

Quality System Procedure

QSP 8.4

Subject: Control of externally provided processes, products and services

1.0 Purpose

2.0 Scope

3.0 Responsibility and Authority

4.0 Control of Externally Provided Processes, Products and Services Procedure

4.1 General

4.2 Purchasing Management

4.3 Outsourcing management

4.4 Management of Supply Chain on behalf of the Organization

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5.0 Criteria and Risks of 'Control of Externally Provided Processes, Products, and Services' Process

5.1 Criteria of 'Control of Externally Provided Processes, Products, and Services' Process

5.2 Actions to address the risks and opportunities of the 'Control of externally provided processes, products and services' process

6.0 Documented information of 'Control of externally provided processes, products and services' Process

7.0 Revision History

Addendum 1

Supplier Evaluation Methodology

1. General
2. Formulating requirements to suppliers
3. Evaluation of weight of each supplier requirement
4. Quantitative supplier evaluation
5. Drafting the Ranked suppliers list

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4.0 Control of Externally Provided Processes, Products and Services Procedure

4.1 General

'Control of externally provided processes, products and services' Process model is displayed on Fig. 1.

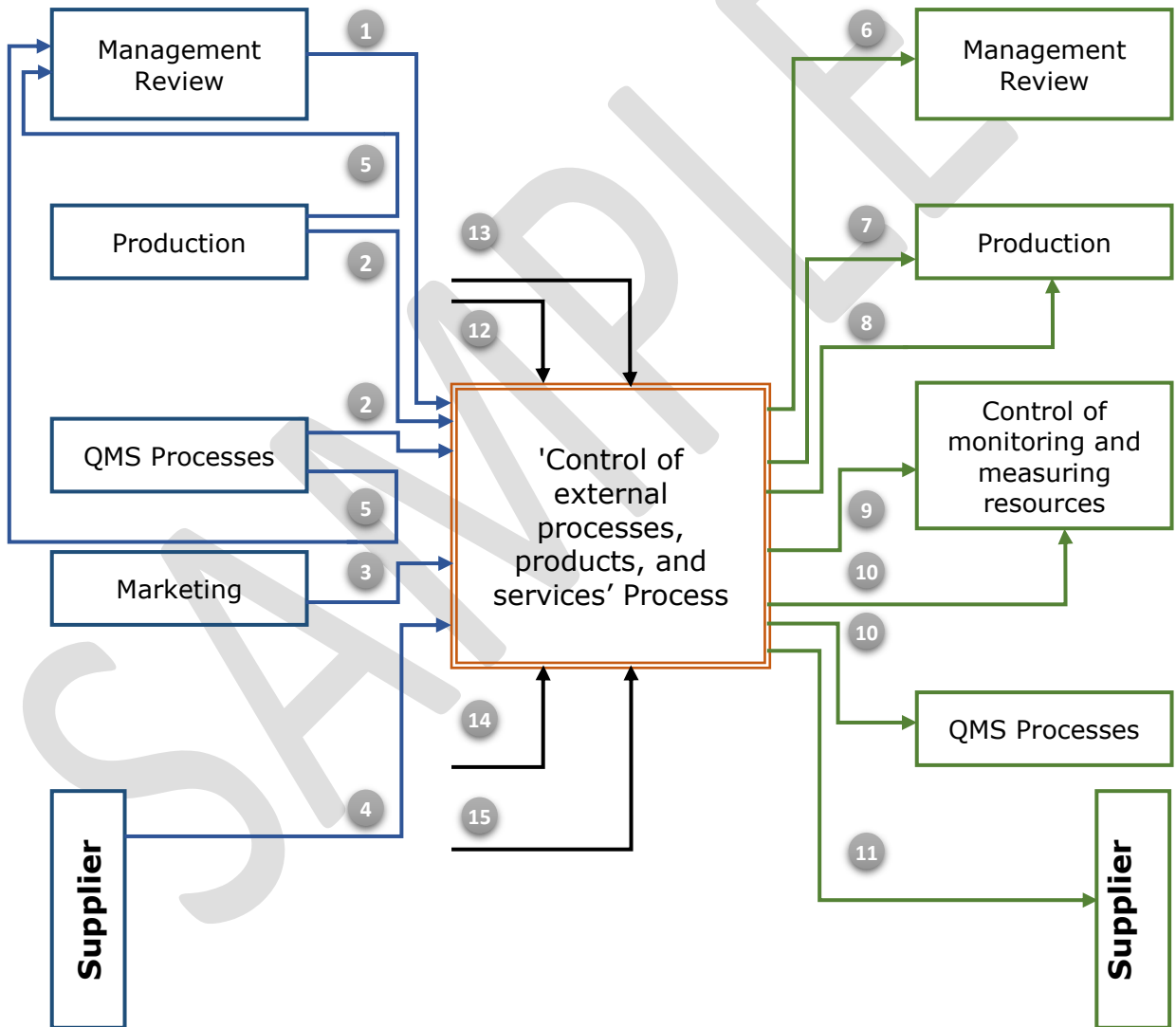


Fig.1 'Control of externally provided processes, products and services' Process Model

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Inputs

- 1
 - Decisions to outsource the processes
 - Decisions to deliver products or services directly to the customer on behalf of the Organization
 - Decisions to conduct a 2nd party audit at the supplier
- 2
 - Purchase orders
- 3
 - Information on the suppliers' market
- 4
 - Tender offer
 - Product (service)
- 5
 - Proposals to outsource the processes

Outputs

- 6
 - Information about the outsourced processes efficiency
- 7
 - Raw materials, supplies, and components
- 8
 - Production equipment
- 9
 - Measuring equipment
- 10
 - Equipment including hardware and software
- 11
 - Information about the tender
 - Information for external providers
 - Contracts to purchase products (services)
 - Information about the non-conformities detected during incoming inspection and while product is in operation
 - 2nd party audits reports (if applicable)
- 12
 - QSP 8.4 Control of external processes, products, and services
- 13
 - Documented information of external origin
- 14
 - Purchasing department resources
- 15
 - 'Control of externally provided processes, products, and services' process budget

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The 'Control of externally provided processes, products and services' process includes three sub-processes:

- 1) Purchasing Management - ensuring delivery of products (equipment, raw materials, components, etc.) and services to be included in the Organization's own products and services (section 4.2).
- 2) Outsourcing management - interaction with external providers who carry out the process or part of the process for the Organization (section 4.3).
- 3) Supply Chain Management on behalf of the Organization, including franchising - the interaction with external providers, that supply products and services directly to the customer(s) on behalf of the Organization (section 4.4).

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