Risks, opportunities and impartiality

Who pays the laboratory and what each could press for, the safeguard against each threat and where it lives in the code, the register of risks and opportunities with likelihood, impact, owner and action, and the declaration of interests each named person signs.

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-01	Name	Cupel Laboratories
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Effective	Not yet in effect; takes effect when approved	Country	Canada
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Applies to	The whole laboratory; every person named		
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1 Purpose

To identify the risks to the laboratory's impartiality and to the validity of its results, the safeguard that exists against each and where it lives in the laboratory's software or documents, so that a reader can check it; to rate each risk and name who owns it and what is still to be done; to record the opportunities for improvement; and to set the declaration of interests each named person signs (ISO/IEC 17025:2017 4.1, 8.5).

2 Scope

The relationships that pay the laboratory or work in it: the sellers who send lots for publication, the buyers who send a vial they bought, the owners, and the two people who sign; the way a report is issued, noticed, published and withdrawn; the fee terms; and the system that holds the records. The general risks to the validity of results (a sample mix-up, an instrument that drifts, lost records, dependence on one person) are in the register below with the same columns.

3 Responsibilities

Role	Responsibility
Management	Owns this register: approves the ratings and the actions, reviews it at every management review and when the work changes (a new kind of customer, a new person, a new instrument, a new service), and answers for the ownership record.
Quality Manager	Keeps the register current, collects the signed declarations, brings the register to the management review as its input on risks (clause 8.9.2 m), and opens a corrective action when a risk materialises.
Everyone named	Signs the declaration of interests on appointment and yearly, and reports at once any approach that seeks to influence a result, a notice, a repeat, a withdrawal or the timing of a report, as a case in the corrective and preventive actions log (/capa) with source "other" and the word impartiality in the nonconformity.

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

4 References and controlled sources

Standards and other documents

- ISO/IEC 17025:2017 4.1 (impartiality), 4.2 (confidentiality), 8.5 (actions to address risks and opportunities) and 8.9.2 m), cited for what they ask; the laboratory claims no conformity with them.
- QM-00 (the summary), QM-02 (the policy), SOP-01 (holds, withdrawal), SOP-07 (review, issue, the notice, the register), SOP-08 (complaints, nonconforming work, corrective action), SOP-10 (internal audit, feedback), SV-01 (the software).

Controlled sources, read at every build

- data.json integrity, audiences, pricing, guarantee, publication, impartiality (ownership, relationships, reviewed_on), org.people (roles and the dates each signed), quality.internal_audit, quality.policy.
- register.py, lab/entry_server.py, lab/results.py, lab/emails.py, lab/orders.py, lab/backup.py, lab/integrity.py, lab/metrics.py: the safeguards below are cited to the file and the function that carries each; a name the file no longer carries prints as not found, and lab/test_sop.py refuses the build.

5 Who pays the laboratory, and what each could press for

ISO/IEC 17025:2017 4.1.4

The laboratory is paid by the party whose product it judges and by the party who bought it, and it is two people. Each relationship is stated here with the pressure it creates; the safeguard against each is in the next section, cited to where it lives.

What the laboratory tells a seller who sends many lots:

> Each lot gets its own accession number and its own page. Put the QR on the listing and the buyer reaches our register, not your site. A box of many lots ships with one manifest, one line per lot.
>
> 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.
>
> A low result is published under its number like any other, next to your lot reference.

The vendor page (data.json audiences.vendor)

The commitments as published on the Why Cupel page (data.json integrity.items), which the safeguards below rest on:

- 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.

Sellers	A seller sends lots so that buyers can check them under the lot reference. A seller sending many lots pays a large share of the fees, and an adverse report under that seller's reference costs the laboratory a customer. The pressure is for a favourable result, a quiet withdrawal, a repeat, or notice of an adverse result in time to act on it.

Who pays the laboratory, and what each could press for, continued

Buyers	A buyer sends a vial from a lot they bought, or reads a report a seller published. A buyer in dispute with a seller may want an adverse result; a buyer who paid for a test may dislike one that confirms the claim. The pressure is the mirror of the seller's, and the safeguards are the same.
Owners	Who owns the laboratory, and what else the owners do in the peptide trade, is not recorded (data.json impartiality.ownership). The undertaking published is quoted under the threats; an owner with an interest in a seller, a reseller or a manufacturer is the pressure this record must name, and the record must say there is none or name it.
The two people	The analyst and the reviewer are the whole staff. An agreement between them cannot be seen by a third person inside the laboratory; a complaint about a report both signed has no independent decider inside it; and the person who freezes control limits, decides a repeat or records a notice is one of the two. Named: Timothy Ian Benedicto, Medical Laboratory Technician; Roxanne Manlapaz, Laboratory Technician.
The comparison partner	The laboratory that runs the interlaboratory comparison of SOP-11 receives coded vials and reports values that are published beside the laboratory's own, whatever the outcome. The pressure is a partner chosen or kept for agreeing, or one with an interest in the lots compared. The control: the partner is independent (no common ownership, director, employee or premises; not a seller of peptides or owned by one; not a supplier of the laboratory's standards or reagents for the method; no customer with a result pending; no fee contingent on the outcome), stated in writing by both laboratories before the first shipment, kept with this record and reviewed annually at the management review. No partner is named yet (data.json quality.ilc.partner), so no statement is signed.
Relationships on record	No relationship is recorded (data.json impartiality.relationships); the threats below are the ones the design itself creates, and the record names the laboratory's actual customers' kinds the day it is written.

6 The threats and their safeguards

ISO/IEC 17025:2017 4.1.3, 4.1.5

Each threat with the pressure it creates, what is in place against it, where that lives (file and function, so it can be checked), the gap that remains and the action, with its owner.

A seller's lot: commercial pressure

Pressure	An adverse report costs a customer who may send many lots; a favourable one keeps them.
In place	Every sample is priced the same, with no volume discount, so no sender's work is worth more per report than another's (the price list, ID, PUR, IDP, QNT, H2O, LAL, FULL; the vendor page); the laboratory takes no payment for a favourable result and holds no inventory, affiliate payment or reseller margin (the published commitments); every issued report is published under its number whatever it says, the register refuses to delete or alter one, and a guard dropped is detected at the next integrity check (SOP-07, SOP-08).
Where	data.json pricing.items; data.json audiences.vendor.points; data.json integrity.items; register.py guard_statements; register.py public; build.py page_report; lab/integrity.py check_register
Gap	Nothing measures how much of the laboratory's work one sender represents: the register carries no sender by design, and only the order ledgers (lab/orders) do.
Action	The share of samples from the largest sender in the period, read from the order ledgers and never published, is brought to each management review as input m; asked of the orders and metrics owners. Owner: Quality Manager.

A laboratory of two

Pressure	No third person inside can see an agreement between the two, decide a complaint about a report both signed, or audit the quality system the quality manager runs.
In place	The backend refuses the analyst as reviewer of their own set and refuses issue when analyst and reviewer are the same person or either is unnamed; every change to a set is recorded under a name in a chained audit trail, and an entry that names nobody cannot be written; the complete record of every report is published so that any reader can recompute it (SOP-07).
Where	lab/entry_server.py review_refusal; lab/entry_server.py issue_blockers; lab/entry_server.py same_person; lab/entry_server.py audit; lab/entry_server.py verify_audit; register.py record_text
Gap	The backend authenticates nobody: the two names are typed (QM-00 7.11). No third person decides a complaint about a report both signed (SOP-08). No external auditor is named for the system audit (SOP-10).
Action	Accounts bound to data.json org.people, checked before entry, review and issue (the backend owner); a complaint decider (a third entry in org.people whose role names complaints); an external auditor (data.json quality.internal_audit). Owner: Management.

The threats and their safeguards, continued

The notice before an adverse report

Pressure	The sender learns of an adverse conclusion before it is published, and may use the time to ask for a repeat, a withdrawal or a change.
In place	A report whose page-1 conclusion is “Below claim”, “Does not meet claim”, “Does not conform” or “Not confirmed” is told to the sender first: the notice is recorded in the audit trail with the hash of the content it was given on, issue is refused until it is on record and again when the content changes after it, and the period is the published one (“We write to you on the day the report is published.”). Nothing the sender answers changes the result or the date: a test is repeated only on a stated criterion (SOP-08), and the commitment published is that no embargo, pre-review or withdrawal after the data exist is offered.
Where	lab/entry_server.py ADVERSE_CONCLUSIONS; lab/entry_server.py notice_state; lab/emails.py pre_publication; data.json publication.notice_days; data.json integrity.items
Gap	data.json publication.notice_days is not set, so no period is promised and the notice may go on the day of publication: a gap for the sender, not for impartiality.
Action	The owner sets publication.notice_days; the internal audit samples notices against the reports they preceded (SOP-10). Owner: Management.

Withdrawal of a logged number

Pressure	A logged number under which no report issues is withdrawn and the lookup says so; a withdrawal after test data exist would take an unwelcome result out of public view.
In place	Only a logged, unissued set can be withdrawn, with one of the recorded kinds (returned or not_tested) and a reason, which the ledger keeps and never publishes; the ledger row stays public as withdrawn and the lookup answers “Logged on <the logged date>; no report was issued under this number, and none will be.”; the sender is told (“Email 7: withdrawn, no report under this number”); the set is locked and the withdrawal is an entry in its audit trail; the commitment published is that no sender is offered a chance to withdraw a sample after the data exist.
Where	lab/entry_server.py post_withdraw; lab/entry_server.py do_withdraw; register.py withdraw; register.py public_samples; lab/metrics.py sec_withdrawals
Gap	The backend checks the set’s status, not whether a test section holds data: a set with a measured adverse identity could be withdrawn by any named actor, and the public ledger would not say that it had been tested.
Action	Refuse a withdrawal once any test section holds data, or publish the row as withdrawn after testing (the backend and register owners; CRITIQUE_17025 F7); until then every withdrawal is counted by lab/metrics.py and read at the management review. Owner: Quality Manager.

Fee terms and the guarantee

Pressure	Payment is due whatever the result, which removes one lever; the guarantee makes a late report free, which could press for haste over care.
In place	The invoice is prepared at logging with the sample-logged email and is the same for every result (“Email 6: invoice”); the guarantee runs from recorded receipt and a late report is free, recorded on the set and counted (Made free by the guarantee); nothing in the issue rules relaxes with time: validate’s refusals and the issue blockers are the same on the first day and the last.
Where	data.json guarantee; lab/emails.py invoice; lab/entry_server.py guarantee_for; lab/metrics.py sec_turnaround
Gap	No gap identified.
Action	The on-time share and the count of free reports are objectives in QM-02, read at every management review. Owner: Quality Manager.

A typed plain-terms paragraph

Pressure	The certificate’s plain-terms paragraph can be typed over the generated one; a softened paragraph beside an adverse conclusion would mislead a reader who reads nothing else.
In place	The generated paragraph is kept beside the typed one in the computed record, the conclusion rows are computed and cannot be typed, and the typed text is in the published record and in the audit trail.
Where	lab/results.py compute (plain_terms_generated); register.py record_text
Gap	The certificate does not mark the paragraph as typed (CRITIQUE_17025 F17).
Action	Label the paragraph, or print the generated text beside the typed one (the model and certificate owners). Owner: Quality Manager.

The threats and their safeguards, continued

Ownership and other interests

Pressure	An owner or a signatory with an interest in a seller, a reseller or a manufacturer would gain from favourable reports.
In place	The undertaking published on the Why Cupel page: “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.”
Where	data.json integrity.items; data.json impartiality; data.json org.people (signed.interests)
Gap	Ownership and the owners’ other interests are not recorded. Declarations of interest signed: Timothy Ian Benedicto not recorded; Roxanne Manlapaz not recorded.
Action	Record the ownership and each owner’s other interests (data.json impartiality.ownership); each named person signs the declaration below and the date goes into that person’s signed.interests in data.json org.people. Owner: Management.

7 The register of risks and opportunities

ISO/IEC 17025:2017 8.5

Likelihood and impact are rated low, medium or high. The ratings are the authors’ estimates, proposed for the owner’s approval with this document; they are revised at every management review (input m) and when the work changes.

Id	Risk	Likelihood	Impact	Owner	Safeguard in place, gap and action
R1	An adverse report under a volume seller’s lot is softened, delayed or withdrawn	medium	high	Management	The safeguards of the threats above. Action: the sender share at management review; refuse withdrawal once data exist.
R2	Two names typed by one person	low	high	Management	Loopback only, a form token on every change, the chained trail (QM-00 7.11). Action: accounts bound to org.people.
R3	A sample mix-up between vials or lots	low	high	Analyst	The accession assigned at logging and printed on every vial and box label with its QR (lab/labels_pdf.py); one set per sample; the intake sheet (SOP-01). Action: the audit samples labels against sets.
R4	An instrument fails or drifts unnoticed	medium	medium	Analyst	System suitability in every run (SOP-02 to SOP-06); the control charts (lab/qc_trend.py westgard); the out-of-service rule and a CAPA case (SOP-09). Action: QC check material lots recorded and run (QM-00 7.7).
R5	Loss or alteration of records	low	high	Quality Manager	The register’s guards, the chained trails, the two hashes, lab/integrity.py run_checks, lab/backup.py backup and the restore drill (lab/drill.py). Gap: every copy of a backup is on the project’s drive. Action: name backup.offsite_path; the drill on its schedule with the operator recorded.
R6	Dependence on one person	high	medium	Management	Two people; a report needs both. Gap: no deputy is named. Action: name deputies in data.json quality.policy.responsibilities; the external auditor and the complaint decider.
R7	The host or the published site is lost	low	low	Quality Manager	The site is rebuilt by one command from the register, the sets and data.json (build.py); site/r is in the archive. Action: the restore drill.
R8	A software change alters a result unnoticed	medium	high	Quality Manager	Every procedure that prints a model constant moves its fingerprint; SV-01 fingerprints every software file and the suites run on every check (python make.py check). Action: approve SV-01 and re-approve it on every change.

The register of risks and opportunities, continued

R9	A wrong formula or mass behind an identity	low	high	Reviewer	chem.py mono recomputes every mass from the formula and self-tests; lab/test_analytes_reference.py; the scope rows marked for confirmation (QM-00 7.2). Action: a chemist's check of the flagged formulas and CAS numbers.
R10	Clocks disagree between the backend and the instruments	medium	low	Analyst	Every backend time is the server's UTC clock; instrument times are copied with their offset. Gap: no synchronisation rule (SOP-09). Action: data.json instruments.time_source.
R11	The form-token key is lost	low	low	Quality Manager	Losing lab/.csrf_key ends open sessions and nothing else; it is never archived or published (lab/integrity.py check_no_secret).

Opportunities

- An interlaboratory comparison published beside the reports it compares (data.json quality.ilc; QM-00 7.7), since no proficiency scheme for peptides exists.
- QC check material lots run beside the samples and charted as their own series (QM-00 7.7).
- Feedback sought from every sender at issue, and read at the management review (SOP-10).
- A public daily anchor of the register's running hash, so a consistent rewrite of a row, its set and its trail would be seen from outside (CRITIQUE_17025 F14).
- Accounts bound to org.people, which would also let the backend enforce the complaint decider and the authorisation per test.

8 Declaration of interests

ISO/IEC 17025:2017 4.1.4, 4.1.5

Each person named in data.json org.people signs the declaration below on appointment and yearly; the signed copy is filed with the quality records and the date is recorded against that person in data.json org.people (signed.interests). The confidentiality undertaking (clause 4.2.4) is signed the same day and recorded the same way (signed.confidentiality).

I, the undersigned, named below with my role, declare that:

8.1 I hold no financial interest in any seller, reseller or manufacturer of peptides, and I will declare one the day I do.

8.2 I receive no payment from any customer of the laboratory other than through the laboratory's published prices, and no gift, commission or favour from a sender or a buyer.

8.3 I will report at once, to the Quality Manager and as a case under SOP-08, any approach that seeks to influence a result, a notice, a repeat, a withdrawal or the timing of a report.

8.4 I will not review, release, audit or decide a complaint about work I took part in.

8.5 I will keep confidential what the terms promise the sender (QM-00, Confidentiality), the sender's identity and anything learned from a sample included.

8.6 I renew this declaration yearly and on any change in my interests.

Name	Role	Declaration signed	Confidentiality signed
Timothy Ian Benedicto	Medical Laboratory Technician	Not recorded	Not recorded
Roxanne Manlapaz	Laboratory Technician	Not recorded	Not recorded

Signed on paper, by name and date; each person's signed block in data.json org.people records the dates and this table prints them.

9 Review of this register

ISO/IEC 17025:2017 8.5.3, 8.9.2 m)

- At every management review, as its input on risks (the record of the review: lab/records/reviews.jsonl); the review records the ratings it changed and the actions it set.
- Whenever the work changes: a new kind of customer, a new person, a new instrument, a new service, a new finding of the internal audit.
- Last reviewed: never (data.json impartiality.reviewed_on).

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.
- Ownership and the owners' other interests are not recorded (data.json impartiality.ownership).
- Declarations not yet recorded for: Timothy Ian Benedicto, Roxanne Manlapaz.
- No complaint decider is named (data.json org.people, a role naming complaints).
- No internal auditor is named (data.json quality.internal_audit).
- A logged set with test data can still be withdrawn (the threat above; CRITIQUE_17025 F7).
- The plain-terms paragraph is not marked as typed when it is (CRITIQUE_17025 F17).
- The ratings in the register are the authors' estimates until the owner approves this document.

11 Records

- This register, approved by fingerprint, and each revision of it.
- The signed declarations of interest and confidentiality undertakings, on paper, filed with the quality records; the dates in each person's signed block in data.json org.people.
- The record of each management review (lab/records/reviews.jsonl), where the register was reviewed.
- Corrective actions opened when a risk materialised, in the corrective and preventive actions log (lab/records/capa.jsonl).

12 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