

Quality Process Instruction Manual

External Laboratory and Organ Recovery Audit Process Instruction

1.0 Purpose:

To describe the process of auditing external donor screening laboratories and organ recovery programs.

2.0 Scope:

This process instruction applies to:

- Trillium Gift of Life Network (TGLN)

3.0 Responsibilities:

Internal Auditors are responsible for:

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

Director Quality is responsible for:

- scheduling audits of external donor screening labs and organ recovery programs biannually, as a minimum
- ensuring that external audits are conducted biannually, as a minimum
- selecting auditors to perform the external 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

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- writing the audit report
- ensuring that any audit non-conformances are followed up

4.0 Process:

General

- 4.1. External audits of external donor screening labs and organ recovery programs are conducted to meet the following objectives:
- to identify any process gaps of external service providers in meeting their Health Canada – related regulation obligations
 - to provide an opportunity for continuous improvement

Pre-Audit Preparation

- 4.2. Donor screening labs and organ recovery programs (auditees) are notified by the Quality Director or his designate approximately one month prior to conducting the audit.
- 4.3. An audit package is prepared, consisting of an audit plan for the event and pertinent checklist(s) are sent to the auditee.

Audit Day

- 4.4. An opening meeting is conducted with the auditee's representative(s) to review:
- objective of audit
 - resources required from auditee (i.e. staff to interview)
 - audit schedule for the day
 - any questions or concerns
- 4.5. The attendees of the opening meeting are all requested to fill in their name and title on an attendance sheet
- 4.6. The audit is conducted by:
- reviewing pertinent records of specified processes
 - questioning auditee staff who perform specified processes

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- visiting locations within the auditee's facility where key processes are performed and making observations
- 4.7. The auditor makes notes on his/her checklist forms on a combination of:
- records reviewed
 - responses to questions
 - physical observations made
- 4.8. The audit activities conclude and a closing meeting with the auditee's representatives is conducted to perform the following:
- provide thanks to auditee for their participation
 - provide a general overview of the audit data
 - advise next steps

Post Audit Activities

- 4.9. The auditor completes his/her audit results on the checklists and presents the evidence to the Lead Auditor for review.
- 4.10. Lead Auditor makes the final determination of any identified non-conformances.
- 4.11. TGLN audit team consisting of Lead Auditor and assigned auditor(s) make a phone call to the auditee's representatives to review the preliminary audit findings.
- at this time the auditee is allowed to raise any information not gathered during the audit to potentially resolve any non-conformances
 - the Lead Auditor makes the decision to over-turn any preliminary non-conformances.
 - the auditee is advised when the final report will be forthcoming.
- 4.12. The final audit report is prepared by the audit team 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.

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4.13. 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)
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External Audit Report	-----	Quality Department	Quality Department	16 years
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6.0 References:

- *Internal Audit Process, QSP-17-1*