Ontario Health
Trillium Gift of Life Network

Quality Process Instruction Manual

Critical Incident Process Instruction

1.0 Purpose:

To describe the process for investigating and resolving critical incidents.

2.0 Scope:

This process applies to:

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

3.0 Responsibilities:

Director Quality is responsible for:

- ensuring adherence to the Corrective and Preventative Action Procedure by all employees
- performing a preliminary investigation for all critical incidents
- assigning the Corrective/Preventative Action Report (CAR/PAR) to the appropriate employee(s) and ensuring that the process is conducted
- conducting a safety check huddle and developing a containment plan
- ensuring that the corrective action solutions are verified and communicating them to the affected employees
- approving CARs/PARs
- distributing CARs/PARs to affected stakeholders for their review and follow-up actions

Manager/Directors are responsible for:

- reporting critical incidents, whenever one is identified
- reviewing critical incident submissions from employees
- participating in safety check huddles, when requested
- attending clinical review meetings, when requested
- implementing any proposed recommendations from the investigation, when requested

Employees are responsible for:

- reporting critical incidents to management whenever a critical incident is identified
- attending safety check huddles, when requested

- attending clinical review meetings, when requested
- investigating and implementing critical incidents, when requested

4.0 Process:

4.1 Critical incidents are a classification of major non-conformances which might occur either internal or external to TGLN. See the *Nonconformance Management Procedure, QSP-13-1* for further details. All critical incidents are reported by the Director Quality and Performance Improvement to the respective Vice President or Chief who leads the process under review.

Internal Critical Incident

4.2 Internal critical incidents are ones in which the root cause of the incident is believed to be caused by factors internal to TGLN.

4.3 The resolution of the critical incident generally follows the *Corrective and Preventative Action Procedure (CAR/PAR) QSP-14-1*.

4.4 Some of the key details of the CAR/PAR process that pertain to internal critical incidents include:

4.4.1 An employee is made aware of a potential critical incident and he/she reports it to his/her manager. The incident description is documented on an *Incident Intake Sheet*. See Exhibit 1. Before being sent to Quality, this *Incident Intake Sheet* is reviewed and approved by the employee's manager.

4.4.2 A safety check huddle may be requested with appropriate employees who have knowledge of the incident, within one (1) business day after the critical incident has been logged. In this huddle, the incident is reviewed to better understand the pertinent case information. A checklist has been developed to assist in the organization of the huddle. See Exhibit 2. Some key aspects of the safety huddle include:

- all OH-TGLN employees whose presence is requested, are required to attend
- OH-TGLN employees who are not at head office will be required to call in, via a conference call number provided
- all attempts will be made to accommodate participants' schedule

4.4.3 If there is material evidence that pertains to the incident investigation, it will be gathered by the OH-TGLN investigator. This evidence does not include any biohazardous materials.

4.4.4 A containment plan is developed as an outcome of the safety check huddle. See Exhibit 3. This plan will serve as an interim solution to mitigate against an immediate repeat of the incident occurrence. If a huddle is not conducted, then the containment plan needs to be developed early in the investigation, typically within two (2) days after the critical incident identification.

4.4.5 Data gathering and employee interviews are conducted to learn the specifics of the incident. This information may be documented on the *Quality Investigation Notes Form*. See Exhibit 4.

4.4.6 If information is required from an external stakeholder(s), a *Stakeholder Follow-up Form* may be sent to those individual(s). See Exhibit 5.

4.4.7 A clinical review is conducted of the incident with appropriate clinical employees, if required.

4.4.8 A corrective/preventive action plan is developed after the investigation information has been gathered.

4.4.9 A draft Corrective Action Report (CAR) is documented and distributed to pertinent management and employees for their input. The CAR is adjusted accordingly and re-distributed to pertinent management and employees.

4.4.10 The close-out timing of the CAR/PAR depends on the specific non-conformance being resolved. The goal is to close-out critical incidents within an eight week period.

External Critical Incident

4.5 External critical incidents are ones in which the root cause of the incident is believed to be caused by factors external to OH-TGLN, such as an organ recovery program or a serology laboratory.

4.6 The resolution of the critical incident is initiated through the *Corrective and Preventative Action Procedure, QSP-14-1*.

4.7 Some of the key details of the CAR/PAR process that pertain to external critical incidents include:

4.7.1 An employee is made aware of a potential critical incident from an external stakeholder and the employee reports it to his/her manager. The incident description is documented on an *Incident Intake Sheet*. See Exhibit 1. Before being sent to Quality, this *Incident Intake Sheet* is reviewed by the employee's manager.

4.7.2 A safety check huddle may be called with appropriate employees and external stakeholders who have knowledge of the incident, within two (2) business days after the critical incident has been logged. In this huddle, the incident is reviewed to better understand the pertinent case information. Some key aspects of the safety check huddle include:

- all OH-TGLN employees whose presence is requested, are required to attend
- OH-TGLN management who are not at head office will need to call in, via a conference call number provided
- non-OH-TGLN participants will be requested to call in to the huddle via a conference number provided
- all attempts will be made to accommodate participants' schedules

4.7.3 A containment plan is developed as an outcome of the safety check huddle. See Exhibit 3. This plan will serve as an interim solution to mitigate against a repeat incident occurrence. If a huddle is not conducted, then the containment plan needs to be developed early in the investigation, typically within two (2) days after the critical incident identification.

4.7.4 The external stakeholder may decide to either investigate the incident themselves or have OH-TGLN conduct the investigation.

4.7.5 If OH-TGLN performs the investigation, steps 4.4.4 to 4.4.8 are repeated.

4.7.6 If the external stakeholder decides to perform the investigation, then they perform this work and send a copy of their investigation report to OH-TGLN Quality.
If delays are encountered in receiving important information from external stakeholders, follow-up communications is initiated. If further delays are expected, escalation within the external stakeholder's organization is conducted.

4.7.7 The close-out timing of the CAR/PAR depends on the specific non-conformance being resolved. The goal is to close-out critical incidents within an eight week period.

5.0 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
Incident Intake Sheet	QSF-14-6	Director Quality	Quality Assurance Department	16 years
Safety Check Huddle Meeting Checklist	QSF-14-7	Director Quality	Quality Assurance Department	16 years
Containment Plan Form	QSF-14-3	Director Quality	Quality Assurance Department	16 years
Quality Investigation Notes Form	QSF-14-4	Director Quality	Quality Assurance Department	16 years
Stakeholder Follow-up Form	QSF-14-5	Directory Quality	Quality Assurance Department	16 years

6.0 References:

- *Corrective and Preventative Action Procedure, QSP-14-1*
- *Nonconformance Management Procedure, QSP-13-1*

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Exhibit 1: Incident Intake Sheet

QSF-14-6

INCIDENT INTAKE SHEET INCIDENT #: INC - YYYY -

REQUESTOR

INITIATED BY: _____ DATE LOGGED: _____

REVIEWED BY: _____ TGLN #: _____

DESCRIPTION of Incident

TYPE OF INCIDENT	STAFF INVOLVED	STAKEHOLDERS INVOLVED
☐ Potential Critical Incident	1	1
☐ Potential Incident	2	2
☐ Complaint	3	3
	4	4
	5	5

CLINICAL CHART NOTES (IF APPLICABLE)

DATE/TIME	EVENT

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Exhibit 2: Safety Check Huddle Meeting Checklist

QSF-14-7

Safety Check Huddle Meeting Checklist

Please check:

- ☐ Safety huddle scheduled within one (1) business day after incident reported.
- ☐ Manager who approved the critical incident reporting to be included.
- ☐ Teleconference details arranged for off-site employees.
- ☐ If critical incident involves external stakeholders – establish a communication plan for notifying them, if not notified already.
- ☐ The huddle has representation from all pertinent, internal functions.
- ☐ The huddle has representation from all pertinent, external stakeholders, where required.
- ☐ Material evidence that needs to be gathered, is accumulated.
- ☐ A review of the key facts of the case, has been presented in the huddle.
- ☐ Any potentially affected patients have been identified.
- ☐ A list of action items has been documented, assigned, and shared with the meeting attendees.
- ☐ A containment plan has been documented.

November 7, 2016

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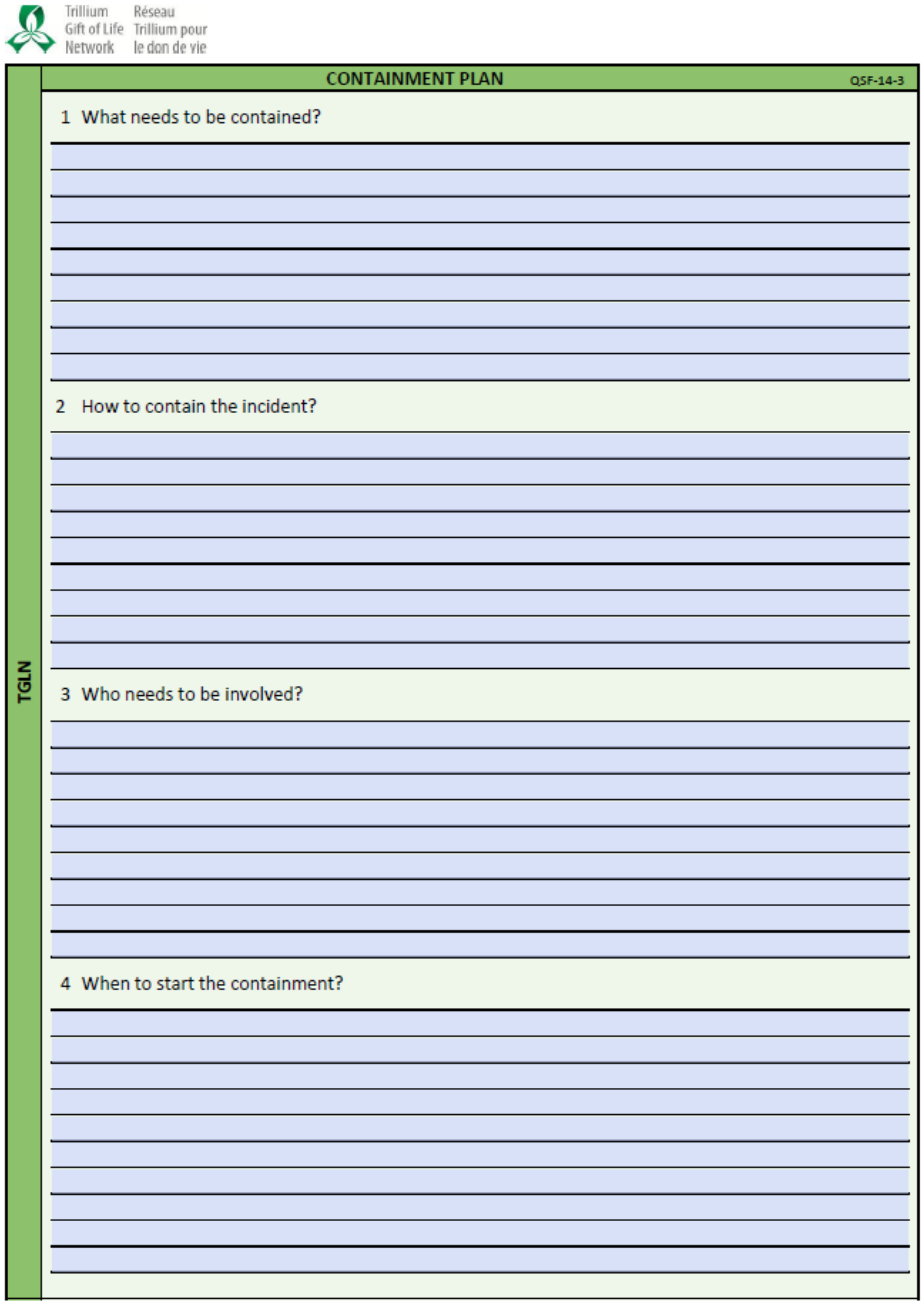
Exhibit 3: Containment Plan Form



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TGLN

CONTAINMENT PLAN QSF-14-3

1 What needs to be contained?

2 How to contain the incident?

3 Who needs to be involved?

4 When to start the containment?

August 31, 2016

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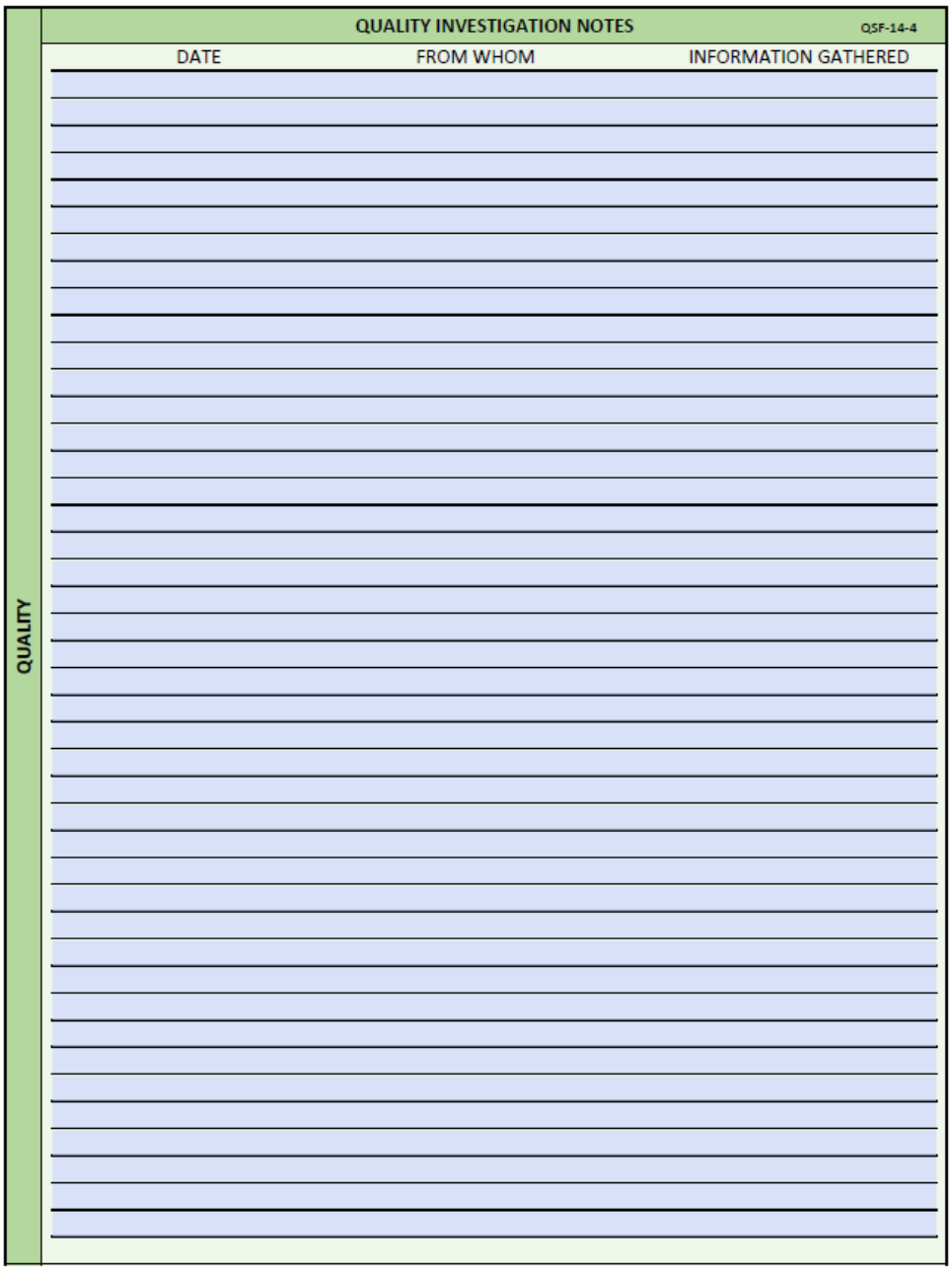
Exhibit 4: Quality Investigation Notes Form



QUALITY

QUALITY INVESTIGATION NOTES QSF-14-4

DATE	FROM WHOM	INFORMATION GATHERED

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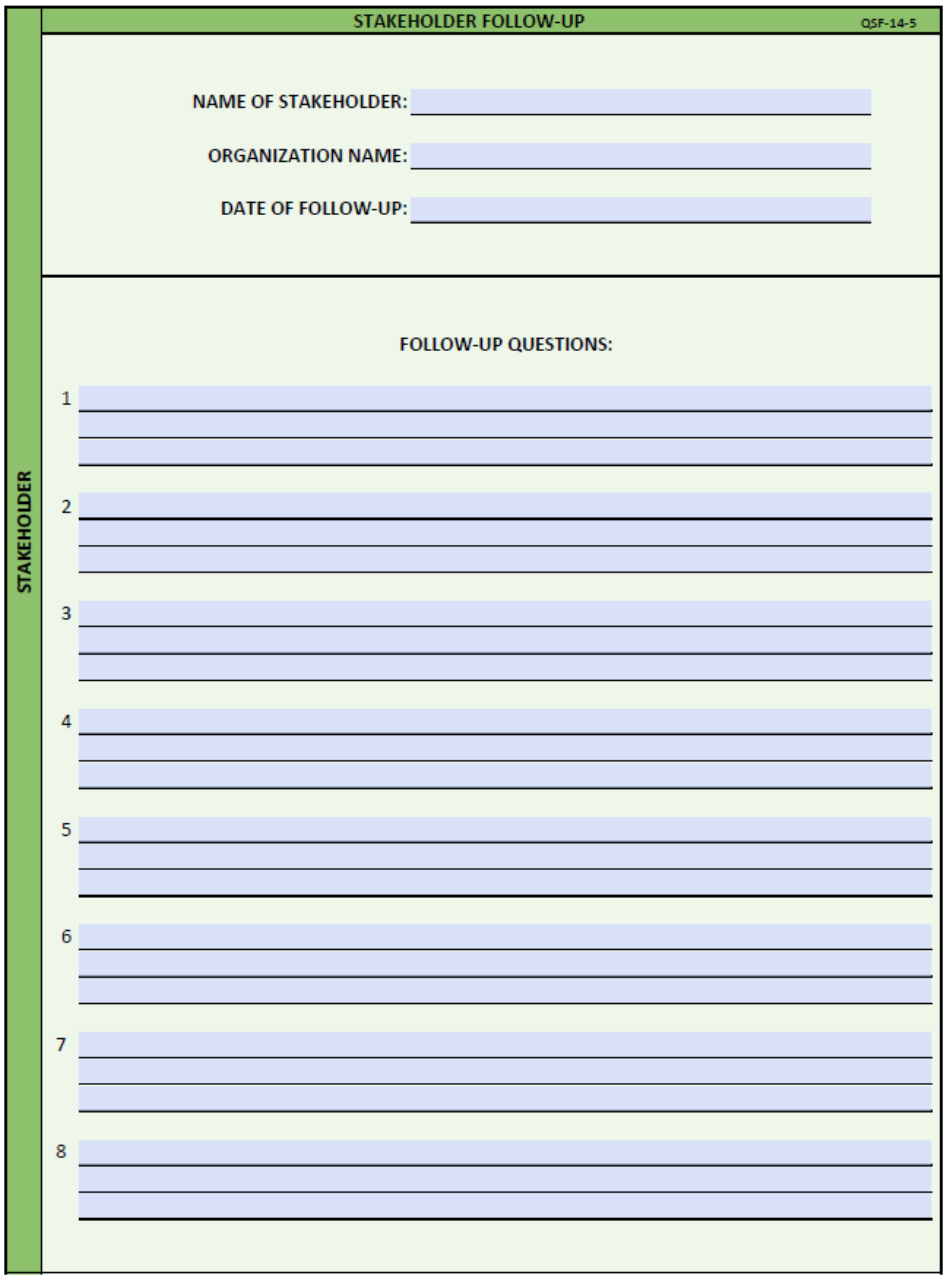
Exhibit 5: Stakeholder Follow-up Form



STAKEHOLDER FOLLOW-UP QSF-14-5

NAME OF STAKEHOLDER: _____

ORGANIZATION NAME: _____

DATE OF FOLLOW-UP: _____

STAKEHOLDER

FOLLOW-UP QUESTIONS:

1 _____

2 _____

3 _____

4 _____

5 _____

6 _____

7 _____

8 _____

August 31, 2016