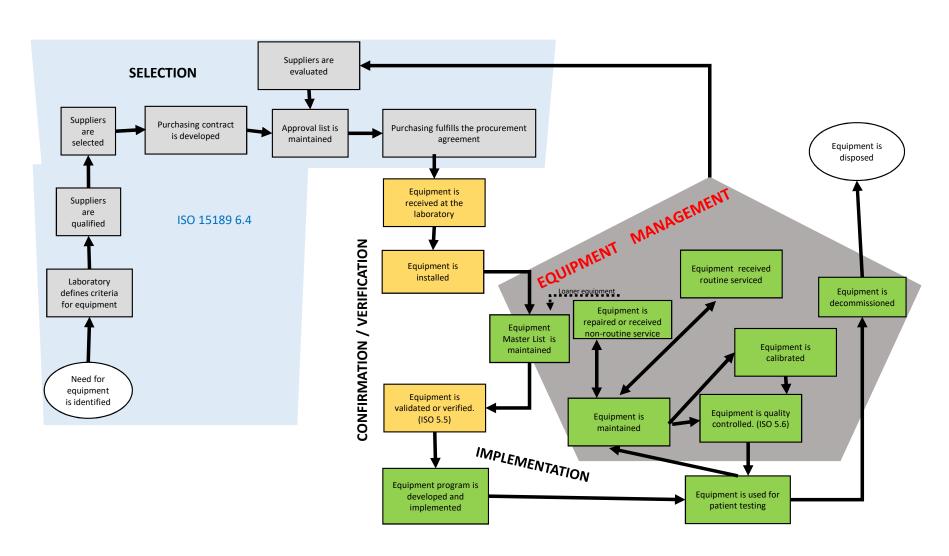
## Job Aid 1: Equipment Process Map 1407v2



Equipment Process Map

Selection Phase Step – Define Criteria for Equipment

### **Selection Qualification - SQ**

Performance Characteristics	Application Characteristics	Methodology Characteristics
Defines how well a method performs  Reportable Range Precision Accuracy Trueness / Bias Interference Limit of Detection (LOD) Limit of Quantification (LOQ) Reference Interval Measurement of Uncertainty	Defines how successful the method can be implemented in a specific laboratory situation  Skill required Volume of sample Type of sample Throughput Size Infrastructure or utility needs Costs/test Safety Waste disposal needs	<ul> <li>Defines which method contributes to the best performance</li> <li>Traceability of assigned values for calibrators</li> <li>Analytical Sensitivity (LOD)</li> <li>Analytical Specificity (no interferences)</li> </ul>



Equipment Process Map

Selection Phase Step – Develop Purchasing Contract

#### **Types of Documents to Solicit from Suppliers**

RFI	RFP	RFQ
Request for <b>Information</b> - serves a formal means to gather information, NOT to make a selection or an award	Request for <b>Proposal</b> - used to obtain information, including specifications and procedures	Request for <b>Quote</b> - used to obtain pricing, delivery information, terms and conditions from suppliers  Make the pricing as specific as possible including services and items (number, description, quantity, unit of measure).

#### Make sure the contract covers the following

- Construction services failure to meet milestones or deadlines should result in monetary penalties or loss of contract
- Equipment installation by manufacturer
- Software and interface information, installation and support
- Operator's manual and package insert information in correct language
- Equipment training provided by manufacturer
- Technical support

- Routine service provided by manufacturer
  - o Is it part of the contract or an additional expense?
  - If a loaner is provided, who pays for all the reagent and calibrators to verify acceptability?
- Ordering supplies and parts
- Performance and application characteristics specified
- Warranty (equipment must fit and work according to the preassessment needs determined by the manufacturer)

Equipment Process Map Confirmation Phase

Step – Install Equipment

The installation may be performed by:

- A manufacturer's representative
- > The laboratory in accordance with manufacturer's instructions.

Installation Qualification (IQ)	Operational Qualification (OQ)
<ul> <li>Documentable evidence that the equipment is ready, safe, and meets all installation requirements</li> <li>All equipment components have arrived.</li> <li>Equipment is placed and installed at the intended location.</li> <li>All equipment requirements are met (correct environmental temperature, correct power, water supply is appropriate).</li> <li>All additional assembly is performed.</li> <li>Equipment can power-on and off.</li> <li>LIS communication and configuration access works.</li> </ul>	Documentable evidence that the equipment is operating correctly  Equipment can start-up Functionality checks are confirmed Initial calibration is performed
	■ Data transfer across interfaces  Acceptable tolerance limits (1.15 – 1.32)  Your result: 1.18 Acceptable: ✓ Unacceptable:
	Tolerance ranges are required for all instrument operational verification activities and any maintenance activity that produces a measured value.

# Equipment Process Map

Implementation Phase

Step – Develop and Implement an Equipment Program

#### How to Develop an Equipment Management Program

- Develop SOPs (internal documents) and their accompanying forms, logs, and workbooks
- Ensure the control and availability of external documents (e.g. manufacturer's operator manual)
- Develop a preventive action schedule (maintenance, calibration, service)

- Ensure the control and review of records (e.g. Supervisor Review).
- Develop training qualifications
- Perform competency assessments

- Select appropriate level of control monitoring that can ensure the acceptability of operating specifications during routine use
  - Internal quality control
  - External quality control
- Update inventory management (sufficient storage needs, stock bin cards)
- Review specimen collection and update client handbook, if needed
- Review result reporting and update reference intervals if needed

An effective equipment management program ensures:

- Increased performance
- Reduced interruption of service (fewer and shorter downtimes)
- Consistency of test results
- Fewer non-scheduled repairs
- Reduced costs by saving money on repairs
- Greater lifespan of the equipment
- Greater customer satisfaction