

Quality System Procedure Manual

Management Responsibility Procedure

1.0 Purpose:

To define the policy for the management of the quality system.

2.0 Scope:

This policy applies to:

- Trillium Gift of Life Network (TGLN)

3.0 Responsibilities:

Director Quality is responsible for:

- facilitating the development of the quality management system
- providing governance over quality
- maintaining the quality system

4.0 Procedure:

4.1 Responsibility and Authority

The responsibility of all personnel who manage, perform and verify work affecting quality is defined below. The inter-relationship of these positions is defined on the organization chart in Exhibit 1.

All Clinical Employees

- perform processes as described in the TGLN quality system documentation
- identify and record any problems relating to services provided
- maintain records which demonstrate conformance to the requirements of the quality system
- provide input to annual training plans and take training to improve their skills

Clinical Managers and Directors

- ensure that staff perform clinical processes and maintain required records, per the quality system documentation
- monitor relevant clinical performance indicators
- initiate, recommend or provide solutions to quality system nonconformances through designated channels
- maintain records which demonstrate conformance to the requirements of the quality system operation

Vice President, Clinical Transplant Systems

- ensures that the organization is supportive of the quality policy and its objectives.
- ensures that the necessary resources of people, equipment and systems are provided to maintain and improve the quality system

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- confirms that clinical services are performed according to requirements

President & CEO

- ensures that the organization is supportive of the quality policy and its objectives
- ensures that the necessary resources of people, equipment and systems are provided to maintain and improve the quality system

Director Quality

- establishes, plans and implements internal quality audits to determine effectiveness of the quality system
- maintains core quality system records
- spearheads continuous improvement process
- maintains the integrity of the quality system documentation
- recommends the necessary resources of people, equipment and systems are provided to maintain and improve the quality system
- coordinates the implementation of corrective and preventive actions
- ensures that quality records are maintained which demonstrate conformance to the requirements of the quality system operation

Manager with Executive Responsibility

For the purpose of TGLN's Quality System, Management with executive responsibility includes the:

- President
- Vice-President of Clinical Transplant Systems
- Vice-President of Clinical Donation Services
- Director, Quality and Performance Improvement

4.2 Verification Resources and Personnel

TGLN is committed to identifying the in-house verification requirements, providing adequate resources and assigning trained personnel for the quality system verification activities.

4.2.1 The areas of in-house quality system verification include the following, as a minimum:

- donor assessment screening
- internal audits

4.2.2. The primary resources used in the verification activities include, as a minimum:

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- Quality Policy, Quality System Procedure, Quality Process Instruction, Clinical Process Instruction and Operations Process Instruction documents
 - trained personnel
 - trained internal auditors
 - computer systems
- 4.2.3 All clinical employees assigned to perform verification activities are trained according to the training-related, Clinical Process Instructions.
- 4.2.4 Quality system internal audits are carried out by personnel independent of those having direct responsibility for the work being performed.
- 4.3. Communication of Organizational and/or Service Changes
- 4.3.1. Organizational changes within TGLN are communicated by the most appropriate management person.
- Board of Directors communicates any President and CEO changes.
 - Resident and CEO communicates any Senior Leadership Team changes.
 - Vice-Presidents communicates organizational changes of their direct reports.
 - Directors, Managers communicate organization changes of their direct reports.
- 4.3.2. Organizational changes of the Senior Leadership Team are communicated to both employees and to external stakeholders, including as a minimum, hospital transplant programs, donor hospitals, tissue banks, and the American Association of Tissue Banks (AATB).
- 4.3.3. Service changes within TGLN are communicated to both employees and external stakeholders identified above.
- 4.3.4. Tools to communicate either organizational or service changes include emails and letters.
- 4.4 Resources and Work Environment
- The Senior Leadership Team is responsible for ensuring that adequate resources (time, materials, personnel and financial) are made available to operate an effective quality system. They are also responsible for ensuring that the facilities where staff perform work are adequate for the duties performed, with a satisfactory work environment.

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4.5 Quality Management Representative

The Director Quality is TGLN's Quality System Management Representative. He/she has the responsibility and authority to ensure that the requirements of TGLN's quality system are implemented and maintained. Specific responsibilities of the quality system management representative include, as a minimum:

- quality system is developed, implemented and maintained in all departments
- quality system audits are carried out effectively
- the implemented quality system complies with external stakeholder and legislative requirements
- continuous improvement processes are effectively implemented

5.0 Records:

No records.

6.0 References:

No references.