



**NEPHROLOGY PROGRAM  
DEPARTMENT POLICIES AND PROCEDURES**

**Renal Transplant - Section 06 - Quality Assurance - RTP 6-00  
Living Kidney Donation and Transplantation Quality Assurance System  
No.: 01515 (TOH Standardized Policy Number)**

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| <b>ISSUED BY:</b><br>Living Donor Working Group /<br>Renal Transplant Steering Committee  | <b>DATE OF APPROVAL:</b><br>2013/09          |
| <b>APPROVED BY:</b><br>Program Clinical Director and Division<br>Head<br><b>Transplant Medical Director</b><br>Dr. G. Knoll: Signature: <u><i>G. Knoll</i></u> Date:<br><u>/08/2018</u> | <b>LAST REVIEW/REVISION DATE:</b><br>2018/08 |
| <b>CATEGORY:</b><br>Quality Assurance   | <b>IMPLEMENTATION DATE:</b><br>2013/09       |

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**POLICY STATEMENT:**

- The overall goal of the Quality Assurance System is to ensure the delivery of consistently high quality, safe and efficient living kidney donation and transplantation services at the Ottawa Hospital (TOH). The following policy outlines the **quality assurance system** in place that complies with the Canadian Standards Association requirements as outlined in CAN/CSA Z-900.1-12(4.3.1), CAN/CSA-Z900.2.3-12 and Health Canada Guidelines for the Safety of Human Cells, Tissues & Organs for Transplantation (2013) for all activities TOH carries out related to living kidney donation and transplantation.

**DEFINITION(S):**

- Quality assurance (QA) is a shared responsibility among members of the renal transplant program, associated departments, staff and facilities. The Renal Transplant Steering Committee is accountable for implementing, monitoring, evaluating, reporting and corrective action on all activities of the QA system as outlined in [RTP Neph 1-03 Renal Transplant Steering Committee – Terms of Reference](#). The quality assurance system ensures all policies, procedures, processes, products, and services conform to standard operating procedures, and CSA requirements. The Renal Transplant Program maintains records of QA activities for a minimum of ten years. These records are available to authorized individuals for inspection on request.

The QA system includes:

- A. Quality Control (CSA 4.3.2).
- B. Process Control (CSA 4.3.3).
- C. Audits (CSA 4.3.4).
- D. Investigations (CSA 4.3.5).
- E. Personnel Training (CSA 4.3.6)

**ALERTS:** N/A

**PROCEDURE:**

### **Section A: Quality Control (QC)**

The QC functions include:

1. Proficiency testing of personnel to assess competency in procedures they perform and corrective actions implemented for poor performance as evidenced by:
  - a. E-performance appraisals of nursing staff completed annually by Manager, and maintained electronically on TOH Human Resources Information System (HRIS).
  - b. Personnel reviews and signs all new and revised policies/procedures as applicable to roles and responsibilities.
  - c. Registered Nurse annual renewal of College of Nurse of Ontario (CNO) Certificate of registration as per TOH Policy:
    - [Nursing Policy, Procedure and Protocol Manual - Nursing General Policies - Professional Practice - Nursing Registration - Requirements - 00113 \(formerly NSG4C050\)](#)
  - d. Physicians/Surgeons maintain credentialing and privileging as per TOH Policy
    - [Medical Staff Rules and Regulations - Medical Affairs - Credentialing Process – 00132 \(formerly MED RR/009\)](#)
  - e. All personnel adhere to roles and responsibilities as outlined in TOH Policy:
    - Renal Transplant - Section 02 - Clinical Practice - RTP Neph 2-16 Living Kidney Donor Eval and Care Pre and Post Donor Nephrectomy **R = Revision Folder (not posted on myHospital as of yet)**
  - f. The Manager or delegate addresses personnel performance or behaviour not in keeping with expected College Standards, TOH Code of Conduct, as per TOH Policy:
    - [Corporate Policies and Procedures – Human Resources - Disciplinary Process for Unionized Employees - 00361 \(formerly ADM X 200\)](#)

### **Section B: Process Control**

PC Functions include:

1. Environmental/Equipment Monitoring

- a. All personnel are responsible and accountable for reporting any faulty equipment or medical device incidents to Biomedical department as per TOH Policies:
  - [Corporate Policies and Procedures - Property and Services - Equipment Repair - 00227 \(formerly ADMV190\)](#)
  - [Corporate Policies and Procedures - Security and Unusual Occurrences - Medical Device Incidents - 00348 \(formerly ADM IX 121\)](#)
- b. Environmental monitoring maintained as per CSA standards as applicable for sterile packaging, storage and decontamination as per TOH Logistical Services Policy
  - [Logistical Services Policies and Procedures – General Information - Central Processing: Environmental Controls in the Central Processing Department – 00896 \(formerly 1.12\)](#)
  - [Logistical Services Policy and Procedure Manual – Central Processing – Main Operating Room Incident Reports - 1.9](#)
- c. Peri-operative equipment standards maintained and validated for Living Kidney donation/transplantation as per TOH Policy
  - [Corporate Perioperative Program Policies and Procedures - Process for Living Donor \(LD\) Kidney Retrieval, Packaging and Labeling – 01030 \(formerly PS-OR-III-12c\)](#)
- d. Internal Audit of OR environment/equipment monitoring records/processing functions as related to Living Donor Kidney transplantation standards completed bi-annually by Living Donor program delegate and Trillium Gift of Life Network.
- e. Products/storage conditions/expiration dates of reagents and supplies documented as per applicable protocols/policies with validation bi-annually as per LD internal audit.
  - [Corporate Perioperative Program Policies and Procedures – Process for Kidney Retrieval without LifePort – 01029 \(formerly PS-OR-III 12b\)](#)
- f. Validation of laboratory services, procedures, test kit licensing as per CSA regulations during internal audit process.

### **Section C: Audits**

1. Completion of an internal audit of all major components of Living Kidney Donation and Transplantation activities at The Ottawa Hospital bi-annually and performed by an individual not directly responsible for the activities being audited.
2. Scope of the audit includes: processing, evaluation, record keeping, error, accident and adverse reaction reporting, distribution, importation or exportation, complaints and recalls of living kidney organs as per audit template. (Appendix II)

### **Section D: Investigations**

1. Investigations for all errors, accidents, and adverse reaction, complaints and recalls are initiated as outlined in standard operating procedures as follows:
  - [Renal Transplant - Section 05 - Quality Management - RTP Neph 5-11 Living Kidney Donation Error-Accident Reporting Procedure](#)
  - [Renal Transplant - Section 05 - Quality Management - RTP Neph 5-12 Living Kidney Donation Unexpected Serious Adverse Reaction](#)

2. The Medical Director reviews all reports, and ensures any necessary corrective actions are taken and documented.
3. The Renal Transplant Steering Committee, in conjunction with the medical director, approves corrective actions prior to implementation.
4. Files on error, accident, and adverse reaction reporting shall be available for review by site inspectors as required and kept for a minimum of ten (10) years.
5. All positive test results for transmissible diseases in the recipient, where the positive test result is attributed to the living kidney donor organ, is reported in writing in a timely fashion to the establishment and physician involved and to public authorities in accordance with CSA regulations and Public Health requirements.
6. Notification is documented in the donor's record.

#### **Section E: Personnel Training:**

1. Standardized orientation package: includes objectives, evaluation forms, ELM updates
2. OR Review – Kidney ELM Powerpoint, Health Canada (HC) document review
3. Lab/OR Personnel: training: OR Training documents on ELM

#### **RELATED POLICIES / LEGISLATION:**

1. [Corporate Perioperative Program Policies and Procedures - Process for Living Donor \(LD\) Kidney Retrieval, Packaging and Labeling – 01030 \(formerly PS-OR-III-12c\)](#)
2. [Corporate Perioperative Program Policies and Procedures – Process for Kidney Retrieval without LifePort – 01029 \(formerly PS-OR-III 12b\)](#)
3. [Corporate Policies and Procedures – Maintenance and Retention of Policies and Procedures – 00166 \(formerly ADMIII170\)](#)
4. [Corporate Policies and Procedures - Security and Unusual Occurrences - Medical Device Incidents - 00348 \(formerly ADM IX 121\)](#)
5. [Corporate Policies and Procedures – Human Resources - Disciplinary Process for Unionized Employees - 00361 \(formerly ADM X 200\)](#)
6. [Corporate Policies and Procedures - Property and Services - Equipment Repair - 00227 \(formerly ADMV190\)](#)
7. [Logistical Services Policies and Procedures – General Information - Central Processing: Environmental Controls in the Central Processing Department – 00896 \(formerly 1.12\)](#)
8. [Logistical Services Policy and Procedure Manual – Central Processing – Main Operating Room Incident Reports - 1.9](#)
9. [Medical Staff Rules and Regulations - Medical Affairs - Credentialing Process – 00132 \(formerly MED RR/009\)](#)

10. [Nephrology Policies and Procedures - Renal Transplant - Section 01 - Program Description - RTP Neph 1-03 Renal Transplant Steering Committee Terms of Reference](#)
11. Nephrology Policies and Procedures –
12. [Nephrology Policies and Procedures - Renal Transplant - Section 05 - Quality Management - RTP Neph 5-11 Living Kidney Donation Error-Accident Reporting Procedure](#)
13. [Nephrology Policies and Procedures - Renal Transplant - Section 05 - Quality Management - RTP Neph 5-12 Living Kidney Donation Unexpected Serious Adverse Reaction](#)

## **REFERENCES:**

1. CAN/Canadian Standards Association (CSA). Cells, Tissues, and Organs for Transplantation and Assisted Reproduction: General Requirements. CAN/CSA Z900 2.3-03. current.
2. Canadian Standards Association (CSA). Perfusable organs for transplantation. CAN/CSA-Z900.2.3-12. current.
3. Health Canada. Basic Safety Requirements for Human Cells, Tissues and Organs (CTO) for Transplantation, Health Products and Food Branch, current.
4. Health Canada, Guidance Document for Cell, Tissue and Organ Establishments: Safety of Human Cells, Tissues and Organs for Transplantation, current. [http://www.hc-sc.gc.ca/dhp-mps/brqtherap/reg-init/cell/cto\\_gd\\_ld-eng.php](http://www.hc-sc.gc.ca/dhp-mps/brqtherap/reg-init/cell/cto_gd_ld-eng.php)
5. Health Canada Guidance Document for Source Establishments – [Reporting Adverse Reactions to Human Cells, Tissues and Organs](#). Health Canada current.

## **COMMENTS / SIGNIFICANT REVISIONS: N/A**