

Clinical Process Instruction Manual

Facility Management Process Instruction

Policy:

Trillium Gift of Life Network (TGLN) is the source establishment in Ontario for deceased organs. Since the best outcome for the recipients is immediate transplant and minimal cold ischemic time is ideal, organs are typically recovered and transplanted immediately. Therefore, there is no real requirement for an organ storage area. Likewise, any further processing of an organ after recovery is done at the transplant hospital.

On an occasional basis, kidneys and pancreas for islet cells are brought to the TGLN head office, as a temporary storage location, just prior to being transplanted. Since both of these organ types have a longer, acceptable cold ischemic time, it is safe for them both to be temporarily stored at TGLN, while waiting for either test results or for an organ recipient to be identified.

As part of facility management, fridges and freezers are required to be monitored and maintained. Fridges and Freezers are monitored continuously online and may be monitored daily manually if required. On an annual basis, at minimum, fridges and freezers are checked via a preventative maintenance plan by a reputable vendor and calibrated as identified by the preventative maintenance activity. All preventative maintenance activities are documented and retained in equipment files.

Process:

General

1. Environmental conditions at TGLN are maintained by the building maintenance personnel. TGLN's environmental conditions are targeted between 18°C to 25°C and a relative humidity between 20 to 70 per cent.
2. Environmental conditions of the room where surgical supplies are kept are monitored and data is downloaded and kept in an appropriate location by Provincial Resource Centre (PRC) Administrative Assistant – Organ or designate. The *Temperature and Humidity Logs* are reviewed by the Quality Department every 3 months. The acceptable range for temperature is between 13°C to 25°C for the room where surgical supplies are kept. The acceptable range for relative humidity is between 20 to 70 percent. 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 as long as no prolonged variances (more than 6 hours) occur.

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3. As required, all organs are stored in the Cold Storage and Supply room at the TGLN head office.
4. If an organ shows any sign of transmissible disease or positive donor culture results, integrity preventing transmission is maintained through three plastic barriers and a cooler. To identify an organ in this condition, a biohazard symbol is used on the exterior label, which is attached to the cooler.
5. The Cold Storage and Supply room shall be cleaned by building cleaning staff on as required basis.
6. Signs are placed on access points to indicate whether an organ is present or not.
7. If there is an organ in the Cold Storage and Supply room, the Provincial Resources Centre (PRC) staff will flip the sign so that the red 'ORGAN PRESENT' is visible. If there are no organs in the room, the PRC staff will ensure the blank side of the sign is visible. When an organ is present, only PRC staff can enter the room. In these instances, the cleaning staff will skip cleaning the room on that day and will clean it on another day as per their schedule.

Security

8. Access to TGLN is granted to personnel as defined by their job function/role. Key entry/card access is required to enter special controlled areas: inventory area and parking garage.
9. If a person requires different access than is defined by their role, a request to one of the following managers is required by their Manager/Director: Surgical Recovery Services (Organ) Manager, Manager Recovery – Tissue or Ocular Recovery Manager (Recovery Manager). Recovery Managers shall review all requests (new and existing TGLN staff). Upon approval, the Recovery Managers will request Human Resources/Facilities Management to enable access.
10. When personnel roles have been changed, their access shall be reviewed by Human Resources/Facilities Management, their Manager/Director, and the Recovery Managers to ensure their access is appropriate for their new role.

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Online monitoring of Fridges

11. Temperature monitoring of fridges is required and is monitored continuously via an automated electronic monitoring system. Temperature monitoring of fridges will be completed manually on a daily basis in the event of a sensor failure.
12. 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 17-20 are followed below.
13. The Manager, Surgical Recovery Services (Organ), Surgical Recovery Coordinator (SRC) or designate is responsible for ensuring that the fridges are in compliance. The Manager, Surgical Recovery Services (Organ), SRC or designate will be alerted if the temperature of the fridge goes below or above the specified range longer than 30 minutes.
14. Any activity such as re-stocking and cleaning may affect the temperature will be recorded in the electronic log as a comment.
15. When the Manager, Surgical Recovery Services (Organ), SRC or designate receives an alert that the temperature of the fridge has gone below or above the specified range, they shall investigate and determine if the problem can be remediated. If it cannot, then they should move the supplies to a fridge that is compliant and notify the PRC-Organ Coordinator or designate to contact the contracted repair company and notifies the SRC group and the Manager On-Call.
16. The SRC or designate makes note of any maintenance/repair work on the *Equipment Repair/Annual Equipment Service Log*.

Manual Daily Monitoring of Fridges and Freezers

17. The SRC or designate observes the temperature recorded on the digital reading of the fridges and freezer.
18. The SRC or designate compares the digital temperature reading with that of the required limits.

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19. If the temperature is not within its limits or the alarm is sounding and nothing has occurred operationally that would increase the temperature (i.e. opening the door or adding new product), the SRC or designate notifies the contracted company for maintenance/repair as posted on the fridge or freezer.
- In case of complete breakdown or risk to the product, the SRC or designate removes the product and places it on wet ice in the coolers.
 - The SRC or designate places a sign on the fridge/freezer indicating that it is out of service and not to use the fridge/freezer.
 - The SRC or designate contacts the contracted repair company as indicated on the sticker and notifies the SRC (in the case of a designate) and in all cases the Manager On-Call.
20. The SRC or designate makes note of any maintenance/repair work on the *Equipment Repair/Annual Equipment Service Log*.

Temperature Monitoring Record Maintenance

21. Recommended monthly, the temperature data is obtained by the PRC Organ Coordinator or designate and placed in the appropriate location on the shared drive.

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Retention Time (as a minimum)
Temperature and Humidity Logs	-	PRC	PRC	16 years
Equipment Repair/Annual Equipment Service Log	CSF-9-74	PRC	PRC	16 years

References:

- Canadian Centre for Occupational Health and Safety. (2013, April 5). Thermal Comfort for Office Work. Canadian Centre for Occupational Health and Safety. Retrieved October 8, 2013; from <http://www.ccohs.ca>



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- Safety of Human Cells, Tissues & Organs for Transplantation Regulations, Health Canada