

[Organization logo]

[Organization name]

Commented [170251]: All fields in this document marked by square brackets [] must be filled in.

EXTERNALLY PROVIDED PRODUCTS AND SERVICES PROCEDURE

Commented [170252]: If you want to find out more about externally provided products and services, see:

How to control outsourced processes using ISO 9001
<https://advisera.com/9001academy/blog/2015/05/05/how-to-control-outsourced-processes-using-iso-9001/>

Commented [170253]: Adapt to the existing practice in organization.

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Change History

Date	Version	Created by	Description of change
	0.1	17025Academy	Basic document outline

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1. Purpose, Scope and Users

The purpose of this procedure is to define the requirements for the purchase of products and services from sources outside the organization.

This procedure applies to all goods and laboratory supplies and services used in laboratory activities, including equipment, laboratory consumables and external providers of laboratory services.

This procedure is to be used by the laboratory Quality Manager and purchasing personnel of [organization name], responsible for recommending, sourcing, purchasing and buying laboratory goods and services.

Commented [170255]: You can add some other job titles according to your organization.

Commented [170256]: Insert laboratory name, which is a part of accreditation under ISO/IEC 17025.

2. Reference Documents

- ISO/IEC 17025:2017, clause 6.6
- Quality Manual

3. Externally Provided Products and Services

3.1. Suitability of externally provided products and services

When selecting external suppliers, [Job title] must ensure their suitability to provide products and services that affect laboratory activities when they are:

Commented [170257]: Purchasing and Quality Manager jointly.

- [Redacted]
- [Redacted]
- [Redacted]

Commented [170258]: E.g. products such as laboratory consumables and reference materials and/or services such as calibration.

[Job title] is responsible for the evaluation, selection, monitoring and re-evaluation of external providers.

Commented [170259]: Purchasing and quality manager jointly.

[Redacted]

Commented [1702510]: Quality Manager for activities that have influence for a quality, and Purchasing manager for purchasing and delivery activities.

[Redacted]
corrective action must be requested through the Quality manager.

[Redacted]

Commented [1702511]: Purchasing and quality manager jointly.

- Laboratory accreditation and/or QMS certification as applicable.

Commented [1702512]: Add additional criteria if necessary.

Commented [1702513]: Evaluations are applicable to new

[organization name]

- [redacted]
- [redacted]

[Job title] takes into consideration all the above factors when making decisions on new suppliers, asking critical questions about each factor. When supplier's laboratory accreditation is absolutely

Commented [1702514]: E.g. Purchasing manager

[redacted]

Commented [1702515]: Use this criterion, when accreditation is required by law or other regulations.

[redacted] and the re-evaluation must be also documented.

Commented [1702516]: At least annually after first evaluation or adapt to your organization's needs.

3.2. Purchasing records

Commented [1702517]: This records (forms) are made by Purchasing department outside of the QMS. They may be stored electronically according to the organizations normal practice.

[Job title] maintains purchasing records to include following:

Commented [1702518]: E.g. Purchasing manager

- The [Organization's] Purchase requests.
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

Commented [1702519]: It is the limited list of necessary documents and organization/laboratory can maintain additional ones.

3.3. Communication with suppliers

[Job title] communicates with external suppliers about the laboratory's requirements for:

Commented [1702520]: E.g. Purchasing manager

- The products and services to be provided (through formal purchase orders).
- [redacted]
- [redacted]
- [redacted]

All of the above requirements should be included in formal purchase orders sent to all vendors and suppliers when they are required to clarify quality requirements.

4. Externally Provided Laboratory Activities

The organization's [job title] is responsible for all externally provided laboratory activities, except

Commented [1702521]: E.g. Purchasing manager

[redacted]

Commented [1702522]: E.g. Quality manager

[Job title] notifies the customer of activities to be performed at the external provider and asks for the

Commented [1702523]: E.g. Person in Sales or customer service.

[organization name]

service, [job title] must resolve the problem with the supplier and [job title] must maintain parallel communication with the customer.

Commented [1702524]: E.g. Purchasing manager

Commented [1702525]: E.g. Person in Sales or customer service.

5. Managing Records Kept on the Basis of this Document

Record name	Code	Storage		Responsibility
		Retention time	Location	
Supplier Evaluation and Approval Record	PR.06.1	Two years	[office of [job title]]	[job title]
List of Approved Suppliers of Products and Services	PR.06.2	Two years	[office of [job title]]	[job title]

Commented [1702526]: Insert the location where this living document will be kept. Records may be stored electronically. If the record is in electronic form, write the name of the folder on [job title]'s computer.

6. Appendices

- Appendix 1 – Supplier Evaluation and Approval Record
- Appendix 2 – List of Approved Suppliers of Products and Services