Purchasing and Supplier Controls Procedure

Purpose

The purpose of this procedure is to ensure that all supplies and services purchased by Lagos State DNA & Forensic Center (LSD&FC) are compliant and consistent with established quality requirements.

Scope

The scope of this SOP applies to all LSD&FC personnel. The document includes procedure for:

1.1 defining, reviewing and approving LSD&FC requirements for externally provided products and services,

1.2 defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of external providers,

1.3 supplier qualification and monitoring and acceptance activities within LSD&FC quality system as defined by the Quality Manual.

1.4 ensuring that externally provided products and services conform to LSD&FC's established requirements.

1.5 taking any actions arising from evaluations, monitoring of performance and re-evaluation of the external providers.

1.6 this document also provides an outline of the requirements for Purchasing Controls.

1.7 This procedure does not apply to suppliers providing materials intended for research use or evaluation purposes, nor does it apply to suppliers providing general items such as office supplies, and services such as garbage removal.

Guidelines & Requirements

- ISO/IEC 17025: 2017 (E) Standards
- R104 - A2LA General Requirements – ISO/IEC 17025:2017 Accreditation of Field Testing and Field Calibration Laboratories
- P113- A2LA Policy on Measurement Traceability for Life Sciences Testing and Forensic Conformity Assessment Bodies (CABs)

- P102a – A2LA Policy on Metrological Traceability for Life Sciences Testing and Forensic Conformity Assessment Bodies for all Calibrations and Verifications of Measurement and Test Equipment.
- AABB's Guidelines "Guidance for Standards for Relationship Testing Laboratories", 12th Edition.
- Supply and Service Request Form (Adm 003).
- Purchase Requisition Form (For 009)
- Supplier Quality Systems Survey/Audit Form (Adm 010).
- Approved Supplier List (Adm 011)
- Preventative Action Report (QAC 007).
- Corrective Action Report (QAC 008).

Definitions

Approved Supplier List (ASL): an index of those suppliers evaluated and approved to provide goods or services to LSD&FC.

Contract Manufacturer (CM): Manufacturers contracted with LSD&FC to manufacture any item that is used by LSD&FC. Although Contract Manufacturers are always considered "Key/Critical" suppliers; special consideration is given to their Quality Oversight.

Specification: any requirement to which a product, service or other activity must conform.

Supplier: an individual or organization that provides a key/critical item or service for LSD&FC.

Supplier audit: an activity intended to evaluate the suitability and capability of a supplier to provide requested goods or services to LSD&FC.

Supplier review: an activity undertaken by LSD&FC at defined intervals to assess the past performance of a supplier and to make determinations regarding the continued use of that supplier.

Vendor: an individual or organization which provides non-critical goods or services for LSD&FC (e.g. items such as office supplies or cleaning solutions that are not used in the laboratory).

Responsibility

Quality Manager: Responsible for ensuring implementation of this SOP and maintaining the ASL.

Procedure

This procedure addresses

1) Defining, reviewing and approving LSD&FC requirements.
2) Supplier Qualification
3) Supplier Categories
4) Supplier Classification
5) Approved Supplier List and Supplier Files
6) Supplier Performance Monitoring
7) Placing a Purchase Order
8) Materials Acceptance Process
9) Equipment Acceptance Process

Defining, reviewing and approving LSD&FC requirements:

All required supplies and services to be purchased from external providers shall be defined on the LSD&FC Supply and Service Request Form (Adm 003) by the person requesting the supply/service.

The completed Supply and Service Request Form (Adm 003) shall be passed to the Section Director or designee for review and approval.

Approved Supply and Service Request Form (Adm 003) shall be passed to the Office Manager or designee for generation of the Purchase Order using the Purchase Requisition Form (For 009).

The completed Purchase Requisition Form (For 009) is reviewed and signed off by a section supervisor.

The section supervisor shall pass the signed Purchase Requisition Form (For 009) to the Center Director or designee for final approval before an order can be placed with the supplier.

Supplier Qualification:

All suppliers shall be qualified prior to inclusion on the approved supplier list.

The qualification/selection process begins with the identification of a need not currently fulfilled.

All potential suppliers of critical supplies and services will undergo a qualification process which involves completion of the Supplier Quality Systems Survey/Audit Form (Adm 010) before inclusion on the approved Supplier list.

The qualification process culminates in the completion of LSD&FC Form Adm 003 which documents the requisition and classification of each supplier/Vendor.

The selection method(s) chosen should be proportionate to the criticality of the goods or services being provided. For example, the requirements for a company providing a service to LSD&FC (e.g. pest control, calibration) will differ from the requirements of a company that provides critical items (e.g. DNA amplification kit) or non-critical item (e.g. Tube Rack).

Supplier Categories:

Suppliers are categorized as follows based on the goods and/or services they provide.

Contract Manufacturers produce custom finished goods for LSD&FC. LSD&FC has no contract manufacturer currently.

Critical/Key materials suppliers provide custom materials or critical/key off-the-shelf materials that are used at LSD&FC. Examples of critical/key suppliers are those that manufacture DNA test kits and consumables that are used routinely.

Materials suppliers provide non-critical off the shelf materials that are used at LSD&FC.

Consultants provide individual consulting services in areas such as complex data interpretation, accreditation, consumer, regulatory Affairs, occupational health and safety, or other areas that have a reasonable potential to impact the services offered by LSD&FC.

Service providers are those companies that provide services in areas such as pest control, calibration, maintenance, validation, information technology, etc. that have a reasonable potential to impact services offered by LSD&FC.

Other providers that do not fit into the above categories.

Each Supplier's Category is documented on FORM-Adm 010.

Supplier Classification:

Supplier status is classified as follows:

Key approved (KA) status indicates approval as a contract manufacturer or supplier of critical/key materials.

Approved (A) status indicates approval to provide services, consulting services, non-key materials or other materials.

Conditional (C) status indicates that approval is contingent on certain requirements being satisfied within a stated timeframe. This status is used in conjunction with Key-approved and Approved statuses described above.

Reasons for applying a conditional approval status include:

- Incomplete information prior to adding to Approved Supplier List
- Perceived or real Quality problems

When considering designating "conditional" status, make selection based on historical performance for the industry, personal experience with supplier and risk assessment based on understanding of the supplier's organization.

When authorizing "conditional" status, consider whether additional oversight or inspection of provided items or services is required.

Conditional or preliminary status should be changed to "approved" by use of Surveys and audits within 2 years of conditional status designations.

Not approved status is applied to those suppliers that were disqualified from Approved status for any reason, or who, after initial evaluation, did not satisfy LSD&FC requirements and/or expectations.

Each Supplier's Status (classification) and change in status are documented on FORM-Adm 011

A plan indicating the way each supplier is continuously evaluated is documented on FRM-010. The plan for ongoing evaluation shall indicate the schedule and type of review to be performed based on past performance and criticality of the supplier.

Approved Supplier List (ASL) and Supplier Files

Quality Assurance will maintain control of the ASL and any changes must be submitted to and made by QA. Changes to the ASL documented on Form Adm 011.

At a minimum, the ASL indicates supplier name, location, date added to ASL, supplier category, supplier classification, an indication of the types of goods or services provided, the method of supplier review, the supplier review schedule and supplier current status.

Key/Critical Supplier files are retained by QA and they include:

- Survey/Audit Records
- Relevant certificates e.g. ISO certificates used as basis of approval
- Correspondence, including complaints and follow-up actions.

Supplier Performance Monitoring

Supplier performance will be reviewed every two years, unless a situation requires that it be performed sooner. Monitoring will be documented with Form Adm 010.

Quality Assurance Manager, or designee, monitors performance of all suppliers for fulfillment of agreed upon requirements.

The most critical aspects are quality of incoming material, shipment of correct material, timely response to Corrective and Preventative Action quality concerns and on-time delivery issues.

Based on the performance monitoring LSD&FC will determine whether the controls established and exercised over a supplier are still appropriate.

Results will be evaluated at management reviews or at specially scheduled meetings, if warranted. Based on these reviews, changes in the supplier's status and changes to incoming inspection documents may be authorized.

Suppliers of more critical items or suppliers with poor historical performance will be targeted for the highest level of monitoring and/or inspection.

Placing a Purchase Order

Any LSD&FC employee may initiate purchases.

With the exception of non-critical items and items required for research or evaluation, all purchases must be made from suppliers indicated on the ASL.

All LSD&FC Product Numbers have associated Purchasing Specifications. The specifications include approved suppliers, supplier catalog or category numbers and other specified requirements.

If a desired supplier is not on the ASL, the requisitioner needs to perform the qualification process and add the new supplier catalog or category number to the purchasing specification via the Change Control Process.

Different size quantities of the same material may be ordered, regardless of the catalog or category number. Attach evidence of this (e.g., a copy of the catalog page) to the Purchase Order and/or receipt record.

Identical items may be purchased from different approved suppliers, regardless of the "purchasing specification" requirements. For example, pH electrodes manufactured by Corning may also be purchased from VWR, Fisher, or Nova Analytics even though the Purchasing Specification may identify Corning as the supplier.

If similar but different materials (e.g. different grade or supplier) are ordered, they may **NOT** be identified by same LSD&FC Product Number.

New suppliers or supplier product numbers will be added to Purchasing Specifications.

Product Requirements are clearly defined in the form of a Purchase Order, contract, letter of agreement or other documentation that is mutually agreed upon between LSD&FC and the supplier.

Each Purchase Order, contract, and agreement must include or reference the specific item to be ordered, and in the case of custom items, a reference to quality requirements and specifications.

Arrangements are made with suppliers of critical/key materials and contract manufacturers to help assure that LSD&FC is notified of any changes to product or services before the change is implemented. This may be stated in a Purchase Order, Quality Agreement, Supply Agreement, etc. A request for information pertaining to changes is also included in the Supplier Survey.

Off-the-shelf items that are manufactured according to a supplier's own specifications are ordered by the supplier product or catalog number. For the convenience of the Incoming Inspector, requests for Certificate of Analysis, Certificate of Compliance, etc., as well as the corresponding LSD&FC product number should be noted on the Purchase Order where possible.

Quality requirements may be communicated to the supplier by providing copies of relevant LSD&FC documentation at the time the order is placed or making

references to any contracts/agreements containing relevant quality requirements.

Material Acceptance process

Laboratory materials including test materials from Contract manufacturers are received and inspected for damages and conformity by the requisitioner, by comparison of supplied item to specification on the Purchase Order.

After inspection, Purchase Orders and Packing slips documenting the receipt of material are returned to the Office Manager or designee to authorize payment or to alert Accounting to unresolved issues.

All critical items e.g. kits, solutions and reagents used for DNA testing are to be carefully inspected to ensure that items have not expired. The minimum acceptance process will consist of a confirmation of the product's identity and quantity as indicated on the Purchase order and shipping documentation.

Acceptance records are filed with Quality Assurance to allow for tracking of inventory and allocation of resources for casework.

All other items will be evaluated against the specified requirements and accepted for use by LSD&FC as indicated by those requirements.

Items that do not conform to specified requirements will be segregated from accepted inventory.

Nonconforming supplies will be documented with Forms QAC 007 and QAC 008.

Equipment Acceptance process

Notify the Requisitioner of receipt

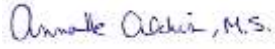
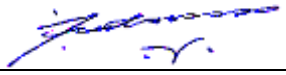
The requisitioner or designee will inspect and test equipment and then notify QA of receipt.

The requisitioner of the equipment authorizes payment by forwarding the Purchase Orders and associated Packing slips to Accounting, or alerts accounting to unresolved issues.

Nonconforming supplies will be documented with Forms QAC 007 and QAC 008.

Procedure Review, Sign Off & Effective Date

Procedure History	
Initial Version Created	
Author	***Date***
Richard I. Somiari, PhD	December 28, 2016
Current Version	***Effective Date***
V3.0	November 29, 2018

Review & Approval History		
Date	***Reviewed & Approved by***	***Title***
07/09/19		***Annette Alchin, M.S. Director, DNA Technical Leader***
07/09/19		***Richard I. Somiari, PhD Center Director***

Revision History			
Date	***Reason for Revision***	***Reviser***	***Version being changed***
07/09/19	• Fix typographical error	Richard I Somiari, PhD	v2.0

Review History		
Reviewed By	***Date***	***Version***