Internal audit, feedback and improvement

The audit programme over every clause and every document in a year, the auditor's independence in a laboratory of two, how an audit is conducted and recorded, the gate a corrective action passes before it closes, and how feedback is sought and used.

Not yet approved
No approval of this revision is on file. This revision states what the laboratory's results system enforces today; it takes effect when a named reviewer approves it.

Document		Laboratory	
Number	SOP-10	Name	Cupel Laboratories
Revision	1, first issue	Address	2599 Speakman Dr Mississauga, ON L5K 1B1
Status	Not yet approved		
Effective	Not yet in effect; takes effect when approved	Country	Canada
		Not on file	Not yet published: legal entity, postal address, telephone and country
Applies to	Every clause, document, record and corrective action	Web	cupel.ca
Supersedes	Nothing; first issue	Email	help@cupel.ca
Fingerprint	f4c1 67bb 6e1e d2d6		

1 Purpose

To audit the laboratory's own work against ISO/IEC 17025:2017 and its own documents on a programme that covers every clause and every activity within a year, by an auditor independent of the work audited; to seek and use feedback; and to close a corrective action only when it has been shown to work (clauses 8.8, 8.6, 8.7).

2 Scope

Every clause of the standard the laboratory applies (4 to 8), every document in QM-00's list, every record the backend keeps, and every piece of software SV-01 names. copy_audit.py is a check of the public pages' prose (the market study's discriminators) and is not the internal audit; nothing it reports counts as an audit finding.

3 Responsibilities

Role	Responsibility
Auditor	Not yet named (data.json quality.internal_audit.auditor, an owner decision; an external auditor is acceptable). Plans each audit, reads the records, raises the findings and writes the report; audits nothing they do themselves.
Quality Manager	Keeps the programme and its dates, gives the auditor the records, opens a corrective action for every nonconformity, verifies closure, and brings the outcome to the management review as input e.
Laboratory Director	Receives the report, allocates the actions and their dates, and answers for the programme being held.
Analyst	Gives access to the sets, the raw data and the instruments, and audits the area the programme assigns to the analyst.

Named: Timothy Ian Benedicto, Medical Laboratory Technician; Roxanne Manlapaz, Laboratory Technician.

4 References and controlled sources

Standards and other documents

- ISO/IEC 17025:2017 8.8 (internal audits), 8.6 (improvement), 8.7 (corrective actions) and 8.9 (management review), cited for what they ask; the laboratory claims no conformity with them.
- ISO 19011, guidelines for auditing management systems, as a guide to conducting an audit.

References and controlled sources, continued

– QM-00, QM-01, QM-02, SOP-08 (the corrective-action path), SV-01.

Controlled sources, read at every build

– data.json quality.internal_audit (auditor, independent_of, first_due, programme) and quality.audits (the audits held).
– lab/entry_server.py: the corrective and preventive actions log, its steps and its sources.
– lab/management_review.py: the inputs of clause 8.9.2 and the record of the review.
– The document list of lab/sop_pdf.py, which this programme reads so that a new document is audited by itself.

5 Independence in a laboratory of two

ISO/IEC 17025:2017 8.8.2 e)

– Nobody audits their own work. The analyst does not audit the testing; the reviewer does not audit the review and release they perform; the quality manager does not audit the quality system they run.
– Each of the two may audit the other's technical area (clauses 6 and 7) in the half of the cycle the programme assigns; the sampled reports are audited by someone who signed none of them, which in a laboratory of two is nobody inside it.
– The quality system as a whole (clauses 4, 5 and 8), the complaints and corrective actions, and the sample of issued reports are therefore audited by an external auditor, named by the owner in data.json quality.internal_audit.auditor with what the auditor does not do here (independent_of). Until the auditor is named the programme has areas and no auditor for them, and no audit of those areas can be held.
– An auditor who finds they took part in the work audited says so in the report and the area is re-audited by another.

6 The programme

ISO/IEC 17025:2017 8.8.1, 8.8.2

Every clause and every document is audited once in a cycle of twelve months, in two halves; the first audit is held before the first real report issues, and a finding in any area may bring that area forward. The first date is not set (data.json quality.internal_audit.first_due).

Area	Clauses	Documents and records	Auditor	When
Impartiality, confidentiality, structure and policy	4, 5, 8.1, 8.2, 8.5	QM-00, QM-01, QM-02; the signed declarations; the ownership record	external	half 1
People and competence	6.2	org.people; competence, training and authorisation records per person	external	half 1
Facilities, equipment, traceability, suppliers	6.3 to 6.6	SOP-09; the register; calibration certificates; logbooks; the standards' certificates	the reviewer	half 2
Requests, methods, validation, uncertainty	7.1, 7.2, 7.6	SOP-01, SOP-02 to SOP-06, VP-01 to VP-05; the validation data files	the reviewer	half 1
Handling, records, reporting and release	7.4, 7.5, 7.8	SOP-01, SOP-07; a sample of issued reports with their sets, trails, notices and emails	external	half 2
Validity of results	7.7	the control charts, the limits record, the QC check material; SOP-11, the comparison log lab/records/ilc.jsonl, the re-tests and replicates	the reviewer	half 2
Complaints, nonconforming work, corrective action, feedback	7.9, 7.10, 8.6, 8.7	SOP-08, SOP-10; the case logs; the feedback threads	external	half 1
Data and software	7.11	SV-01; python make.py check; the integrity check; backups and the restore drill	the analyst	half 2

The programme, continued

Documents, records, audits and review	8.3, 8.4, 8.8, 8.9	QM-00; data.json documents; this programme; the review record	external	half 2

The auditor column names who may audit the area given who does the work; “external” is an area the two cannot audit themselves.

7 Conducting an audit

ISO/IEC 17025:2017 8.8.2

7.1 Plan: the area, the clauses and documents it covers (the criteria), the records to sample (for reports: issued reports across every test code, with their sets, audit trails, notices and emails; for equipment: the register against the sets that name each instrument; for validation: the data files against their raw data), and the date.

7.2 Open: the auditor states the scope and the criteria to the person whose area it is.

7.3 Evidence: read the records, watch a run or a review where one is scheduled, and run the software’s own checks (python make.py check; python lab/integrity.py); read what each document claims against what the record shows, since a document that claims more than the mechanism does is itself a finding.

7.4 Findings: a nonconformity (a requirement of the standard or of a document not met) or an observation (met, with a weakness worth recording), each with the evidence and the clause or document.

7.5 Report: the date, the auditor, the area, the records sampled, the findings and the person who received them; written within five business days of the audit and filed with the quality records.

7.6 Every nonconformity opens a case in the corrective and preventive actions log (/capa) with source “internal audit” and the audit’s date as its reference, and runs the corrective-action path of SOP-08.

7.7 Record the audit in data.json quality.audits (held_on, auditor, covered, findings, and the corrective actions opened), the shape lab/launch_facts.py documents; QM-00 and this procedure print the audits held from it. No audit is on record: none has been held.

7.8 Bring the outcome to the management review (input e, outcome of recent internal audits).

8 Follow-up: the effectiveness of corrective action

ISO/IEC 17025:2017 8.7.1 d), 8.7.1 e)

A corrective action is closed only when it has been shown to work. SOP-08 gives the path (cause, extent, correction, change, verification); this section sets the gate on the verification, the step the backend records as “verified” with the field “How the action was shown to work”.

8.1 The interval: a verification is recorded no sooner than the action’s due date has passed and the activity the action changed has been carried out at least once since the change (a report issued, a run made, an audit sample read), and in any case not within thirty calendar days of the action. The interval is the laboratory’s default, proposed for the owner’s approval with this procedure.

8.2 The evidence: the verification names what was read (which accessions, runs, records or pages), what it showed, and the date it was read. A verification that names no evidence is not a verification.

8.3 Who: the person who verifies did not carry out the action; in a laboratory of two that is the other person, and for an action both took part in, the auditor at the next audit.

8.4 Until the corrective and preventive actions log carries an earliest-verification date and an evidence field, both are written into the verification note and the Quality Manager refuses to close a case whose note lacks them; the field is asked of the backend owner (open points).

8.5 The next audit reads every corrective action closed since the last one and re-opens any whose verification does not meet this section.

9 Feedback

ISO/IEC 17025:2017 8.6.2

9.1 Feedback is sought from every sender when a report issues (the issued email does not yet ask: asked of the emails owner, open points), and from buyers and readers through the contact address on every page and every certificate (help@cupel.ca).

9.2 What counts: a sender's or buyer's view of the service, a suggestion, a question a report left open, praise. A complaint is not feedback: it goes to SOP-08 and the complaints log.

9.3 Each item is filed as a dated email thread with "Feedback" in the subject, under the quality records, with the accession where there is one; the sender's identity stays in the thread and never reaches a result set or a report. The backend keeps no feedback record (open points).

9.4 Feedback from the two people themselves is raised at the management review, where it is recorded.

9.5 The quality manager summarises the period's feedback for the management review (input i, customer and personnel feedback); an improvement decided there is an action of the review, and one that corrects a nonconformity is a case in the corrective-action log with source "management review".

10 Deviations and open points

- A departure from this procedure, planned or found afterwards, is nonconforming work and is handled under SOP-08. One that bears on a result is stated on the certificate, in the open point or the notes of the section concerned, never left out.
- No internal audit has been held, and no auditor is named (data.json quality.internal_audit).
- The corrective and preventive actions log's verification step is a note: it has no earliest-verification date and no evidence field. Asked of the backend owner: a date the verification may not precede, and an evidence field, both required to record the step.
- The issued email does not ask for feedback; asked of the emails owner.
- The backend keeps no feedback record; feedback is filed as email threads until it does.
- The thirty-day interval is the laboratory's default until the owner approves this procedure.
- copy_audit.py is a prose check of the public pages, not the internal audit; it keeps its name so that nobody mistakes it for one.

11 Records

- The audit plan and report of each audit, with the records sampled and the findings, filed with the quality records; the entry in data.json quality.audits.
- The corrective actions each audit opened, in the corrective and preventive actions log (lab/records/capa.jsonl).
- The feedback threads, under the quality records.
- The record of the management review that read them (lab/records/reviews.jsonl).

12 Revision history

Revision	Change	Approval
1	First issue.	Not yet approved

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Current revisions

End of document