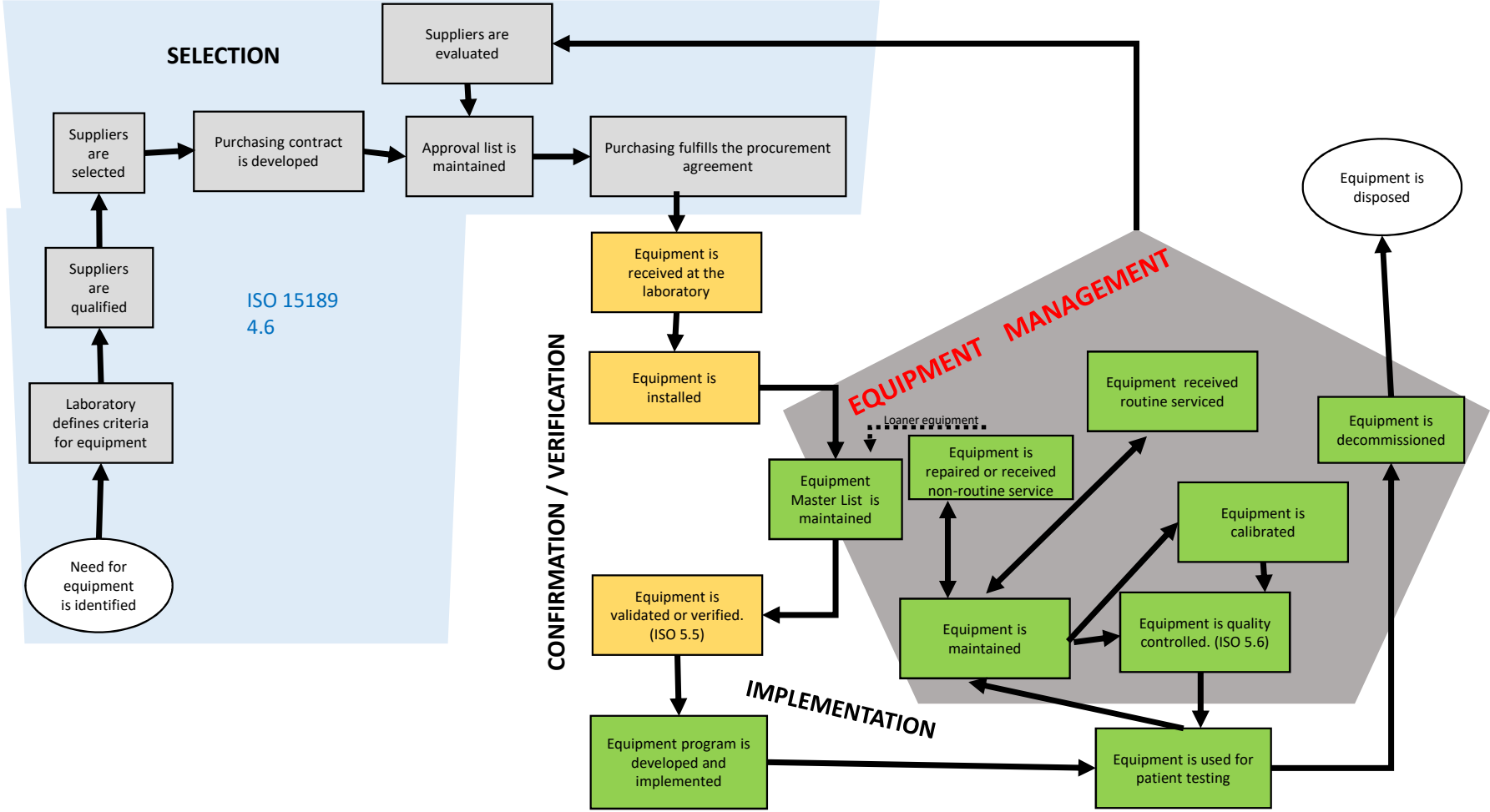


Job Aid 1: Equipment Process Map 1407v2



Equipment Process
Map

Selection
Phase

Step – Define
Criteria for
Equipment

Selection Qualification - SQ

Performance Characteristics	Application Characteristics	Methodology Characteristics
<p>Defines how well a method performs</p> <ul style="list-style-type: none">▪ Reportable Range▪ Precision▪ Accuracy▪ Trueness / Bias▪ Interference▪ Limit of Detection (LOD)▪ Limit of Quantification (LOQ)▪ Reference Interval▪ Measurement of Uncertainty	<p>Defines how successful the method can be implemented in a specific laboratory situation</p> <ul style="list-style-type: none">▪ Skill required▪ Volume of sample▪ Type of sample▪ Throughput▪ Size▪ Infrastructure or utility needs▪ Costs/test▪ Safety▪ Waste disposal needs	<p>Defines which method contributes to the best performance</p> <ul style="list-style-type: none">▪ Traceability of assigned values for calibrators▪ Analytical Sensitivity (LOD)▪ Analytical Specificity (no interferences)

Three Options

Purchase

Lease
(equipment and/or
reagent)

Rent

Equipment Process
Map

Selection
Phase

Step – Develop
Purchasing
Contract

Types of Documents to Solicit from Suppliers

RFI	RFP	RFQ
Request for Information - serves a formal means to gather information, NOT to make a selection or an award	Request for Proposal - used to obtain information, including specifications and procedures	Request for Quote - 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
 - 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 pre-assessment needs determined by the manufacturer)



The installation may be performed by:

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

Installation Qualification (IQ)	Operational Qualification (OQ)
<p>Documentable evidence that the equipment is ready, safe, and meets all installation requirements</p> <ul style="list-style-type: none"> ▪ All equipment components have arrived. ▪ Equipment is placed and installed at the intended location. ▪ All equipment requirements are met (correct environmental temperature, correct power, water supply is appropriate). ▪ All additional assembly is performed. ▪ Equipment can power-on and off. ▪ LIS communication and configuration access works. 	<p>Documentable evidence that the equipment is operating correctly</p> <ul style="list-style-type: none"> ▪ Equipment can start-up ▪ Functionality checks are confirmed ▪ Initial calibration is performed ▪ Data transfer across interfaces <div style="background-color: #e0f0e0; padding: 5px; margin: 10px 0;"> <p>Acceptable tolerance limits (1.15 – 1.32) Your result: <u>1.18</u> Acceptable: <input checked="" type="checkbox"/> Unacceptable: <input type="checkbox"/></p> </div> <p>Tolerance ranges are required for all instrument operational verification activities and any maintenance activity that produces a measured value.</p>

Equipment Process
Map

Implemen-
tation 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