Quality System Procedure Manual

Document and Data Control Procedure

1.0 Purpose:

To describe the process for creating, reviewing, revising, maintaining and controlling all quality system documentation and data.

2.0 Scope:

This procedure applies to:

- Ontario Health- Trillium Gift of Life Network (OH-TGLN)

3.0 Responsibilities:

Quality Authority or designate is responsible for:

- maintaining and updating the master copy of all documentation under his/her guardianship
- ensuring documents are available during normal hours of operation
- ensuring that the *Controlled Documentation Distribution Log* is kept up-to-date
- ensuring that all controlled quality documents are reviewed annually and that the *Quality System Documentation Review Form* is updated
- ensuring that all document changes are logged on the *Document Revision Log*
- ensuring that all new documents and document changes are communicated
- determining the impact of revisions on other quality systems documentation
- developing an approved schedule for the release of any controlled documentation revisions when notified of any Canadian Standards Association (CSA) Standard related updates occur
- ensuring that any CSA standard pertinent documents are published before Health Canada's required go-live date

Organ/Tissue/Hospital Program/Professional Practice/Medical Authorities are responsible for:

- reviewing proposed changes to documents submitted by employees
- submitting proposed document revisions under his/her responsibility to the Quality Authority
- approving new controlled documents and revised ones under his/her jurisdiction
- reviewing documents under his/her jurisdiction on an annual basis, to determine whether or not they are current
- determining the impact of revisions on other quality system documentation

Employees are responsible for:

- reading and following the documented processes, for which the "Responsibilities" section describes their role
- using all relevant, controlled versions of the documentation when carrying out their assigned responsibilities
- communicating proposed document revisions to the Quality Authority and/or the appropriate TGLN authority

4.0 Procedure:

General

4.1. Controlled documents are ones which provide instructional value and have a mechanism to ensure that all copyholders are updated automatically when a revised version is released. Examples of controlled documents include procedures, standards, forms, checklists and regulations, to name just a few. Controlled data is information that is secure from being altered, from which decisions are made. Examples of controlled data include electronic databases, as a minimum.

4.2. The controlled documentation and data which is used at TGLN includes the following, as a minimum:

Document/Business Systems Name	***Media Type (Master Copy)***	***Controlled By***
Documents		
Quality Policy Manual	Electronic	TGLN
Quality System Procedure Manual	Electronic	TGLN
Quality Process Instruction Manual	Electronic	TGLN
Clinical Process Instruction Manual	Electronic	TGLN
Operations Process Instructions	Electronic	TGLN
On-Line Resources Centre Documents	Electronic	TGLN

Safety of Human Cells, Tissues and Organs (CTO) for Transplantation Regulations	Electronic	Health Canada
Cells, tissues, and organs for transplantation: General requirements	Electronic	Canadian Standards Association
Perfusable organs for transplantation	Electronic	Canadian Standards Association
Tissues for transplantation	Electronic	Canadian Standards Association
Ocular tissues for transplantation	Electronic	Canadian Standards Association
Trillium Gift of Life Network (TGLN) Act	Electronic	Government of Ontario
Coroner's Act	Electronic	Government of Ontario
College of Nurses Standard	Electronic	College of Nurses Ontario
ORNAC Standards	Electronic	Operating Room Nurses Association of Canada
Standards for Tissue Banking	Electronic	American Association of Tissue Banks
External Organ Recovery Program Procedures	Electronic	External Organ Recovery Programs
Document/Business Systems Name	***Media Type (Master Copy)***	***Controlled By***
Business Systems		
TOTAL	Electronic	TGLN
iTransplant	Electronic	TGLN
Telephone System	Electronic	TGLN
E-mail	Electronic	TGLN

4.3. *The Quality Policy Manual, Quality System Procedure Manual, Quality Process Instruction Manual and Clinical Process Instruction Manual* are all controlled, using the methodologies outlined in this procedure. All controlled documents are identified on the *Controlled Documentation Distribution Log*, *QSF-5-1*. See Exhibit 1.

4.4. The standards, acts and regulations used by the various departments are developed and controlled by several governmental, healthcare and regulatory authorities. For some standards and regulations, TGLN is a controlled copy recipient. As revisions occur, these documents are kept up to date by the originating healthcare and government organizations that created them. These organizations send revised documents to TGLN document holders, who are designated controlled copy recipients.

4.5. All TGLN-originated business systems are controlled by TGLN. The data storage, maintenance and access to these business systems are further detailed in the *Business System Data Control Process Instructions*, *QPI-5-1*.

4.6. Each quality policy, quality system procedure, quality process instruction and clinical process instruction is reviewed at least once every two years by the appropriate TGLN Authority or his/her designate or the Quality Authority to ensure that it continues to conform to the customer's needs, Health Canada's requirements and TGLN's needs. Tissue program related documents are reviewed annually to meet the American Association of Tissue Banking (AATB) requirements. To provide evidence of these reviews, a form entitled *Quality System Documentation Review*, *QSF-5-2* is used. See Exhibit 2. The Quality Authority is responsible for ensuring that this activity is conducted and maintaining the records of these reviews.

4.6.1. Any documents identified as having sufficient medical risk are reviewed annually by the Medical Authority in addition to the TGLN Authority or designate.

4.7. All forms with a number identification, which are used to collect data regarding quality system procedures, quality process instructions, clinical process instructions and operations process instructions are controlled.

4.8. Approved master copies of the quality policies, quality system procedures, quality process instructions, clinical process instructions and operations process instructions are stored on TGLN's network system. The documentation guardian for the master copies of the quality policies, quality system procedures, quality process instructions, clinical process instructions and operations process instructions is the Quality Authority. Only the Quality Authority and his/her designate(s) have access to the controlled versions of the documents.

4.9. All copies of quality documents printed off from TGLN's network system are considered to be uncontrolled.

4.10. The revision history of all quality policies, quality system procedures, quality process instructions, clinical process instructions and operations process instructions is captured on a form entitled Document Revision Log, QSF-5-3. See Exhibit 3.

4.11. All quality policy, quality system procedure, quality process instruction, clinical process instruction and operations process instruction manuals are accessible to all employees during normal hours of operation.

Quality Document Approvals

4.12. Each controlled quality document has been reviewed to determine the TGLN staff member who has the expertise to approve the document on behalf of the organization. While Health Canada refers to these positions as Medical Directors/Scientific Directors, TGLN refers to these positions as Authorities. Outlined below are the TGLN Authorities about which all documents have been categorized.

- *Medical Authority* — Licensed Physicians acting as TGLN's Chief Medical Officers (CMO) approve all documents that contain sufficient medical risk (this excludes the on-call CMOs)
- *Organ Authority* — Director Provincial Resource Centre (PRC) or Manager PRC - Organ approves all organ-related documents
- *Tissue Authority* — Director Provincial Resource Centre (PRC) or Manager PRC - Tissue approves all tissue-related documents
- *Hospital Program Authority* — Director Hospital Programs or Manager Hospital Programs approves all hospital program-related documents
- *Professional Practice Authority* — Director Hospital Programs or designate approves all clinical-related, training, education, competency and public reporting documents
- *Quality Authority* — Director Quality or designate approves all quality framework documents
- *Senior Director* — Senior Director or designate approves all corporate related documents
- *Digital Health Authority* — Director Digital Health or designate approves all IS documents
- *Other* — To be determined, as required

4.13. In the event that a document covers the jurisdiction of more than one TGLN Authority, one Authority will be selected to represent the governance over that document by the Quality Authority.

4.14. For documents that contain sufficient medical risk, the Medical Authority will approve the document, in addition to the TGLN Authority jurisdiction. The Medical Authority will determine which TGLN documents have sufficient medical risk and advise the Quality Authority.

4.15. Quality system documents including all policies, procedures and process instructions, are approved on a *Controlled Document Approvals Form, QSF-5-4*. See Exhibit 4.

Creation and Approval of New Documents

4.16. New quality policy, quality system procedure, quality process instruction, clinical process instructions and operations process instructions are developed using the following methodology:

4.16.1. An employee decides that a document should be written to add to the quality system, for various reasons such as:

- new process has been introduced into TGLN that needs to be documented and communicated
- corrective measure to resolve an existing process issue
- preventative measure to resolve a potential problem area
- improvement idea to streamline current clinical/operations processes

4.16.2. Employee discusses his/her new document idea with the appropriate functional manager and Quality Authority.

4.16.3. Employee writes a draft document, as the author.

4.16.4. The author of the draft document solicits input from other functional representatives, as required and incorporates the input received into the draft document.

4.16.5. The author submits the draft document to the Quality Authority, who has the document reviewed by appropriate TGLN staff/management. The Quality Authority may use a designated meeting, a circulated email or document management system to solicit input, from relevant stakeholders, for the following types of documents:

New Document Type	New Document Reviewers
• Clinical documents	• Quality Authority / Specialist Team
• Clinical documents – potential medical risk	• Quality Authority / Medical Authority/ Specialist Team
• Clinical documents – potential legal risk	• Quality Authority / Corporate Lawyer / Specialist Team / Privacy Officer (if privacy implications)

New Document Type	New Document Reviewers
• Quality framework documents	• Quality Authority / Functional Managers or Specialists
• Corporate documents	• Quality Authority / Vice President representative
• Operations documents	• Quality Authority/Functional Directors
• Other	• To be determined in the future

4.16.6. The Quality Authority incorporates all written input from document reviewers into the draft document, and sends it to the appropriate TGLN Authority who has jurisdiction over the process for final approval.

4.16.7. The Quality Authority is responsible for ensuring that:

- the approved document gets included into the master set of controlled documents
- the *Controlled Documentation Log QSF-5-1* is updated
- the existence of this new document is communicated to the appropriate TGLN employee(s) with a document transmittal

Changes to Quality System Documentation

4.17. Changes to existing quality policy, quality system procedures, quality process instructions, clinical process instructions and operations process instructions are developed using the following methodology:

4.17.1. An employee authors a recommended change to a document.

4.17.2. The employee reviews the proposed change with both the Quality Authority and the applicable Organ/Tissue/Hospital Program/Professional

Practice/Medical Authorities, depending on the scope and risk of the proposed change.

4.17.3. The TGLN Authority who is responsible for the document determines whether the document needs to be reissued immediately or not. A marked-up copy of the affected quality document is provided to the Quality Authority for his/her review.

4.17.4. The Quality Authority will determine the methodology to use to review and approve the revised document, based on the type of revision involved. Either a designated meeting or a circulated email alternative will be used to solicit input from relevant stakeholders, for the following types of document revisions:

Revision Type	Revision Reviewers
• Content changes	• Quality Authority / Specialist Team
• Clarification changes	• Quality Authority / Functional Managers or Specialists
• Typographical/grammatical/format/ minor word changes	• Quality Authority
• Potential medical risk changes	• Quality Authority / Medical Authority / Specialist Team
• Potential legal risk changes	• Quality Authority / Corporate Lawyer / Specialist Team / Privacy Officer (if privacy implications)

4.17.5. The Quality Authority consolidates the revised document feedback received and generates an updated document for review by the original review group, if deemed necessary. This step may be repeated until all the necessary modifications have been made and incorporated into the document.

4.17.6. The Quality Authority sends this revised document to the appropriate Authority who has jurisdiction over the process, for final approval. For document revisions that pertain to typographical errors, grammatical changes, document format and minor word changes, that don't affect any clinical content, the Quality Authority can approve the additions/ deletions/ revisions, in lieu of the designated TGLN Authority, including the Medical Authority.

4.17.7. All new and revised controlled clinical documents are distributed to the affected staff to have the additions/deletions/ revisions "read and understood" before the document is published. A file is kept to demonstrate that the affected staff have performed this task.

4.17.8. The Quality Authority is responsible for ensuring that:

- the approved document is included into the master set of controlled documents
- the *Document Revision Log QSF-5-3* is updated. See Exhibit 3
- the existence of this revised document is communicated to the appropriate TGLN staff with a document transmittal

4.17.9. For minor changes to existing quality system documentation, such as typos, the Quality Authority ensures that the affected documents are updated after a practical number of minor revisions have been logged. He/she will ensure that the logged changes are captured on an uncontrolled copy of the affected document. When these changes are ready to be issued, the same document revision routine is followed, as above, with the exception of the 'read and understand' process. Minor, non-clinical changes to documents do not require the affected staff to 'read and understand' these revisions before they are published.

4.17.10. An assessment of all revisions made to quality system documentation in terms of its impact on other quality systems documentation is made by the Quality Authority. Appropriate actions are taken by the Quality Authority and/or document author to have other quality system documentation revised.

All obsolete documents that are to be retained for information purposes are archived. As a minimum, all versions of quality policies, quality system procedures, quality process instructions, Clinical Process Instructions and Operations Process Instructions are kept for sixteen (16) years after discontinuation. Only the Quality Authority and his/her designate(s) have access to the obsolete versions of documents.

Training in new or revised Quality System Documentation

4.18. All staff are required to "Read and Understand" new documents and revised ones before they are published.

4.18.1. New and revised documents are sent to staff before any documents can be published.

4.18.2. Quality maintains records of documents that have been "Read and Understood".

4.18.3. Tissue Banks are sent clinical process instructions that pertain to the donor assessment or medical social history questionnaire before they are published.

Exceptions

4.19. A draft procedure and/or form may be used while a process is being developed or when circumstances are rapidly changing (e.g. emerging disease, endemic, pandemic, etc.). In these situations, rather than having new or revised document continually updated as a controlled document, the new / revised procedure and/or form can be used initially as an uncontrolled document with the Director of Quality's approval. Once the process or situation has stabilized, the procedure and/or form will proceed with the normal document approval steps outlined above

5.0 Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Controlled Documentation Distribution Log	QSF-5-1	Quality Assurance Department	Quality Assurance Department	16 years
Quality System Documentation Review	QSF-5-2	Quality Assurance Department	Quality Assurance Department	16 years
Document Revision Log	QSF-5-3	Quality Assurance Department	Quality Assurance Department	16 years
Controlled Document Approvals Form	QSF-5-4	Quality Assurance Department	Quality Assurance Department	16 years
Read and Understood Record	_____	Quality Assurance Department	Quality Assurance Department	16 years

6.0 References:

- *Business System Data Control Process Instruction, QPI–5-1*

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Exhibit 1: Controlled Documentation Distribution Log, Form QSF-5-1

QSF-5-1

Controlled Documentation Distribution Log

Location: _____

Document Name	Document ID #	HARDCOPY: Document Holder/Location	ELECTRONIC: Drive ID/Folder

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Exhibit 2: Quality System Documentation Review, Form QSF-5-2

QSF-5-2

Quality System
Documentation Review, Form QSF-5-2
for
____

Year____________________

Document Name	Document ID#	Reviewed By	Review Date

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Exhibit 3: Document Revision Log, Form QSF-5-3

QSF-5-3

Document Revision Log

Package Number: _____ Read and Understand Date: _____ Published Date: _____

Document Name	Document Number	Issue Number	Revision Number	Description of Changes

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Exhibit 4: Controlled Document Approvals Form, Form QSF-5-4

QSF-5-4

Controlled Document Approvals

Document Name	Document # (if applicable)	Approver(s)'s Title	TGLN Authority's Approval	Medical Authority's Approval	Date of Approval