Table of Contents

[I. Management of Equipment 2](#_Toc488311077)

[A. Policy 2](#_Toc488311078)

[B. Purpose 2](#_Toc488311079)

[C. Responsibility 2](#_Toc488311080)

[D. Equipment Selection 2](#_Toc488311081)

[E. Equipment Identification 2](#_Toc488311082)

[F. Monitoring 2](#_Toc488311083)

[G. Calibration 2](#_Toc488311084)

[H. Conformance 2](#_Toc488311085)

[I. Storage Devices 3](#_Toc488311086)

[J. Warming Devices (as may be applicable) 3](#_Toc488311087)

[K. Alarm System 3](#_Toc488311088)

[L. Equipment Records 3](#_Toc488311089)

[II. Equipment Repair 3](#_Toc488311090)

[A. Purpose 3](#_Toc488311091)

[III. Equipment Validation 4](#_Toc488311092)

[A. Policy: 4](#_Toc488311093)

[B. Purpose: 4](#_Toc488311094)

[C. Validation Protocol Outline 4](#_Toc488311095)

[D. References: 8](#_Toc488311096)

# Management of Equipment

## Policy

GENETWORx identifies equipment that is critical to the provision of services and ensures that calibration, maintenance, and monitoring of equipment conforms to standards and other specified requirements. The Laboratory uses only state-of-the-art equipment, acquired through business associations that ensure continued support and service throughout each device’s useful life.

## Purpose

This policy provides direction for the processes and procedures to effectively manage the laboratory’s instruments, equipment and computer systems.

## Responsibility

### Each Department is responsible for ensuring the electrical safety, inspection, service, and repair of equipment. Laboratory Supervisors are responsible for retiring equipment from active use.

### The Laboratory is responsible for acquisition/replacement, installation, calibration, maintenance, operation, and troubleshooting of equipment.

### The Information Technology Department is responsible for acquisition/replacement, installation, validation, maintenance and repair of all computer hardware and software in collaboration with the Laboratory staff.

### The Laboratory may collaborate with the manufacturer in the validation and qualification of equipment on installation.

## Equipment Selection

### The Laboratory maintains a process for defining the selection criteria for equipment. Equipment is qualified for its intended use. Devices and equipment are validated. Equipment, including computer hardware is used in conformance with manufacturer’s written instructions.

### The Laboratory Director is required to approve the selection of all clinical laboratory equipment. Approval is documented in Quality Manual Attachment 6.

## Equipment Identification

Critical equipment is given a unique identification.

## Monitoring

The Laboratory maintains a process and schedule for monitoring all critical equipment.

## Calibration

Critical equipment is calibrated and adjusted prior to use, after activities that may affect the calibration, and at prescribed intervals. Calibration equipment is used that has adequate accuracy and precision.

## Conformance

Assessment of conformance of blood, components, tissue, and services is made when equipment is found to be out of calibration.

## Storage Devices

The Laboratory maintains storage devices that have the capacity and design to ensure that the proper temperature is maintained. The Laboratory maintains a process to monitor and record the temperature of storage devices.

## Warming Devices (as may be applicable)

Warming devices are equipped with a visible thermometer and a warning system to detect malfunctions and prevent hemolysis or other damage.

## Alarm System

Blood Bank storage devices (if used) are equipped with alarm systems. The Blood Bank maintains a process for immediate investigation and appropriate corrective action upon activation of the alarm system. (Currently, GENETWORx does not provide any transfusion services.)

## Equipment Records

The following equipment records are kept:

* Equipment identification
* Results of calibrations and follow-up actions
* Results of maintenance and follow-up actions
* Temperatures of heat-regulated equipment

# Equipment Repair

## Purpose

The purpose of this procedure is to monitor, document, and arrange for repair of defective or malfunctioning equipment.

### Preparation

|  |  |
| --- | --- |
| If | Then |
| **Equipment is not functioning properly** | Notify supervisor.  Fill out Equipment/Instrument repair form and contact Tech Service for the instrument. |

### Equipment

### The following is required to perform the procedure:

### Materials

|  |  |  |
| --- | --- | --- |
| Equipment | Materials | Controls |
|  | Equipment/ Instrument Repair Form (Quality Manual Attachment 7) |  |

### Perform this procedure per the following steps:

|  |  |
| --- | --- |
| Step | Action |
| **1** | Fill out form. |
| **2** | Contact Tech service as appropriate. |
| **3** | Post Repair form on defective equipment. |
| **4** | Upon completion of repair, obtain signature of service person and return completed form to supervisor who will place the documentation in the appropriate maintenance log. |

# Equipment Validation

## Policy:

It is the policy of this Laboratory to validate all new equipment. Each section will define specific requirements but will follow the generally outlined protocol below.

## Purpose:

To validate the accuracy of the methods and devices used at GENETWORx, it is imperative that the equipment is installed properly and maintained as the manufacturer indicates.

### Note: Some minor equipment is too simplistic in operation to require this protocol.

## Validation Protocol Outline

|  |  |
| --- | --- |
| **Title** | State the name of the equipment or system being validated |
| **Purpose** | State the process parameters and product outcomes that the validation study will attempt to prove. |
| **System Description** | * Develop comprehensive system description and attach to include: * Description of all subsystems including support systems * Explanation of what the system/process is supposed to do (can be obtained from the manufacturer) * A flow diagram, as appropriate, to explain how the system/process will be used in the Laboratory or facility |
| **Installation Qualification** | **Installation**   * Each piece of equipment that is brought into the laboratory will be installed or set up by the representative (trainer) of that company. * The trainer will demonstrate the device with the appropriate staff. * The trainer will review the manufacturer’s manual with the appropriate staff. * The trainer will answer any questions. * Retain a copy of the trainer’s phone number for future reference. * Complete and mail in the warranty card, if applicable.   **Equipment Stability:**   * Evaluate design issues * Identify critical features that have the potential to affect the process and/or product * Assess the suitability for meeting Laboratory requirements * Determine requirements for * Calibration * Maintenance * Adjustments * Determine adequacy of * Environmental support (weight-bearing, air quality, water) * Utilities (electric, ventilation, humidity, temperature)   **Equipment Repairs:**  Determine requirements for Preventive maintenanceTroubleshootingParts listPost-repair cleaning and calibration **Operating Procedures:**  Write SOPs for CalibrationMaintenanceQuality ControlPerformance MonitoringRevalidation after change or repair **Final Set up**  The instruments/equipment are Set-upTurned onCalibratedTested for functionality All results are documented, signed, and dated. Often the manufacturer will assist in this process. |
| **Study Summary** | Briefly summarize The system/process to be validatedValidation method to be usedNumber of test trialsSampling methodAnalysis methodAcceptance criteria to be satisfied |
| **Acceptance Criteria** | Develop acceptance criteria before the validation study (Refer to CLSI Guidelines EP5-A2, EP10-A2 and GP29-A). Describe how the results will be evaluated to determine if the study was successfulInclude any applications of statistical analysisDefine the acceptance criteria for data collection in each study phaseSpecify allowable run-to-run variationSpecify conditions that will allow one trial or the entire trial validation to be repeated |
| **Responsibilities** | **Supervisor**—develops specific validation protocol  **Supervisor and/or Laboratory Manager—**approve the protocol  **Departmental personnel or other involved personnel**—conduct the study  **Supervisor, Laboratory Manager—**Review and approve study data |

|  |  |
| --- | --- |
| **Validation Plan (Study Procedure/s)** | For each validation protocol, briefly describe the following:Number and qualifications of personnel to execute the protocolEquipment and materials required to complete the studySOPs needed to perform the study and support activitiesCalibration and maintenance required during the studyFor each validation protocol, briefly summarize the following:Number of trialsSample collectionHandlingTesting requirementsThe step-by-step procedure for the following:Conducting the validation studyDocumenting the study data |
| **References** | List all references used to develop the protocol and establish acceptance criteria |
| **Attachments** | The following documents, if used, are attached to the protocol Process flowchartCompleted data formsReference documentsData not captured on study forms (instrument printouts, outside test results, etc)Manufacturers’ forms for documenting protocol |
| **Preliminary review and approval** | Signature block for those responsible for reviewing and approving the proposed protocol before testing actually begins |
| **Test results comparison** | Summarize and compare the actual results with the acceptance criteria. |
| **Study conclusions** | Include the following in conclusions derived from the analysis of the data Explanations of deviations from the expected resultsAssessment of the impact of deviations on the studyExplanation and justification of any revisions to the acceptance criteriaA record of the discussion and evaluation of the dataConclusion as to whether the process can be considered validatedDescription of any limitations on the process |
| **Final review and approval** | Signature block for those responsible for reviewing and approving the entire protocol, results, and conclusions |

## References:

### AABB Association Bulletin 97-4: Quality program implementation. Bethesda, MD: American Association of Blood Banks, 1997.

### NCCLS. Quality system model of healthcare; approved guideline GP26-A. Wayne, PA: NCCLS, 999.

### Nevalainen, David and Berte, Lucia M, Quality Systems for the Laboratory, Chicago, Il: ASCP Press, 2000.

**Revision History**

|  |  |  |  |
| --- | --- | --- | --- |
| Revision Number | Reason for Revision | Author | Effective Date |
| 0 | Original SOP | Bill Miller | Upon Signature |
| 1 | Reformat Quality System, Add CEO signature Line | Sarah Jacobs-Helber | Upon Laboratory Director Signature |

|  |  |  |
| --- | --- | --- |
| **Review & Approval History** | | |
| **Printed Name** | **Signature** | **Date** |
| Sarah Jacobs-Helber, PhD HCLD(ABB), Laboratory Director |  |  |
| William Miller, HTL, MBA Chief Executive Officer |  |  |

**Reviewed by:**

|  |  |  |
| --- | --- | --- |
| **Printed Name** | **Signature** | **Date** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| **Printed Name** | **Signature** | **Date** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |