Complaints and nonconforming work

How a complaint is received, investigated and answered, how nonconforming work is stopped and corrected, and the one path the register allows for an issued report found wrong.

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-08	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	Every complaint, every nonconformity	Web	cupel.ca
Supersedes	Nothing; first issue	Email	help@cupel.ca
Fingerprint	8292 965f 3bac fb0a		

1 Purpose

To receive, record, investigate and answer every complaint, and to identify, stop, evaluate and correct nonconforming work, including an issued report found to be wrong, by the one path the register allows: a new report that supersedes the old, which stays published and marked retracted.

2 Scope

Every complaint about the laboratory's work, from a sender, a buyer holding a certificate or anyone else; and every piece of nonconforming work, wherever it is found: at receipt, in a run, at validate or review, after issue, or by the build's guards and the integrity check.

Measurements carry uncertainty. When an error is found in an issued report, a correction is published as a new record, the original is marked retracted rather than deleted, and both remain reachable at their original addresses for the life of the register.

3 Responsibilities

Role	Responsibility
Anyone	Stops work they find nonconforming and tells the reviewer. Nobody repeats a test to obtain a different answer.
Reviewer	Receives and investigates complaints, decides whether work is nonconforming and what is done about it, and reviews every correction before it issues (SOP-07).
Analyst	Supplies the record and the raw data, and makes the correction a revision needs; does not decide the outcome of a complaint about their own work.

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

4 References and controlled sources

Standards and other documents

- ISO/IEC 17025:2017 7.9 (complaints), 7.10 (nonconforming work) and 8.7 (corrective action), cited for what they ask; the laboratory claims no conformity with them.
- SOP-01 (holds and withdrawal), SOP-07 (review, issue, revision), RUNBOOK.md sections 10 (a revision) and 16 (troubleshooting).

Controlled sources, read at every build

- data.json limitations (corrections and retractions), terms (publication), org.email.
- register.py: retract(), correct(), withdraw() and the guards listed below.
- lab/entry_server.py: revise, withdraw, the history page and its chain check, the export of a set's record; the complaints log (/complaints) and the corrective and preventive actions log (/capa).

5 Definitions

Complaint	An expression of dissatisfaction about the laboratory's work that expects a reply.
Nonconforming work	Work, or a result, that does not conform to the laboratory's procedures or to what was agreed with the customer.
Correction	The remedy for an issued report found wrong: a new report that supersedes it (a revision).
Retraction	The mark the original carries once corrected. It stays published at its address, with the reason and a link forward.
Withdrawal	Closing a logged number under which no report will issue (SOP-01). Not a correction: there is no report to correct.
Corrective action	What removes the cause of a nonconformity, so that it does not recur.

6 Receiving and investigating a complaint

Every complaint is a case in the complaints log (/complaints, kept in lab/records/complaints.jsonl), under its own number of the form CMP-YYYY-NNN, given when the case is opened. Its steps are recorded in order (opened, acknowledged, investigated, decided, closed), each under the name of the person recording it and the server's time; a note may be added at any step, and nothing but a note after it is closed. One event is one line, chained to the line before it as a set's audit trail is, and the log's page checks the chain.

6.1 Complaints arrive at help@cupel.ca, the address on the contact page and on every certificate, or in reply to a laboratory email.

6.2 Open the case on /complaints, filling the fields of its form: "Received (UTC)"; "How it came"; "From (who complained; kept here only)"; "Accession it concerns (if any)"; "The complaint, as received". How it came is one of email, telephone, letter, in person or other. The complainant's name is kept in the log only, never in a result set or a report.

6.3 Acknowledge it in writing from the laboratory mailbox, naming the accession if one is given and who is investigating, and record the acknowledgement as the next step.

6.4 Keep the email thread, with "Complaint", the case number and the accession in the subject line, filed with the set's records.

6.5 Decide whether it concerns the laboratory's work. A complaint about a seller's product, or one that disagrees with a result without faulting it, is answered with what the report does and does not show, as the limits page sets it out ("Results describe the sample received").

6.6 Look the number up on /verify and open the set: the result set, its audit trail (the history page checks its chain) and its emails.

6.7 Recompute both hashes over the served files and compare them with the register; the certificate page does it in the browser.

6.8 Re-read the raw data files named on the certificate; re-integrate or recalculate only from them.

Receiving and investigating a complaint, continued

6.9 Where vials were retained and the retention period has not run out, the reviewer may have one re-tested. A re-test that changes the result is issued only as a correction; one that confirms it is reported in the reply.

6.10 Record what the record and the raw data show as the case's investigation.

6.11 Decide whether the complaint is justified; if it is, the work is nonconforming (below). Record the decision with its reason; a decision recorded by an analyst or reviewer of a report under the accession is flagged on the record as taken by someone involved.

6.12 Reply in writing with the outcome; when a report is corrected, the correction email is the reply. Close the case with the answer sent, and the number of the corrective action it opened, if any.

7 Nonconforming work: where it is found and what happens

Found	What happens	On the record
At receipt: opened, damaged, unlabelled, below the minimum, not on the scope list	Logged as received; a hold puts it to the sender before any test (SOP-01)	The hold and its email
In a run: a suitability criterion missed	Printed as not met; the reviewer decides whether the run stands	The certificate; the trail
In a run: the endotoxin curve, spike recovery or negative control fails	The assay is invalid, the result "Not evaluated", and the assay is repeated	The set; the trail
At validate: a problem, or a rule refused at issue	Issue is refused until it is fixed	The validate page
After review: an edit to the content	The set returns to draft and the signature is cleared	The trail
The turnaround is missed	The report is free: the invoice is cancelled or the payment refunded	The set (guarantee); the trail
The identity does not match	Reported as found; no other vial is tested and nothing is re-run until it matches; the sender is told before publication	The certificate
No report will issue	The number is withdrawn (SOP-01)	The ledger; the trail
After issue: an error in a report	Corrected by a new report (below)	The register; the corrections log
The build's hash guards or the integrity check fail	Nothing is published; the file is restored from backup, never edited	The build log
The audit chain of a set is broken	Work on the set stops; the file is restored from backup and the break investigated	The history page

- Nonconforming work is stopped where it is found: nothing is issued from it until the reviewer has decided.
- A test is repeated only when the first run is invalid on a stated criterion (a validity check of the method, or a suitability failure the reviewer does not accept), never because a result was unwelcome; the replaced values stay in the audit trail.
- The sender is told, from the laboratory mailbox, whenever nonconforming work touches their result or their turnaround.
- A departure from the method as written that bears on a result (a narrower gradient, a test on an opened vial) is reported only with the sender's written acceptance, asked for with Email 3c: a departure from the method needs your acceptance, which the backend prepares at that step, before anything from that run is reported; the clock is paused until the answer arrives, either answer is recorded on the set, and an accepted departure is printed on the certificate and named in the issued email.

Nonconforming work: where it is found and what happens, continued

- At the bench: stop the sequence, plate or titration when a suitability, validity or hold-time rule of the method is failed, when a solution is dropped, spilled, mislabelled or out of time, or when the instrument shows a fault; write what happened, the time and what was done on the worksheet line. Then, the same day: an event the method itself handles (a failed suitability repeated by its own steps, a dropped tube replaced from the stock within its hold time) is a note entry on the set naming the worksheet line; anything that stops work on the set until someone decides (an instrument fault, a stock past its hold time with no retained vial, a contaminated plate series) is a stop-work hold on the set's Stop page (/stop/<id>,), placed by any named person with the reason and lifted only by a person authorised to release reports for the set's tests; a departure from the method as written that will be reported is a deviation on the set's Deviation page (/deviation/<id>,), which asks the sender's acceptance before anything from that run is reported. Tell the reviewer before any repeat. Nothing acquired is deleted or renamed.
- Each case is judged for its significance: could the same cause have touched other reports? If so, corrective action follows.

8 Correcting an issued report

An issued report is never edited and never deleted. It is corrected by a new report, and the register makes that the only way.

8.1 Open the issued set and press Revise; write what was wrong and what the revision changes. The reason becomes the original's public retraction note.

8.2 A draft opens with the next revision number and "supersedes" set to the original's number. Only one revision of a report can be open at a time.

8.3 Correct the data from the raw files, validate, and have a second person review it (SOP-07).

8.4 Press Issue. In one transaction the original is marked retracted with the reason, the correction takes the next serial of the one sequence, and the original links forward to it. If any step is refused, nothing is written.

8.5 "Email 5: correction issued" is prepared with the previous figures beside the new ones; send it to the sender with the new certificate attached.

8.6 Rebuild and publish. The corrections log lists the pair; the retracted certificate stays at its address as issued, and its page says so first and links its replacement (SOP-07).

What the register refuses

These guards are in register.db itself, so any program that opens the file meets the same refusals, not only the backend; a program can drop or alter a guard, and lab/integrity.py detects that at the next check by comparing every guard by name and text. The register is built to refuse, and the integrity check to detect. Each guard refuses with the words shown.

Guard	Refuses with
reports_no_delete	the register is append-only: reports are never deleted
reports_immutable	report content is immutable: issue a correction instead
reports_no_unretract	a retracted report cannot be reinstated
reports_supersede_requires_retraction	a correction may only supersede a retracted report
damm_no_delete	the Damm quasigroup is fixed: rows are never deleted
damm_no_update	the Damm quasigroup is fixed: rows are never changed
migrations_no_delete	the migration log is append-only
migrations_no_update	the migration log is append-only
samples_no_delete	the register is append-only: logged samples are never deleted
samples_immutable	a logged sample is immutable: number, time, set, analyte and source are fixed at logging
samples_one_way	a sample is closed once: logged becomes issued or withdrawn, and nothing after that changes
files_no_delete	the register is append-only: the fingerprint of an issued file is never deleted
files_immutable	the fingerprint of an issued file is immutable: a changed file is a correction, never an update

Correcting an issued report, continued

files_valid	a file is recorded only for a report that is in the register; a file name is one name under site/r/<accession>/, with no path in it; sha256 must be 64 lowercase hex digits
files_no_replace	the register is append-only: this file is already recorded for this report, and a fingerprint is never replaced; the register is append-only: an insert may not take the row id of a recorded file
reports_required	reports.<column> is required, for each of: received_utc, issued_utc, specimen, analyte, formula, matrix, method, result, figure, impurities, analyst, plain_terms, record_sha256, record_fields, payload, payload_sha256, status
reports_accession_valid	accession is malformed: the form is CL-YYYY-NNNNN-C; accession fails its Damm check digit; serial 00000 is not a number; specimen flag disagrees with the serial: 99900-99999 are the example reports
reports_hashes_hex	payload_sha256 must be 64 lowercase hex digits; record_sha256 must be 64 lowercase hex digits
reports_serial_once	this number is closed in the sample ledger: a number is issued under once; this serial is allocated in the sample ledger under another accession
reports_supersedes_rules	a report cannot supersede itself; a new report cannot be born superseded
reports_forward_link	the forward link is written once; a report cannot be superseded by itself; only a retracted report is superseded; the forward link must name the correction that supersedes this report
reports_retraction_fixed	a retraction is recorded once: its time and note do not change
samples_accession_valid	accession is malformed: the form is CL-YYYY-NNNNN-C; accession does not encode the year and serial logged; accession fails its Damm check digit
samples_serial_once	this number is already issued in reports; a ledger row is born issued only for a report that exists
samples_issue_requires_report	a sample is issued only once its report is in reports
reports_no_replace	the register is append-only: this accession is already in the register, and a report is never replaced; the register is append-only: an insert may not take the row id of a report; the register is append-only: this report is already superseded, and its correction is never replaced
reports_rowid_fixed	the register is append-only: the row id of a report never changes
samples_no_replace	the register is append-only: this number is already logged, and a logged sample is never replaced; the register is append-only: an insert may not take the row id of a logged sample
samples_rowid_fixed	the register is append-only: the row id of a logged sample never changes
damm_no_replace	the Damm quasigroup is fixed: a cell is never replaced
migrations_no_replace	the migration log is append-only: a step is recorded once and never rewritten
samples_withdrawal_stated	a withdrawal states its kind: untested or after_testing; a withdrawal after testing began states its reason: sender_request, sample_insufficient or method_failure; an untested withdrawal carries no reason category
samples_withdrawal_inserted	a withdrawal states its kind: untested or after_testing; a withdrawal after testing began states its reason: sender_request, sample_insufficient or method_failure; an untested withdrawal carries no reason category; only a withdrawn number carries a withdrawal kind
samples_withdrawal_fixed	the withdrawal kind and reason are written in the one step that withdraws the number, and never again

9 Corrective action

Every corrective action is a case in the corrective and preventive actions log (/capa, kept in lab/records/capa.jsonl), numbered CAPA-YYYY-NNN and kept as the complaints log is: steps (opened, cause, action, verified, closed) forward only, each line chained to the one before it. A case records its source (complaint, nonconforming work, internal audit, management review or other) and its reference (the complaint's number, an accession) where there is one.

9.1 Find the cause: the data, the instrument, the standard or reagent, the method, the person, or this or another procedure.

9.2 Find the extent: every report that shares the cause (the same instrument identifier, column, standard lot, analyst or period), read from the result sets, which record each of them.

9.3 Correct every affected report by the path above and tell each sender.

9.4 Change what let it happen (a procedure, the model, the backend) as a new revision, approved like any other; record it as the case's action, with the date it is due.

Corrective action, continued

9.5 After the interval SOP-10 sets (the action's due date passed and the activity it changed carried out at least once since), check that the change worked, and record the check with the evidence read (which reports, runs or records) and the date it was read as the case's verification, then close it. A verification without evidence, or before the interval, is not accepted (SOP-10, Follow-up).

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.
- Independence: the outcome of a complaint is to be decided by a person not involved in the work complained of. With the analyst and the reviewer of a report the only people who could decide, this cannot be met for a report both signed, and the reply says so; the log flags such a decision on its record, it does not prevent it. It is closed by an owner decision: a third entry in data.json org.people whose role names complaints (an external quality consultant is acceptable), who then decides every such complaint.

11 Records

- The complaints log and the corrective and preventive actions log (lab/records/complaints.jsonl, lab/records/capa.jsonl): every case and step, append-only, chained line by line; never edited and never deleted.
- The complaint and every reply, as the email thread, filed with the set's records.
- The result set and its audit trail: every edit, review, issue and revision, with the replaced values.
- The register: the retraction time and note, the supersedes and superseded-by links, written once each.
- The corrections log on the public site, built from the register.

12 Revision history

Revision	Change	Approval
1	First issue.	Not yet approved

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Current revisions

End of document