PDCA) methodology for process improvement.

Source: ISO 9001:2008 Clause 0.2
Consolidations and Exclusions

• Consolidated Standards
  – The 1984 family: three versions depending on the scope of the supplier’s work.
  – The current family: one version using scope and exclusions

• The new standard is more dependant on exclusions to define the system.
The 2008 Versions

• In November 2008, ISO issued a new version of ISO 9001
• The current immediate family is now:
Exclusions Carried Over to the 2008 Version

• Clause 1.2 says, in part,
  – “Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.
  – “Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.”

• Clause 4.2.2.a requires:
  – “The organization shall establish and maintain a quality manual that includes the scope of the quality management system, including details of and justification for any exclusions (see 1.2)”
Scope and Exclusions

• The registrar’s certificate usually includes the scope
• The registrar’s certificate usually doesn’t include the exclusions
  – Exclusions can be to words or phrases, not just to clauses or sub-clauses
  – If you want to know about the exclusions, you should ask the supplier for the details and the justification
Guidance on Exclusions

- ISO has a guidance document on exclusions:
  www.iso.org/iso/iso_catalogue/management_standards/iso_9000_iso_14000/iso_9001_2008/guidance_on_iso_9001_2008_sub-clause_1.2_application
Example 2 – Exclusion of design and development by a contract manufacturer

- **Situation:**
  XYZ Electronics is building a new factory to perform manufacturing of mobile phones, as a subcontractor. It has only one customer and this customer maintains responsibility and authority for product design. XYZ Electronics is responsible for purchasing of all components and for performing the manufacturing activities. The customer provides XYZ with the manufacturing and parts specifications, and is also responsible for notifying XYZ of any design changes and providing the appropriate change information.

  XYZ Electronics, in the development of its QMS, has excluded the requirements of ISO 9001:2008 sub-clause 7.3 *Design and development*. XYZ Electronics considers the customer specifications as a customer supplied product and therefore controls this according to ISO 9001:2008 sub-clause 7.5.4 *Customer property*.

- **Issue(s):**
  Can the XYZ Electronics exclude sub-clause 7.3 *Design and development* from its QMS and claim conformity to ISO 9001:2008?
Example 2 – Exclusion of design and development by a contract manufacturer

- **Issue(s):**
  Can the XYZ Electronics exclude sub-clause 7.3 Design and development from its QMS and claim conformity to ISO 9001:2008?

- **Analysis and Conclusion:**
  XYZ Electronics was justified with its decision to exclude sub-clause 7.3 Design and development from its QMS since it does not have any authority or accountability for design of the mobile phone product. Its customer provides the design.
ISO Developed Specific Applications for Certain Industries

<table>
<thead>
<tr>
<th>Industry</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automotive</td>
<td>ISO/TS 16949:2002</td>
</tr>
<tr>
<td>Education</td>
<td>IWA 2:2007</td>
</tr>
<tr>
<td>Energy</td>
<td>PC 242, ISO 50001</td>
</tr>
<tr>
<td>Food safety</td>
<td>ISO 22000:2005</td>
</tr>
<tr>
<td>Information security</td>
<td>ISO/IEC 27001:2005</td>
</tr>
<tr>
<td>Health care</td>
<td>IWA 1:2005</td>
</tr>
<tr>
<td>Local government</td>
<td>IWA 4:2005</td>
</tr>
<tr>
<td>Medical devices</td>
<td>ISO 13485:2003</td>
</tr>
<tr>
<td>Petroleum and gas</td>
<td>ISO 29001:2003</td>
</tr>
<tr>
<td>Ship recycling</td>
<td>ISO/PAS 30000:2008</td>
</tr>
<tr>
<td>Supply chain security</td>
<td>ISO 28000:2007</td>
</tr>
</tbody>
</table>
ISO Developed Supporting Documents for the QMS Implementation (Part 1)

- ISO 10001:2007 Quality management – Customer satisfaction – Guidelines for codes of conduct for organizations
- ISO 10002:2004 Quality management – Customer satisfaction – Guidelines for complaints handling in organizations
- ISO 10003:2007 Quality management – Customer satisfaction – Guidelines for dispute resolution external to organizations
- ISO 10005:2005 Quality management systems – Guidelines for quality plans
- ISO 10007:2003 Quality management systems – Guidelines for configuration management
ISO Developed Supporting Documents for the QMS Implementation (Part 2)

- ISO 10012:2003 Measurement management systems – Requirements for measurement processes and measuring equipment
- ISO/TR 10013:2001 Guidelines for quality management system documentation
- ISO 10014:2006 Quality management – Guidelines for realizing financial and economic benefits
- ISO 10015:1999 Quality management -- Guidelines for training
- ISO 10019:2005 Guidelines for the selection of quality management system consultants and use of their services
- ISO 19011:2002 Guidelines for quality and/or environmental management systems auditing
Purchasing Requirements

Understanding the requirements of Clause 4.7 - Purchasing
Clause 7.4 - Purchasing

• Clause 7.4 has three sections
  – 7.4.1 Purchasing process
  – 7.4.2 Purchasing information
  – 7.4.3 Verification of purchased product
• We will look at each of them to understand the requirements
• The summary of changes in the participant package has the full text of the Clause 7.4
7.4.1 Purchasing Process

• The basic requirements are:
  – Product must conform to specified purchasing requirements
  – Exercise appropriate control over the supplier and the product
  – Establish criteria for selection, evaluation, and re-evaluation
  – Evaluate and select suppliers
  – Keep records of evaluations and actions
7.4.2 Purchasing Information

• The basic requirements are:
  – Describe the product to purchase using purchasing information
  – Ensure specified purchasing requirements are adequate
7.4.3 Verification of purchased product

• The basic requirements are:
  – Ensure the product meets specified purchasing requirements through inspection or other activities
  – When using verification at the supplier
    • State the intended verification arrangements
    • State the method of product release
You need to evaluate suppliers based on their ability to meet your requirements.

You need to establish criteria to select and evaluate suppliers.

You need to keep records of any evaluations you perform.

You need to keep records of actions that come from the evaluation.
Example Selection Criteria

Criteria

**Capability** – Can the supplier make the product you require?

**Capacity** – Can the supplier fill your orders without backorder?

**Pricing** – Does the supplier have a competitive price structure?

**Quality System** – Does the supplier have correct the QMS (scope & exclusions)?

**Financial Stability** – Will the supplier be in business 5 years from now?

**Workforce stability** – Does the supplier expect a labor action (strike) in the next five years?

**Regulatory Compliance** – Does the supplier have a clean record with OSHA, EPA, debarment lists, etc.?
Necessary Action

- Your evaluation or re-evaluation may point to action
  - For many customers, this is documented as a Supplier Corrective Action Request (SCAR)
  - Many suppliers will bring it in as a Customer Complaint
  - The Customer Complaint should enter the Corrective Action process (Clause 8.5.2)
Type and Extent of Control

- This is a risk management question
  - If a product supply failure has a **low risk**, you don’t need much control
  - If a product supply failure has a **high risk**, you need a lot of control

- One approach:
  - Build a risk matrix
  - Determine a plan for each cell
  - Classify each supplier – product combination
    - Any given supplier could provide both high and low risk products
## Example Risk Matrix

<table>
<thead>
<tr>
<th></th>
<th>Distributor</th>
<th>OEM</th>
<th>Single Source</th>
<th>Sole Source</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Commodity</strong></td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Long lead time</strong></td>
<td>Medium</td>
<td>Medium</td>
<td>Medium</td>
<td>Medium</td>
</tr>
<tr>
<td><strong>Simple variant</strong></td>
<td>Medium</td>
<td>Medium</td>
<td>Medium</td>
<td>Medium</td>
</tr>
<tr>
<td><strong>Complex variant</strong></td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td><strong>My drawing</strong></td>
<td>N/A</td>
<td>N/A</td>
<td>Medium</td>
<td>Medium</td>
</tr>
<tr>
<td><strong>My drawing &amp; specialized</strong></td>
<td>N/A</td>
<td>N/A</td>
<td>High</td>
<td>High</td>
</tr>
</tbody>
</table>
Specified Purchase Requirements

Develop Requirements
Each purchased product must be specified.

Ensure Adequacy
Each specification should be reviewed for adequacy.

Communicate To Supplier
Communicate the requirements to the supplier, usually on a PO

Ensure Conformance
Implement methods, including inspection, to assure conformity

ISO 9001 for Purchasing Professionals
## Specified Purchase Requirements

The requirements and verification should match the product!

<table>
<thead>
<tr>
<th>SIMPLE</th>
<th>COMPLEX</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product:</strong> A wooden #2 pencil purchased from an office supply catalog</td>
<td><strong>Product:</strong> A proprietary chemical blend used as a raw material</td>
</tr>
<tr>
<td><strong>Requirement:</strong> The catalog number</td>
<td><strong>Requirement:</strong> Detailed chemical specifications including materials and blending specs</td>
</tr>
<tr>
<td><strong>Adequacy:</strong> Negotiated contract</td>
<td><strong>Adequacy:</strong> Review and approval by design, process, and quality engineering</td>
</tr>
<tr>
<td><strong>Communicate:</strong> Ordering form (probably web based order entry)</td>
<td><strong>Communicate:</strong> Purchase order with specification number and revision</td>
</tr>
<tr>
<td><strong>Conformance:</strong> User check</td>
<td><strong>Conformance:</strong> Chemical test of samples from incoming lots</td>
</tr>
</tbody>
</table>
Purchasing Information

- Describes the product to purchase
- Includes, as appropriate:
  - Requirements for approval of
    - Product
    - Procedures
    - Processes
    - Equipment
  - Qualification of personnel
  - Quality management system

? What would you include in our simple case (pencils)?

What would you include in our complex case (chemical blend)?
Sampling - A Typical Application

• You just received a shipment of 5,000 widgets from your supplier.
• Is the shipment good enough to put into your inventory?

How will you decide?
You have a few approaches

- Consider three potential solutions
  - Look at all 5,000 widgets (100% inspection)
  - Don’t look at any, put the whole shipment into stock (0% inspection)
  - Look at some of them, and if enough of those are good, keep the lot (Acceptance sampling)

- In a sampling plan, we need to know:
  - How many to inspect or test?
  - How to distinguish “good” from “bad”?
  - How many “good” ones are enough?
Two Standards

- Two Standards are commonly used for inspection
  - Attributes data
    - Commonly uses ANSI/ASQ Z1.4
    - Derived from MIL-STD-105
  - Variables data
    - Commonly uses ANSI/ASQ Z1.9
    - Derived from MIL-STD-414
A simplified view of the relationship between process control and acceptance sampling

Producer

Production Process

Control Method
SPC: p-chart
Standard given: $p_0 = 0.02$
Central Line: $p_0 = 0.02$
Control Limits:

$ p_0 \pm 3 \sqrt{\frac{p_0(1-p_0)}{n}} $

Consumer

Acceptance Process

Control Method
Attribute Sampling
AQL = 4.0%
Use Z1.4
Single Sample
Level II
Verification at the Supplier’s Premises

• The standard anticipates two cases:
  – You want to check the material before it ships to you
  – Your customer wants to check the material before it ships to you

• You must inform the supplier:
  – About the arrangements you will make
  – The criteria to release the product
ISO 9001 in the Supply Chain

Supplier’s Conformance
Goods and Services
Supplier Conformance

- **Supplier’s declaration of conformity**
  - Your supplier affirms that its QMS meets ISO 9001, often supported by legally-binding signatures.

- **Second party assessment**
  - Your supplier has been assessed by a customer to check if its QMS meets ISO 9001.

- **Third party assessment**
  - Your supplier hires an impartial third party to assess conformity to ISO 9001. The third party issues a certificate describing the scope of the QMS. This is usually called certification or registration.
  - Third parties can be accredited by recognized accreditation bodies, who verify the certification body’s independence and competence to carry out the certification process.

- We provide a reformatted copy of the ISO information on Supply Chain in your participant's package.
Accreditation

The IAF is an association of Accreditation Bodies and other interested parties from around the world, who work together to promote confidence and consistency in the ISO 9001 accreditation and certification process.

Accreditation Body

The accreditation process provides additional confidence that the certification body is competent and has the necessary integrity to issue an ISO 9001 certificate. Accreditation is usually carried out by national or regional accreditation bodies, and their accreditation mark will appear on the certificate.

Certification Body / Registrar

A common way for a supplier to demonstrate conformity to ISO 9001 is via an independent ("Third-party") certification process. A certification body (sometimes known as a "registrar") conducts an audit of the supplier and if all is OK, they will issue a certificate of conformity.

"The organization" (Your supplier)

If you know your supplier well and have confidence in them, it may be sufficient for you to accept a "Supplier Declaration of Conformity to ISO 9001" issued by them. Alternatively, you may choose to audit your supplier yourself or rely on audits that have been carried out by other reputable customers. These are known as "second-party audits".

"The customer" (You!)

You are the one who is buying the goods or the services from your supplier. You need to make sure you tell them clearly what you want. Depending on how well you know your supplier, the confidence you have in their products, and the importance of their products for your own business, you might not even need them to demonstrate conformity to ISO 9001 at all.

In the US this is ANAB
Products and Services

• Can your supplier claim a product or service satisfies ISO 9001?
  – No, ISO 9001 only applies to the quality management system

• There is a strong possibility that the product or service is covered by another ISO standard
Outsourced Processes

Definition

Guidance Document
Outsourced Process Definition

- ISO 9001:2008 added some notes on outsourced processes
  - An “outsourced process” is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.
  - The type and extent of control to be applied to the outsourced process may be influenced by factors such as . . . the capability of achieving the necessary control through the application of clause 7.4.

- Common examples of an outsourced process:
  - Customer service
  - Production processes
  - Internal audits

- We provide a reformatted copy of the Guidance on Outsourced Processes in your participant's package.
Who Performs an Outsourced Process?

• An outsourced process can be performed
  – by a supplier that is totally independent from the organization
  – or part of the same parent organization (e.g. a separate department or division that is not subject to the same quality management system).

• It may be provided within:
  – the physical premises or work environment of the organization,
  – at an independent site, or
  – in some other manner.
Payment may not be a criteria

- In some situations, the organization might not “purchase” the outsourced process in the traditional sense.
- It might, for example, receive the service from a corporate head office or from another division within a group of organizations, without any monetary transaction taking place.
- Under these circumstances, however, ISO 9001:2008 Clauses 7.4 and 4.1 are still applicable.
What to Do

• Compile a list of outsourced processes
  – Determine who performs each one
  – Classify the performer as independent or the same parent
  – Understand if the intent is permanent outsourcing or temporary outsourcing

• Determine if the control of the process requires you to apply the Purchasing clause.
Analysis of Data
Analysis of Supplier Data

- You have to determine, collect, and analyze data to show the suitability and effectiveness of the QMS.
- ISO 9001:2008 added to reference to clause 7.4 in the analysis of data for suppliers.
- This is a clarification, so you probably don’t need to do anything different
  - You should ensure supplier data is considered in the Management Review
Customer Satisfaction
Customer Satisfaction – What is it

• What is customer satisfaction?
  – Customer satisfaction is the “customer's perception of the degree to which the customer's requirements have been fulfilled” (ISO 9000:2005, clause 3.1.4)

• ISO 9001 (clause 5.2) requires that customer requirements are determined and are met

• ISO 9001 (clause 8.2.1) requires information relating to customer perception as to whether the organization has met customer requirements.
Customer Satisfaction – How to decide

• Your ISO 9001 supplier has to “monitor information relating to customer perception”
• The 2008 revisions added a note with potential sources which includes:
  – customer data on delivered product quality
  – user opinion surveys
  – warranty claims
• You ISO 9001 supplier should be contacting you regularly to learn your perception of their ability to your requirements
Summary & Questions
Summary and Questions

• We looked at the:
  – Implementation timeline
  – The changes from the 2000 version to the 2008 version
  – A short history of the standard
  – Analysis of Clause 7.4 on Purchasing
  – Changes in control of outsourced processes
  – Some other minor changes

• Do you have any questions?

• Feel free to contact me:
  – Dan@OmbuEnterprises.com
  – 603-209-0600