

Outsourcing and ISO 9001:2008

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Speaker Biography

- Dan O'Leary
 - Dan O'Leary is President of Ombu Enterprises, LLC, an education, training, and consulting company focusing on Operational Excellence using analytical skills and a systems approach to operations management.
 - 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 holds a Masters Degree in Mathematics; is an ASQ certified Biomedical Auditor, Quality Auditor, 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.

Outline

- ISO 9001:2008
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- Summary and Conclusions
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ISO 9001

A short history
Changes from the 2000 edition

What 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/Cor.1:2009 Quality management systems – Requirements
 - ISO 9004:2009 Managing for the sustained success of an organization – A quality management approach

Sep. 15, 2005

Nov. 15, 2008

Nov. 1, 2009

Jul. 17, 2009

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:
 - 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

- “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

The 2008 Versions

- In November 2008, ISO issued a new version of ISO 9001
 - ISO 9001:2008 *Quality Management Systems – Requirements*
- The differences between the 2000 version and the 2008 version are outlined in Table B.1 – Changes between ISO 9001:2000 and ISO 9001:2008

Outsourced Processes (Clause 4.1)

What is a process?
What is an outsourced process?
The ISO Guidance Document

Product and Process

- According to ISO 9000:2005, 3.4.1:
 - A *process* is a set of interrelated or interacting activities which transforms inputs into outputs (3.4.1)
 - A *product* is the result of a process (3.4.2)
 - Note: There are four generic product categories: services, software, hardware, and processed materials

Outsourced Processes

- According to ISO 9001:2008 Clause 4.1 Note 2:
- 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 underlined portions are new additions

Process Evaluation

- ISO 9000:2005, 2.8.1 suggests:
When evaluating quality management systems, there are four basic questions that should be asked in relation to every process being evaluated.
 - a) Is the process identified and appropriately defined?
 - b) Are responsibilities assigned?
 - c) Are the procedures implemented and maintained?
 - d) Is the process effective in achieving the required results?

The Requirement

- ISO 9001:2008 Clause 4.1 says:
Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

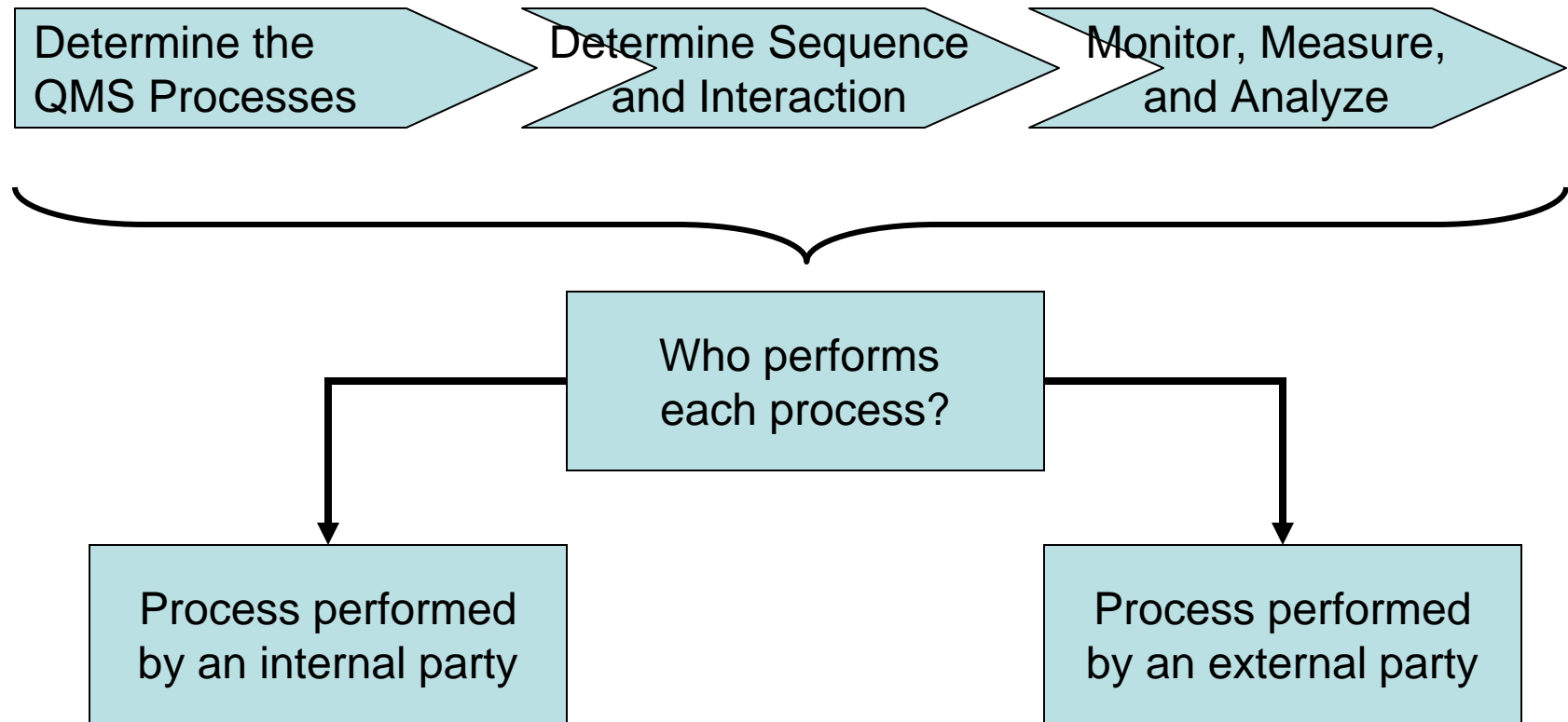
The underlined portions are new additions

The Requirement (cont.)

- ISO 9001:2008 Clause 4.1 NOTE 3 says:
Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as:
 - a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements
 - b) the degree to which the control for the process is shared
 - c) the capability of achieving the necessary control through the application of 7.4 (Purchasing)

The underlined portions are new additions

The Process Plan



The Guidance Document

- ISO issues Guidance Documents to help with ISO 9001 implementation

http://www.iso.org/iso/iso_catalogue/management_standards/iso_9000_iso_14000/iso_9001_2008.htm#support_package

ISO Guidance Documents Available

➔ **Guidance on ‘Outsourced processes’**

Guidance on ISO 9001:2008 sub-clause 1.2
"Application"

Guidance on the documentation requirements
of ISO 9001:2008 Guide to the Terminology
used in ISO 9001 and ISO 9004

Guidance on the concept and use of the
process approach for management systems

Implementation guidance for ISO 9001:2008

Frequently Asked Questions (FAQs)

Who Performs the Outsourced Process?

- An outsourced process can be performed by a supplier
 - that is totally independent from the organization, or
 - is part of the same parent organization
 - (e.g., a separate department or division that is not subject to the same quality management system)
- The best test is the scope of the QMS
 - An indicator is internal quality audits

Guidance Document Paragraph 2.1

Where is the Outsourced Process Performed?

- It may be provided:
 - within the physical premises or work environment of the organization
 - at an independent site
 - in some other manner

Guidance Document Paragraph 2.1

Call Center Example

- You contract for a call center in India run by another company. They provide the facility, manage employees, and train them to your specifications
- This is an outsourced process
 - Supplier is totally independent
 - The work is performed at an independent site

Cleaning Company Example

- You contract for a cleaning service run by another company. They manage employees, train them to their specifications, and provide the necessary cleaning supplies.
- This is an outsourced process
 - Supplier is totally independent
 - The work is performed within the physical premises or work environment of your organization

Calibration of IM&TE

- Your division is small, but close to a larger division of the same parent company. This larger division operates an internal calibration facility. Because they have capacity, you send your IM&TE to them for calibration. They provide the facility, manage employees, and send you calibration certificates.
- This is an outsourced process
 - Supplier is part of the same parent organization
 - The work is performed at an independent site

Corporate Compliance Audits

- Your division is part of a large parent company. After some law suits, the Law Department established a compliance audit program that covers labor laws, OSHA, EPA, ISO 9001 based QMS, *etc.* Corporate procedures require you to include these Law Department audit results in your Management Review as if they were your internal quality audits.
- This is an outsourced process
 - Supplier is part of the same parent organization
 - The work is performed within the physical premises or work environment of your organization

Our Four Cases

		Supplier	
		Same Parent	Totally Independent
Work	Your Location	Corporate Compliance	Cleaning Service
	Independent Site	IM&TE Calibration	Call Center

Some Discussion Points

- Collectively, let's address these points about our four cases:
 - Is the “supplier” in the scope of your QMS?
 - Do you expect a PO, contract, quality agreement, *etc.*?
 - Do expect the relationship is controlled using the Purchasing methods of Clause 7.4?
 - Do you think this is a monetary transaction, *i.e.*, do you pay for the service?
- The four cases:
 - Call Center
 - Cleaning Company
 - Calibration of IM&TE
 - Corporate Compliance Audits

First –Think about how your organization would address it today!

Second –Think about how your organization should address it to fully implement ISO 9001:2008

Purchase

- Section 2.3.1 of the guidance says:
 - 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.

Situation #1

- When an organization has the competence and ability to carry out a process, but chooses to outsource that process (for commercial or other reasons).
- In this situation the process control criteria should already have been defined, and can be transposed into requirements for the supplier of the outsourced process, if necessary.

Situation #2

- When the organization does not have the competence to carry out the process itself, and chooses to outsource it.
- In this situation the organization has to ensure that the controls proposed by the supplier of the outsourced process are adequate. In some cases it may be necessary to involve external specialists in making this evaluation.

Process Validation

- In some situations it might not be possible to verify the output from the outsourced process by subsequent monitoring or measurement.
- In these cases, the organization needs to ensure that the control over the outsourced process includes process validation in accordance with ISO 9001:2008 clause 7.5.2.

Purchasing (Clause 7.4)

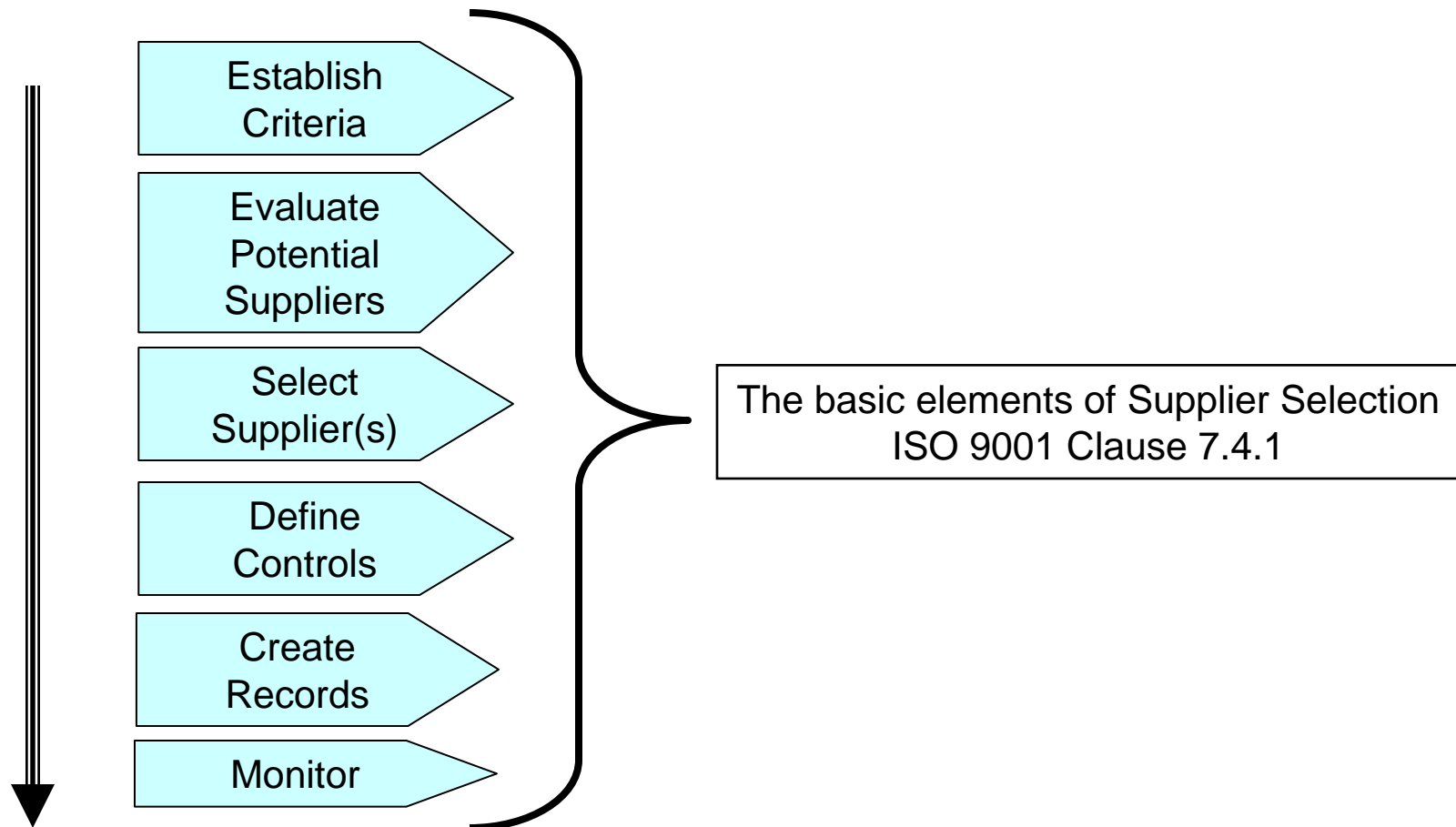
Requirements

Evaluation

Selection

Supplier Agreements and Other Controls

Supplier Selection ISO 9001 Approach



ISO 9001

Purchasing Process

Purchasing
Process

Requirement 7.4.1

The organization shall ensure that purchased product conforms to specified purchase requirements.

Discussion

There are two major points here:

- You have specified purchase requirements
- You have a method to verify conformity

In our example, you're "purchasing" a process from a second party, i.e. somebody outside the scope of your QMS.

Establish Criteria



Establish
Criteria

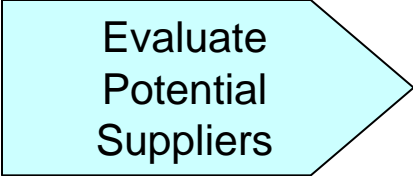
Requirement 7.4.1

Criteria for selection, evaluation, and re-evaluation shall be established.

Discussion

- Establish the criteria for evaluation and selection before starting the process.
- Note that the criteria for re-evaluation are also included in this clause.
- In some cases, corporate policy may not give you an opportunity to develop independent selection criteria. However, the use of selection criteria is still important to the process.
- The evaluation criteria, is critical to establishing controls.

Evaluate Potential Suppliers



Evaluate
Potential
Suppliers

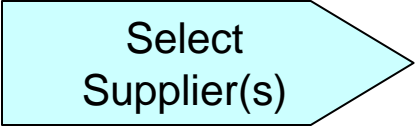
Requirement 7.4.1

The organization shall evaluate ... suppliers based on their ability to supply product in accordance with the organization's requirements.

Discussion

- Establish the criteria for evaluation and selection before starting the process.
- Product includes services, software, hardware, and processed materials
- Supplier includes both “monetary” and “non-monetary” transactions
- Suppliers can be totally independent or part of the same parent organization

Select Suppliers



Select
Supplier(s)

Requirement 7.4.1

The organization shall ... select suppliers based on their ability to supply product in accordance with the organization's requirements.

Discussion

- The selection criteria are set in an earlier step.
- Potential suppliers are evaluated against the selection criteria.
- Select the supplier(s) that is the best match against the criteria.
- You may not have a supplier that fully matches the criteria, so you may need to exercise controls to help close the gap.

- If the supplier selection is dictated by corporate policy (part of the same parent organization), then the choice is easy
- You still need to maintain a record showing why you selected the supplier

Define Controls



Define
Controls

Requirement 7.4.1

The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

Discussion

- Controls can come from two sources:
 - Base Control Plan
 - Additional Control Plan
- The Final Control Plan consolidates the Base Control Plan and the Additional Control Plan
- Control is written in a risk based fashion, based on the effect of purchased product (including services) on the effect of the final product.

Create Records



Create
Records


Requirement 7.4.1

Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

Discussion

- As always, maintain records.
- Actions resulting from the evaluation means that you might ask the supplier to perform additional tasks, develop new capabilities, *etc.*
- I could also include actions that you take as part of the control.

Monitor



Monitor

Requirement 7.4.1

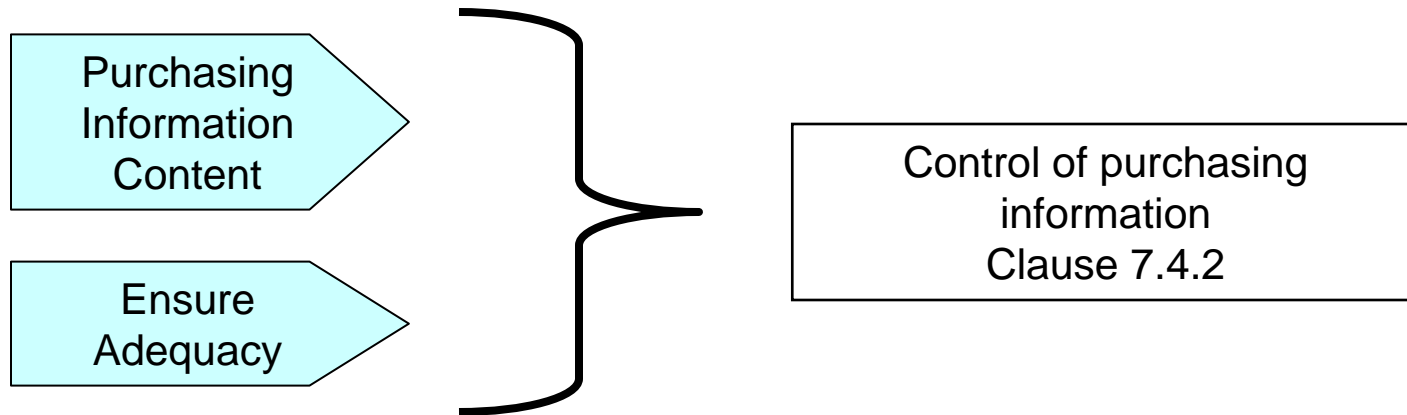
Criteria for selection, evaluation and re-evaluation shall be established.

Discussion

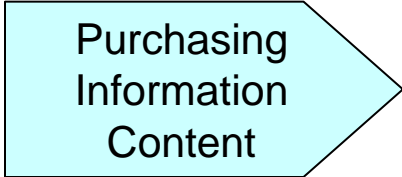
- We will implement monitoring through the Supplier Scorecard
- Monitoring also comes from Clause 4.1.e which says, “The organization shall ... monitor, measure where applicable, and analyze these processes”

ISO 9001

Purchasing Information



Purchasing Information Content



Purchasing
Information
Content

Requirement 7.4.2

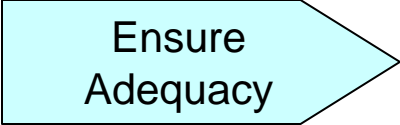
Purchasing information shall describe the product to be purchased, including where appropriate

- a) requirements for approval of product, procedures, processes and equipment,
- b) requirements for qualification of personnel, and
- c) quality management system requirements.

Discussion

- The purchasing information defines the relationship between the supplier and customer. It should include requirements and specification about the product as well as additional information ranging from process qualification to the QMS system.
- We will divide the Final Control Plan into two components
 - The Supplier Agreement becomes part of the purchasing agreement
 - The Additional Activities are the things you will do to help exercise control

Ensure Adequacy



Ensure
Adequacy

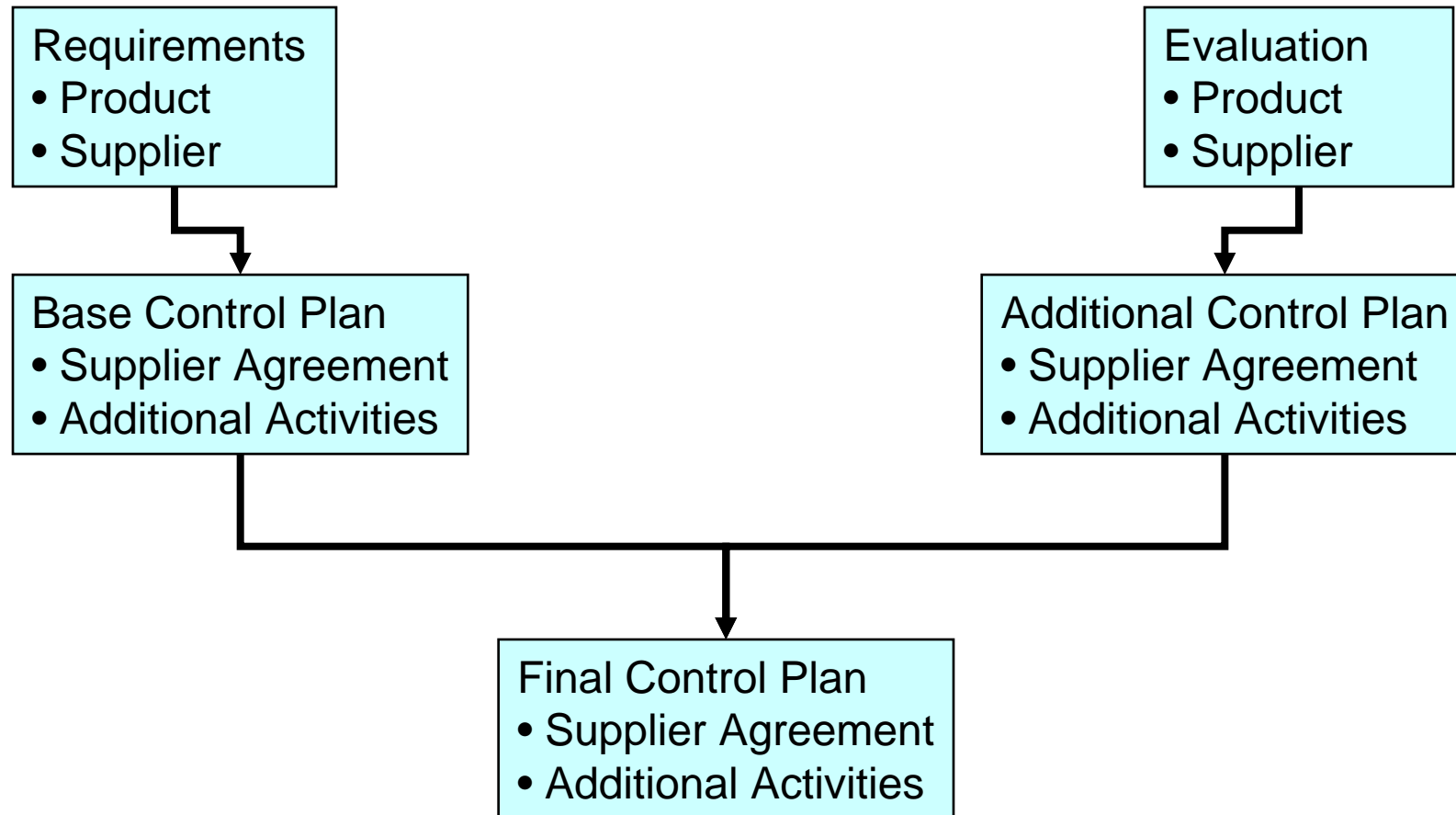
Requirement 7.4.2

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

Discussion

- The standard doesn't stipulate document control, but it a best practice.
- Follow the established methods to review and approve documents, place them under document control, and ensure the correct revision is sent to the supplier.

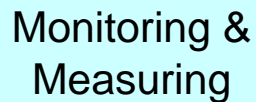
Overall Structure



Monitoring and Measuring of Processes (Clause 8.2.3)

Principles
Supplier Scorecards

Monitoring & Measuring



Monitoring & Measuring

Requirement 8.2.3

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes.

Discussion

- A measurement process is a set of operations to determine the value of a quantity (ISO 9000:2005 3.10.2)
- Monitoring is not defined in the family of standards
- For our purposes, we will use the Supplier Scorecard as the monitoring and measurement tool.

Monitoring & Measuring

Monitoring &
Measuring

Requirement 8.2.3

These methods [for monitoring and measurement] shall demonstrate the ability of the processes to achieve planned results.

Discussion

- The implication is that we have planned the results the process should achieve.
- Out monitoring and measurement methods need to be tied to the planned results

Monitoring & Measuring

Monitoring &
Measuring

Requirement 8.2.3

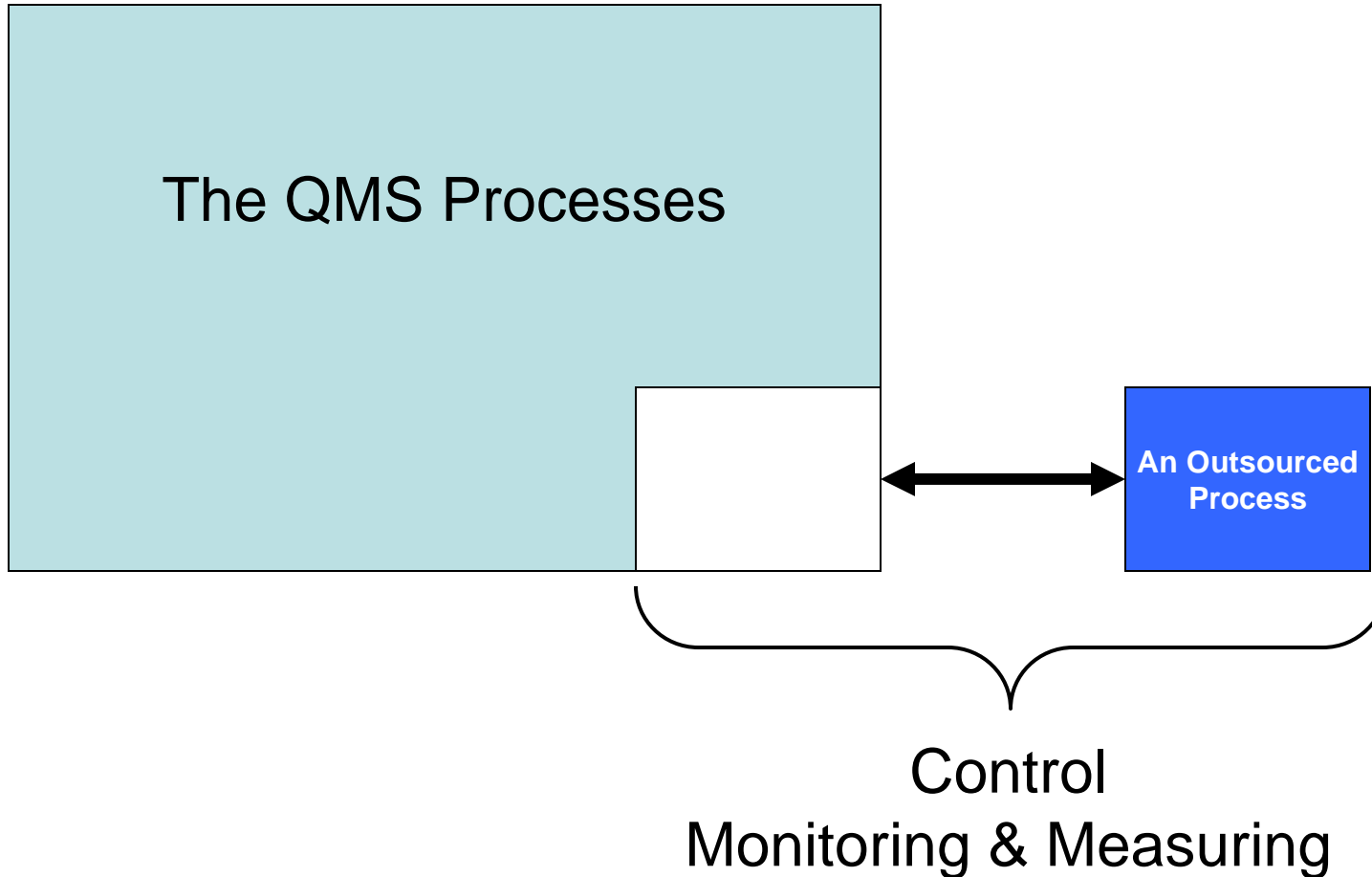
When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

Discussion

- Correction is action to eliminate a detected nonconformity
- Corrective action is action to eliminate the cause of a detected nonconformity or other undesirable situation

- Monitoring and measurement may detect a nonconformity. Eliminate the nonconformity and eliminate its cause.

The Outsourced Process



Supplier Scorecards

- Frequency
- Information
 - Quantitative Information
 - Qualitative Information
- There are two cases
 - You have the competence and ability to carry out a process, but choose to outsource it
 - Monitoring and measurement has probably been established. It is transferred to the Supplier
 - You don't have the competence to carry out the process itself, and choose to outsource it.
 - You will probably engage the Supplier to help determine the Scorecard contents

Supplier Scorecard – Frequency

- The frequency depends on factors such as:
 - the importance of the process
 - the rate at which the information changes
 - The difficulty in collecting the information
- Rule of Thumb
 - Prepare the report card in conjunction with the Management Review or more frequently

Supplier Scorecard – Information

- Quantitative Information
 - For us, this will be measurements
 - On time delivery
 - Acceptance rate
 - Cost

- Qualitative Information
 - For us, this will be monitoring, and may be subjective
 - Customer Satisfaction
 - Supplier Social Responsibility

Quantitative Information

- On time delivery

$(\# \text{ number received on time} \div \# \text{ received}) \times 100\%$

Also show aging (1 to 5 days, 6 to 10 days, *etc.*)

- Acceptance rate

$(\# \text{ accepted} \div \# \text{ received}) \times 100\%$

- Cost

Landed cost per item \times # received

Qualitative Information

- Customer Satisfaction
 - Survey the supplier, customers, and stakeholders of the outsourced process
 - Give each person a rating scale
 - Plus (+), Minus (-), and Neutral (0)
 - A numerical rating from 1 to 5
 - A numerical rating from 1 to 10
 - Report the histogram of the results
 - Report mean and standard deviation
- Supplier Social Responsibility
 - Can range from carbon emissions to gender ratios of employees
 - Usually most valuable when using comparative ratings across multiple suppliers

Summary & Conclusions

Summary

- Your QMS is composed of processes that interact
- You may choose to perform the process yourself or outsource it.
 - You have the capability
 - You don't have the capability
- Your partner could be:
 - External
 - Part of the same parent

Summary

- ISO 9001:2008 requires that you have control over the outsourced process
- The standard recommends using the Supplier Management process for control
 - Establish requirements
 - Develop controls
 - Evaluate and select suppliers
 - Build a Supplier Scorecard as part of process monitoring and measurement

Conclusions

- While ISO 9001:2008 didn't add many new requirements, it addresses outsourced processes
- The standard encourages the use of the Purchasing Process
- Supply Chain Management has an even more important role in managing QMS processes



QUESTIONS

Guidance on Outsourced Processes

Document: ISO/TC 176/SC 2/N 630R3

October 2008

1. Introduction

The aim of this document is to provide guidance on the intent of ISO 9001:2008 clause 4.1, regarding the control of outsourced processes.

ISO 9001:2008 clause 4.1 states:

“Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

NOTE 1: Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization and measurement, analysis and improvement.

NOTE 2: 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.

NOTE 3: Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory, and regulatory requirements. The type and extent of control to be applied to the outsourced process may be influenced by factors such as:

- a) the potential impact of the outsourced process on the organization’s capability to provide product that conforms to requirements;

- b) the degree to which the control for the process is shared;

- c) the capability of achieving the necessary control through the application of clause 7.4.”

2. Guidance

2.1 What is an “outsourced process”?

The Oxford English Dictionary defines the verb “outsource” as “to obtain ... by contract from a source outside the organization or area; to contract (work) out”

As now defined in ISO 9001:2008 Sub clause 4.1 NOTE 2, 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.

Note: ISO 9000:2005 clause 3.4.1 defines “process” as “set of interrelated or interacting activities which transforms inputs into outputs”.

An outsourced process can be performed by a supplier that is totally independent from the organization, or which is 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.

2.2 Intent of Clause 4.1

The intent of Clause 4.1 of ISO 9001:2008 is to emphasize that when an organization chooses to outsource (either permanently or temporarily) a process that affects product conformity with requirements (see ISO 9001:2008 clause 7.2.1), it can not simply ignore this process, nor exclude it from the quality management system.

The organization has to demonstrate that it exercises sufficient control to ensure that this process is performed according to the relevant requirements of ISO 9001:2008, and any other requirements of the organization's quality management system. The nature of this control will depend on the importance of the outsourced process, the risk involved, and the competence of the supplier to meet the process requirements. Based on the nature of the control, it should consider the processes referred to quality management system for management activities, provision of resources, product realization and measurement, analysis and improvement. The outsourced organization does not necessarily have to have a certified Quality Management System, but it has to demonstrate the capability of the previously mentioned processes. Outsourced processes will interact with other processes from the organization's quality management system (these other processes may be carried out by the organization itself, or may themselves be outsourced processes). These interactions also need to be managed (see ISO 9001:2008 clause 4.1 (a) and (b)).

2.3 Control of outsourced processes

2.3.1 The acquisition of outsourced processes will normally be subject to the capability of achieving the necessary control through the application of requirements of both ISO 9001:2008 clause 7.4 (Purchasing) and clause 4.1 (General Requirements)

As mentioned in the Note, 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 (see 2.1 above). Under these circumstances, however, ISO 9001:2008 Clauses 7.4 and 4.1 are still applicable.

2.3.2 There are two situations that frequently need to be considered when deciding the appropriate level of control of an outsourced process:

- When an organization has the competence and ability to carry out a process, but chooses to outsource that process (for commercial or other reasons).

In this situation the process control criteria should already have been defined, and can be transposed into requirements for the supplier of the outsourced process, if necessary.

- When the organization does not have the competence to carry out the process itself, and chooses to outsource it.

In this situation the organization has to ensure that the controls proposed by the supplier of the outsourced process are adequate. In some cases it may be necessary to involve external specialists in making this evaluation.

2.3.3 It may be convenient, or even necessary, to define some or all of the methods to be used for control of the outsourced processes in a contract between the organization and the supplier. The potential impact of the outsourced process is based on the outsourcing's capability to provide product that conforms to requirements. Care should be taken, however, not to inhibit the supplier from proposing innovations to the outsourced process. The organization's control of the outsourced process has to be based on the need for product conformity to requirements.

Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory, and regulatory requirements.

2.3.4 In some situations it might not be possible to verify the output from the outsourced process by subsequent monitoring or measurement. In these cases, the organization needs to ensure that the control over the outsourced process includes process validation in accordance with ISO 9001:2008 clause 7.5.2.