Ontario Health
Trillium Gift of Life Network

Quality Process Instruction Manual

Supplier Audit Process Instruction

1.0 Purpose:

To describe the process of auditing suppliers.

2.0 Scope:

This process applies to:

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

3.0 Responsibilities:

Supplier Auditors are responsible for:

- performing supplier audits
- preparing the necessary audit documentation to be used
- conducting the supplier audits
- documenting supplier audit findings
- following up any non-conformances found with action plans to resolve the process gaps

Director of Quality is responsible for:

- scheduling audits of suppliers, as a minimum
- ensuring that supplier audits are conducted annually, as a minimum
- selecting audit methods and auditors to perform the supplier audits
- ensuring that any non-conformances found are resolved through the implementation of the post audit action plan

Quality Lead Auditor is responsible for:

- ensuring that the audit preparation is performed and sending out the audit plan and checklists to the auditees
- supervising the audit team to conduct the audit
- writing the audit report
- ensuring that any audit non-conformances are followed up

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4.0 Process:

General

4.1 Supplier audits are conducted to meet the following objectives:

- to identify any process gaps of service providers in meeting the required legislated or standard related requirements
- to provide an opportunity for continuous improvement

4.2 Supplier audits may be conducted in the following forms, as determined by the Director of Quality:

- paper
- virtual (over the phone or via a web conference)
- on-site

4.3 The following are examples of supplied contracted services require audits:

- donor infectious disease testing
- microbiology testing
- environmental monitoring
- sterilization validation
- irradiation dose auditing
- lot release testing
- calibration services (which may also be included in maintenance services)
- clean room certification

Pre-Audit Preparation

4.4 Suppliers (auditees) are notified by the Quality Director or his/her designate approximately one month prior to conducting the audit, if being performed virtually or on-site.

4.5 An audit package is prepared, consisting of an audit plan for the event and pertinent checklist(s) and sent to the auditee. If a paper audit is being conducted, a due date will be provided for the return of the completed material(s) sent.

4.6 If the audit is being conducted virtually, the auditee is requested to submit objective evidence of each checklisted item prior to the scheduled date of the virtual audit.

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Audit (virtual or on-site)

4.7 An opening meeting is conducted with the auditee's representative(s) to review:

- objective of the audit
- resources required from the auditee (i.e. staff to interview)
- audit schedule
- any questions or concerns

4.8 The attendees of the opening meeting (on-site only) are all requested to fill in their name and title on an attendance sheet.

4.9 The audit is conducted by:

- reviewing pertinent records related to the product or services offered
- questioning auditee staff who perform processes related to the product or service offered
- visiting locations within the auditee's facility where key processes are performed and making observations

4.10 The auditor makes notes on his/her checklist forms on a combination of:

- records reviewed
- responses to questions
- physical observations made

4.11 The audit activities conclude and a closing meeting with the auditee's representatives is conducted to perform the following:

- provide thanks to the auditee for their participation
- provide a general overview of the audit data
- advise next steps

Audit (paper)

4.12 The auditor reviews the completed checklist(s) and objective evidence provided by the auditee. The auditor will follow-up with the auditee if questions are unanswered and/or objective evidence is missing or insufficient.

Post Audit Activities

4.13 The auditor completes his/her audit results on the checklists and presents the evidence to the Lead Auditor for review.

4.14 Lead Auditor makes the final determination of any identified non-conformances.

4.15 OH-TGLN audit team of Lead Auditor and assigned auditor(s) make a phone call to the auditee's representatives to review the preliminary audit findings.

4.15.1 At this time the auditee is allowed to raise any information not gathered during the audit to potentially resolve any non-conformances

4.15.2 The Lead Auditor makes the decision to over-turn any preliminary non-conformances

4.15.3 The auditee is advised when the final report will be forthcoming

4.16 The final audit report is prepared by the Auditor who conducted the audit and it is reviewed by the Lead Auditor. After any adjustments have been made, the audit report is signed by the Lead Auditor and sent out to the representatives of the auditee.

4.17 The auditor follows up with the auditee to gather any evidence required to close-out non-conformances. Once all of the evidence has been acquired and approved, an amended audit report is sent out to the auditee's representatives to reflect that the audit process has been closed.

5.0 Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Audit Report	QSF-17-1	Quality Department	Quality Department	16 years

6.0 References:

- Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. K1.310.
- *Internal Audit Process, QSP-17-1*.