Clinical Process Instruction Manual

Tissue Recovery Office Facilities Management Process Instruction

Policy:

Trillium Gift of Life Network (TGLN) provides and promotes a safe working environment by developing, implementing and enforcing safety process instructions as they relate to facilities. Safety process instructions shall include details for contacting emergency personnel and the establishment of evacuation routes and procedures in the event of fire or disaster. All safety process instructions shall be approved and reviewed annually.

Designated space shall be designed or arranged to meet operational needs. Premises shall be maintained in a clean, sanitary, and orderly manner with adequate plumbing, drainage, lighting, ventilation, and space. Adequate, clean, and convenient hand washing facilities shall be available for personnel where applicable.

Process:

1. This process instruction describes the requirements and obligations under the Provincial Occupational Health and Safety regulations and Health Canada requirements as it relates to TGLN facilities and associated processes.

2. To prevent errors and contamination, there are designated spaces for each of the following activities:
   - quarantine storage of in-process materials
   - other quarantining such as supply and reagents prior to approval
   - labelling
   - quality assurance and control functions
   - receipt and storage of supplies, reagents, containers and container labels
   - storage of biohazardous and other medical waste

3. TGLN facilities are intended to store supplies, reagents, in-process tissue and equipment used in recovery operations where there is the potential for cross-contamination. This requires that facilities be subjected to routine, scheduled and documented sanitation procedures. All cleaning events performed by tissue department personnel, shall be documented and retained for sixteen (16) years. Cleaning performed by TGLN staff will be performed on a regular basis, the frequency and cleaning requirements are outlined in CPI-9-548 Routine Cleaning & Quality Control Tasks.

4. All TGLN areas (i.e., administrative and storage) are controlled access and unaccompanied visitors are not permitted. There is controlled access to the entrance to the suite, entrances to Provincial Resource Centre (PRC), entrance to organ/tissue spaces, and entrance to Information Technology rooms (i.e., server room).

5. The PRC and designated tissue spaces are restricted access areas in which unauthorized staff are not permitted entry.

6. The building is responsible for maintaining and providing services relating to plumbing, drainage, lighting, electrical, ventilation, and locksmithing. Equipment maintenance is the responsibility of TGLN. The building maintains a list of contractors who are approved to undertake alterations to the finishes and systems within the building.

7. TGLN uses a recording device (i.e., Cobex, Monnit, etc.) to monitor the temperature and humidity of the supply rooms to maintain required storage conditions for supplies stored at room temperature. If the Cobex system is used, the chart paper must be changed at least once every 7 days. See Appendix 1 for instructions. The Temperature and humidity are also recorded on the *Temperature/Humidity Log for Supply Storage Room.* See Exhibit 1.

   7.1. Tolerance limits have been set for temperature and Relative Humidity (RH) in accordance with supply manufacturer and medical device reprocessing requirements.
   - Temperature: 15 - 25°C
   - RH: ≤ 60

   7.2. Data that falls outside of the acceptable ranges for temperature and humidity are reviewed by the Quality Department to determine if corrective action is necessary. Periodic variances in temperature and humidity ranges are acceptable. However, frequent incidents in which RH rises to between 60% and 70% should indicate that adjustments or improvements to the environment may be necessary.

      7.2.1. If RH exceeds 70%, the Tissue Manager or designate(s) shall be notified as soon as possible and any affected supplies quarantined until supplies can be assessed for moisture. An Incident Intake Sheet (QSF-14-6) is required to be filed for variances more than 24 hours.
      7.2.2. If affected supplies are visibly wet or damaged (e.g. label peeling, visible moisture on the package), the items should not be used. Contents should be sent for re-sterilization or discarded if they are single-use medical devices.
      7.2.3. If affected supplies are not visibly wet or damaged, the packages may be used. If the relative humidity reading 24 hours later remains greater than 70%, a risk assessment should be performed to determine which items can be used and which items need to be re-sterilized or discarded.

8. Building management employs qualified tradespeople to oversee or perform any jobs related to these services.

9. In the event of emergency, building management is available to tend to relevant services that are affected.

10. Building management shall ensure that adequate plumbing, drainage, ventilation and lighting are available for a safe and effective work environment.

11. The premises are cleaned 5 days a week by building cleaning staff.

12. TGLN will follow all policies and procedures set forth by building management, including fire, medical emergency, power outage, threat, and bomb threat protocols. The procedures shall conform to relevant legislation such as the *Occupational Health and Safety Act*. TGLN is responsible for providing building management with the names of its fire wardens.

13. All PRC and recovery personnel will be familiar with the policies and procedures set forth by Human Resources. Continuing education shall be documented in the employee's training records to document workplace hazardous materials handling procedure and safety protocol training.

14. TGLN's Occupational Health and Safety Committee shall provide pertinent information regarding proper storage, handling and utilization of hazardous materials, reagents and supplies (WHMIS controlled products).

15. TGLN provides staff with annual Workplace Hazardous Materials Information System (WHMIS) training. Copies of WHMIS training documentation shall be maintained in individual training files. Staff shall be familiar with all WHMIS principles, including the contents and use of the Material Data Sheets (MDS). Staff has access to the MDS manual at all times.

16. Fire safety and security training will be provided on an annual basis and records kept in staff training files.

17. Instructions for contacting staff and the establishment of evacuation routes in the event of natural disaster are provided by building management and posted throughout the TGLN office.

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Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Temperature Humidity Log for Supply Storage Room	CSF-9-184	Tissue Department	Tissue Department	16 Years
Cleaning Log: Quarantine, Storage and Receiving Area	CSF-9-140	Tissue Department	Tissue Department	16 Years
Cleaning Log: Utility Room	CSF-9-142	Tissue Department	Tissue Department	16 Years

References:

- *Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. J2.400 (4 and 5), J3.100, J3.200 (1 and 4), J4.100, J4.200*
- CSA-Z314.23: Canadian Medical Device Reprocessing in all Health Care Settings, Canadian Standards Association, 2023
- 483 Bay Street Occupants Fire Safety Plan
- Building Evacuation Guidelines

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Appendix 1: Changing the CoBex Recorder Charts

Changing the CoBex Recorder Chart Paper

1. Press the “change chart” button #3 (fig. 1).

2. Both pens will begin to move, one at a time, to the left of the chart.

3. Wait until both pens have moved.

4. To remove the chart paper, unscrew the chart “hub” knob at the center of the chart (fig. 2).

5. Remove the old chart paper. Refer to ADM-10-006 for documenting review on back of the chart.

6. Position a new chart paper onto the hub, and ensure the correct time line coincides with the time line groove on the chart plate (fig. 2).

7. Reattach the chart “hub” knob and screw it securely, but not too tight, by hand.

8. Press button #3 again until the pens begin to move back onto the chart one at time.

9. Check to make sure that pens are marking on the chart paper. If not, carefully adjust pen arms to establish contact with paper.

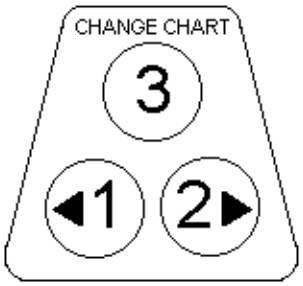

Fig. 1: Change Chart Button

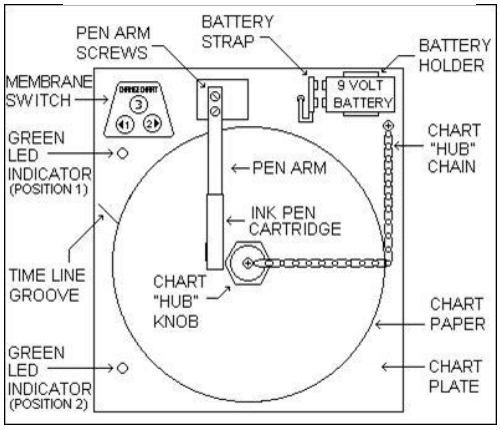

Fig.2: Chart Plate

<u>NOTE</u>:
FOLLOW ONLY THE DIRECTIONS ABOVE FOR CHANGING THE CHART PAPER. IF ANY OTHER COMBINATION OF BUTTONS ARE PRESSED, CALIBRATION OF THE CHART RECORDER MAY BE AFFECTED.

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Exhibit 1: Temperature / Humidity Log for Supply Storage Room

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Trillium Gift of Life Network

CSF-9-184

TEMPERATURE/HUMIDITY LOG FOR RECOVERY SUPPLY STORAGE ROOMS

Month: _____ **Year:**_____ **Circle which room:** Sterile Supply / Clean Supply / Receiving Supply / FSCC Supply Room / FSCC Recovery Room

Name of Recording Chart: _____ **Model #:** _____ **Serial #:** _____

Acceptable temperature range: 15°C - 25°C **Acceptable humidity range:** ≤ 60% RH

Date/Time	Shift	Temperature (°C)	Humidity (%)	Recording Chart Checked (√)	Initials	Comments *if outside of the range, record reason and report to the quality assurance department*
1	Day					
	Night					
2	Day					
	Night					
3	Day					
	Night					
4	Day					
	Night					
5	Day					
	Night					
6	Day					
	Night					
7	Day					
	Night					
8	Day					
	Night					
9	Day					
	Night					
10	Day					
	Night					
11	Day					
	Night					