**Job Aid: Purchasing and Inventory Process Steps**

**Please note:** 5.3.2.6 Reagent Adverse Reporting is a nonconformity and addressed in QMS 4: Evaluation and Continual Improvement

| **Activity Step** | **What Happens** |
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| Need for a new product is identified |   |
| Laboratory defines criteria for product. | The necessary characteristics or functional requirements are defined for critical (essential) products. Critical products directly affect the quality of examination results.  |
| Suppliers are qualified. | The supplier’s capability of fulfilling the specified requirements is evaluated. This evaluation should consider the supplier’s organizational commitment to quality, financial stability, quality and compliance history, customer complaint program, regulatory and accreditation requirements, and customer notification program for recalls. establishing criteria• Requesting evidence of third party certification (i.e. ISO9001 certificate)• Reviewing and analyzing past experiences and evaluations for that supplier• Requesting references from other customers to contact • Requesting the supplier to complete and submit a self-assessment of their services |
| Suppliers are selected. | **A**) The supplier’s capability of fulfilling the specified requirements is evaluated. The suppliers must demonstrate that they are capable of providing the critical product which fulfills the criteria, the critical product is made and stored according to applicable requirements, The amount of the product can be reliably furnished. |
|   | **B**) Prospective suppliers are ranked according to their ability to meet the laboratory’s requirements. This information is used to determine the final selection and is documented. |
| Approval list is maintained. | The laboratory maintains a listing of suppliers that were approved through the qualification step and from which purchases can be made. |
| Purchasing fulfills the procurement agreement. | A documented agreement is created outlining the provision of products the laboratory purchased from the supplier. |
|  | **Supply chain management** – manages product or service movement from the manufacturer or distributor to the laboratory |
| Products are received at facility. | Incoming products arrive at the main facility and are transferred to the laboratory according to guidelines communicated by laboratory regarding timeliness of temperature-sensitive products and EQA materials.  |
| Products are received at laboratory. | The original purchasing document is compared with the shipping document, and with the items received to ensure the shipment contains the correct item, the correct amount, the complete order, no damaged or missing items, and appropriate lot numbers and expiration dates. |
| Product is segregated (or quarantined), stored and handled appropriately. | Critical products that must be inspected or verified are placed in designated storage areas away from materials already verified for use or in-use. Manufacturer recommendations and applicable safety requirements are followed for the storage and handling of the product.• Received, not yet evaluated. • Evaluated, ready for use. • Not acceptable for use, to be returned or disposed.  |
| **INVENTORY MANAGEMENT** |
| Products are stored and handled appropriately. | Manufacturer recommendations and applicable safety requirements are followed for the storage and handling of the product. |
| Segregated product undergoes acceptability testing. | Critical products are verified as working properly before use in the examinations on patient samples. The results of the function testing is documented. Any critical product that fails testing must be quarantined. |
| First-in-first-out (FIFO) is applied. | Rotating product so that those products received first are used first to minimize outdating and waste. |
| Products are used. | Available and verified products are consumed to provide quality and uninterrupted laboratory services |
| Stock count is performed. | Available products are physically counted and monitored. |
| Forecasting and calculating is performed. | Reorder levels are calculated based on the analysis of consumption data and available stock present. |
| Product is ordered. | Management reviewed and approved the purchasing request. |
| Suppliers are evaluated. | Copies of complaints or problems with the supplier’s performance are reviewed to determine if the supplier should maintain qualified and approved status. |
| Product is no longer needed or orderable |   |