**Job Aid: Equipment Process Steps**

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

| **Activity Step** | **What Happens** |
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| **Need for equipment is identified.** | The need should define: •Purpose for which the equipment is intended; •How it will improve the service to the laboratory users; •The medical context in which the population served will utilize this information (e.g. diagnostic, monitoring). |
| **Laboratory defines criteria for equipment.** | The laboratory decides on its quality goals and specifies requirements (performance specifications). |
| **Suppliers are qualified.** | The manufacturer or third party's capability of fulfilling the requirements is evaluated and determined to be acceptable. |
| **Suppliers (equipment) are selected.** | The laboratory selects the manufacturer, or third party, best capable of fulfilling its quality goals and requirements. |
| **Purchasing contract is developed.** | Through negotiations, the laboratory and purchasing departments, and the supplier agree and document the contract details. |
| **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.** | The terms of payments are sufficiently met for the supplier to ship the equipment. |
| **Equipment is received at the laboratory.** | The shipping invoice confirms that the equipment and all its accompanying components have arrived at the laboratory. Do not unpack. |
| **Equipment is installed.** | The equipment and all accompanying components are in acceptable condition and placed in the location intended for use. Detailed operational checks are only performed after basic functionality is met. Records confirming that the equipment is operating as intended are retained. |
| **Equipment Master List is maintained.** | The equipment is uniquely identified which is traceable to its serial number and added to the list of all equipment in the laboratory. This list summarizes the life history of each piece of equipment in the laboratory. If a naming convention is used (i.e. Centrifuge #1, Centrifuge #2, Refrigerator #1, Refrigerator #2), it must be traceable to the manufacturer’s serial number. Document control this master list Include loaner equipment |
| **Equipment is validated or verified (ISO 5.5)** | Through objective evidence, the laboratory confirms that the performance characteristics meet performance specifications and/or manufacturer's performance claims. (Performance Evaluation- investigation of a procedure intended to become an examination procedure for the purpose of establishing or verifying performance claims; remember to including loaner equipment on loan. |
| **Equipment program is developed and implemented.** | Through related activities, proper equipment handling (and use) and control are organized and managed. These related activities are based upon the manufacturer's instructions for the equipment. |
| **Equipment is used for patient testing.** | The laboratory puts the examinations into routine use. |
| **Equipment is maintained.** | Using the manufacturer's information, tasks are performed to keep the equipment in its current or desired state. |
| **Equipment is calibrated.** | The instrument's measurement system is tested and adjusted to correlate the measurement value for the analyte being tested and the actual concentration of that analyte. The accuracy of the measuring component of the equipment is confirmed. |
| **Equipment is quality controlled. (ISO 5.6).** | The laboratory controls operating specifications through internal and external quality assessment. |
| **Equipment is repaired or received nonroutine service.** | A non-scheduled service interruption occurs that requires further troubleshooting to resolve the issue. |
| **Equipment received routine serviced.** | A scheduled service interruption is performed in accordance with manufacturer's information. |
| **Equipment is decommissioned** | The instrument is retired from laboratory use. |
| **Equipment is disposed.** | The retired instrument is removed from the laboratory. |
| **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. |
| **EQUIPMENT MANAGEMENT** | Through the collection and analysis of records, which are traceable to the serial number, the equipment's performance is optimized. |