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LABORATORY MANAGEMENT PROCEDURE

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Change history

Date	Version	Created by	Description of change
	0.1	16949Academy	Basic document outline

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1. Purpose, scope and users

The purpose of this procedure is to define specific requirements for selection and utilization of external laboratories, if needed, and requirements for internal laboratories regarding technical procedures, competency of laboratory personnel, testing methods, compliance to relevant process standards and customer-specific requirements, and records management.

This procedure applies to all employees who work in internal laboratory and outsourced tests performed by external laboratories, where applicable.

2. Reference documents:

- IATF 16949:2016, clauses: 7.1.5.3; 7. 1.5.3.1; 7.1.5.3.2

3. Laboratories Management Process

3.1. Review internal laboratory management system

[Job title], who is in charge of managing laboratories performs the following activities:

- Establishes, reviews and updates the laboratory scope. The results of tests or activities are traceable to national, international or customer standards and requirements, internal laboratory procedures and relevant process standards.
- Assures competence of technical personnel, according to Procedure for Competence, Training and Awareness
- Establishes and updates files of tests requested by internal and external customers, following the laboratory form.
- Manages records according to internal rules and customer specific requirements, if needed.
- Documents laboratory scope by using Internal Laboratory Scope form.

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Commented [AT6]: Laboratory scope includes all the tests that can be performed, equipment and methods (traceable to national, international or customer standards). A good practice is to be documented as a list:

Test Equipment Method

3.2. Assessment and acceptance of external laboratories

[Job title] analyzes potential external laboratories based on the following requirements:

- Laboratory accreditation
- Equipment and methods traceable to national, international or customer standards
- Compliance to customer requested test or activities scope in compliance with applicable governmental agencies.

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[Job title] assesses potential and actual laboratories and records the evaluation result in the External Laboratory Acceptance checklist. The key for a

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[organization name]

Accepted laboratories are recorded in the list of approved suppliers - see Procedure for Purchasing and Evaluation of Suppliers.

3.3. Schedule and follow-up tests

When the laboratory tests according to the standard does not ensure the completion of the tests, in the event that tests do not meet the product-process specifications, the Procedure for Management of Nonconformities and Corrective Actions is applied.

4. Managing records kept on the basis of this document

Record name	Code	Storage			Responsibility
		Retention time	Location	Protection	
Internal Laboratory Scope	PR.17.1		[office]	Locked room	[job title]
External Laboratory Acceptance Checklist	PR.17.2		[office]	Locked room	[job title]
Test Schedule Form	PR.17.3		[office]	Locked room	[job title]

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5. Appendices

- Appendix 1 – Internal Laboratory Scope
- Appendix 2 – External Laboratory Acceptance Checklist
- Appendix 3 – Test Schedule Form