1) Equipment:

A systems view of an organization recognizes that performance is a function of taking in inputs (marketplace requirements, operating funds, materials and supplies, and employees) and effectively and efficiently converting them to outputs deemed of value by our clients. It is therefore in the best interest of laboratories to ensure that they select and work with suppliers in ways that will provide for high quality of those inputs.

Supplier performance is recognized as being about more than just a low purchase price. The costs of transactions, communication, problem resolution, and of switching suppliers all impact overall cost. The reliability of supplier delivery as well as their own internal operational policies, such as inventory levels, all impact overall supply chain performance.

The process for selecting equipment and supplies should be based on the type of product or service being purchased, uniqueness of the product or service, and total cost. If the item is a standard product (for example, available “off the shelf”) and does not have a critical impact (for example, quality or cost) on the laboratory’s performance, then purchase price and availability may be all that needs to be considered. An example of such a product might be standard office supplies.

However, this simple view does not suffice for the many laboratory products and services that will have a significant performance impact. The Laboratory must define what criteria will be applied, then determine ways that prospective suppliers will be evaluated against the criteria to make a final decision.

The Laboratory must be able to demonstrate that suppliers are evaluated on the basis of performance. Records of the evaluation and subsequent actions must be maintained. Responsibilities for reviewing the data and approving the purchase should be clearly assigned to appropriate personnel.

Purchasing should be planned and carried out under adequate control by the Laboratory. Planning and controls should include, but not limited to, the following:

- Evaluation and selection of suppliers;
- Development of clear and unambiguous purchasing requirements
- Performance of suitable verification and implementation of receiving inspection procedures.
Once purchased, the Laboratory is required to establish and implement an inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Receiving inspection is one method to verify that purchased items delivered to the Laboratory meets specified requirements for quality.

OLA requires there shall be a process for installing all new pieces of equipment and instrumentation to verify proper functioning prior to use in the live environment. The process should include verifying the adequacy of the support utilities, such as electricity, ventilation, and humidity, and the environmental requirements for operation, such as air and water quality. Verification activities shall be documented.

A comprehensive equipment management process shall include a means of tracking all equipment, from request through final disposition; assigning unique identifying information; verifying calibration and maintenance schedules, and tracking service requirements, with designated responsible persons to review the plan and respective records at defined intervals.

In addition, OLA requires that the organization should determine the requirements and have written procedures for calibration, maintenance, adjustments, quality control, and performance monitoring. Schedules for calibration and maintenance should be derived, documented, and followed. When problems occur, there should be documented processes to follow for troubleshooting, repair and post-repair recalibration or revalidation.

2) Inventory Control:

To maintain its ability to function efficiently and provide uninterrupted data that contribute to patient care, a clinical laboratory must have on hand an adequate quantity of supplies. A consumer survey by NCCLS showed that 47% of users experienced a stock-out at least once a month. Weekly stock-outs were noted by 13% of those who replied. In the same survey, 52% of the stock-outs were attributed to vendor backorders. The laboratories themselves accepted responsibility for the remaining 48% of stock-outs for reasons including failure to order promptly, inappropriate stock levels for average use, and other laboratory-based reasons. There is a need to establish better consumer buying practices and an improved capability to respond to inventory shortages.

Acquiring supplies and controlling the inventory may be an operations function that occurs totally within the clinical laboratory. However, external departments are always involved, at least to the extent of receiving incoming shipments, transferring goods to the laboratory, and in payment through accounts payable. Staff members within the clinical laboratory must recognize their finite roles and establish clearly defined procedures to be implemented by well-trained personnel. Careful attention to the entire process is essential so that the system works smoothly and does not burden the laboratory or external departments.
Generally, the laboratory is responsible for specifications, as well as storage and use of products. Most often, communication with the vendor is required, especially concerning product improvements, method changes, and similar information that affects the test procedure or quality control. The clinical laboratory must accept the responsibility for these functions and provide accurate records to allow traceability for overall audit purposes.

The Laboratory’s procedures specify the method of verifying that shipments received are in accordance with specifications, are complete, have proper identification, and are undamaged. The procedures also include provisions for verifying that incoming items, materials or services are accompanied by the required supporting documentation (ie. package inserts). Appropriate action in the event of non-conformities should be specified. Analysis of past receiving inspection data (ie. past rejection history) should influence the Laboratory’s decisions regarding how much inspection is required and whether a vendor should be reassessed.

When productive communication exists between all groups in the supply network, the systems should work well so that the need for, and frequency of, emergency orders is minimal. Because the functioning of the laboratory is a critical element in health care delivery, sound inventory control is essential.