Clinical Process Instruction Manual

General Equipment Process Instruction

Policy:

All equipment used to recover, package, process and store tissue or blood will be appropriately sized, designed and located to facilitate use, cleaning and maintenance. The equipment must be operated according to manufacturer's specifications, cleaned, calibrated and regularly scheduled preventative maintenance must be performed.

Trillium Gift of Life Network (TGLN) monitors clinical equipment to ensure that the equipment is able to perform as per its intended use. Regular calibration of the clinical equipment is determined based on the manufacturer's recommendation and according to the manufacturer's recommended intervals. If the accuracy and precision limits are not met during a calibration, remedial action is taken to investigate the cause and evaluate if any adverse effects on quality have occurred. The Inventory Assistant (IA) or designate will establish and maintain all equipment files. The equipment file for each equipment model will have an *Equipment Profile* (see Exhibit 1) which will outline all required actions and activities that need to be performed on that particular piece of equipment. Documentation of equipment activities will be maintained in the equipment files for 16 years.

Process:

Equipment Selection

1. All equipment will be evaluated prior to purchase to determine it is appropriate for its intended function.

2. Prior to using the equipment or putting it into circulation, it will be qualified consistent with the manufacturer's recommendations and checked that it can perform as per its intended use.

Operation

3. Equipment should be operating in adherence to the manufacturer's recommendations.

4. When performing a procedure that requires operation or administration of a piece of equipment, the manufacturer's operational instructions for that procedure should be followed (i.e., centrifugation of blood).

5. Particular pieces of equipment, depending on their complexity of its operation, may have their own individual instructions.

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Cleaning

6. Equipment shall be cleaned or decontaminated at appropriate intervals to prevent malfunction, contamination or cross contamination or accidental exposure. See *Surgical Instrument Handling and Sterile Re-processing Process Instruction, CPI-9-539*.

Preventative Maintenance

7. If applicable, preventative maintenance will be performed according to each *Equipment Profile*.

8. The IA or designate will determine if the preventative maintenance is required based on the manufacturer's recommendations for the optimal operating conditions of the equipment.

Calibration

9. Specific equipment must be routinely calibrated. This will be documented in the *Equipment Profile.*

10. Upon major repair or relocation, the equipment should be re-calibrated where applicable to ensure it operates within the manufacturer's specifications.

11. Calibration may be contracted to an approved vendor. The *Tissue Equipment Maintenance Log CSF-9-144 (Exhibit 2)* should be used to document when the equipment is calibrated. The contractor will also provide calibration documentation.

12. Both the *Tissue Equipment Maintenance Log CSF-9-144* and the calibration documentation provided by the contractor must be filed in the equipment file.

13. A schedule must be maintained for applicable equipment on when calibration and service activities are due.

Requalification and Recalibration

14. If a piece of equipment breaks or has a system upgrade, that equipment will be required to be re-qualified and/or re-calibrated when required to ensure that it is in compliance with the manufacturer's requirements and specifications. This will be documented in the *Tissue Equipment Maintenance Log CSF-9-144.*

Record Retention

15. The owner's manual and all related documentation will be kept with the equipment file.

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Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Tissue Equipment Maintenance Log	CSF-9-144	Tissue Department	Tissue Department	16 years
Equipment Profile	CSF-9-145	Tissue Department	Tissue Department	16 years

References:

- See *Surgical Instrument Handling and Sterile Re-processing Process Instruction, CPI-9-539.*
- Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. J5.000, J5.100, J5.200, J5.300, J5.310, J5.400.

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Exhibit 1: Equipment Profile

CSF-9-145

Ontario
Trillium Gift of Life Network

Equipment Profile

Equipment type	
Manufacturer	
Serial Number	
TGLN Identifier	
Does this type of equipment require its own CPI?	☐ Yes ☐ No **CPI Number:** _____
Equipment cleaning required?	☐ Yes ☐ No **Time Interval:**_____
Preventative Maintenance required?	☐ Yes ☐ No **Time Interval:**_____
Validation required upon installation?	☐ Yes ☐ No
Calibration required?	☐ Yes ☐ No **Time Interval:**_____
If equipment malfunctions or breaks: 1. **Re-qualification required?** 2. **Re-calibration required?**	1. **Yes / No** 2. **Yes / No**

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Exhibit 1: Tissue Equipment Maintenance Log

CSF-9-144

Ontario
Trillium Gift of Life Network

Tissue Equipment Maintenance Log

Name of Equipment		Manufacturer's contact details:	
Label:		Date of purchase:	
Serial number:		Role responsible for equipment:	
Manufacturer:		Date put into service:	

Date:	Maintenance Description	Maintenance Performed by:	Date of Qualification Before Put Into Service:	Qualification Performed by:	Next Maintenance Planned on (date):	Remarks: