



Clinical Process Instruction Manual

Tissue Refrigerators and Freezers Process Instruction

Policy:

All refrigerators and freezers used for the storage of tissue, reagents, media, or other solutions must be temperature controlled, continuously monitored and maintained within the appropriate ranges as defined by the process. Tissue freezers and refrigerators shall not be utilized for the storage of food and/or liquids for human consumption and shall be marked accordingly.

Trillium Gift of Life Network (TGLN) monitors equipment to ensure that required environmental conditions are maintained. Accordingly, TGLN verifies proper functioning of fridges and freezers used for storing temperature-sensitive supplies. Temperature recordings are documented and retained. If there is any indication that temperature ranges are not maintained, observations are noted and the appropriate person is notified. The Inventory Assistant (IA) or designate is responsible for performing the monitoring of temperature in tissue refrigerators and freezers process.

Process:

1. All refrigerators and freezers used in the tissue program to store supplies will be labeled to indicate that the refrigerator/freezer is not to be utilized for the storage of food and/or liquids for human consumption.
2. All refrigerated and frozen supplies must be maintained in a clean and orderly manner to maximize space and facilitate inventory accessibility.
3. The intended operating range of the tissue refrigerator is 2°C to 8°C and the intended operating range of the tissue freezer is -10°C to -25°C.
4. Temperature monitoring of the refrigerator and freezer is required and is monitored continuously via an automated electronic monitoring system. Temperature monitoring of the refrigerator and freezer will be completed manually on a daily basis in the event of a sensor failure.
5. If the automated electronic monitoring system is not working or is not being used for that particular refrigerator/freezer, the temperature must be monitored manually. Steps 9 - 14 are followed below.
6. The IA or designate is responsible for ensuring that the refrigerators and freezers are in compliance. The IA or designate will be alerted if the temperature of the refrigerators or freezers goes below or above the specified range longer than 30 minutes.
7. Any activity such as re-stocking and cleaning which causes the system to alert will be recorded in the Electronic Monitoring Note Log or in case of a power outage under the comments section of the *Refrigerator/Freezer Temperature Log*. See Exhibit 1.



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8. When the IA or designate receives an alert during or after office hours that the temperature of the refrigerators or freezers has gone below or above the specified range, the IA, TRC or designate will troubleshoot the issue as per *Appendix 1, Troubleshooting Refrigerator/Freezer Alerts*. Alerts do not need to be documented as long as it returns to normal temperature within 6 hours.

Manual Daily Temperature Monitoring for Refrigerators (if applicable):

9. Temperature monitoring must be carried out using a calibrated thermometer.
10. Calibrated thermometers must be monitored daily and recorded legibly on the *Refrigerator/Freezer Temperature Log*.
11. Any activity such as re-stocking and cleaning which may affect the temperatures will be recorded under the comments section of the *Refrigerator/Freezer Temperature Log*.
12. Acceptable range for refrigerators is +2°C to +8°C. If the temperature is out of the recommended range due to a specific reason, then action taken to resolve this issue should be recorded under the comments. For example, if re-stocking was performed then closing the refrigerator to allow it go back to appropriate temperature range should be recorded in the comments.
13. If the temperature reading is out of range for an unknown reason, this should be reported to the direct supervisor/manager and the equipment service provider for the refrigerator. The Tissue Equipment Maintenance Log is completed as per *General Equipment, CPI-9-538*.
14. The person checking the daily readings must sign and date the *Refrigerator/Freezer Temperature Log*.

Quarterly Review of Temperature Monitoring for Refrigerators and Freezers:

15. The IA or designate performs a quarterly review of electronic records. The temperature data is downloaded by the IA or designate to ensure there were no fluctuations within the temperatures. The IA or designate downloads the data in the appropriate location on the common drive.
16. If the temperatures are outside of the tolerances on the chart recorder/electronic data event log, the IA or designate will troubleshoot using the manual appropriate for the freezer or refrigeration unit. If that is unsuccessful, this issue is reported to the direct supervisor/manager and call the equipment service provider. The IA or designate will complete the Tissue Equipment Maintenance Log.



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Preventative Maintenance and Calibration Activities:

17. Preventative maintenance of the refrigerator and/or freezer will be completed twice a year. The IA or designate will complete the form, Tissue Equipment Maintenance Log, when the preventative maintenance is performed.
18. Calibration of the refrigerator is required yearly. If the refrigerator requires service due to a malfunction, the IA or designate will contact the equipment service provider and request a re-calibration. The IA or designate will complete the form, Tissue Equipment Maintenance Log.

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
Refrigerator/Freezer Temperature Log	CSF-9-123	Tissue Department	Tissue Department	16 years
Electronic Monitoring System Log	-----	Tissue Department	Tissue Department	16 years

References:

- *Equipment Maintenance Process Instruction, CPI-9-426*
- Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. J5.300, J5.310, J5.600.



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Exhibit 1: Refrigerator/Freezer Temperature Log



CSF-9-123

REFRIGERATOR/FREEZER TEMPERATURE LOG

Unit #: _____ Range: _____ °C Month: _____ Year: _____

Date	Temp (°C)	Initials	Chart recorder changed or electronic event data printed (weekly)	Initials	Comments
1			Yes / No		
2			Yes / No		
3			Yes / No		
4			Yes / No		
5			Yes / No		
6			Yes / No		
7			Yes / No		
8			Yes / No		
9			Yes / No		
10			Yes / No		
11			Yes / No		
12			Yes / No		
13			Yes / No		
14			Yes / No		
15			Yes / No		
16			Yes / No		
17			Yes / No		
18			Yes / No		
19			Yes / No		
20			Yes / No		
21			Yes / No		
22			Yes / No		
23			Yes / No		
24			Yes / No		
25			Yes / No		
26			Yes / No		
27			Yes / No		
28			Yes / No		
29			Yes / No		
30			Yes / No		
31			Yes / No		



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Appendix 1: Troubleshooting Refrigerator / Freezer Alerts

Issue	Action to be taken	Most Responsible Staff Member	Staff to be Informed
Refrigerator/Freezer door is ajar	Close door	TRC Or Inventory Assistant Or PRC Designate	Office Hours: Inventory Assistant After Hours: TOC PRC
Temperature spike due to restocking of refrigerator /freezer (room temperature supplies were placed in freezer and door was open while products were placed in freezer)	Wait until temperature resets	Staff restocking	Office Hours: Inventory Assistant After Hours: TOC PRC
Calibration issues with monitoring device	Office Hours: Swap out device After Hours: move supplies to properly monitored fridge/freezer	Inventory Assistant or designate	Office Hours: Inventory Assistant After Hours/Weekend: TOC PRC
Calibration issues with refrigerator /freezer	Contact equipment maintenance personnel and move supplies to a working fridge/freezer in the meantime	Inventory Assistant or designate	Office Hours: Inventory Assistant After Hours: TOC PRC
Building Power Outage	Building has a back-up generator. If that is not utilized, TGLN can rent a refrigerator truck to store supplies (supplies can be left outside refrigeration for 5-6 hours)	Office Hours: Inventory Assistant or designate After Hours: TRC or designate	Office Hours: Inventory Assistant After Hours: TOC PRC
If refrigerator/freezer temperature rises without warning and due to an unknown cause	Move supplies to a working refrigerator/freezer	Inventory Assistant or designate	Office Hours: Inventory Assistant After Hours: TOC PRC