Sections Included in this Document and Document History

1. Purpose

This procedure provides policies and instructions for procurement of supplies, materials, equipment, and services. It documents the procedures for purchasing, receiving, inspecting and disbursing these items.

2. Scope

This procedure applies to activities handled by personnel who request and purchase services and goods. The Unified Financial Management System (UFMS) incorporates iProcurement for purchase requisitions and the Purchase Request Information System (PRISM) for purchasing.

3. Responsibilities

A. [Second Level Manager]:

- [add responsibility]
- [add responsibility]

B. [First Level Manager]:

- [add responsibility]
- [add responsibility]

C. [Quality Systems Manager]:

- [add responsibility]
- [add responsibility]

D. Purchasing Agent:

- ensures procurement of materials, supplies and services in accordance

with FDA acquisition procedures and guidelines;

- ensures that vendors adhere to requirements rules and specifications;
- ensures corrective actions are taken and implemented; and
- completes correction action form and submits completed forms to the Quality Management System (QMS) Manager.

E. Shipping and Receiving Clerk:

- receives materials and supplies, and inspects and distributes them;
- returns and ships items as needed in accordance with applicable regulations, such as Department of Transportation (DOT);
- closes out purchase orders; and
- initiates and performs correction actions by completing corrective action form and submitting completed forms to the QMS Manager.

4. Background

None

5. References

GAO Policy and procedures manual.

Staff manual guide (SMG). Guide 2610 Procurement and Supply Management Federal Acquisition Regulations (FAR).

Office of Management and Budget (OMB),General Services Administration (GSA), Health and Human Services (HHS), *Federal Property Management Regulations* (FPMR), FDA and ORA manuals and procurement issuances

Public Law (PL) 95-507

6. Procedure Purchase Requests

A. [Name of Laboratory Management] are authorized to electronically approve through iProcurement requests for supplies or services for purchases coming out of their respective budgets. (The Form HHS-393 Purchase/Service/Stock Requisition is submitted through iProcurement.)

B. The approved request will contain at a minimum:
- vendor (address, telephone and fax numbers),
- item description,
- catalogue number,
- unit cost and unit of issue,
- quantity total cost (calculated by iProcurement),
- defined specifications and level of product quality,
- Common Accounting Number (CAN),
- object class number,
- date of request, and
- date for delivery.

C. All approvals (Approver 1, Approver 2, Budget Approving Officer) in iProcurement are required before any procurement action is authorized and received by a vendor for processing. The Budget Approving Officer in iProcurement certifies that funds are available.

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6.1 Purchase Orders

A. Purchase Orders

1. Purchase Orders are completed electronically through PRISM by the Purchasing Agent with the required information in 6. B. (The OF 347,Order for Supplies or Services, is completed in PRISM.) Purchase orders include clearly stated needs, essential physical characteristics, performance criteria, technical specifications, terms, conditions, Freight Origin Billing (FOB) point, and serial numbers of equipment being serviced or repaired.

2. Requisitions for accountable property are screened by the Purchasing Agent for availability from excess, other clearances, and correct object class assignment (usually identified by object class code 31).

3. Three quotations are needed for open-market purchases between $2500 and $25,000. Small businesses or Section 8 businesses are preferred.

4. For non-competitive purchases between $2500 and $25,000, *sole source* or specific make and model justification is needed.

B. Authorized Procurement Channels

- International Merchants Purchase Authorization Card (IMPAC) for orders under $2500; NOTE: Purchasing Agent is authorized up to $25,000.

- Government Services Administration (GSA) for scheduled contract services, bulk services, and supplies maintained on a scheduled basis and provided at a discount (e.g. computers, office furniture);

- Mandatory sources of supply which include:

  a. Agency inventories,
  b. Excess from other agencies,
  c. Federal prison industries,
  d. Committee for the Blind or Severely Handicapped,
  e. GSA or Veterans Administration,
  f. Federal Supply Schedules, and
  g. Optional use of Federal Supply Schedules.

C. International Merchant Purchase Authorization Card (IMPAC) Purchases

1. Only authorized cardholders will make these purchases.

2. Requests for confirmation of receipt of order and estimated delivery date, as well as any instructions are included.

3. All orders over $2500 will have the same documentation as purchase orders.

D. Processing Orders

1. The Purchase Order is approved electronically through PRISM by the warranted Purchasing Agent and contain the fund certification.

2. Ordering information is sent to the vendor.

3. UFMS tracks requisitions, purchase orders, and receipt electronically. Upon receipt, the shipping and receiving clerk closes the file by matching the receiving documents, such as packing slips, with the corresponding purchase order and distributes copies (packing slip and

purchase order copies) to the originator with the order, to be kept with the file and to the Regional Accounting Office. NOTE: Partial orders are noted and not closed until all items have been received.

E. Evaluation Criteria of Vendors

1. The vendor is evaluated and selected based on of the ability to meet contract conditions including the quality system and any quality assurance criteria. Vendors are selected in accordance with Federal Acquisition Regulations Simplified Acquisition Procedures. However, vendors may be requested due to specification in methods being used, past experience with vendor, and cost.

2. To ensure quality, supplies are purchased from approved vendors with an acceptable rating.

3. Suppliers and vendors are rated acceptable or not acceptable based on the level of service provided and registrations 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.

   a. Acceptable: Vendor meets international standards such as ISO 9000.

   b. Acceptable: Vendor meets nationally certified standards such as those of the National Institute for Science and Technology (NIST), United States Pharmacopeia (USP), American Type Culture Collection (ATCC).

   c. Acceptable: Vendor has been awarded FDA contracts for identified products and services. All FDA offices are bound to use only these vendors when applicable.

   d. Not Acceptable: Vendor's documented history has demonstrated its inability to meet product specifications including the quality system and quality assurance criteria (e.g. timeliness and service response). The vendor card will be clearly marked as *Not Acceptable.*

4. If a vendor does not meet all of the criteria below, it will be considered unacceptable:

a. Meets product specifications and delivery schedule.

b. Responds expeditiously in resolving problems and discrepancies, and values customers.

c. Consistent service and product performance.

F. Receiving, Inspecting and Disbursing of Material

(NOTE: The Purchasing Agent does not perform this function).

1. Materials and supplies are delivered and received for the [Name] at entrance [Location].

2. Materials and supplies are signed for by the Shipping and Receiving Clerk with date of receipt and initials annotated on the receiving documents and containers.

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

4. If a discrepancy is found that could affect the product quality [Examples] , the material is either discarded or returned to the vendor.

5. Documentation of unsatisfactory materials and supplies and their disposition are maintained.

6. This documentation establishes trends in vendor performance and ensures that continuing quality material is accepted.

7. Materials and supplies are distributed to the branch or the individual is notified of receipt of material for pick-up.

6.2 Corrective Action

Corrective action is taken on any non-conformity. Procedures to be taken include reporting and recording the occurrence. If a quality problem is discovered, corrective action is initiated by completing a Corrective Action Report form located at [Location]. The problem, identified cause and the corrections which were made are entered on this form.

7. Definitions

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

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

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

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

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

8. Records

iProcurement and PRISM electronic records
Receiving documents including packing slips

9. Supporting Documents

Sole source justification
Determination of reasonableness of price

10. Attachments

None

Document History					
Version No.	**Status** (I, R, C)	**Date Approved**	**Location of Change History**	**Name & Title**	
				Author	**Approving Official**
1.3	R	11/16/05	In Document	LMEB	LMEB

Approving Official's signature: _____ Date: _____