

Quality System Procedure Manual

Quality System Framework Procedure

1.0 Purpose:

To define the quality system framework that ensures that the services provided conform to specified requirements.

2.0 Scope:

This policy applies to:

- Trillium Gift of Life Network (TGLN)

3.0 Responsibilities:

Director Quality is responsible for:

- Ensuring that the complete quality system is maintained

Management is responsible for:

- Ensuring that all employees follow the procedures detailed in the quality system
- Providing the necessary resources and support
- Maintaining and improving the quality system

All employees are responsible for:

- Following documented procedures and process instructions

4.0 Procedure:

General

4.1 TGLN will manage its quality system to ensure:

- TGLN Quality Policy is maintained
- Health Canada, Safety of Human Cells, Tissues and Organs for Transplantation Regulations and the ISO 9001:2008 (E) Quality Standard form the minimum basis of the TGLN Quality System

4.2 Quality System documentation includes:

- *Quality Policies*
- *Quality System Procedures*
- *Quality Process Instructions*
- *Clinical Process Instructions*
- *Operations Process Instructions*
- *Transplant Process Instructions*

Quality System Procedure Manual

Quality System Framework Procedure

4.3 System is implemented and maintained.

Quality System Documentation

4.4 TGLN policies, procedures and process instructions are tools used to achieve the quality policy objectives.

4.5 The documented quality system is consistent with an emphasis on preventive actions while not sacrificing the ability to respond to quality problems and to take appropriate corrective actions.

4.6 All documentation in the quality system is consistent with the requirements of the Health Canada, 2007 Safety of Human Cells, Tissues and Organs for Transplantation Requirement and the *ISO 9001:2008(E) Quality Standard*.

Documentation Structure

4.7 TGLN has documented its quality system in four (4) tiers:

Tier 1: *Quality Policy Manual*

Tier 2: *Quality System Procedure Manual*

Tier 3: *Quality Process Instruction Manual*

Tier 4: *Clinical Process Instruction Manual / Operations Process Instruction Manual / Transplant Process Instruction Manual*

4.8 References are provided within the four (4) tiers of documentation to simplify and link the documentation within the system.

4.9 Procedure documentation as described in *Document and Data Control QSP-5-1* are used to ensure control of all documents within the quality system.

Quality Policy Manual

4.10 The Quality Policy Manual is intended to describe the policies of TGLN in accordance with the requirements of the *ISO 9001:2008(E) Quality Standard*. The layout of the quality system follows the element descriptions of the *ISO 9001: 1994 (E) Standard*.

4.11 The Quality Policy Manual also provides a description of the system to serve as a permanent reference point for the implementation, maintenance, auditing and evaluation of the system. A secondary purpose of the manual is to demonstrate to our customers that a comprehensive quality system is in place at TGLN.

Quality System Procedure Manual

4.12 Quality system procedures are documents that specify the purpose and scope of the activities; what shall be done and by whom; where it shall be done; what

Quality System Procedure Manual

Quality System Framework Procedure

materials, equipment and documentation shall be used; how activities are to be performed; and how the procedures shall be controlled.

Quality Process Instructions

- 4.13 Quality process instructions are documents that further detail the who, what, when, where and how of subjects that are mentioned in the corresponding quality system procedures.
- 4.14 Depending on the level of detail required or on the preferred organization of the quality system documentation, quality process instructions may be included as part of the quality system procedures or may be stand-alone documents.

Clinical Process Instructions

- 4.15 Clinical Process Instructions are documents that further detail the who, what, when, where and how of clinical processes that are performed. These process instructions are referenced by the quality system procedures.

Operations Process Instructions

- 4.16 Operations Process Instructions are documents that further detail the who, what, when, where and how of operations processes that are performed. These process instructions are referenced by the quality system procedures.

5.0 Records:

No records.

6.0 References:

- *Document and Data Control Procedure, QSP-5-1*
- *Quality Records Procedure, QSP-16-1*