Quality System Procedure Manual

Corrective and Preventative Action Procedure

1.0 Purpose:

To describe the process to mitigate against recurrence of an actual or potential major nonconformance.

2.0 Scope:

This procedure applies to:

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

3.0 Responsibilities:

Director Quality is responsible for:

- ensuring adherence to the *Corrective and Preventative Action Procedure* by pertinent quality staff who action this process
- ensuring that Corrective and Preventive Actions are logged and investigated
- approving corrective and preventive action plans
- assigning corrective and preventive recommended actions to appropriate managers / directors or their designate(s)
- assigning the *Corrective/Preventative Action Report* (CAR/PAR) to the appropriate quality employee(s) to conduct verification and closure of corrective and preventive actions
- approving closure of CARs/PARs

Manager/Directors are responsible for:

- completing recommended action plans documented on CARs/PARs

Employees are responsible for:

- reporting potential major nonconformances, wherever one is identified
- assisting Quality Director or designate in investigating major nonconformances, when required

4.0 Procedure:

Corrective Action Process

4.1 The Corrective Action Process is used for to identify and resolve a major nonconformance. A major non-conformance is defined as “the non-fulfillment of a requirement that is likely to significantly impact the /service’s quality, safety and compliance”. The Corrective Action process is used in conjunction with one of the following situations:

- Standalone Corrective Action Report (CAR) investigation with no prior internal investigative report or reported, adverse findings from an external stakeholder
- Internal incident investigation has been conducted or have received investigation, adverse findings from an external stakeholder

CAR Process – No Investigative Report already Conducted or no External Findings Provided

4.2 The quality department receives verbal or written notification of an incident or an audit report, for which it is believed that a major non-conformance occurred.

4.3 Director Quality performs a preliminary investigation into the potential major non-conformance, to determine if a corrective action process is warranted.

4.4 If a CAR is warranted, the Director Quality assigns an investigator from the Quality Department.

4.5 Director Quality or designate assigns a CAR number to have the problem resolved. The CAR is recorded in the *Corrective Action Report Directory*, *QSF-14-2*. See Exhibit 2.

4.6 CAR Investigator ensures that the following are documented on the *Corrective/Preventative Action Report, QSF-14-1*. See Exhibit 1.

- CAR #
- Date Logged

- CAR Initiator
- Department Name, Location
- Problem Description
- CAR Investigator and Due Date

4.7 CAR Investigator documents the following on the CAR upon completion of the investigation:

- root cause(s) of the problem
- corrective/preventative action(s) to be taken

4.8 The recommended CAR action plan is approved by the Director Quality. The Quality Director or designate distributes the approved CAR to the appropriate process owner(s).

4.9 The corrective action is implemented by the appropriate process owner. Evidence of completion of assigned action items are submitted to the Director Quality or designate.

4.10 The Director Quality reviews the evidence and determines the verification period and verification plan.

4.11 The Investigator documents the following on the CAR as determined by the Director Quality:

- verification period
- verification plan for the proposed corrective action

4.12 The Director Quality or designate performs the verification. Evidence of a successful resolution to a CAR is gathered so that it can be closed-out.

4.13 Director Quality closes out the CAR by approving and dating it. The CAR is then closed-out in the CAR Directory.

4.14 For permanent changes, new or revised quality system documentation may be needed. As required, the Director Quality or designate documents the identification number of the document to be created or revised on the CAR. He/she directs this

action request to the appropriate employee, to have the required quality system documentation created or revised.

4.15 The original CAR, complete with supporting evidence, is filed in the Quality Assurance Department.

CAR Process – Incident Investigative Report Already Conducted or External Findings Provided

4.16 The quality department issues a Critical Incident report which includes recommendations or receives an external stakeholder's findings about an adverse process/event that needs to be corrected.

4.17 The assigned CAR investigator documents a *Corrective/Preventative Action Report, QSF-14-1* using information from the published report or external.

4.18 The CAR Investigator completes steps 4.5 to 4.13

Preventative Action Process

4.19 All managers/directors and/or their designates are responsible for identifying future potential major nonconformances and potential solutions that could be used to prevent internal nonconformances, customer and/or supplier complaints from occurring.

4.20 All employees who identify a need for preventative actions advise the Director Quality. Upon review of the data supplied, the Director Quality issues a Preventative Action Report (PAR) to the appropriate employee(s) to have the potential problem/defect resolved, when appropriate.

4.21 A preventative action process is conducted following the previously defined steps from 4.1 to 4.15, as deemed applicable.

5.0 Records:

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Corrective / Preventative Action Report	QSF-14-1	Director Quality	Quality Assurance Department	16 years
CAR/PAR Directory	QSF-14-2	Director Quality	Quality Assurance Department	16 years

6.0 References:

- None

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Exhibit 1: Corrective / Preventative Action Report, Form

QSF-14-1

CORRECTIVE / PREVENTIVE ACTION REPORT

CAR/PAR #: _____ Date Logged: _____

CAR/PAR Initiator: _____ TGLN #: _____

Corrective/Preventative Action Report Initiated By:		
☐ Critical Incident	☐ Stakeholder Audit	☐ Preventative Action
☐ Stakeholder Complaint	☐ Health Canada Inspection	☐ Other
Problem Description:		
CAR/PAR Investigator:		Due Date:
Root Cause of Problem: The root causes include:		
Corrective/Preventive Action Plan:		
Task Description	Responsibility	Due Date
Containment Actions • • • Preventive Actions • • •		
Approved by:		Date:
Verification Period:	From:	To:
Verification Plan:		
Director Quality Approval: _____ Signature		_____ Date
Permanent Changes, if applicable: _____		
Procedure # / Process Instruction # / Form #: _____		
Action Request:	To: _____	Date: _____

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Exhibit 2: CAR / PAR Directory, Form QSF-14-2

QSF-14-2

CAR / PAR DIRECTORY

CAR C# / PAR P#	Date Logged	Problem Description	Initiated By	CAR / PAR Solution	Approved By	CAR / PAR Verification Date (Closeout)