OUTSOURCING STRATEGIES & RISKS

FROM AN ISO 9001-2000 PERSPECTIVE

Amera-Veritas

Experts in Quality, Safety & Supply Chain Assurance

TOPICS

1. Outsourcing - Requirements of ISO 9001:2000
2. Dialogue of ISO Tech. Committee 176 Subcommittee #2, Working Group 18
3. An Outsourcing Strategy & Process
4. Possible Risks of Outsourcing

OUTSOURCING REQUIREMENTS
ISO 9001-2000 Standard

What is an outsourced Process?

An "outsourced process" is a process that is provided by an external organization.

An outsourced process can be:

- Purchased from an independent supplier, or
- Provided by another part of the larger organization, or
- Provided at your facility or at an independent site, or
- In some other manner.

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OUTSOURCING REQUIREMENTS ISO 9001-2000 Standard

Official Position

Since the publication of ISO 9001:2000, TC 176 has received a number of requests to formally define the term "outsourcing", as used in the Standard.

To date, we have not been successful in our attempt to Internationally agree upon a suitable definition for this term. Our efforts continue today in various working groups.

OUTSOURCING REQUIREMENTS
ISO 9001-2000 Standard

Registrar Auditor Position

The Oxford Dictionary defines outsourcing; "to obtain…by contract from a source outside the organization or area; to contract …out"

Using this definition, any work that is not accomplished in-house which impacts your ability to provide "conforming" product is technically an "outsourced" item.

OUTSOURCING REQUIREMENTS
ISO 9001-2000 Standard

Clause 4.1

"Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure <u>control</u> over such processes."

"Control of such outsourced processes shall be <u>identified</u> within the quality management system."

OUTSOURCING REQUIREMENTS
ISO 9001-2000 Standard

Expectation When of Outsourcing Processes

Outsourced processes typically involve interactions with other processes needed for the organization's QMS.

As such, the expectation is that you will not only ensure conformity of process *outputs*, but also the process itself, and any interactions with internal processes.

OUTSOURCING REQUIREMENTS
ISO 9001-2000 Standard

Control of Outsourced Processes

The organization must demonstrate it exercises sufficient control to ensure that outsourced processes are performed according to:

- ISO 9001:2000 Standard
- Customer Requirements
- Regulatory & Statutory Requirements

OUTSOURCING REQUIREMENTS
ISO 9001-2000 Standard

How is this control typically accomplished?

The type and extent of control depend on what is outsourced and the potential risks involved.

Examples may include:

- Contractual agreement with the provider along with a clear specification,
- Validation requirements for the process,
- Quality management system requirements,
- On-site inspections or verifications,
- Audits and/or 3rd Party Registrations

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An Outsourcing Strategy & Process

Gate Process
(7 Stages)

An Outsourcing Strategy & Process

KEY POINTS

- Keep a low profile but maintain openness
- Internal message & timing is critical
- Use a cross functional team approach
- Upfront planning is essential
- Use a fact based decision making process
- Consider both short term (0-5 Years) & long term (6-10 Years) information

An Outsourcing Strategy & Process

Outsourcing

Gate Process
(7 Stages)

An Outsourcing Strategy & Process

SEVEN (7) GATE PROCESS

- I → GATHER & VALIDATE DATA
- II → ESTABLISH INDICATORS
- III → PREPARE FOR QUOTATION
- IV → SELECT CONTRACTOR
- V → MIGRATION PLAN
- VI → POST TURNOVER MAINTENANCE
- VII → MONITORING & RE-VALIDATION

An Outsourcing Strategy & Process

I → II → III → IV → V → VI → VII

GATHER & VALIDATE DATA

- Establish true costs of doing business,
- Gather performance data on existing processes,
- Determine the stability of existing processes,
- Ensure that clear criteria for acceptance of both products is in place,
- Identify fixed costs that may remain regardless of outsourcing activities.

An Outsourcing Strategy & Process

I → II → III → IV → V → VI → VII

ESTABLISH INDICATORS

- Define the critical control points,
- Place weights to scoring criteria,
- Understand financial indicators,
- Define specific performance metrics

An Outsourcing Strategy & Process

PREPARE FOR QUOTATION

- Define the criteria to be used when evaluating potential contractors,
- The more specific the contract scope, the more accurate the proposal,
- Consider establishing an interface procedure and attach it to the RFQ,
- Communicate any requirements upfront,
- Seek at least three potential contractors.

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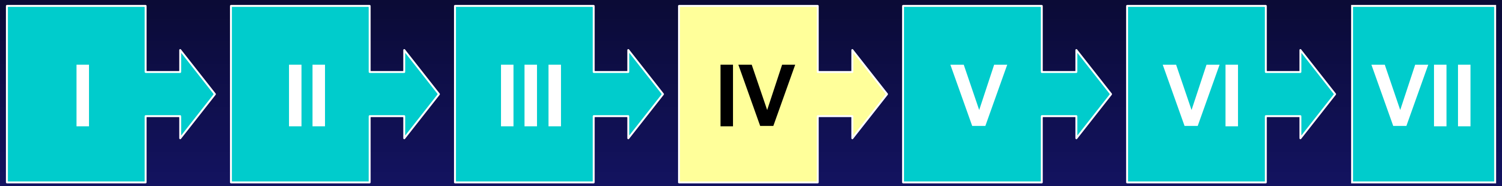
An Outsourcing Strategy & Process



SELECT CONTRACTOR

- Create a multi-disciplinary review team,
- Ask each contractor to formally present their proposal, plan and key project persons,
- Mandate the creation and walk thru of a migration plan,
- Apply the previously defined scoring system,
- Witness first hand the contractors operations to ensure capabilities.

An Outsourcing Strategy & Process

I → II → III → IV → **V** → VI → VII

MIGRATION PLAN

- Consider temporarily posting personnel at the contractors operation to ease the transition,
- Ensure the plan includes aspects such as resources, infrastructure, performance measures, etc…
- The plan should cover up to 18 months,
- Continue parallel operations until the contractors capability is confirmed.

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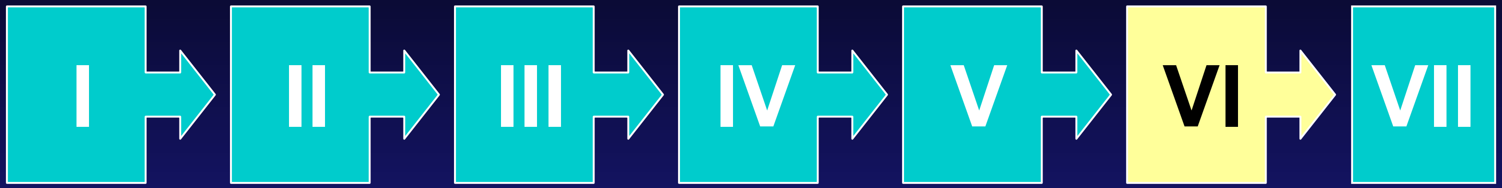
An Outsourcing Strategy & Process



POST TURNOVER MAINTENANCE

- Limit contract to three-year renewable cycles,
- Allow for a competitive assessment at renewal,
- Establish systematic meetings to review performance,
- Initiate formal corrective actions to resolve issues,
- Include the contractor as part of the internal audit schedule.

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An Outsourcing Strategy & Process

I → II → III → IV → V → VI → **VII**

RE-VALIDATION

- Annually conduct an in depth re-Validation of the contractors processes,
- Update the contractor of pending changes so that inputs can be provided upfront,
- Perform a cost assessment on the outsourcing relationship,
- Evaluate your working relationship,
- Assess potential risk exposure by contractor.

OUTSOURCING RISKS & GAINS

RISKS

- THE UNKNOWN
- VULNERABILITY
- LOSS OF CONTROL
- COST OVERRUNS
- LACK OF TECHNOLOGICAL CHANGE
- COMPETITIVE PRICING PRESSURES

GAINS

- COST SAVINGS
- FOCUS ON CORE PRODUCTS
- DIVESTMENT OF RISK
- TECHNOLOGICAL ADVANCEMENTS
- EFFECTIVE USE OF RESOURCES

THANKS!

OPEN Q&A

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