Goals:
- To ensure that treatments are performed utilizing an evaluable QA process.
- To ensure proficiency of staff who perform apheresis procedures.
- To ensure procedures are performed utilizing safe and evaluable medical devices.

Apheresis procedures utilize specialized medical devices under the operation of specially trained registered nurses. Most apheresis procedures require infusions of large amounts of blood products. Without the implementation of quality assurance standards the safety and efficacy of these procedures cannot be evaluated.

Purpose:
To develop guidelines of quality assurance for apheresis procedures.

1. Staffing:
- The apheresis physician must have sufficient training and experience in clinical medicine to ensure that the apheresis client’s health care needs are adequately met.
- There must be appropriate physician availability while therapeutic apheresis procedures are being done.
- Apheresis RN’s must be currently certified as registered nurses in the relevant Province.
- Apheresis RN’s must have current BCLS certificates.
- Documentation of ongoing competency of apheresis nurses must be available and up to date.
- Competency must be reviewed annually.
- Continuing education opportunities are made available to meet the needs of apheresis RN’s
- RN’s engage in self-evaluation practices and document evidence of ongoing professional growth on an annual basis.
- There are sufficient personnel with adequate documented training and experience available to meet the needs of the department.

2. Space:
- There is adequate space available to safely perform apheresis procedures and allow for rapid access by emergency medical personnel.
- Fire/smoke detectors are present and functional.
- There is adequate ventilation in the space provided.
o Noise levels are at or below the decibels recommended by occupational health and safety guidelines.
 o The temperature of the room is adequate to maintain comfort for both the client and the health care providers.
 o There is a system in place to summon help in an emergency.

3. Medical devices:
o All medical devices have been tested for electrical current leakage and documented as having adequate grounding.
 o All cell separators have undergone preventive maintenance at least q6months.
 o PM maintenance is documented and records of such retained for a period of not less than 5 years.
 o Apheresis staff performs daily alarm checks.
 o There is documentation of daily alarm checks.
 o If a device does not pass alarm checks there is a documented mechanism to contact service technicians in a timely manner.
 o Service requirements are documented.
 o Machines are cleaned with virocidal solution after each use.
 o There is a mechanism to monitor and document machine efficiency on a regular basis.
 o Temperature controls for blood warmer devices are monitored on a regular basis.
 o Documentation of temperature monitoring for blood warmer devices is available for review.
 o All IV pumps are subject to regular preventive maintenance.
 o All automated blood pressure devices are monitored for ongoing accuracy at least monthly.
 o There is documentation of QC monitoring of automated BC devices.

4. Documentation:
o The apheresis unit should have a clear and easily interpreted organizational chart, which is accessible to all staff.
 o There is a mission and vision statement for the healthcare institution overseeing apheresis procedures.
 o Testing and competency records are kept and updated annually for all apheresis RN’s.
 o Preventive and ongoing maintenance records are maintained for all cell separators, as well as any additional medical devices, utilized by the apheresis unit staff.
Supply documentation records are kept with regard to, record of receipt, lot numbers, expiration dates, and defective products.

Practice guidelines of each type of therapeutic procedure are available.

Practice guidelines for blood product ordering and handling are available.

Practice guidelines for bio-hazardous waste disposal are available.

S.O.P.’s of peripheral blood stem cell processing are available for the following:

- Client assessment
- Procedural
- Labeling
- Transportation to cryopreservation facility.

Adverse events are reported and documented as per institutional guidelines.

Serious adverse events are documented and reported to CAG.

5. Validation:

Validation is the establishment of evidence and records that assure a process, which when followed without deviation, will produce consistent results.

1. References:
