

# Quality in Outsourcing 2.0\*

(Based on ISO 9001:2015)

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\*Quality in Outsourcing 1.0 presentation was offered to HKSQ members in 2009. See reference slide

# How does ISO 9001 describe suppliers?

**We have two varieties of external providers.  
Suppliers and Outsource Organization.**

## **external provider**

*external supplier*

*provider (3.2.5) that is not part of the organization (3.2.1)*

*EXAMPLE Producer, distributor, retailer or vendor of a product (3.7.6) or a service (3.7.7)*

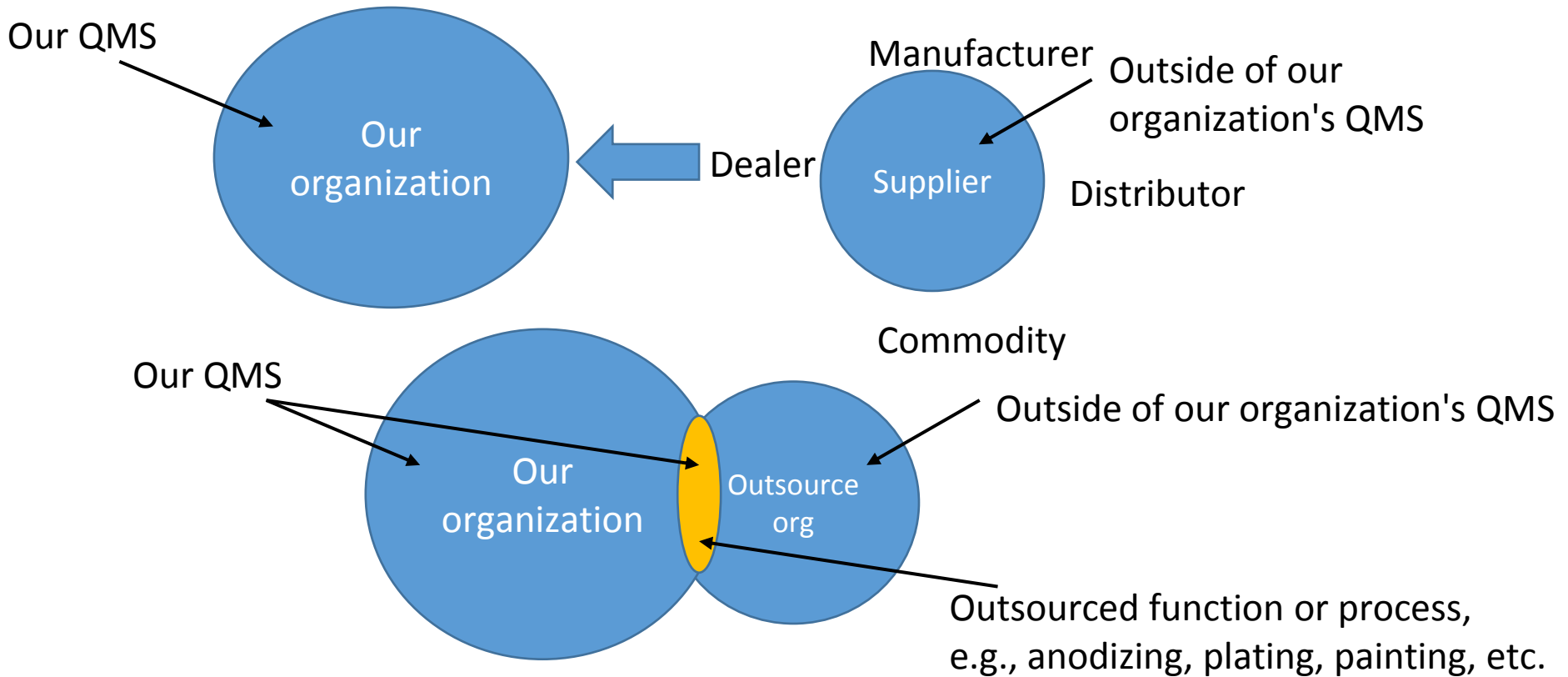
## **Outsource (verb)**

*make an arrangement where an external organization (3.2.1) performs part of an organization's function or process (3.4.1)*

*Note 1 to entry: An external organization is outside the scope of the management system (3.5.3), although the outsourced function or process is within the scope.*



# What is within our QMS and outside QMS?



# Strategic planning process

- (4.1) We as an organization shall determine external issues (emerging from external providers) that are relevant to our purpose and strategic direction affecting our ability to achieve the intended result(s) of our quality management system
  - E.g. Bankruptcy or exiting business by key external providers, ongoing litigation, product recall from external providers, On a positive note - Consolidation of external providers, expansion of capacities and new geographies, etc.
- (4.1) Our organization shall monitor and review information about these external issues.
- (4.2) Our organization shall monitor and review information about these interested parties (external providers) and their relevant requirements
  - (e.g. fair bidding process, cost, quality, SLC, life cycle management, etc.)



# Control of externally provided processes, products and services

- (8.1) The organization shall ensure that outsourced processes are controlled (see 8.4). –
  - Comprehensive planning during the make/buy decision by our organization
  - Understand the nature of the commodity purchased or process outsourced
  - Understand the risk and opportunities
  - Risks and opportunities may vary dependent on how they are received (8.4.1)
    - Products and services built into organization’s offering of products and services – e.g. Parts and materials that are from a “Bill of Materials” for a product assembly, consulting, third party warehousing, etc.
    - Products and services offered directly to the customer on behalf of the organization –e.g. onsite product installation, operations and maintenance, etc.
    - Processes offered to the customer – e.g. warranty replacement



# Selection, evaluation and monitoring (8.4.1)

- **Determine and apply criteria**
  - Criteria shall include but not limited to Quality, On time delivery, service, cost, sustainability focus, etc.
  - Keep in consideration risk and opportunities for sourcing a given product and services
  - Which external providers require such control? Which one risk of doing nothing is acceptable?
  - Strategic to long term relationship (Technology road map, collaborative innovation, etc)
- **Evaluation**
  - Onsite pre-award assessment
  - Assessment of risks
- **Selection (and qualification)**
  - Approved, Conditional approval, Disapproval
  - Additional due diligence like “Production Part Approval Process” – PPAP may be required
- **Monitoring of performance**
  - Performance monitoring on Quality, On time delivery, service, cost, sustainability focus, etc.
  - Periodic review of performance with external provider
  - Periodic assessment of risks and opportunities
- **Re-evaluation**
  - Perform periodic full scale review of the external provider to ensure risk are reduced, improvements are effective. No degradation in changes made within external provider



# Key considerations

- (8.4.2) The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers (Organization owns the risk and accountable to customer)

(8.4.2.c) The organization shall take into consideration:

1. the potential impact of the externally provided processes, products and services (Risk based thinking)
2. effectiveness of the controls applied by the external provider (periodic review of performance and feedback for improvement)

(8.4.2.d) Our Organization shall determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements. (e.g. Periodic onsite audits, Incoming Quality controls, on going reliability testing, disciplined process change approval, effective ongoing communication)



# External provider communication (8.4.3)

The organization shall ensure the adequacy of requirements prior to their communication to the

external provider. The organization shall communicate to external providers its requirements for:

- a) the processes, products and services to be provided; (SLC, Purchase order, drawings, procurement specifications, etc.)
- b) the approval of:
  - 1) products and services; (e.g. Product and service attributes with acceptable variations)
  - 2) methods, processes and equipment; (e.g. Process and equipment qualifications, special processes)
  - 3) the release of products and services; (e.g. Third party onsite inspection)
- c) competence, including any required qualification of persons; ( ASQ Certifications, ESD, welding, soldering, etc.)
- d) the external providers' interactions with the organization; (Communication protocol)
- e) control and monitoring of the external providers' performance to be applied by the organization;
- f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.





# External provider property (8.5.3)

- This can both ways: External provider's control on our organization's property and our controls on External provider's property
- External provider property can be both tangible (Equipment, material, tool, jig, fixture, drawing, etc. OR non tangible like IP information provided)
- Our organization shall exercise care with property belonging to external providers while it is under the organization's control or being used by the organization (define accountability and responsibility as agreed in contract)
- Our organization shall identify, verify, protect and safeguard external providers' property provided for use or incorporation into the products and services. (who owns periodic maintenance?)
- When the property of external provider is lost, damaged or otherwise found to be unsuitable for use, our organization shall report this to the external provider and retain documented information on what has occurred.



# Management presentation

- Our organization shall analyze and evaluate appropriate data and information arising from monitoring and measurement (Quality, delivery, cost, responsiveness, sustainability, etc.) the performance of external providers (9.1.3)
- The management review shall take into consideration the performance of external providers (9.3.2.c.7) – presenting to the Top management risks and opportunities based on the monitoring and measurement information



# References

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- ISO 9000:2015 Quality Management Systems - Fundamentals and vocabulary
- ISO 9001:2015 Quality Management System - Requirements
- Quality in Outsourcing, Govind Ramu  
[www.slideshare.net/govindramu/QualityinOutsourcing](http://www.slideshare.net/govindramu/QualityinOutsourcing)
- [www.hksq.org/Quality\\_in\\_Outsourcing.pdf](http://www.hksq.org/Quality_in_Outsourcing.pdf)
- In the know, Govind Ramu - <http://asq.org/quality-progress/2008/08/global-quality/in-the-know.pdf>

# Q & A

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# Appendix

- Other ISO 9001:2015 references on External providers

## Annex-Control of externally provided processes, products and services

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All forms of externally provided processes, products and services are addressed in 8.4, e.g. whether through:

- a) purchasing from a supplier;
- b) an arrangement with an associate company;
- c) outsourcing processes to an external provider.

Outsourcing always has the essential characteristic of a service, since it will have at least one activity necessarily performed at the interface between the provider and the organization.

The controls required for external provision can vary widely depending on the nature of the processes, products and services. The organization can apply risk-based thinking to determine the type and extent of controls appropriate to particular external providers and externally provided processes, products and services.