

ISO\IEC 17025 Crosswalk – SUPPLIES AND SUPPLIER EVALUATION

2005	ELEMENT FOCUS	2017	ELEMENT FOCUS
4.5.1	4.5.1 Competent subcontractor	6.6.1	6.6.1, b <i>Suitable</i> externally provided products and services when used in part or directly for the customer
4.6.1	4.6.1 <u>Policy</u> and procedure(s) for the selection and purchasing of services and supplies it uses that <i>affect the quality</i> of the tests and/or calibrations.	6.6.1 6.6.2 a to d	6.6.1 a, c, Ensure <i>suitable</i> products and services that <i>affect laboratory activities</i> are used, when such products and services: 6.6.2 a to d The laboratory shall have a procedure and retain records for defining, reviewing and approving products and services <i>No policy required (Best practice a purpose in QM or Procedure; doesn't hurt to retain a policy.)</i>
4.6.1	4.6.1 Procedures shall exist for the purchase, <u>reception and storage of reagents and laboratory consumable materials</u> relevant for the tests and calibrations. (Records in 4.6.2)	6.6.2	6.6.2 a The laboratory shall have a procedure and retain records for <u>defining, reviewing and approving</u> products and services
4.6.2	4.6.2 Inspection records showing compliance prior to use. Records of actions taken to check compliance shall be maintained.	6.6.2	6.6.2 a The laboratory shall have a procedure and retain records for <u>defining, reviewing and approving</u> products and services, ensuring conformance prior to use, <i>taking any actions arising from evaluations, <u>monitoring</u> of performance and <u>re-evaluations</u> of providers</i> <i>Added: taking actions, monitoring and re-evaluation records.</i>
4.6.3	4.6.3 Purchasing documents with data describing services and supplies ordered. Purchasing documents with technical content reviewed and approved	6.6.2	6.6.2 a The laboratory shall have a procedure and retain records for: defining, reviewing and approving requirements <i>Purchasing in procedure; not just documents</i>
4.6.3 Note	NOTE: Examples of criteria	6.6.2 Note	NOTE: Examples of products and services
4.6.4	4.6.4 Supplier Evaluation and Records. <u>List</u> of those approved.	6.6.2	6.6.2 a The laboratory shall have a procedure and retain records for: defining, reviewing and approving requirements for products and services; <i>List no longer required. Best practice for tracking, ,monitoring and reevaluations.</i>
	New	6.6.3	6.6.3 a to d The laboratory shall communicate its requirements to external providers for products and services, acceptance criteria, competence, activities to be performed at provider's premises. <i>Communication is new – but standard practice in purchases.</i>

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2005	ELEMENT FOCUS	2017	ELEMENT FOCUS
4.5.1	4.5.1 <i>Competency of subcontractors (and 17025).</i>	6.6.3	6.6.3 c The laboratory shall communicate its requirements to external providers for <i>competence</i> , including any personnel requirements <i>Communication is new – but standard practice in subcontracting.</i>
5.6.2.1.1 5.6.3.1	Calibration services from laboratories that can demonstrate competence, measurement capability and traceability; certificates must comply with 17025. Calibration of reference standards	6.5.2 a 6.6.2 c Annex A	Calibrations from competent lab (17025); Conformance to this document (e.g., certificates implied); Accredited providers or NMIs with suitable CMCs
Records			
4.6.2 4.6.3.	4.6.2 Inspection records showing compliance prior to use. Records of actions taken to check compliance shall be maintained. 4.6.3 Purchasing documents with data describing services and supplies ordered. Purchasing documents with technical content reviewed and approved	6.6.2	6.6.2 The laboratory shall have a procedure and retain records for a) defining, reviewing and approving products and services b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers; c) ensuring that externally provided products and services conform to requirements, relevant requirements of this document, before use d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of providers.
4.6.4	4.6.4 Supplier Evaluation and Records. <u>List</u> of those approved.	*	List no longer required; best practice
		6.6.2 d	Records of actions from evaluations, monitoring of performance and re-evaluations of providers