Sections in This Document

1. Purpose

This procedure provides policies and instructions for procurement of supplies, materials, equipment, and services that affect the quality of laboratory activities.

2. Scope

This procedure applies to activities handled by personnel who request and purchase services and goods within the Office of Regulatory Science (ORS) laboratories.

In addition to Federal laws pertaining to purchasing, quality system accreditation requires the laboratory evaluate suppliers of critical consumables, supplies and services which affect the quality of laboratory

activities, and maintain records of these evaluations. This document's focus is on those quality system requirements.

3. Responsibility

A. Requestor

1. Initiates request for services and supplies. Ensures critical specifications and requirements are provided. Ensures vendor is on the laboratory's approved vendor list.

B. Laboratory Management

1. Reviews and approves purchase request for technical content and bona fide need.
2. Ensure requirements and criteria for evaluation of externally provided products and services are defined.
3. Ensures performance of external providers are evaluated and monitored.
4. Ensures actions are taken, when relevant, arising from evaluations

C. Quality System Manager (QSM):

1. Ensures laboratory's approved vendor list is maintained.
2. Ensures records of evaluation and monitoring activities of external providers are maintained.

D. Division of Field Administration (DFA):

1. Ensures procurement of materials, supplies and services in accordance with FDA acquisition procedures and guidelines.
2. Assists laboratory personnel in following agency procurement guidelines and requirements.
3. Ensures that records of purchasing activities are retained as required.

4. Background

FDA requires use of Government Purchase Cards (GPC) and The Unified Financial Management System (UFMS) which incorporates iProcurement for purchase requisitions and the Purchase Request Information System (PRISM) for purchasing completed by administrative purchasing agents.

Requests for purchase of services and supplies directly related to the quality assurance program are preceded with a vendor and product review for compliance to specified requirements defined in the test methods and quality specific standards. Records of actions taken to check compliance shall be maintained.

5. References

A. ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories. Section 6.6.

B. AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analysis of Food, Dietary Supplements, and Pharmaceuticals – An Aid to Interpretation of ISO/IEC 17025:2017; August 2018.

C. ISO 17034:2016 or Guide 34 General Requirements for the Competence of Reference Material Producers

D. SOP-000048 ORA Programmatic vs. Geographical Expenses

E. SOP-000194 ORA Acquisition and Planning

F. SOP-000204 ORA Purchase Card (PCARD)

6. Procedure

Laboratories shall adhere to both agency and accreditation requirements on purchasing, receipt, and management of externally-provided products and services.

6.1. Agency Policies and Requirements

A. Laboratories follow agency policy and procedures for the purchase of products and services.

B. Laboratory management should consult with DFA staff on matters of purchasing to ensure current agency requirements are being met.

C. Local work instructions may be written to outline the process for procurement, receipt, and management of procurement records.

6.2. Laboratory Accreditation Requirements

Laboratories shall ensure that externally-provided products and services that affect laboratory activities are suitable.

Examples of products include: measurement standards and equipment, auxiliary equipment, consumable materials, reference materials, etc.

Examples of services include: calibration services, testing services, facility and equipment maintenance services, proficiency testing services, assessment and auditing services, etc.

6.2.1. Procurement

Laboratories follow agency procedures for procurement. Product and service criteria are communicated to vendors through the purchasing request processes.

6.2.2. Selection of Vendors

A. Vendors are initially evaluated and selected based on the ability to meet contract conditions and quality system criteria. Additionally, vendors are selected in accordance with agency requirements and policies. However, vendors may be requested due to specifications in methods being used, past experience with vendor, and cost.

B. Products and services are purchased from approved vendors with an acceptable rating.

C. Laboratories define local processes for rating suppliers and vendors as acceptable or not acceptable based on the level of service provided and any required accreditation or certifications held. A vendor is considered unacceptable and is not used when the quality of product or service does not meet expectations or specifications.

D. Vendor approval shall be summarized for example on a vendor list and maintained by each laboratory. The vendor approval shall be reviewed and updated periodically according to a schedule and responsibility determined by the laboratory.

E. Vendors of calibration services and reference materials shall meet traceability requirements in ORA-LAB.5.6 Traceability.

6.2.3. Monitoring and Re-evaluation of Vendors

A. The performance level and accreditation status (when required) of routinely used vendors are monitored over time to ensure an acceptable level of service is maintained. For example: a laboratory may track instances of incorrect orders received, product quality issues, recalls, and other unsatisfactory events, and make a determination on suitability for continued use of the vendor.

B. Minimum evaluation criteria include (where applicable):

1. Does vendor's continued use meet agency requirements?
2. Does vendor meet product/service specification and delivery schedule?
3. Does vendor have consistently good service and product performance?
4. How is vendor's customer service and response to addressing problems?
5. Is vendor accredited when required?

C. Documentation of this evaluation and the outcome shall be maintained by the laboratory.

6.2.4. Receiving, Inspecting, and Disbursing of Materials

The laboratory shall ensure that purchased supplies, reagents, consumable materials, and services that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the test and/or calibrations concerned. These services and supplies used shall comply with specified requirements.

A. When materials and supplies are delivered and received they are signed for by the designated individual with date of receipt and initials annotated on the receiving records and containers.

B. Materials and supplies received are inventoried and verified against the original purchase order for completeness.

C. If a discrepancy is found that could affect the product quality the material is either discarded or returned to the vendor.

D. Records of unsatisfactory materials and supplies and their disposition are maintained by the laboratory. These records establish trends in vendor performance and ensure that continuing quality material is accepted.

E. Materials and supplies are distributed.

6.2.5. Purchasing and Receipt Records

A. Laboratories shall retain records for the following:

1. Purchasing records;
2. Vendor evaluation, selection, monitoring, and re-evaluation;

3. Verification that received products and services meet the laboratory's requirements; and
4. Actions taken as a result of vendor evaluation, monitoring, or re-evaluation.

7. Glossary/Definitions

A. Contract – This is the agreed terms between a supplier and customer transmitted by any means.

B. Corrective action – This is action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence.

C. Non-conformity – This is the non-fulfillment of a contract term or condition.

D. Material – This refers to hardware, software media, raw materials or components used in the development or testing of products.

E. Supplies – This is the inventory needed to perform the work processes of an organization.

F. Vendor/Supplier: Vendor and supplier are used interchangeably for an entity from which the laboratory procures items or services that could affect laboratory activities.

8. Records

A. Agency-required purchasing records

B. Receiving records including packing slips

C. Vendor evaluation

D. Records of unsatisfactory materials, supplies, services, and actions taken

9. Supporting Documents

A. ORA Laboratory Manual, Volume II, ORA-LAB.5.6 Traceability

10. Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title
1.3	R	11/16/05	LMEB	LMEB
1.4	R	12/31/07	LMEB	LMEB
1.5	R	08/15/08	LMEB	LMEB
02	R	06/06/2019	LMEB	LMEB

* - D: Draft, I: Initial, R: Revision

11. Change History

Revision #	Change
02	Added use of ISO Guide 34 vendors when possible; added “services” as appropriate where “product” is mentioned; clarified requirements for products/services related to quality processes; added items to Records section; refocused procedure on accreditation requirements; took out specifics on agency requirements and required lab management to consult with DFA for agency procurement requirements. Other revisions made as needed to align this procedure with new ISO/IEC 17025 and AOAC requirements. Revision to formatting and policy clarifications were also made.

12. Attachments

None