Pediatric Blood and Marrow Transplant
Adult Blood and Marrow Transplant
Stem Cell Laboratory

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DOCUMENT TITLE:
Instrument Equipment Validation Protocol

DOCUMENT NOTES:

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Protocol Number:

Instrument/Equipment Validation Title:

Prepared By:	Date:
Approved By: Department Supervisor/Manager	Date:
Approved By: Medical Director	Date:
Approved By: APBMT Clinical Quality Program (CQP)	Date:

This form is to be used as a guide in the development of an instrument/equipment qualification protocol. Based on type of qualification to be performed, applicable contents can be imported into an MS Word document to create the protocol and final report.

1. TABLE OF CONTENTS

2. BACKGROUND

2.1 Purpose

Identify the instrument/equipment to be validated. Include all pertinent information to distinguish the instrument/equipment from others of its make and or equivalent design. Specify the intended use for the instrument/equipment and performance requirements.

Table 2.1

Instrument/Equipment Name	
Manufacturer	
Model Number/Unit Type	
Serial Number	
Internal Identification Number	
Location of Instrument/Equipment	
Intended use of Instrument/Equipment	
Performance Requirements	

2.2 Maintenance, Cleaning and Re-Qualification Schedule

Describe plans for maintenance, cleaning, and re-qualification for this instrument/equipment, if applicable.

2.3 Validation Execution Prerequisites

Detail any pre-execution requirements for the validation protocol. This may include verification of qualification status of any equipment/systems required in the execution of protocol, any change controls necessary.

2.4 Supplemental Data/Information

Describe any supplementary data/reports/summaries or company-driven procedures expected. These may be appended to the final report.

3. INSTALLATION QUALIFICATION (IQ)

3.1 Scope and Responsibility

Insert information about scope, such as the test procedures and acceptance criteria specific to this qualification. Identify who will be completing the validation and describe required pre-validation training including who will be conducting the training, if applicable.

3.2 Reference(s)

List any reference standards used for IQ of the instrument/equipment.

3.3 Documentation

List SOPs, attachments, or operator's manuals needed for IQ.

3.4 Installation Checklist for Environmental and Utilities Requirements

List utilities necessary to properly operate the instrument/equipment.

Example:

*The following utilities are necessary to properly operate the **XXX** and are available at the **XXX** location. Refer to Operator's Manual for more information. (Add/Delete as applicable)*

Table 3.1

Utility	***Specification***	***Additional Requirements***	***Utilities as Found***	***Available***
Electricity	*Volts* *Hertz* *Amps*			*Yes No*
Space Requirements				
Humidity				
Ambient Temperature	*Temperature Range:*			*Yes No*

3.5 System Features

Describe system features of the instrument/equipment being validated.

Example:

System features are described in detail in the Operator's Manual. A copy of the manual is located in this document, in Appendix X.

Table 3.2

System Feature	***Specifications***	***Range***

3.6 Uncrating Procedure

Describe steps for uncrating or unpackaging the instrument/equipment. (Refer to operator's manual.) If already in use, state that the instrument/equipment was already in use. List all of the components required to complete the instrument/equipment installation and specify if available.

Table 3.3 Instrument/Equipment Verification

Instrument/Equipment	*Catalogue Numbers*	*Available (circle one)*
		Yes No
		Yes No
		Yes No
		Yes No

3.7 Installation Procedure

List the steps to properly install the instrument/equipment as defined in the operator's manual. If the equipment is portable, refer to the steps in the manual defined for prior to first use, e.g., install a battery, limited assembly, or proper connection to a power supply to perform OQ.

3.8 Calibration/Preventive Maintenance Procedures

Note any special maintenance requirements. Determine if an SOP is needed. Attach calibration certificates as part of the OQ.

3.9 Safety/Environmental Evaluation

Identify any safety features or special safety handling operating requirements here. Identify any special protective equipment that will be needed to operate the equipment. Ensure that any special safety devices have been installed. Identify any special environmental concerns such as disposables, biological or hazardous waste, with a potential release into the environment.

3.10 Spare Parts List

Identify the part number of any spare parts that may be required for the instrument/equipment. If the list is lengthy, ensure that a parts list is copied and attached to a labeled Appendix.

Table 3.4

Spare Part	*Catalogue Number*

3.11 Acceptance Criteria

Table 3.5 *Circle yes/no, as applicable***.**

1. All procedural steps contained in this document have been followed.	*Yes No*
2. Any and all deviations from the approved protocol have been documented and approved.	*Yes No*
3. All applicable space, environmental and utility requirements have been met.	*Yes No*
4. The equipment has been installed or set up according to the manufacturer's instructions. Exceptions have been noted and approved in a deviation report.	*Yes No*
5. All safety, environmental and warranty information have been identified and documented.	*Yes No*
6. Master Equipment List updated.	*Yes No*

4. OPERATIONAL QUALIFICATION (OQ)

4.1 Scope and Responsibility

Insert information about scope, such as the test procedures and acceptance criteria specific to this qualification. Identify who will be completing the work and describe required pre-validation training including who will be conducting the training, if applicable.

4.2 Reference(s)

List any reference standards used for OQ of the instrument/equipment.

4.3 Documentation

List SOPs, attachments, or operator's manuals needed for OQ.

4.4 Test Module Acceptance Criteria

- *All test modules must be performed according to the procedure included in each test module.*
- *Failure of any or all of the replicate data sets to meet acceptance criteria will constitute a trial failure. If a root cause can be found for one trial failure, the single trial is repeated under the corrected condition and with the approval of CQP. If no root cause is found, all replicates must be repeated.*
- *In the event of a trial failure, remedial action taken to correct a given variance shall be undertaken and documented.*

4.5 OQ Procedure

Describe the OQ procedure.

Example:

- *Identify all operational SOPs that are in place or that need to be developed.*
- *Test modules may be listed together or each test module may be given a new number. State whether the modules are to be performed in order or whether they can be performed in any order.*
- *Perform each test module as described. Enter the data in the spaces provided.*

4.6 Verification of SOPs

Define SOPs needed to properly operate the instrument/equipment. Note: These should be approved, or at a minimum drafted, before the qualification can be approved.

Table 4.1

SOP #	***Title***	***Verified***

4.7 Test Modules

List and verify that all required materials/instruments/equipment are present.

Table 4.2

Material/ Instrument/ Equipment	*Manufacturer*	*Model Number/ Catalogue Number*	*Serial Number/Lot Number*	*Expiration Date*	*NIST Certification Number*	*Verified By*

4.7.1 Procedure for the Test Module

Provide details of test module procedure. Write test procedures for general verification that engineering safety controls are working properly, test basic operating functionality critical to its intended use, and verify equipment settings produce reproducible results. Verify any required PPE is available and applicable as indicated.

4.7.2 Results of Test

Record results of the test and initials of persons verifying and checking the results. What mode the instrument/equipment will be left in between the different time intervals should be stated.

4.7.3 Data Analysis

Provide a brief description of the data analysis methodologies to be used.

Example:

Determine the Standard Deviation of the test points to the known weights. Calculations may be performed on separate sheets and appended to this document or written into the module.

5. PERFORMANCE QUALIFICATION (PQ)

5.1 Scope and Responsibility

Insert information about scope, such as the test procedures and acceptance criteria specific to this qualification. Identify who will be completing the work and describe required pre-validation training including who will be conducting the training, if applicable.

5.2 Reference(s)

List any reference standards used for PQ of the instrument/equipment.

5.3 Documentation

List SOPs, attachments, or operator's manuals needed for PQ.

5.4 Test Module Acceptance Criteria

List test module acceptance criteria.

Example:

- *All test modules must be performed according to the procedure included in each test module.*
- *Failure of any or all of the replicate data sets to meet acceptance criteria will constitute a trial failure. If a root cause can be found for one trial failure, the single trial is repeated under the corrected condition and with the approval of CQP. If no root cause is found, all replicates must be repeated.*
- *In the event of a trial failure, remedial action taken to correct a given variance shall be undertaken.*

5.5 PQ Procedure

Provide details of the PQ procedure.

Example:

- *Verify all operational SOPs are approved and in place.*
- *Test modules may be listed together or each test module may be given a new number.*
- *Perform each test module as described. Enter the data in the spaces provided.*
- *Complete the PQ Summary Section. The Supervisor/Manager is responsible for reviewing this report.*

5.6 Verification of SOPs

List SOPs needed to properly operate the instrument/equipment. Note: These should be approved, or at a minimum drafted, before the qualification can be approved.

Table 5.1

SOP #	*Title*	*Verified*

5.7 Test Modules

Verify that all required materials/instruments/equipment are present.

Table 5.2

Material/ Instrument/ Equipment	*Manufacturer*	*Model Number/ Catalogue Number*	*Serial Number/Lot Number*	*Expiration Date*	*NIST Certification Number*	*Verified By*

5.7.1 Procedure for the Test Module

Provide details of the test and initials of persons verifying and checking the results. State what mode the equipment will be left in between the different time intervals.

5.7.2 Results

Record results of the test and initials of persons verifying and checking the results.

5.7.3 Data Analysis

Provide a brief description of the data analysis methodologies to be used.

Example:

Determine the Standard Deviation of the test points to the known weights. Calculations may be performed on separate sheets and appended to this document or written into the module.

6. AMENDMENT REVISION HISTORY (AS APPLICABLE)

Provide a brief description of the change(s) from the previous review and approval. Include justification for the change(s).

7. FINAL PROTOCOL SUMMARY REPORT

A final summary report should be generated after execution of the protocol. The final report will include completed tables with data and other information as described in the protocol. In addition, summaries, conclusions, and recommendations should also be included.

7.1 Non-Conformances

Describe any protocol generation errors, non-conformances, or deviations that occurred during execution of the protocol. Minimally, this will also include an assessment/justification of any perceived impact to the qualification of this instrument. If no instances of non-conformance are noted, thus deviations are not required, this rationale should be stated within the summary report.

If, during the execution of a validation protocol, there is a deviation from an existing, effective version of an SOP in MasterControl, a formal deviation and investigation report, per COMM-QA-042 Deviations and Investigations, will be launched and referenced. All events associated with the execution of a validation protocol must be closed before signoff of the associated validation summary report.

***NOTE**: If a deviation is launched within MasterControl, this number must be referenced in the validation summary report. See COMM-QA-044 Approaches to Validation for clarification on requirements for situations when a MasterControl event is required.*

7.2 Post-Execution Requirements

Following execution of the validation protocol, describe in the report if any change control requests are necessary as a result of this validation in order to ensure the validated parameters/processes are incorporated into applicable SOPs/batch records. If change controls are not determined to be necessary, this rationale should be stated within the summary report.

***NOTE**: If a change control request is launched within MasterControl, this number must be referenced in the validation summary report.*

Signature Manifest

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