Quality manual summary

How the laboratory is organised to produce results a reader can check: what is built into the register and the backend, what the eleven procedures and the five validation protocols govern, what QM-01, QM-02, SV-01, SAF-01 and the eight bench worksheets (WS-01 to WS-08) add, and, topic by topic, what is not yet in place.

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	QM-00	Name	Cupel Laboratories
Revision	1, first issue	Address	2599 Speakman Dr Mississauga, ON L5K 1B1
Status	Not yet approved	Country	Canada
Effective	Not yet in effect; takes effect when approved	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	332a 8185 2e6f cd89	Email	help@cupel.ca

1 Purpose and status of this summary

This summary describes how Cupel Laboratories is organised to produce results a reader can check, as it stands at this revision. It follows the clause order of ISO/IEC 17025:2017 so that each requirement a reader looks for can be found under its number; following that order is not a claim of conformity with the standard.

Cupel holds no ISO/IEC 17025 accreditation; results are not accredited results. No application for accreditation is on file.

Each topic says what is in place, and the procedure that governs it, and then what is not yet in place. Nothing is described as done that is not; the open points are gathered in the last section but one.

The management system is run as Option A of clause 8.1: the requirements of clauses 8.2 to 8.9 are met by the documents listed in the next section (the policy and objectives in QM-02, the risks in QM-01, the internal audit and feedback in SOP-10), not by a management system certified to ISO 9001.

2 The documents

Number	Title	Governs
QM-00	Quality manual summary	The whole laboratory
QM-01	Risks, opportunities and impartiality	The whole laboratory; every person named
QM-02	Quality policy and objectives	The whole laboratory
SOP-01	Sample receipt, logging and custody	Every sample, every test code
SOP-02	Purity by RP-HPLC–UV	Test codes PUR, IDP, FULL
SOP-03	Identity by LC–MS	Test codes ID, IDP, FULL
SOP-04	Bacterial endotoxin by kinetic chromogenic LAL	Test codes LAL, FULL
SOP-05	Water content by coulometric Karl Fischer	Test codes H2O, FULL
SOP-06	Mass per vial by external standard	Test codes QNT, FULL
SOP-07	Review, release, revision and the register	Every report, every revision
SOP-08	Complaints and nonconforming work	Every complaint, every nonconformity
SOP-09	Equipment, calibration and maintenance	Every instrument behind a result
SOP-10	Internal audit, feedback and improvement	Every clause, document, record and corrective action

The documents, continued

SOP-11	Interlaboratory comparison and intra-laboratory checks	Every method; every comparison, re-test and replicate
SV-01	Validation of the laboratory's own software	Every program in the project folder
VP-01	Validation of purity by RP-HPLC–UV	Test codes PUR, IDP, FULL; every analyte of the scope table, one report each
VP-02	Validation of identity by LC–MS	Test codes ID, IDP, FULL; every analyte of the scope table, one report each
VP-03	Validation of bacterial endotoxin by kinetic chromogenic LAL	Test codes LAL, FULL; every analyte of the scope table, one report each
VP-04	Validation of water content by coulometric Karl Fischer	Test codes H2O, FULL; every analyte of the scope table, one report each
VP-05	Validation of mass per vial by external standard	Test codes QNT, FULL; every analyte of the scope table, one report each
WS-01	Receipt and vial numbering	Every sample at receipt
WS-02	Daily checks: balance, room and instruments	Every day a measurement is made
WS-03	Dissolution by mass	Every vial dissolved for Mass per vial, Purity by RP-HPLC–UV, Identity by LC–MS or Bacterial endotoxin
WS-04	Purity by RP-HPLC–UV: the run	Test codes PUR, IDP, FULL
WS-05	Mass per vial: the standard and the levels	Test codes QNT, FULL; the suitability standard of PUR and IDP
WS-06	Water content: the run	Test codes H2O, FULL
WS-07	Bacterial endotoxin: the assay	Test codes LAL, FULL
WS-08	Identity by LC–MS: the run	Test codes ID, IDP, FULL
SAF-01	Laboratory safety and chemical hygiene	Every person and every procedure in the laboratory

3 Organisation, people and facilities

ISO/IEC 17025:2017 5, 6.2, 6.3

In place

- The laboratory's name, web address and email are on file: Cupel Laboratories, cupel.ca, help@cupel.ca.
- Two roles sign every report, the analyst and the reviewer, and the backend will not let one person hold both on the same report: the review page refuses the analyst, an unnamed analyst and a blank "Working as" (SOP-07).
- Every change to a result set is recorded under the name of the person who made it and the server's UTC time, and an entry that names nobody cannot be written (SOP-07).
- The quality policy, its measurable objectives and the organisation of clauses 5.5 to 5.7 are set out in QM-02, a draft until a person named in org.people approves it and signs it (data.json quality.policy).
- Named: Timothy Ian Benedicto, Medical Laboratory Technician; Roxanne Manlapaz, Laboratory Technician.

Not yet in place

- Not yet published: legal entity, postal address, telephone and country. The legal responsibility for the laboratory's activities (clause 5.1) cannot be stated until the entity is.
- Written competence requirements for each role, and training and authorisation records per person (clause 6.2). They begin the day a person is named: nobody signs a report for a test whose procedure they are not recorded as trained on.
- Named holders and deputies for the technical and the quality responsibility (clause 5.6): none recorded (data.json quality.policy.responsibilities); QM-02 names the roles.
- Premises and environmental conditions (clause 6.3): the address is on file; no storage temperature record and no environmental monitoring is described yet (SOP-09).

Organisation, people and facilities, continued

Competence per method: what a person demonstrates before signing alone

The matrix below (from the bench review, CRITIQUE_BENCH 5) is what an analyst demonstrates before running a method alone and signing as analyst, after reading and being examined on the procedure and observing and performing it under supervision; a reviewer holds the same for every method they review plus the reviewer row. One training file per person records the procedure revision trained on, the date, the trainer, the evidence (the worksheets and set ids of the qualifying runs) and the authorisation; re-qualification after six months without the method, after a revision that changes a bench step, and after a nonconformity traced to the person. With one analyst and one reviewer the observed columns cannot be met before the first real sample: the first analyst qualifies through the validation campaigns, whose data are the evidence, and the matrix applies in full to the second person and every later one; who the trainer is and who approves the first authorisation are the owner's decisions.

Method	Demonstrate alone (criterion)	Records
Before any method	A documentation test (a worksheet with planted errors corrected properly), a balance check and a pipette gravimetric check within tolerance; read and examined on QM-00, SOP-07 (Working as, the trail, the worksheet as the original record), SOP-08 (stop and record), the safety documents, UTC and clock offsets, good documentation practice	The training file; WS-01 and WS-02 copies
SOP-01 receipt	Two consecutive receipts with no reviewer correction on the worksheet or the set	WS-01; set histories
SOP-06 dissolution by mass and content	Ten repeat weighings of one sealed vial with SD at most 0.03 mg; three whole-vial preparations by mass with clarity recorded and G within twice its uncertainty of the trainer's for the same lot; the standard weighed at or above 10 mg within 30 s; a five-level calibration with r^2 at or above 0.999 and every level back-calculating within 98–102%; prepared-vial recovery 98–102% at one level, n = 3	WS-02, WS-03, WS-05 of the runs
SOP-02 purity	Suitability passed on three sequences on three days without steps beyond the procedure's; a blind retained sample within 0.3% area of the trainer's purity and every impurity at or above 0.1% within 0.05% area; six re-integrations of one chromatogram with SD at most 0.05% area; a correct deviation entry for a staged suitability failure	WS-04, data files, set ids
SOP-03 identity	Calibration within 2 ppm on three days; the reference standard of two analytes (one above 3 kDa) confirmed with every state within 5 ppm; the monoisotopic peak identified on a printed cluster of a 4–5 kDa peptide; the bench check before Not confirmed performed on a staged miscalibration	WS-08, data files
SOP-04 endotoxin	Three valid plates on three days (|r| at or above 0.980, every standard CV at most 10%, no onset in the negative control, PPC on a reference peptide 50–200%); a spiked water sample read within the PPC window; a new-lot tube check performed and recorded	WS-07, reader files
SOP-05 water	Six consecutive standard recoveries 97.5–102.5% over two days with start and end within 2%; blanks on one day, at least three, with SD at most 3 µg; duplicate vials of one lot within the repeatability limit; the 15-second open-to-crimp step timed on three empty vials; the three weighings as the SOP-06 row	WS-06, titrator files
Reviewer (SOP-07)	All of the above for the methods reviewed; finds every planted discrepancy in a set whose worksheet and form disagree in five places; signs nothing they ran	The review log

4 Impartiality and confidentiality

ISO/IEC 17025:2017 4.1, 4.2

Impartiality, in place

The commitments as the site publishes them, on the Why Cupel page, the pricing page and in the terms:

- 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.
- The same price per sample whether you send one or two hundred. No volume discount, so no reason for us to want a particular result.
- Every report is published at its own address under its accession number and listed on /reports, whatever the result says. A result you dislike is published the same way as one you like, and we will not delete it: the register is built to refuse a deletion and to show one at its next integrity check. Corrections are issued as new reports and the original stays, marked retracted.

The backend adds a rule of its own: the analyst of a report cannot review it, and the reviewer cannot be unnamed (SOP-07).

QM-01 analyses the risks to impartiality (clause 4.1.4): who pays the laboratory and what each relationship could press for, the safeguard against each and where it lives in the code, the register of risks and opportunities (clause 8.5) and the declaration of interests each named person signs.

Confidentiality, in place

What the terms promise the sender:

> No sender's name, company or contact is recorded in the register or printed on any report. The lot or batch reference you give us is printed verbatim so that a buyer can match the report to the vial. If you do not want a reference printed, do not give one.
>
> We keep your email correspondence for as long as is needed to answer it and to invoice, and no longer. It is not linked to any published record. We do not use it for marketing.
>
> The terms, "Publication" and "Email and records"

- The sender's email address is kept in the order ledger and the laboratory mailbox, never in a result set, the register or a report.
- Published for each report: the certificate, its data summary (payload.json) and its complete record (record.json). Never published: the sender's identity, the working set id, the reason a number was withdrawn, the order the vial arrived in (register.RECORD_PRIVATE) and the words of any hold, of which the record keeps only the dates and the kind (register.RECORD_HOLD_KEYS) (SOP-07, The two hashes and the record).
- The results backend answers on this computer only (127.0.0.1); its runner refuses any other address unless told so in so many words (RUNBOOK section 1).

Impartiality and confidentiality, continued

Not yet in place

- Declarations of interest and confidentiality undertakings (clauses 4.1.4, 4.2.4), as data.json org.people records them: Timothy Ian Benedicto, interests not recorded, confidentiality not recorded; Roxanne Manlapaz, interests not recorded, confidentiality not recorded.
- Who owns the laboratory, and each owner's other interests in the peptide trade (clause 4.1.4): not recorded (data.json impartiality.ownership); QM-01 says what the record must hold.
- The impartiality analysis has not been reviewed at a management review (none held; data.json impartiality.reviewed_on).

5 Requests, orders and contracts

ISO/IEC 17025:2017 7.1

In place

- The tests, their codes and prices, and which add-on rides on which test are published: ID (Identity); PUR (Purity); IDP (Identity + Purity); QNT (Mass per vial, with IDP); H2O (Water content, with ID or PUR or IDP); LAL (Bacterial endotoxin, with ID or PUR or IDP); FULL (Full panel).
- The scope table names every analyte with its formula and its identity and purity methods. A peptide not on it is asked about before it is shipped, and one that arrives anyway is held before any test (SOP-01).
- Orders arrive as an email composed by the order page; lab/orders.py reads each into an append-only order ledger (received, acknowledged, drafts created, closed) and prepares one draft result set per sample.
- The terms the sender accepts (revised 29 October 2026) are published and summarised on the intake sheet the sender signs.
- A full panel is received against what the method as written consumes, 5 vials (mass per vial 3; water content 2; HPLC from the mass per vial preparation; LC–MS from the HPLC preparation; endotoxin from the mass per vial preparation) (results.vials_required): a box with at least that many vials of one lot is logged and not held; one with fewer is held with a question to the sender (SOP-01). In the design's own words, as the intake sheet and page 1 of the certificate print them: "Full panel: 5 vials. Three are dissolved whole, by mass, to 2.0 mg/mL nominal in LAL reagent water (10 mM Tris of LAL grade for semaglutide, tirzepatide and retatrutide), for content per vial; purity, identity and endotoxin are taken from those solutions. Two more are used whole for water content."
- The capacity the turnaround is promised for is published:

> The 10-day guarantee applies per accession up to our weekly capacity. Above that, tell us before you ship and we give you a date in writing; that date, not 10 days, is then the one we are held to. A box above capacity sent without warning is received, logged and dated honestly, and the guarantee does not apply to it.
>
> The pricing page (data.json intake.volume)

Not yet in place

- International shipments: We accept samples from anywhere in the world. Before you ship from outside Canada, email us first: we confirm with you who is the importer of record and how the lyophilised peptide is to be declared for your shipment.

6 Methods and their validation

ISO/IEC 17025:2017 7.2

In place

Test	Method	Reference	Procedure
Purity by RP-HPLC–UV	RP-HPLC–UV 214 nm, area percent, n = 3 injections of one preparation; their RSD is injection repeatability. Mass per vial uses three independent vials	USP <621>; Ph. Eur. 2.2.46	SOP-02
Identity by LC–MS	LC–MS (ESI+); $[M+nH]^{n+}$ within 10 ppm of theoretical	Molecular formula, IUPAC masses	SOP-03
Bacterial endotoxin	Kinetic chromogenic LAL	USP <85>; Ph. Eur. 2.6.14 Method D	SOP-04
Water content	Coulometric Karl Fischer	USP <921> Method Ic; Ph. Eur. 2.5.32	SOP-05
Mass per vial	RP-HPLC–UV, external standard	USP <621>	SOP-06

- Every method parameter is published on the methods page from data.json and fills the defaults of every new result set; a parameter changed there changes the fingerprint of the procedure that prints it.
- Validation protocols VP-01 to VP-05, one per method, set before any data exist the characteristics the method's category requires (ICH Q2(R2) and USP <1225>; USP <85> and <921> for endotoxin and water), the experiments, the statistics and the acceptance criteria, the laboratory's own defaults marked as such. A validation report is composed from each analyte's data file with every statistic and decision printed; a scope row reads validated only when every criterion passes and a named person approves the report.

Not yet in place

- No method is validated: 0 of 14 scope rows carry a signed validation report, and the status of every row reads "written".
- Limits of quantitation are not published: the scope table's column stays empty until measured on the laboratory's own instrument in the matrix concerned.
- The uncertainty floors are provisional: the floor is a provisional pre-validation constant, the laboratory's prior estimate, until the method's validation has measured intermediate precision.
- CAS numbers not yet checked against the CAS registry: Retatrutide, BPC-157, TB-500 (Tbeta-4 17–23), Ipamorelin, CJC-1295 (no DAC), Melanotan II, AOD-9604, Epitalon (AEDG), GHK (sold as GHK-Cu).

What a signed validation report establishes, as the scope and methods pages list it:

- Specificity: the analyte peak is resolved from its known impurities and from the blank, and what it was not resolved from is recorded.
- Linearity across the working range, with the correlation coefficient and the residual plot retained.
- Repeatability and intermediate precision, reported as relative standard deviation rather than as a single figure.
- Accuracy, as recovery of the reference standard at three levels, for mass per vial; the working range; and solution stability over the length of a sequence.
- Limit of detection and limit of quantitation, measured rather than inferred from a signal-to-noise rule of thumb alone.
- A signed report, dated, naming the analyst. That signature is what marks a method validated.

7 Sampling and the handling of test items

ISO/IEC 17025:2017 7.3, 7.4

In place

The laboratory does not sample. Every item is supplied by the customer and tested as received, and the result applies to the item as received:

> A result describes one container at one moment. It says nothing about other vials in the lot, about what the seller ships next week, or about how the material was handled after it left us.

Sampling and the handling of test items, continued

> This result describes the composition of the sample as received under this accession only. It is not an assessment of safety, suitability for human or animal use, sterility, or regulatory status, and nothing in it is clearance to use any material.
>
> The limits page, and the use limitation on page 1 of every certificate

- Receipt is SOP-01: the condition of the sealed container and the intake sheet is recorded and photographed, the photograph recorded on the set (/photo/<id>/<name>), the accession assigned at logging, every vial labelled, and a deviation put to the sender as a written question before any test.
- Leftover material is held for the published period and then destroyed, as the intake conditions say (SOP-01); the destruction is recorded on the set (/destroy/<set>: the vials, how, a witness where there is one, and the reason if before the period ends), an entry in its audit trail, and the board lists every set past its period with none recorded.

Not yet in place

- The storage condition is recorded per sample; the refrigerator and freezer used and their temperature records are not yet listed (SOP-09).

8 Equipment, traceability and supplies

ISO/IEC 17025:2017 6.4, 6.5, 6.6

In place

- Every reported result names the instrument that produced it (identifier, make and model, software), the column, the data file and the acquisition time; validate() refuses to issue without them (SOP-09).
- Reference materials are recorded per result with their lot: the reference standard with its supplier, catalogue number and content and how the content was assigned; the control standard endotoxin with its potency; the water standard with its certified value. The certificate prints them.
- Theoretical masses are computed from the molecular formula with IUPAC 2013 monoisotopic masses (chem.py), so an identity result is traceable to the formula and those masses.
- Every time the backend writes (logging, each audit entry, review, issue) is the server's UTC clock; acquisition and analysis times are copied in UTC from the instrument's data system.
- Externally provided products and services (clause 6.6): suppliers of reference standards, the control standard endotoxin, the lysate and the medium, and providers of subcontracted analyses, are evaluated before first purchase and at each new lot on the record SOP-09 sets (legal identity; certification or accreditation verified on the body's own register; the lot certificate's content with its U and k; agreement with the laboratory's own tests), with three approval states, approved, conditional (no U stated: the model's default uncertainty applies) and not approved; a term of an uncertainty budget is taken only from a certificate or a provider that states U with its k; the approved-supplier list is a quality record reviewed at the management review (SOP-09; SOP-06 for the standard's routes).

Not yet in place

- No instrument is listed yet: make, model and serial number are published on the methods page and on each certificate once the instrument is installed and its serial plate can be photographed, and never for an instrument the laboratory does not own.
- Calibration of the balance, pipettes and thermometers, with certificates traceable to national standards and set intervals: none on file (SOP-09).
- No supplier or provider is on the approved-supplier list yet (data.json standards.items is empty); suppliers are recorded per result only, and no subcontracting arrangement is on file.

9 Measurement uncertainty

ISO/IEC 17025:2017 7.6

Test	Method floor (expanded, k = 2)	Reported as
Purity by RP-HPLC–UV	±0.3% area	value ± U
Mass per vial	±2% relative	value ± U
Water content	±0.1% w/w	value ± U
Bacterial endotoxin	×/÷ 1.5	value ×/÷ factor, with the interval
Identity by LC–MS	none	mass error in ppm per charge state

In place

– U combines the standard error of the replicate mean with the method floor, k = 2, with the effective degrees of freedom reported (each test procedure, and lab/results.py).

Not yet in place

– The floors are provisional: the floor is a provisional pre-validation constant, the laboratory's prior estimate, until the method's validation has measured intermediate precision.

10 Ensuring the validity of results

ISO/IEC 17025:2017 7.7

In place, in every run

Test	Checked in every run	Procedure
Purity by RP-HPLC–UV	Blank; reference standard: symmetry factor, plate number, resolution, area RSD over 5 or 6 injections; three sample injections and their RSD	SOP-02
Identity by LC–MS	Every observed charge state against the criterion; instrument class and resolving power recorded; ions tied to the HPLC main peak	SOP-03
Bacterial endotoxin	Standard curve |r|; positive product control recovery; negative control; replicate onset CV	SOP-04
Water content	Drift before titration; water standard recovery; solvent blank	SOP-05
Mass per vial	Calibration r^2; every sample response inside the calibration range; back-calculated levels; mass balance against whole-vial water	SOP-06

Control charts, from every issued run

Control charts (lab/qc_trend.py): the suitability values every issued run records are charted, one point per run, read from the arithmetic the certificate prints and never recomputed: Purity by RP-HPLC–UV: standard retention time, standard area RSD, symmetry factor, plate number (apparent, gradient), resolution, QC check material: purity, re-test or replicate: purity; Identity by LC–MS: mass error of the main ion; Mass per vial: calibration slope, calibration r^2, QC check material: content, re-test or replicate: content; Water content: water standard recovery, drift before titration, QC check material: water, re-test or replicate: water; Bacterial endotoxin: standard curve |r|, standard curve slope, positive product control recovery, QC check material: endotoxin, re-test or replicate: endotoxin. A series is one parameter on one instrument and, for the analyte-specific ones, one analyte. Each run is judged against the limits then in force by the rules the acceptance criterion, 1-3s, 2-2s, R-4s, 4-1s and 10x, any of which puts the series out of control, and 1-2s and 7T, which warn. Limits are the mean and standard deviation of a series' first 20 runs, drawn from 5 runs and provisional below 20; they are frozen only by a named person who has read those runs (establish asks for the name; the software never freezes them on its own, not at issue and not during an evaluation) and changed only by another named action with its reason, each a chained entry in lab/qc_limits.json. The backend serves them at /qc and /qc.pdf and takes the limits actions at /qc/establish and /qc/recalculate; at issue it shows how the set's runs sit against the current limits, and a value outside them is worth checking, not a blocker.

Ensuring the validity of results, continued

QC check material: none recorded. qc_materials.json does not exist; a characterised in-house reference lot per method, with its assigned value and limits, is recorded there by the owner and charted from the first run that carries it. The lot's assigned value and limits are recorded by the owner in lab/qc_materials.json from the characterisation the record names (nothing invents one); each run records what it found beside its result; a series is one lot on one instrument, and a value outside the lot's limits is out of control whatever the statistics say (series qc_content, qc_endotoxin, qc_purity, qc_water).

Not yet in place

- Control charts: no real report has issued, so no run is charted, and no series has frozen limits (lab/qc_limits.json does not exist yet). No QC check material lot is recorded in lab/qc_materials.json, so the material series are empty and what is charted is each run's own suitability values (clause 7.7.1).
- Proficiency testing and interlaboratory comparison (clause 7.7.2): no proficiency-testing scheme covers any of the five methods on a synthetic peptide (ILC_PROGRAMME.md section 1, the providers' own pages read on the date it records), so the laboratory runs a two-laboratory split-lot comparison per method, scored by E_n from both laboratories' expanded uncertainties and cross-checked by zeta (SOP-11). The partner is accredited to ISO/IEC 17025 by an ILAC MRA signatory with the test in its scope, reports U, is independent of the laboratory and agrees in writing to publication whatever the outcome (SOP-11, the partner): no partner is named yet (data.json quality.ilc.partner). Two lots a year go through all five methods, one lipidated incretin and one lot from another family in rotation, so every family is compared within three years; the plan: none is planned yet (data.json quality.ilc.plan); the first follows the instrument running and the first validation report signed, and its date is an owner fact. The verdict is E_n's (|E_n| at most 1.0 satisfactory, above it unsatisfactory and a CAPA), with zeta beside it (|zeta| at most 2.0 satisfactory, between 2.0 and 3.0 a recorded warning); identity is scored by agreement of the conclusion and endotoxin in ln space. Every result is published on /reports beside the reports it compares, failures included, within 15 business days of both results (the site does not render the section yet; ILC_PROGRAMME W1). Last result per method: none completed yet (data.json quality.ilc.results). No comparison has been run: the clause is not yet met.
- Retained vials: once a month per method one retained vial of an issued accession, chosen at random by the reviewer inside the retention period, is re-logged under a blind re-test code, run as a sample and compared with the original as zeta_r; once a quarter per method, when a second analyst holds the authorisation, both analysts run the QC check lot independently on one day (SOP-11, intra-laboratory checks; the frequencies are SOP-11's until data.json quality.ilc.retests_per_month and replicates_per_quarter are set). lab/qc_trend.py charts the re-test and replicate pairs.

11 Reporting

ISO/IEC 17025:2017 7.8

In place

- Every report is a certificate composed from its result set by one composer, every number computed from the data. It carries both signatures, the accession with its check digit, the QR to the public lookup, the SHA-256 of its data summary and of its complete record, and "Page n of m" on every page.
- Conformity is stated only against a specification supplied with the order or a claim on the sender's label (marked "label claim"); identity against the laboratory's own criterion ("laboratory criterion"). Without either the result reads "None supplied; for information".
- Decision rule (ISO/IEC 17025:2017 7.8.6; ILAC-G8:09/2019): the conclusion is reached by simple acceptance (guard band w = 0) on the value rounded to its reported precision; the statement beside it says whether the conclusion still holds with the expanded uncertainty (k = 2) included, the guard band w = U. Where a limit is stated more coarsely than the result, comparing at the reported precision is stricter than USP General Notices 7.20 and Ph. Eur. General Notices 1.2, which round to the limit's own digits.
- A report whose page-1 conclusion is "Below claim", "Does not meet claim", "Does not conform" or "Not confirmed" is told to the sender before it is published: the notice ("Email 3b: told before publication") is recorded in the set's audit trail, and issue is refused until it is (SOP-07).

Reporting, continued

- Information supplied by the customer (the lot reference, the label claim, a salt form stated by the supplier) is marked as such on the certificate.
- An issued report is never amended in place: a correction is a new report and the original stays published, marked retracted (SOP-07, SOP-08).

Not yet in place

- No real report has been issued: the register holds 0, and the three worked examples say on their face that no sample was analysed.

12 Complaints, nonconforming work and corrective action

ISO/IEC 17025:2017 7.9, 7.10, 8.7

In place

- SOP-08: a complaint is received at help@cupel.ca, acknowledged, investigated against the record and closed in writing; an issued report found wrong is corrected by a new report that supersedes it, and the original stays published, marked retracted.
- Nonconforming work is stopped where it is found: validate() refuses to issue, an edit after review returns the set to draft, a question on receipt holds the clock, a number that will have no report is withdrawn, and a late report is free.
- The register enforces the correction path itself: 34 guards in register.db refuse a deletion, a change to an issued report, a second retraction and a correction that supersedes nothing (SOP-08 lists them).
- Complaints log (/complaints, lab/records/complaints.jsonl): every case under its own number, CMP-YYYY-NNN, its steps (opened, acknowledged, investigated, decided, closed) recorded forward only, one event per line, each line chained to the one before it as the audit trail is; the page checks the chain (SOP-08).
- Corrective and preventive actions log (/capa, lab/records/capa.jsonl): every case under its own number, CAPA-YYYY-NNN, its steps (opened, cause, action, verified, closed) recorded forward only, one event per line, each line chained to the one before it as the audit trail is; the page checks the chain (SOP-08).
- A complaint decided by an analyst or reviewer of the report it concerns is flagged on the record of the decision.
- The effectiveness of every corrective action is checked after an interval, against evidence, before the case is closed (SOP-10, Follow-up).

Not yet in place

- Independence: the outcome of a complaint is to be decided by a person not involved in the work (clause 7.9.6), which a laboratory of two signatories cannot do for a report both of them signed; the log flags such a decision, it does not prevent it. The owner's decision closes it: a third entry in data.json org.people whose role names complaints (an external quality consultant is acceptable).

13 Control of data and information management

ISO/IEC 17025:2017 7.11

In place

- The register is built to refuse a deletion of any report or logged sample and any change to an issued report's content, whichever program holds the file, and to show a guard dropped or altered at its next integrity check: refusal in register.db, detection by lab/integrity.py (SOP-08).
- Each result set's audit trail is append-only and chained: every entry carries the SHA-256 of the entry before it, so an entry edited, removed or inserted later breaks the chain, and the history page says where.
- Every issued report carries two SHA-256 hashes, of its data summary and of its complete record, both served beside the certificate; the build refuses to publish when a served file does not hash to what the register holds.

Control of data and information management, continued

- lab/integrity.py re-verifies the register, the served files and the result sets from disk.
- lab/backup.py makes and verifies an archive of the register, the result sets, the served certificates and data.json.
- One set's complete record can be exported for an inspector as a zip with a manifest of SHA-256 hashes, the export itself written to the trail.
- Every change posted to the backend carries a per-session form token and must come from the backend's own address, so a page on another site cannot post to it.

Not yet in place

- The backend has no passwords: the "Working as" name records who acted but does not authenticate them, which is why the backend stays on this computer.
- Raw data files stay in each instrument's data system and are named on the certificate; their retention and backup cannot be described until an instrument is installed (SOP-09).
- A validation run recorded against an approved SV-01: SV-01 is the plan for the laboratory's own software (the functions that affect results, the risk of each, the suite that covers it, the version by file fingerprint, the change-control rule), and its evidence is python make.py check passing every suite (register, test_analytes_reference, test_cds_import, test_e2e, test_emails, test_launch_facts, test_launch_preview, test_management_review, test_metrics, test_orders, test_qc_trend, test_report_api, test_results, test_safety, test_sop, test_tracking, test_validation, test_vendor_kit, test_worksheets, selftest, build, integrity, integrity_selftest, backup_selftest); it is not yet approved, so no run is recorded against it.

14 Documents, records, audits and review

ISO/IEC 17025:2017 8.2–8.9

In place

- Document control: every laboratory document is composed from its controlled sources at build. Its fingerprint changes when any source does; approval is recorded in data.json with the fingerprint approved, and a document whose fingerprint has moved says so on its face.
- Review of documents (clause 8.3.2): every document is reviewed at least once a year, and whenever a controlled source changes its text (the fingerprint shows it); the review is recorded by approving the current fingerprint again in data.json documents, so the date of the last review is the approval date printed on page 1. The interval is the laboratory's own, in effect when this summary is approved.
- Risks and opportunities (clause 8.5): QM-01 keeps the register, with likelihood, impact, owner and action for each, and the impartiality analysis; it is reviewed at every management review (input m).
- Internal audit (clause 8.8) and feedback (clause 8.6): SOP-10 sets the programme over every clause and every document in a cycle of a year, the auditor's independence in a laboratory of two, the records, the follow-up through the corrective-action log, and how feedback is sought and recorded.
- Records that cannot be regenerated are never deleted: register.db, every result set with its audit trail and emails, the complaints log (lab/records/complaints.jsonl) and the corrective and preventive actions log (lab/records/capa.jsonl), and every certificate and record file as issued (SOP-07).

Documents, records, audits and review, continued

- The input to the management review (clause 8.9.2) is composed from the records by python lab/management_review.py (the backend serves it at /metrics/review.pdf for the month asked): Management review input (summary; a) Changes in internal and external issues; b) Fulfilment of objectives: turnaround and the guarantee; c) Suitability of policies and procedures; d) Actions from previous management reviews; e) Outcome of recent internal audits; f) Corrective actions: corrections, retractions and the action log; g) Assessments by external bodies; h) Changes in the volume and type of work; i) Customer and personnel feedback; j) Complaints; k) Effectiveness of implemented improvements; l) Adequacy of resources: capacity and open work; m) Results of risk identification; n) Assurance of the validity of results: the control charts; o) Other factors: monitoring, training: holds and training; effectiveness of the management system and its processes; improvement of the laboratory activities; provision of required resources; any need for change; record of the review; how each figure is computed), for a month and since the laboratory opened, worked examples excluded; an input no record can answer is listed as such. It is the input to a review, not the record of one, and it names who data.json names to hold the review.
- The record of a management review (clause 8.9.3) is written by python lab/management_review.py record to lab/records/reviews.jsonl: who held it, the decisions on effectiveness of the management system and its processes, improvement of the laboratory activities, provision of required resources and any need for change, and the actions with their owners and dates, one chained line per review as the case logs are, read back into the next month's input. No review is recorded yet: the file does not exist.

Not yet in place

- The risk register (QM-01) has not been reviewed at a management review, and its ratings are the authors' estimates until the owner approves QM-01.
- Internal audit (clause 8.8): none has been carried out; SOP-10 sets the programme, and no auditor is named yet (data.json quality.internal_audit, an owner decision).
- Management review (clause 8.9): none has been held; its input is composed (above), but the decisions and actions of clause 8.9.3 are not recorded and nobody is named to hold it.
- Feedback from customers beyond complaints (clause 8.6): SOP-10 sets how it is sought and recorded; the issued email does not yet ask for it, and none has been received.

15 Open points

Open point	Clause	Where it is closed
Legal entity, address, telephone, country	5.1	data.json org
Competence and training records	6.2	QM-00
Instruments: listed, qualified, calibrated	6.4, 6.5	SOP-09
Method validation, 14 of 14 analytes	7.2	scope table
Formulas and CAS numbers checked at source	7.2	data.json scope
Uncertainty floors measured	7.6	lab/results.py
Control charts: runs charted, limits frozen	7.7.1	lab/qc_trend.py, /qc
Interlaboratory comparison: partner named, first comparison run	7.7.2	SOP-11, data.json quality.ilc
Declarations of interest and confidentiality undertakings signed	4.1.4, 4.2.4	QM-01, data.json org.people
Ownership and other interests on file	4.1.4	data.json impartiality
Quality policy approved and signed	8.2.1	QM-02, data.json quality.policy
Complaint decider named	7.9.6	data.json org.people
Internal auditor named	8.8	data.json quality.internal_audit
Internal audit held; management review held	8.8, 8.9	SOP-10, lab/management_review.py
Software validation run recorded	7.11.2	SV-01
Backend authentication	7.11	QM-00

16 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.

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Current revisions

End of document