Ontario
Trillium Gift of Life Network

# Quality System Procedure Manual

## Nonconformance Procedure

### 1.0 Purpose:

To describe the methodology of detecting, recording and handling nonconforming processes/services.

### 2.0 Scope:

This procedure applies to:

- Trillium Gift of Life Network (TGLN)

### 3.0 Responsibilities:

Employees are responsible for:

- identifying process and service nonconformances

Managers/Directors are responsible for:

- identifying process and service nonconformances

Director Quality is responsible for:

- identifying process and service nonconformances
- documenting nonconformances and lesson(s) learned
- ensuring that nonconformances and lesson(s) learned are identified, logged, discussed and actioned
- communicating the resolution to nonconformances and lesson(s) learned to employees and customers

### 4.0 Procedure:

***General***

4.1 Nonconformances are identified from the following:

- internal and external audits conducted
- services not conducted according to pre-established processes, standards, regulations or legislation

4.2 The primary causes of nonconformances consist of the following:

- failure to meet the requirements of a service or project
- failure to comply with acts, standards and regulations

- failure to satisfy customer requirements
- failure to follow approved procedures and process instructions

4.3 Nonconformances are minimized due to the following types of communication which are conducted:

- internal meetings
- informal cross-dialogue between functions and between TGLN and stakeholders
- project review meetings

***Nonconformance Methodology***

4.4 A nonconformance is detected by an employee, the customer, or by a regulatory authority and brought to the attention of the Director Quality. Thresholds that define a major nonconformance, also referred to as a "critical incident", consist of one or more of the following criteria:

- recipient safety is at risk
- incorrect organ allocation / loss of organ
- systemic breakdown
- at the discretion of a clinical Vice President, other criteria may be classified as critical incidents.

***Minor Nonconformances and Lesson(s) Learned***

4.5 For nonconformances which do not exceed any one of the thresholds outlined in step 4.4, the following activities occur:

4.5.1 Employee /2nd party customer auditor /3rd party registrar auditor identifies a nonconformance and brings it to the attention of the Director Quality or his designate.

4.5.2 Director Quality or designate logs the nonconformance on the *Lesson(s) Learned Log*, *QSF-13-1*. See Exhibit 1.

4.5.3 Lesson(s) learned may be discussed at the next department meeting or other venue to share with other staff. The root cause of any nonconformance is discussed and the potential solution(s) is brainstormed and recorded.

4.5.4 Manager/director initiates action(s) at the department level to solve issues that are best resolved by him/her.

4.5.5 Evidence of a successful solution to a lesson(s) learned/minor nonconformance is gathered to close-out the nonconformance.

4.5.6 Manager/director initiates a *Corrective Action Report* (CAR) for any nonconformance(s) in which:

- there is a trend of other similar nonconformances
- there are lessons to be learned by all other staff from the logged nonconformances
- the major nonconformance threshold is exceeded, based on the addition of several, similar minor nonconformances

4.5.7 A CAR # is requested to resolve any of the situations above and this number is recorded on the *Lesson(s) Learned Log*, *QSF-13-1*.

***Major Nonconformances***

4.6 For major nonconformances which equal or exceed any one of the thresholds outlined, the following activities occur:

4.6.1 Employee/2nd party customer auditor/3rd party registrar auditor reports the nonconformances to the Director Quality or his designate.

4.6.2 For major nonconformances detected, the Corrective Action process is conducted according to the *Corrective and Preventative Action Procedure*, *QSP-14-1*.

## 5.0 Records:

| Record Name | Form No. (if applicable) | Record Holder | Record Location | Record Retention Time (as a minimum) |
|---|---|---|---|---|
| Lesson(s) Learned Log | QSF-13-1 | Quality Assurance Department | Quality Assurance Department | 16 years |

## 6.0 References:

- No references.

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### Exhibit 1: Lesson(s) Learned Log, Form QSF-13-1

Lesson(s) Learned Log QSF-13-1

**Lesson(s) Learned Log**

| LLL L# | LLL Category | Date Logged | Minor Non-conformance vs. OFI (NC or OFI) | Description of Nonconformance or Opportunity | Logged By | Assigned To | Root Cause | Solution | Status | Date closed | CAR# (if required) | Year | Estimated Completion Date | TGLN# |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
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October 26, 2017