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QSE 6: Equipment Management

Policy	The laboratory keeps detailed records on each piece of equipment that is critical in the processes across the laboratory's path of workflow.
Purpose	This policy provides direction for the processes and procedures to effectively manage the laboratory's equipment.
Responsibility	The Laboratory Director is responsible for laboratory acquisition decisions, implementing an instrument verification and maintenance program, and documentation review. The Purchasing Department is responsible for the actual purchasing process associated with instrument purchases. The Laboratory Supervisor is responsible for instrument justification and comparative analyses. The Lead Technologists and Quality Manager are responsible for the validation, maintenance and repair once the instruments are on-site.
Equipment Selection, Acquisition, Installation, and Inventory	The laboratory acquires and installs the equipment needed for producing quality results. An inventory of all laboratory equipment is maintained.
Validation Studies	Validation studies are performed and documented as required on laboratory instrumentation to include accuracy, precision, linearity, reportable ranges, reportable reference ranges, sensitivity (as needed) and specificity (as needed).
Method Comparison	When more than one method or instrument is used to conduct the same test, the methods or instruments are compared semi-annually.
Carryover	Studies are performed to show non-FDA approved instruments or test systems do not have any carryover.
Maintenance, Calibration, Use, Troubleshooting, Service, Repair, and Records	Each instrument in use has a separate manual that includes all instructions and documentation generated during the life of the instrument indefinitely or as otherwise directed.
Retiring Instruments	The laboratory retires instruments that are no longer in use and has procedures for storage of retired instruments and their records.
Supporting Documents	The following processes support this policy: • Equipment Acquisition, Installation, Identification, and Inventory • Instrument Validation Studies • Method Comparisons • Carryover Studies • Instrument and Equipment Preventative/Corrective Maintenance • Troubleshooting and Corrective Actions • Retiring Instruments

Process for Equipment Selection, Acquisition, Installation, Identification, and Inventory

What Happens	Who's Responsible	Procedures
Decision is made to purchase new equipment or replace equipment in use	• Laboratory Director • Laboratory Supervisor • Lead Technologist	• Laboratory Testing Turn Around Times • Equipment Inventory • Specific Equipment Service and Maintenance Records
Research is performed for available instrumentation	• Laboratory Director • Laboratory Supervisor • Lead Technologist	• Requesting Bids from Suppliers • Test-Specific Procedures • Equipment Selection
Equipment justification is performed	• Laboratory Director • Laboratory Supervisor • Finance Department	• Finance Department Policies and Procedures
Equipment purchase request is completed and approved	• Laboratory Supervisor • Purchasing Department	• Completing a Purchase Request Form • Equipment Acquisition
New equipment is installed by manufacturer or approved representative	• Laboratory Supervisor • Lead Technologist • Quality Manager • Manufacturer/ Representative	• Manufacturers' Equipment Manuals • Installing New Laboratory Equipment
Equipment is assigned a unique identifier	• Laboratory Supervisor • Lead Technologist	• Equipment Identification
Equipment is included in an inventory	• Laboratory Supervisor • Lead Technologist	• Equipment Inventory
All instructions and documentation related to an instrument are kept in an equipment manual specific to that piece of equipment	• Laboratory Supervisor • Lead Technologist • Quality Manager • Technicians/Technologists	• Documenting Equipment-Related Activities • Equipment-Related Records

Process for Instrument Validation Studies

What Happens	Who's Responsible	Procedures
New instrument validation studies are performed, documented, and evaluated for approval in-house	• Laboratory Director • Lead Technologists • Quality Manager • Technicians/Technologists	• Instrument-Specific Validation Procedures • Laboratory Section-Specific Validation Procedures
Annual or as needed validation studies are performed, documented, and evaluated for approval	• Laboratory Director • Lead Technologists • Quality Manager • Technicians/Technologists	• Instrument-Specific Validation Procedures • Laboratory Section-Specific Validation Procedures
When equipment is removed from the laboratory or is serviced/repaired, performance is validated before use in patient testing	• Laboratory Director • Lead Technologists • Quality Manager • Technicians/Technologists	• Instrument-Specific Validation Procedures • Laboratory Section-Specific Validation Procedures

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Process for Method Comparisons

What Happens	Who's Responsible	Procedures
Two laboratory instruments or methods are used in testing of the same analytes	• Lead Technologist • Quality Manager • Technicians/Technologists	• Performing Comparison Studies • Test-Specific SOPs • Instrument-Specific User Manuals
Both manual and automated methods are used to result a laboratory analyte	• Lead Technologist • Quality Manager • Technicians/Technologists	• Performing Comparison Studies • Test-Specific SOPs • Instrument-Specific User Manuals
A manual method is used to confirm an analyzer-generated result	• Lead Technologist • Quality Manager • Technicians/Technologists	• Performing Comparison Studies • Test-Specific SOPs • Instrument-Specific User Manuals
An instrument/method comparison study is performed semi-annually	• Lead Technologist • Quality Manager • Technicians/Technologists	• Performing Comparison Studies • Test-Specific SOPs • Instrument-Specific User Manuals

Process for Carryover Studies

What Happens	Who's Responsible	Procedures
New instrument carryover studies are performed, documented, and evaluated for approval	• Laboratory Director • Lead Technologists • Quality Manager • Technicians/Technologists	• Instrument-Specific Carryover Study Procedures
Additional instrument carryover studies are performed, documented, and evaluated for approval as needed	• Laboratory Director • Lead Technologists • Quality Manager • Technicians/Technologists	• Instrument-Specific Carryover Study Procedures

Process for Instrument and Equipment Preventive/Corrective Maintenance

What Happens	Who's Responsible	Procedures
Instrument and/or equipment maintenance is performed on a daily, weekly, monthly, quarterly, semi-annual, or annual schedule	• Lead Technologist • Technologists/ Technicians	• Equipment-Specific Procedures • Manufacturer's Equipment Manual • Maintenance Schedule
Maintenance, service, or repair is performed on instruments or equipment at times other than scheduled	• Lead Technologist • Technologists/ Technicians • Instrument Manufacturer Service Personnel • Facility Engineering Department Service Personnel	• Equipment-Specific Procedures • Manufacturer's Equipment Manual • Emergency Service Requests • Requesting Service or Repair from Facility Engineering Department
All maintenance, service, and repair activities are documented and maintained in the equipment manual	• Lead Technologist • Technologists/Technicians	• Maintenance, Service, and Repair Records • Equipment-Specific Procedures
Documentation is reviewed at least monthly	• Quality Manager • Laboratory Director	• Equipment-Specific Procedures • Maintenance, Service, and Repair Records • Maintenance Schedule • Review and Storage of Laboratory Records

Process for Calibration

What Happens	Who's Responsible	Procedures
Calibration schedule is developed based on manufacturer's recommendations	• Laboratory Supervisor • Lead Technologist • Quality Manager	• Manufacturer's Equipment Manual • Calibration Procedure • Instrument/Equipment-Specific Procedures
Calibration is performed and documented at regularly scheduled intervals or as needed for troubleshooting	• Lead Technologist • Quality Manager • Technicians/Technologists	• Manufacturer's Equipment Manual • Calibration Procedure • Instrument/Equipment-Specific Procedures
Documentation is reviewed and filed	• Quality Manager • Laboratory Director	• Manufacturer's Equipment Manual • Calibration Procedure • Instrument/Equipment Specific Procedures- • Review and Storage of Laboratory Records

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Process for Troubleshooting and Corrective Actions

What Happens	Who's Responsible	Procedures
Trouble-shooting and training schemes are developed	• Laboratory Supervisor • Quality Manager • Lead Technologist • Technologists/Technicians	• Instrument/Laboratory Section-Specific Procedures • Manufacturer's Manuals
Problem is identified and documented	• Quality Manager • Lead Technologist • Technologists/Technicians	• Instrument/Laboratory Section-Specific Procedures • Manufacturer's Manuals • Documenting Problems and Corrective Actions
Corrective Action is performed and documented	• Technologist/Technicians • Lead Technologist • Quality Manager	• Instrument/Laboratory Section-Specific Procedures • Manufacturer's Manuals • Documenting Problems and Corrective Actions
Corrective Action documentation is reviewed and filed	• Laboratory Director • Quality Manager	• Documenting Problems and Corrective Actions • Review and Storage of Laboratory Records

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Process for Retiring Instruments

What Happens	Who's Responsible	Procedures
New instrument validation studies are completed	• Lead Technologist • Quality Manager	• Technical SOPs • Instrument-Specific Validation Procedures
Retired instrument is cleaned and decontaminated for storage	• Quality Manager • Technicians/Technologists	• Retiring Laboratory Instruments/Equipment • Equipment Decontamination
Instrument is packed and removed for storage	• Facility Maintenance Department • Facility Engineering Department • Quality Manager	• Retiring Laboratory Instruments/Equipment
Instrument records are stored indefinitely (or as otherwise directed) after retirement	• Laboratory Supervisor • Laboratory Director • Quality Manager	• Retiring and Archiving Laboratory Records • Retiring Laboratory Instruments/Equipment