




LABORATORY EQUIPMENT PURCHASING, SELECTION AND MANAGEMENT



BIOGENIX

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2. REVISION HISTORY

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4. POLICY STATEMENT

The policy is implemented as per the following procedure.

5. PURPOSE

The main objectives of this procedure are to:

- 5.1. Conduct procurement activities in a fair and ethical manners
- 5.2. Promote sound competition to obtain best values for goods and services
- 5.3. Simplify approval processes and minimize delay in placing orders
- 5.4. Assure quality of procured services as well as on schedule delivery
- 5.5. Minimize the risk associated with goods and services.
- 5.6. Acceptance testing of the equipment

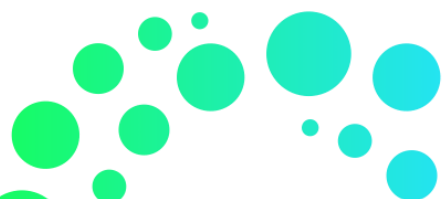
This procedure is in accordance with ISO 15189: 2012 clinical laboratories Requirements of Quality and competence clause 5.3.1.

6. SCOPE

- 6.1. All the purchases in the laboratory related to equipments, reagents, consumables and external services.
- 6.2. Target Audience:
 - 6.2.1. BIOGENIX procurement staff
 - 6.2.2. BIOGENIX Biomedical Engineer
 - 6.2.3. BIOGENIX Laboratory staff

7. DEFINITIONS

- 7.1. Procurement: the act of obtaining equipment, materials, or supplies
- 7.2. New items: are the items which are not included in the contracts with vendors
- 7.3. Vendor: One that provides products or services to a business for a fee.
- 7.4. Reagents: includes reference materials, calibrators and quality control materials.
- 7.5. Consumables: includes culture media, pipette tips etc.
- 7.6. Laboratory equipment: includes hardware and software of instruments, measuring systems, and laboratory information system.





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8. ACRONYMS

N.A.

9. RESPONSIBILITIES

- 9.1. BIOGENIX Management
- 9.2. BIOGENIX Laboratory Staff.

10. PROCEDURE

PURCHASING OF EQUIPMENT:

Procurement of equipment starts with the process of identification of a need and an analysis of how this need can be satisfied. After that, the procurement is planned and a calculation of the total value of the contract is made.

When purchasing equipment following steps are being followed:

- 10.1.1. **NEED GENERATION:** Once the technical staff arises the need of the new instrument or upgrade the old instrument (on the basis of supply, maintenance issues, addition of more parameters, prices etc.). Need identification and demand is generated by Biomedical engineer and pass over to the Laboratory Director.
- 10.1.2. Laboratory director is responsible for selecting the equipment after following the criteria for selection, which is as follows:

Selection Qualification:

- i. Customer expectations: cover vast range of tests
- ii. Time and effort needed to maintain and operate equipment: Time required for daily maintenance and PPM
- iii. Facility/environment requirement: It fits in the available space and no special environmental conditions needed;
- iv. Ongoing cost to maintain and operate equipment: presently available instrument or outsourcing costs.
- v. Vendor/supplier considerations:
 - of reputable brand;
 - delivery of supply on time;
 - prompt after sales service;
 - can take care of urgent needs;



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- Have qualified engineers.
- Credibility in the market.
- vi. Time and effort needed to place equipment into use
- vii. Medical appropriateness of examination equipment: Results are reliable
- viii. Laboratory staff (e.g., "end user") considerations: User friendly.
- ix. Equipment function and features: e.g. Graphs, inventory, backup, Database of results;
- x. LIS connectivity.
- xi. Stability and availability of reagents for the specific equipment: By doing market survey.
- xii. Cost to place equipment into use: Total expenditure on the equipment (e.g. Transportation, Freight charges, LIS connection).
- xiii. After Sales service support
- xiv. Payment terms and conditions;

10.1.3. **QUOTATIONS:** Quotations are asked from 3 different companies.

10.1.4. **SCRUTINY OF QUOTATIONS:** Comparison is made on the basis of technical requirement, Price and market research.

Note: In some special cases we ask the supplier/manufacturer to give demonstration, in that case they place the instrument in the laboratory and we mark the instrument as

"INSTRUMENT UNDER VALIDATION NOT FOR RELEASE OF PATIENT RESULTS".

10.1.5. **NEGOTIATION:**

- i. After finalizing quotations final negotiations are done on the basis of after sale service /reagent contracts/price/ term and condition.
- ii. Contract is signed between the lab and the manufacturer/Supplier by laboratory Director, after checking the payment terms and other terms and conditions by procurement department.

10.1.6. **PURCHASE ORDER:** Purchase orders are prepared after all the demands are satisfied. Purchase order is issued by procurement department.

10.2. EQUIPMENT ACCEPTANCE TESTING:

10.2.1. **EQUIPMENT IDENTIFICATION:** After equipment is received, it is uniquely labelled to enable traceability for all activities related to a particular piece of equipment throughout its lifetime. The equipment makes, model, serial number, manufacturer's name, and instrument identification is recorded, and the information added to the equipment asset file.





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NOTE: Equipment is labelled as **"Do Not Use for Patient Examination"** until Validation/verification/ acceptability process is complete.

10.2.2. EQUIPMENT VERIFICATION PLAN:

10.2.2.1. Installation Qualification (IQ):

Proper installation of laboratory equipment is verified by IQ activities. The IQ is a set of formal check and records that confirm the equipment and its components were supplied as ordered and properly installed in the laboratory and/or other environment. Usually, the manufacturer's installation engineer provides (or can be asked to provide) documentation that certifies the instrument is ready, safe and meets installment specifications. Biomedical Engineer overlook whole installation.

The IQ covers the various facts and requirements of the installation, including the following:

- System components
- Environmental conditions
- Utility requirements
- Instructions for operation and backup mechanism
- LIS communication
- Configuration access
- Documents and records

10.2.2.2. Operational Qualification(OQ):

OQ is the process to confirm that the equipment is operational for its intended use and location.

Although this activity is frequently conducted by the manufacturer's technical service engineer, the laboratory is responsible for ensuring that OQ documentation meets international, national, accreditation, local, and organizational requirements.

The relevant manufacturer's specifications and the operational attributes listed below are used to test the operational functionality of the equipment and test any interfaces to computerized systems, as well. All pieces of the equipment need testing to ensure that operational specifications are met.

Examples of operational attributes include:

- Calibration
- Quality control (QC) testing
- Process control limits, including monitoring and alarms
- Security limits
- Data transfer across electronic interfaces





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Whenever equipment is moved to a new location (eg, within the laboratory, to another laboratory, to another facility), after maintenance, or after any modification, it is important to reverify appropriate functioning by performing and documenting IQ and OQ.

10.2.2.3. Performance Qualification (PQ)

PQ is the process to confirm the equipment is performing as per specified needs. The laboratory's equipment operator or testing personnel need to perform all PQ activities. PQ confirms that the equipment produces acceptable results under normal operating conditions by testing both the device and the process's ability to manage the work in the anticipated time frame, and meets international, national, accreditation, local, and organizational requirements. The PQ incorporates test cases and protocols to evaluate the full range of intended use; PQ represents the final qualification of the equipment.

PQ components include the following:

- Accuracy, to include the effects of interferences, analytical sensitivity, and carryover
- Precision
- Linearity
- Method comparison to previous methodology/equipment
- verifying reference interval
- Completeness and correctness of operating procedures
- Staff training and competence

10.2.2.4. Reverification:

When equipment located in a fixed location is moved, serviced, or modified, installation and operational qualifications need reverification. This activity includes comparing data from the original IQ and OQ to the results of reverification activities to identify any significant changes. Where the manufacturer's recommendations are more stringent, the laboratory needs to follow these instead. Under routine operating conditions, as long as the process operates in a state of control verified by the IQ and OQ activities stated above and no changes were made to the process or output result, there is no need to revalidate the process through PQ. Depending on the amount of time the equipment is offline, it is also necessary to retrain staff in its use and assess competence before using the equipment in laboratory operations.

10.2.2.5. Hazard Analysis (HA)

An HA is to be undertaken when new equipment is brought into the laboratory.

- i. The HA consider all standard safety precautions for laboratory equipment (eg, electrical safety at the time of IQ, proper disposal of hazardous waste in OQ, and the need for personal protective equipment [PPE] in PQ as well as the additional electrical, physical, and chemical hazards unique to that equipment performance approval of the plan and postperformance approval/follow-up of the results are obtained when the plan is followed by staff.
- ii. Manufacturers are obligated to identify their equipment's hazards, label them and advise as to mitigation.



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Although this activity is frequently conducted by the manufacturer's technical service engineer, the laboratory technical staffs are responsible for ensuring that it meets international, national, accreditation, local, and organizational requirements. The relevant manufacturer's specifications and the operational attributes listed below are used to test the operational functionality of the equipment and test any interfaces to computerized systems, as well:

Examples of operational attributes include:

- Calibration
- Quality control (QC) testing
- Process control limits, including monitoring and alarms
- Security limits
- Data transfer across Laboratory Interface System.

10.3. EQUIPMENT INSTRUCTIONS FOR USE:

All the equipment is operated at all times by trained and authorized personnel only. Current instructions on the use and maintenance of equipment, including any relevant manuals and directions for use provided by the manufacturer of equipment are present as a hard copy near the instrument or as a soft copy in the computer system of the main laboratory.

All the equipment is disinfected externally by the universal wipes for disinfecting the surface.

10.4. EQUIPMENT ADVERSE INCIDENT REPORTING:

10.4.1. All problem are logged in the non conformance/Incident/ Biomedical Engineering department Work request form in which a summary of the troubleshooting episode is recorded. Each event is recognised and recorded in the order of occurrence. All troubleshooting actions taken are recorded.

10.4.2. At a minimum, troubleshooting records includes the following:

- 10.4.2.1. Instrument or equipment identification
- 10.4.2.2. Date of occurrence
- 10.4.2.3. Description of the problem
- 10.4.2.4. Batch, load, and/or run number, as applicable
- 10.4.2.5. Date and time troubleshooting was performed
- 10.4.2.6. Identity of the person performing troubleshooting
- 10.4.2.7. Any necessary follow-up actions taken
- 10.4.2.8. Review and approval.

10.5. EQUIPMENT RECORDS:

Following records are maintained for the equipment:

- 10.5.1. Identity of the equipment;
- 10.5.2. Manufacturer's name, model and serial number or asset number (Life Dx number)
- 10.5.3. Contact information for the supplier or the manufacture
- 10.5.4. Date of receiving and date of entering into the service;
- 10.5.5. Location;
- 10.5.6. Condition when received (e.g. new, used or reconditioned);



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- 10.5.7. Manufacturer's instructions;
- 10.5.8. Acceptability testing records;
- 10.5.9. Ongoing acceptability records (calibration, verification records)
- 10.5.10. Maintenance record and the schedule for preventive maintenance;
- 10.5.11. Damage to, or malfunction, modification, or repair of the equipment.

11. CROSS REFERENCE

- 11.1. ISO 15189 :2012 Medical laboratories – Requirements for Quality and Competence
- 11.2. CLSI guidelines QMS 13A.

12. RELEVANT DOCUMENTS & RECORDS

