Ontario Health
Trillium Gift of Life Network

Quality System Procedure Manual

Internal Auditing Procedure

1.0 Purpose:

To describe the internal auditing process of the quality system.

2.0 Scope:

This procedure applies to:

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

3.0 Responsibilities:

Internal Auditors are responsible for:

- performing quality system internal audits according to the requirements of the ISO 10011 auditing standards
- preparing the necessary documentation for internal audits to be conducted
- conducting the internal audits
- documenting internal audit findings
- following-up any nonconformances found with lesson(s) learned and corrective actions

Director Quality is responsible for:

- scheduling internal audits of the complete quality system biannually, as a minimum
- ensuring that internal audits of the quality system are conducted biannually, as a minimum
- selecting internal auditors
- ensuring that any nonconformances detected are resolved by initiating lesson(s) learned and corrective actions

Quality Lead Auditor is responsible for:

- preparing the audit report
- supervising audit team to conduct the audit

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4.0 Procedure:

General

4.1 Internal audits of the quality system are conducted to meet the following objectives:

- to determine the conformance or nonconformance of the quality system sections against the documented requirements and external audit criteria
- to determine the effectiveness of the implemented quality system in meeting documented quality policy objectives
- to provide an opportunity for continuous improvement

4.2 The benefits of internal audits include:

- ensures staff compliance for all quality system sections, to the documented requirements
- identifies any nonconforming activities which need to be corrected
- identifies possible opportunities to improve the quality system
- provides confidence to the senior management team that the requirements for quality are being fulfilled and that quality improvement takes place
- provides confidence to customers that the requirements for quality are being consistently achieved in the delivered services
- improves the effectiveness in the manner by which clinical and operations processes are conducted

4.3 Internal audit staff used to conduct audits are appropriately trained. The audit staff does not perform audits of the quality system sections for which they are directly responsible.

4.4 The key stages of the internal auditing process consists of the following:

- scheduling the internal audit activities
- planning the audit
- conducting the audit
- preparing the audit report
- performing the audit follow-up

Scheduling the Internal Audit

4.5 As a minimum, every year, an internal audit schedule is prepared, to meet the following objectives:

- to review complete quality system for compliance
- to review specific, troublesome areas for compliance
- to follow-up with the re-audit of any nonconforming areas

See Exhibit 3 for a sample of an internal audit schedule.

4.6 In developing the internal audit schedule, the following considerations are kept in mind:

4.6.1 Each quality system element is to be audited at least once biannually. Troublesome or nonconforming areas will require additional audits.

4.6.2 An audit schedule is prepared and distributed.

4.6.3 The audit schedule is designed as a planning tool. Depending on the audit resources available, the schedule might not be followed on a monthly basis. However, every quality section is audited biannually, as a minimum.

Planning the Audit

4.7 In preparation for an internal audit, the following activities are conducted:

4.7.1 Internal audit team is assembled and audit assignments are allocated to each member of the team.

4.7.2 Quality system documentation is reviewed including any recent internal audit reports.

4.7.3 An audit plan is prepared and distributed among the internal audit staff.

4.7.4 Audit checklists are reviewed and revised to ensure that the essential audit criteria is current. The checklist criteria comes from the quality system documentation, previous audit reports, nonconformances found and changes made to quality system documentation.

4.7.5 An internal audit team meeting may be conducted to coordinate team members and to assign responsibilities based on the size of the audit team.

4.7.6 An internal memo or verbal communication is provided to the affected departments or individual staff to provide advance notification of the internal audit.

Conducting the Audit

4.8 In conducting the audit, the following activities are performed:

4.8.1 An opening meeting may be conducted with the affected department staff or individual(s) to be audited depending on the size and complexity of the internal audit. If a meeting is conducted, the following topics are included in the meeting agenda:

- audit objective and scope
- methods of conducting the audit
- timing and location of a closing meeting, if required
- clarification of unclear details

4.8.2 Internal audit evidence is collected using a combination of the following methodologies:

- conduct interviews
- examine records
- observe activities

4.8.3 A closing meeting may be conducted with the affected department staff or individual(s) that were audited, depending on the size, complexity or findings of the internal audit. If a closing meeting is conducted, the following topics are included in the meeting agenda:

- internal audit summary
- good audit findings
- nonconformances documented
- timing of the internal audit report

Preparing the Audit Report

4.9 The writing of the audit report is conducted under the guidance of the Quality Lead Auditor. The Lead Auditor is responsible for the accuracy and completeness of the *Internal Audit Report*.

4.10 The contents of the Internal Audit Report include:

- audit scope and objectives
- names of the audit staff involved
- observations of any nonconformances noted

- overall compliance with the documented quality system sections audited

See Exhibit 1 for a sample of an *Internal Audit Report Form*, *QSF-17-1*.

4.11. The draft audit report is sent out to the pertinent managers/directors for feedback, as a courtesy.

4.12. The Internal Audit Report is dated and signed by the Quality Lead Auditor and the *Internal Audit Report Log*, *QSF-17-2* is updated. See Exhibit 2.

4.13. The audit report is sent to the applicable clinical vice presidents for their review, prior to sending out to the pertinent TGLN management and staff.

Performing Audit Follow-up Activities

4.14 Between internal audits of the quality system, the Quality Lead Auditor or his/her designate performs the following activities:

4.14.1 Queries managers and staff on the status of the audit nonconformances identified.

4.14.2 Keeps senior management team informed of the action activities and their follow-up status, when appropriate.

4.14.3 Reviews and revises the audit checklists annually to reflect the current quality system process.

5.0 Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Internal Audit Report	QSF-17-1	Quality Lead Auditor	Quality Assurance Department	16 years
Internal Audit Report Log	QSF-17-2	Quality Lead Auditor	Quality Assurance Department	16 years
Internal Audit Schedule	--	Quality Lead Auditor	Quality Assurance Department	16 years

6.0 References:

- Nonconformance procedures, QSP-13-1
- Corrective and Preventive Action Procedure, QSP-14-1

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Exhibit 1: Internal Audit Report, Form QSF-17-1

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Internal Audit Report

QSF-17-1
Page 1

Internal Audit Report No. _____

INTERNAL AUDIT REPORT

Organization Audited: _____ Location: _____

Lead Auditor: _____ Audit Team: _____
_____
_____
_____

AUDIT SUMMARY:

Date(s) of Audit: _____

Quality Sections Audited: Section Nos.
_____
_____
_____
_____
_____

No. of Nonconformances Found: Major: _____ Minor: _____

No. of Unresolved Nonconformances found from the previous audit: Major: _____ Minor: _____

OVERALL REMARKS:

Approved by: _____ Date: _____
Quality Lead Auditor

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NONCONFORMANCE DETAILS

Quality Element Name/Number: _____

Type of Nonconformance: Major ☐ Minor ☐

Description:

Responsibility: _____ Date identified: _____

Quality Element Name/Number: _____

Type of Nonconformance: Major ☐ Minor ☐

Description:

Responsibility: _____ Date identified: _____

Quality Element Name/Number: _____

Type of Nonconformance: Major ☐ Minor ☐

Description:

Responsibility: _____ Date identified: _____

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Exhibit 1: Internal Audit Report, Form QSF-17-1

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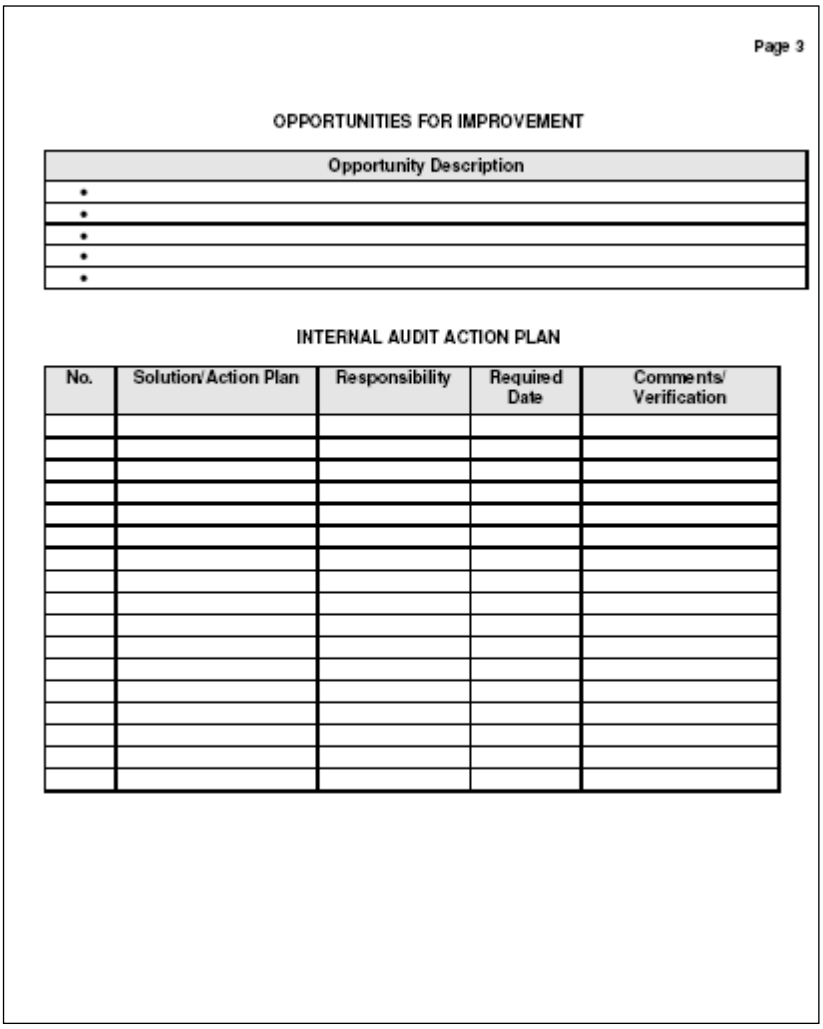

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OPPORTUNITIES FOR IMPROVEMENT

Opportunity Description
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•
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•
•

INTERNAL AUDIT ACTION PLAN

No.	Solution/Action Plan	Responsibility	Required Date	Comments/ Verification

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Exhibit 2: Internal Audit Report Log, Form QSF-17-2

QSF-17-2

INTERNAL AUDIT REPORT DIRECTORY

IAR #	QUALITY SECTIONS INCLUDED	DATE REPORTED	COMMENTS

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Exhibit 3: Sample Internal Audit Schedule

INTERNAL AUDIT SCHEDULE
FOR
_____
(Year)

Calendar / Health Canada Requirements		Jan.	Feb.	Mar.	Apr.	May	Jun.	Jul.	Aug.	Sept.	Oct.	Nov.	Dec.
1.	Source Establishment Description												
2.	General Processing												
3.	Donor Suitability Testing												
4.	Retrieval												
5.	Testing												
6.	Packaging												
7.	Labeling												
8.	Quarantine												
9.	Storage												
10.	Exceptional Distribution												
11.	Errors & Accidents Reporting												
12.	Adverse Reaction Investigation & Reporting												
13.	Health Canada Investigation & Reporting												
14.	Records												
15.	Personnel and Training												
16.	Facilities												
17.	Equipment and Supplies												
18.	Quality Assurance System												