Ombu Enterprises

ISO 9001 for Purchasing Professionals

Dan O'Leary CQE, CRE, CSSBB, CIRM
Ombu Enterprises, LLC
603-209-0600
Dan@OmbuEnterprises.com

Introduction

Ombu Enterprises

- 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

Ombu Enterprises

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

The Workshop

Ombu Enterprises

- 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

Ombu Enterprises

- 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

Ombu Enterprises

Outline

Our Perspective

The Topics We Will Cover

Perspective

Ombu Enterprises

- 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

Ombu Enterprises

- 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

Ombu Enterprises

ISO 9001:2008

What Changed?

When do my suppliers need to recertify?

Guidance on transition

Ombu Enterprises

- ISO (International Organization for Standardization) and the IAF (International Accreditation Forum)
  - Issued a joint communiqué 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?

Ombu Enterprises

- 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?

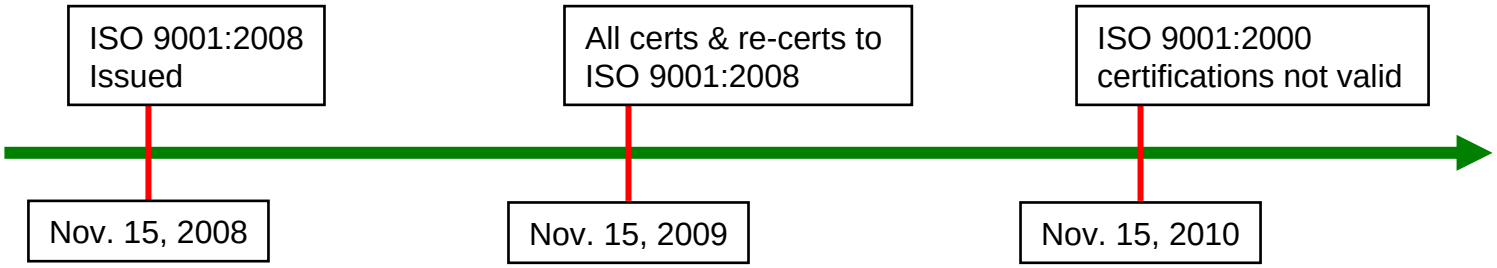
Ombu Enterprises

- 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.
  - Twenty four months after publication by ISO of ISO 9001:2008, any existing certification issued to ISO 9001:2000 shall not be valid.

The Timeline

Ombu Enterprises

- ISO 9001:2008 was issued on Nov. 15, 2008



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

Tracking Suppliers

Ombu Enterprises

- 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

Ombu Enterprises

- 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

Ombu Enterprises

- 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.

Ombu Enterprises

A Little History

Who is ISO?

A brief review of the versions

Specific applications & supporting documents

Who is ISO?

Ombu Enterprises

- 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

Ombu Enterprises

- 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

Ombu Enterprises

- 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

Ombu Enterprises

- 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

Ombu Enterprises

- 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

Ombu Enterprises

- 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

Ombu Enterprises

- 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:
  - ISO 9000:2000 Quality management systems – Fundamentals and vocabulary
  - ISO 9001:2000 Quality management systems – Requirements
  - ISO 9004:2000 Quality management systems – Guidelines for performance improvements

Process Approach

Ombu Enterprises

- “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

Ombu Enterprises

- 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

Ombu Enterprises

- In November 2008, ISO issued a new version of ISO 9001
- The current immediate family is now:
  - 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

Exclusions Carried Over to the 2008 Version

Ombu Enterprises

- 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

Ombu Enterprises

- 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

Ombu Enterprises

- 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

Ombu Enterprises

- ***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

Ombu Enterprises

- ***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

Ombu Enterprises

Automotive	ISO/TS 16949:2002
Education	IWA 2:2007
Energy	PC 242, ISO 50001
Food safety	ISO 22000:2005
Information security	ISO/IEC 27001:2005
Health care	IWA 1:2005
Local government	IWA 4:2005
Medical devices	ISO 13485:2003
Petroleum and gas	ISO 29001:2003
Ship recycling	ISO/PAS 30000:2008
Supply chain security	ISO 28000:2007

ISO Developed Supporting Documents for the QMS Implementation (Part 1)

Ombu Enterprises

- 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 10006:2003 Quality management systems – Guidelines for quality management in projects
- ISO 10007:2003 Quality management systems – Guidelines for configuration management

ISO Developed Supporting Documents for the QMS Implementation (Part 2)

Ombu Enterprises

- 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/TR 10017:2003 Guidance on statistical techniques for ISO 9001:2000
- 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

Ombu Enterprises

Purchasing Requirements

Understanding the requirements of Clause 4.7 - Purchasing

Clause 7.4 - Purchasing

Ombu Enterprises

- 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

Ombu Enterprises

- 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

Ombu Enterprises

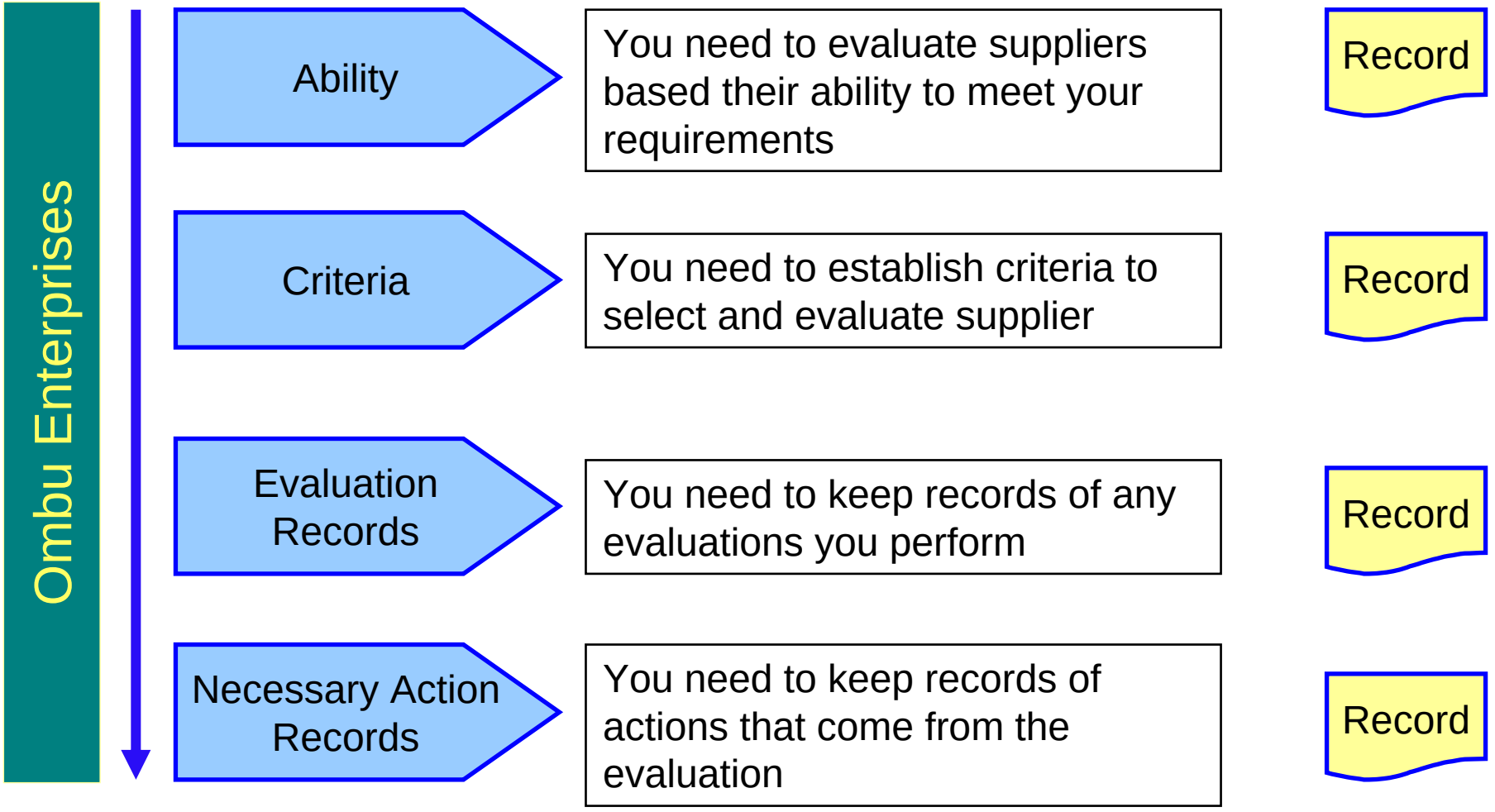
- The basic requirements are:
  - Describe the product to purchase using purchasing information
  - Ensure specified purchasing requirements are adequate

7.4.3 Verification of purchased product

Ombu Enterprises

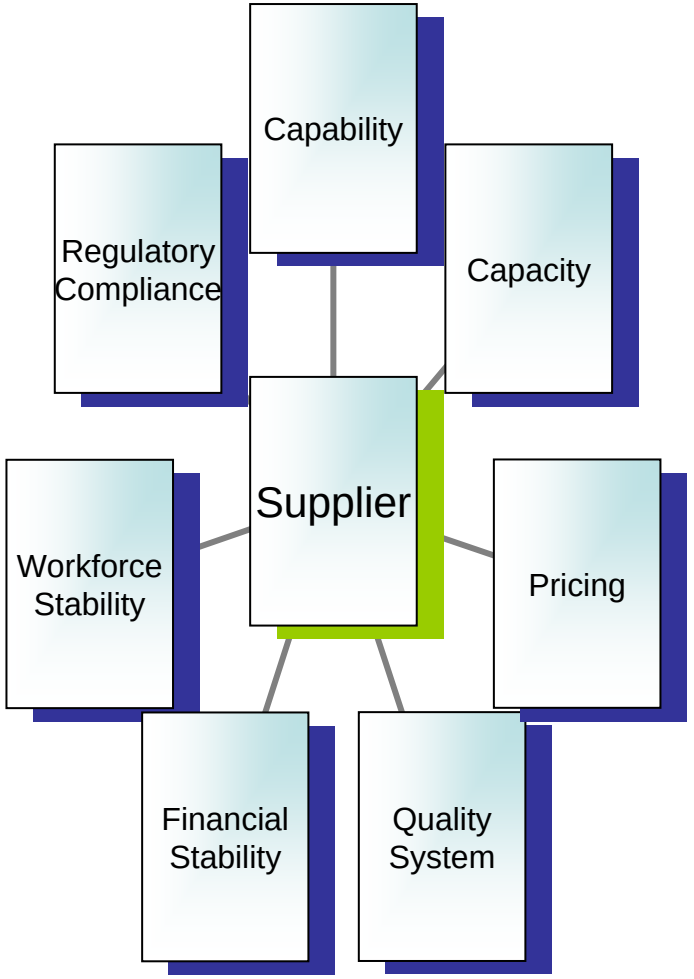
- The basic requirements are:
  - Ensure the product meets specified purchasing requirements through inspection or other activities
  - When using verification at the supplier
    - State the intended verification arrangements
    - State the method of product release

Evaluate and Select Suppliers



Example Selection Criteria

Ombu Enterprises



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

Ombu Enterprises

- 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

Ombu Enterprises

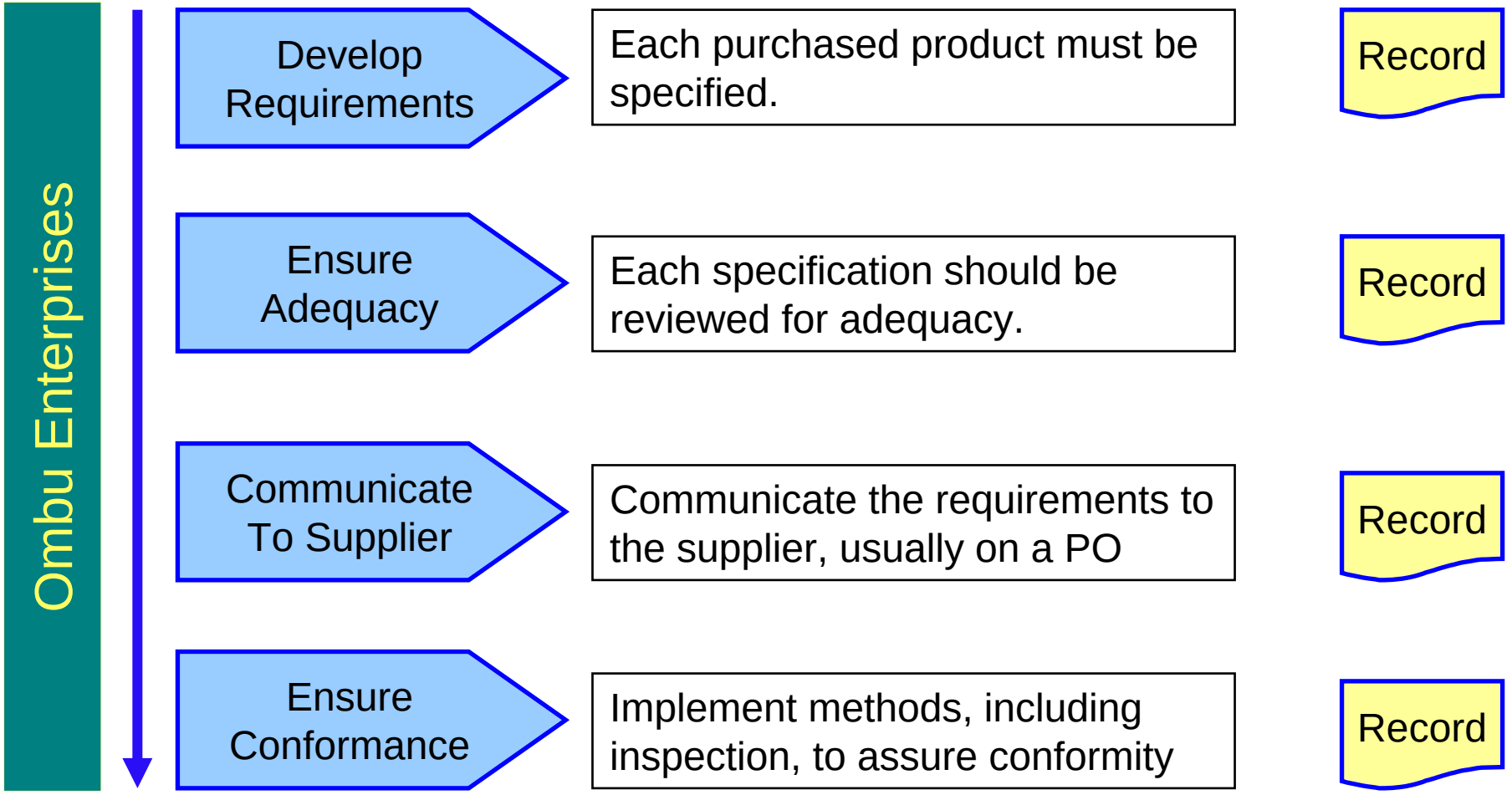
- This is a risk management question
  - If a product supply failure has a **low risk**, you don't need much control
  - If a product supply failure has a **high risk**, you need a lot of control
- One approach:
  - Build a risk matrix
  - Determine a plan for each cell
  - Classify each supplier – product combination
    - Any given supplier could provide both high and low risk products

Example Risk Matrix

Ombu Enterprises

	Distributor	OEM	Single Source	Sole Source
Commodity	Low	Low	Low	N/A
Long lead time	Medium	Medium	Medium	Medium
Simple variant	Medium	Medium	Medium	Medium
Complex variant	High	High	High	High
My drawing	N/A	N/A	Medium	Medium
My drawing & specialized	N/A	N/A	High	High

Specified Purchase Requirements



Specified Purchase Requirements

Ombu Enterprises

The requirements and verification should match the product!

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

Purchasing Information

Ombu Enterprises

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

?

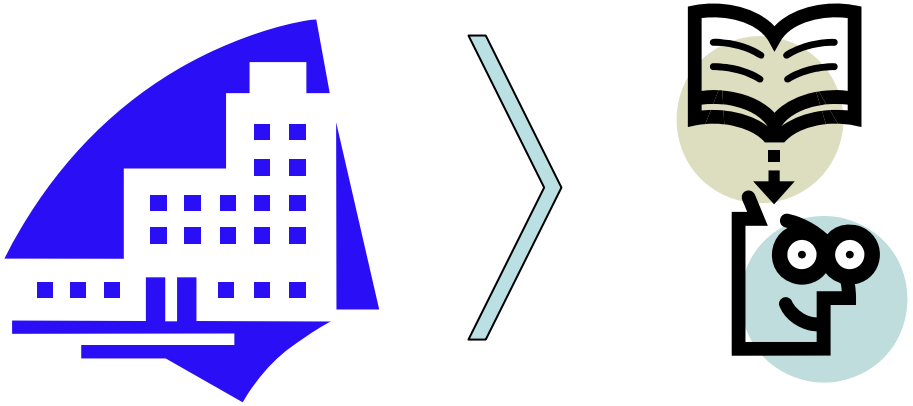
What would you include in our simple case (pencils)?

What would you include in our complex case (chemical blend)?

Sampling - A Typical Application

Ombu Enterprises

- 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

Ombu Enterprises

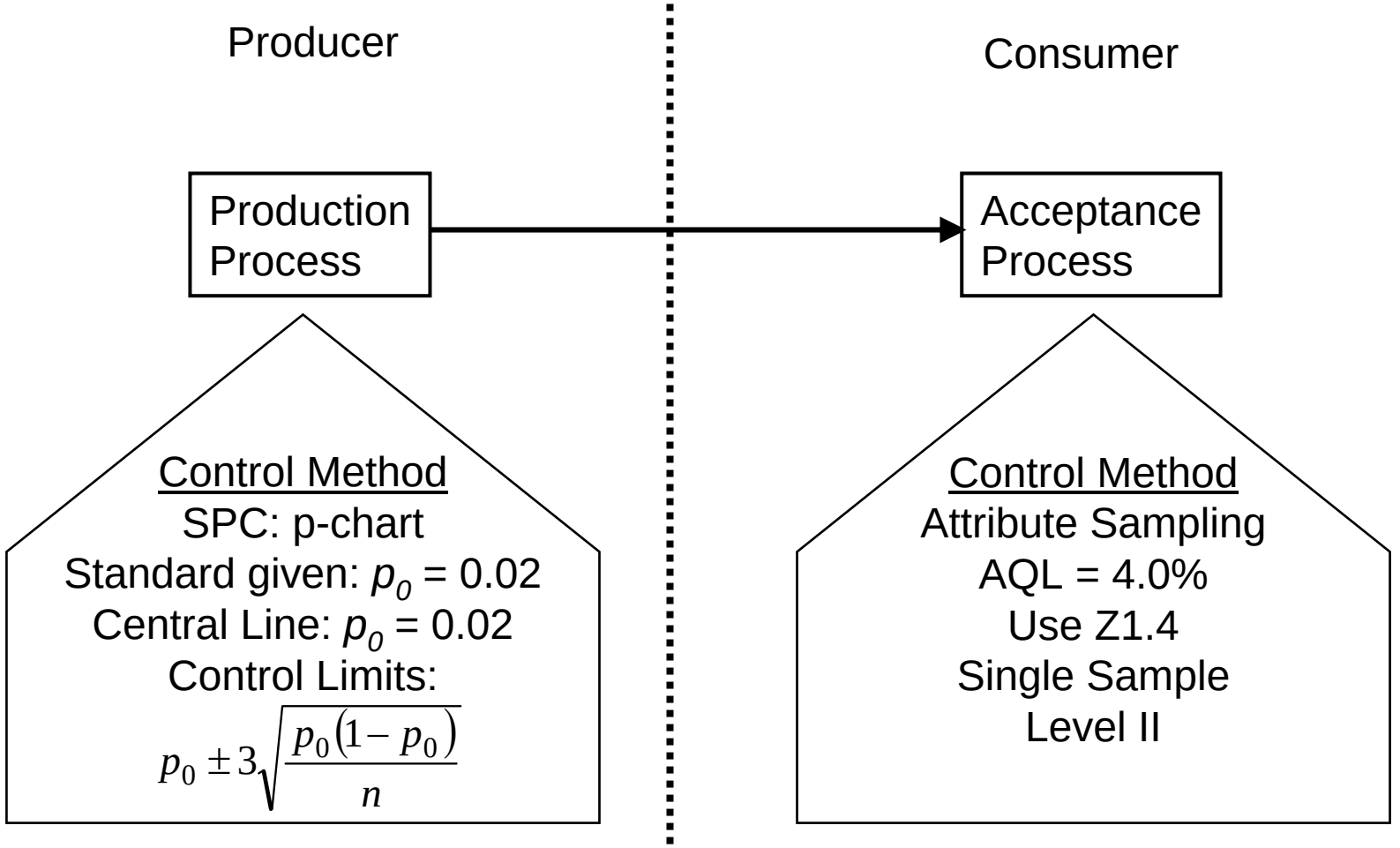
- Consider three potential solutions
  - Look at all 5,000 widgets (100% inspection)
  - Don’t look at any, put the whole shipment into stock (0% inspection)
  - Look at some of them, and if enough of those are good, keep the lot (Acceptance sampling)
- In a sampling plan, we need to know:
  - How many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

Ombu Enterprises



Verification at the Supplier's Premises

Ombu Enterprises

- 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

Ombu Enterprises

ISO 9001 in the Supply Chain

Supplier's Conformance
Goods and Services

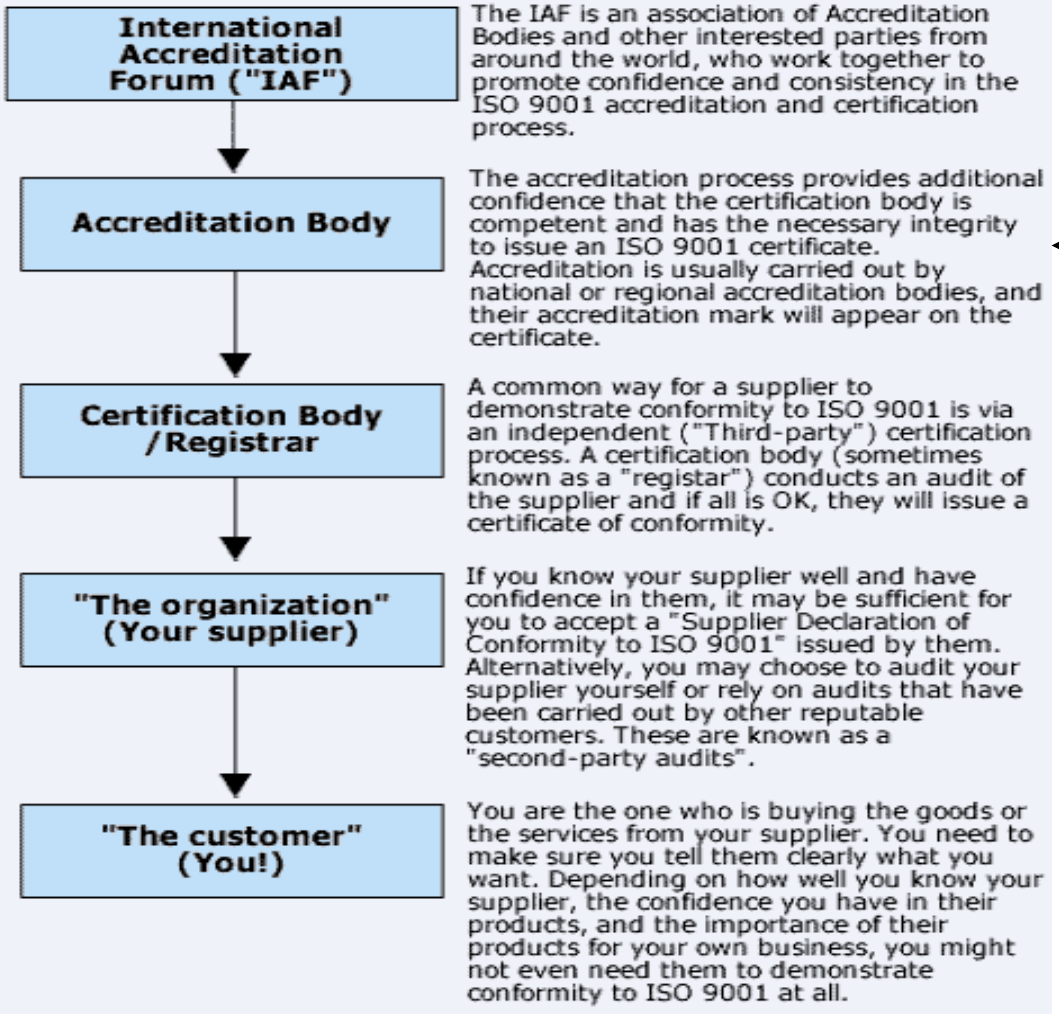
Supplier Conformance

Ombu Enterprises

- 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

Ombu Enterprises



In the US this is ANAB

Products and Services

Ombu Enterprises

- 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

Ombu Enterprises

Outsourced Processes

Definition

Guidance Document

Outsourced Process Definition

Ombu Enterprises

- 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?

Ombu Enterprises

- 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

Ombu Enterprises

- 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

Ombu Enterprises

- 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.

Ombu Enterprises

Analysis of Data

Analysis of Supplier Data

Ombu Enterprises

- 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

Ombu Enterprises

Customer Satisfaction

Customer Satisfaction – What is it

Ombu Enterprises

- 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

Ombu Enterprises

- 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

Ombu Enterprises

Summary & Questions

Summary and Questions

Ombu Enterprises

- 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