Quality policy and objectives

The policy the laboratory works to, the objectives it is measured by with the figure lab/metrics.py computes for each, who holds the technical and the quality responsibility, and how the system's effectiveness is communicated. A draft until a named person signs it.

Not yet approved

No approval of this revision is on file. This document is a draft for the owner's approval: the policy and objectives below are proposed, not adopted, until a named person approves this text and signs the policy (data.json quality.policy).

Document		Laboratory	
Number	QM-02	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	The whole laboratory		
Supersedes	Nothing; first issue	Web	cupel.ca
Fingerprint	73a8 9bb8 aaa1 0738	Email	help@cupel.ca

1 Purpose

To state the laboratory's quality policy, the measurable objectives it is judged by, who holds the technical and the quality responsibility and who deputises for whom, and how the system's effectiveness is communicated (ISO/IEC 17025:2017 5.5 to 5.7, 8.2.1, 8.2.2).

Status: a draft for the owner's approval. The policy below is proposed by the authors of the system and is not the laboratory's policy until a person named in data.json org.people approves this document (data.json documents) and signs the policy (data.json quality.policy signed_by, signed_on).

The policy is in effect only once signed; the signature and its date are read from data.json quality.policy and printed in the Signature section, and the approval of this text is in the control block.

2 The quality policy

ISO/IEC 17025:2017 8.2.1, 8.2.2

Cupel Laboratories, as a laboratory, undertakes that:

- Every result is reported as measured, with its uncertainty and the decision rule stated beside it, and is published under its number whatever it says; no result is negotiated, softened, delayed or withdrawn after the data exist.
- Each method is run only under a procedure in effect, by a person recorded as competent on it and, once validated, within its validated range; what is not yet validated is said so on the certificate and the scope table.
- Every record a result rests on is kept so that a reader can check the result from the raw data to the certificate, and nothing is deleted.
- Impartiality is a condition of the work: the laboratory sells nothing but measurement, prices every sample the same, and names in QM-01 the pressures on it and the safeguard against each.
- The laboratory works to good professional practice and to the requirements of ISO/IEC 17025:2017 as the quality manual describes them, audits itself against them (SOP-10), reviews the system at management review, and claims no accreditation it does not hold: Cupel holds no ISO/IEC 17025 accreditation; results are not accredited results.

Published commitments the policy rests on (the Why Cupel page, data.json integrity.items):

The quality policy, continued

- We do not delete reports, for ourselves or for the customer who paid for one. The register is built to refuse a deletion and to show one at its next integrity check; a result you dislike is published the same way as one you like.
- Corrections are issued as new reports. The superseded report stays reachable at its original address, marked retracted, linking forward to what replaced it.
- Every report carries a SHA-256 of its own data, printed on the certificate, and the data is published beside it. Recomputing the hash shows whether the published data is the data the number was issued with; the certificate file itself is checked on the verify page against the fingerprint the register recorded when it issued, and the figures on any paper against the published report. It does not vouch for us: we publish the report, the data and the hash, so it cannot show that we measured correctly.
- Measurement is our only line of business: we undertake to hold no inventory, to take no affiliate payment and no reseller margin, and to say so on this page if that ever changes. That also means nothing subsidises the price list, so we cannot undercut a laboratory that sells what it tests.
- We do not accept payment for a favourable result, and we do not offer vendors an embargo period, a pre-review, or a chance to withdraw a sample after the data exist.

3 Objectives and their measures

ISO/IEC 17025:2017 8.2.2, 8.9.2 b)

Each objective is measured by a figure lab/metrics.py computes from the records, or by a record data.json holds, and the figures are read at every management review (input b). A target is the owner's to set: a target recorded in data.json quality.policy.objectives is printed as the owner's; one marked proposed is the authors' default for the owner's approval with this document.

Objective	Measure and its source	Target
Every report on time	Share issued on time (lab/metrics.py, Turnaround and the guarantee); Median turnaround (lab/metrics.py, Turnaround and the guarantee); Made free by the guarantee (lab/metrics.py, Turnaround and the guarantee)	The guarantee itself: every report within 10 business days of recorded receipt, and a late one is free (data.json guarantee).
Few corrections	Corrections issued (lab/metrics.py, Corrections and retractions), per 100 reports issued (Reports issued, lab/metrics.py public)	Proposed: at most one correction per 100 reports issued in a year
Complaints answered promptly	Median days to close (lab/metrics.py, Complaints); Open at the end of the period (lab/metrics.py, Complaints)	Proposed: every complaint acknowledged within two business days and closed within twenty
Corrective actions shown to work	Shown to work (verified) (lab/metrics.py, Corrective actions); Open past their due date (lab/metrics.py, Corrective actions)	Proposed: none open past its due date; every one verified against evidence after the interval SOP-10 sets
Results in control	Runs with a rule rejection on the control charts, and the QC check material series, QC check material: none recorded (lab/qc_trend.py; QM-00 7.7)	Proposed: no rejection without a recorded cause, and limits frozen for every series after its first 20 runs
Agreement with another laboratory	E_n for each split-sample comparison, data.json quality.ilc.results; lab/metrics.py computes no figure for it yet	Proposed: every comparison with |E_n| at most 1, one per method and year
Methods validated before use	methods_validated of methods_in_scope (data.json counts, derived from the scope rows): 0 of 14 today	Proposed: no real report on an analyte before its identity and purity methods are validated for it

4 Organisation and responsibilities

ISO/IEC 17025:2017 5.5, 5.6, 5.7

Technical	The methods, the equipment, the validity of results and the competence to run each test: the Laboratory Director.
Quality	This system, its documents, the internal audit, complaints and corrective actions, and the management review's input: the Quality Manager.
Deputies	Each deputises for the other where impartiality allows: a deputy never reviews their own work (SOP-07) and never decides a complaint about it (SOP-08).

Organisation and responsibilities, continued

Holders	Not recorded (data.json quality.policy.responsibilities). Named: Timothy Ian Benedicto, Medical Laboratory Technician; Roxanne Manlapaz, Laboratory Technician.
Communication	The effectiveness of the system is communicated through the record of each management review (lab/records/reviews.jsonl) and the revisions of this document; a change to a procedure is a new revision approved by fingerprint, and the methods page publishes the current revisions.

5 Signature

Signed by	Not signed (data.json quality.policy signed_by)
On	Not signed (data.json quality.policy signed_on)

The approval in the control block records that this text was approved as a document; the signature here records that the policy is the laboratory's. Both are read from data.json.

6 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.
- The policy is not signed: data.json quality.policy names no signatory and no date.
- Targets marked proposed are not the owner's until this document is approved or data.json quality.policy.objectives records them.
- Holders and deputies are not named (data.json quality.policy.responsibilities).
- lab/metrics.py computes no figure for the interlaboratory comparison; the E_n is read from data.json quality.ilc.results.

7 Records

- data.json quality.policy (text, signed_by, signed_on, objectives, responsibilities).
- The figures, as python lab/metrics.py prints them for a period, and the management review's input and record (lab/management_review.py).

8 Revision history

Revision	Change	Approval
1	First issue.	Not yet approved

The fingerprint in the control block is the SHA-256 of this document's text as composed, first 16 hex digits. A change in any controlled source changes it; a copy whose fingerprint differs from the approved one is not the approved text, and a change is approved as a new revision.

Cupel holds no ISO/IEC 17025 accreditation; results are not accredited results.

This document is published so that a chemist can judge how a result was produced and what it can and cannot show; it is not an accredited procedure and claims no conformity with any standard it cites.

The current revision of every laboratory document is the one published at cupel.ca/methods. A printed copy is uncontrolled: compare its fingerprint with the published one.

Current revisions

End of document