Getting It Right the First Time

A Roadmap for Writing Effective Corrective Action Plans

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BEFORE WE START

This is not a talk about bad laboratories

1 Competence is not the problem

The plans that get rejected are written by people who know their methods cold.

2 The reviewer is checking a list

There is a specific set of things an assessor looks for.

3 Nobody tells you why

A denial says the plan did not address the finding. It usually does not say which part was missing.

By the end you will know exactly what a reviewer looks for, and in what order.

WHY THIS MATTERS

A rejected plan is not a paperwork problem

One more chance

30

additional days to submit a revised plan, if the first one is found deficient.

Then

Deny, suspend, or revoke

accreditation for the Fields of Accreditation affected by the failure to take corrective action.

If a revised Corrective Action Plan does not demonstrate the issue would most likely be prevented in the future, ELAP will take action to deny, suspend, or revoke accreditation.

22 CCR § 64802.20(h)

THE TIMELINE

Four thirty-day windows, and two of them are yours

1

Assessment

You receive the on-site assessment report within 30 days.

2

Your plan

You have 30 days from receipt to submit the plan.

3

Review

The assessor approves or denies within 30 days.

4

Your revision

30 days to submit a revised plan. There is no third round.

The deadline of the CAP shall not be extended by the Provider. Both of your thirty-day windows are the ones in this diagram that nobody can widen for you.

State Water Board third-party assessment MOU · 22 CCR § 64802.20(g)

THE REGULATORY DEFINITION

Three things, by rule

A Corrective Action Plan is defined in California regulation. It is not a matter of house style — three elements are named, and a plan missing any one of them is incomplete on its face.

1

Root Cause Analysis

of the findings identified in the on-site assessment report

2

The corrective actions

that will take place to address the findings

3

The date

by which the findings will be corrected

Read the instructions included in the assessment report. The assessment instructions add two more items: the name of the person responsible for each action, and completion of every action within six months of the assessment date.

22 CCR § 64801.00(h)

The form gives you room to tell the whole story

FINDING 1	
2016 TNI Standard	V1M2 4.13.2.1
Requirement	The laboratory shall retain records of…
Finding	The laboratory had not retained…
Laboratory Response including Root cause analysis	*your full response goes here*

Form IAS/ELAP/005a

One open field. Room for every element.

This form asks one open question and gives you the space to answer it fully — no word limit, nothing left out because the grid had no line for it.

That openness rewards a well-organized response: label the box yourself and all seven elements the reviewer looks for land in one pass.

Bring your own structure to the open field. Bold headings are how you show the reviewer that every element is present.

THE CHECKLIST

Seven things a reviewer looks for

1. **Root cause**
   why it happened, at the system level
2. **Corrective action**
   what changes so the cause is gone
3. **Action to prevent recurrence**
   where else the same cause lives
4. **Timetable**
   named person and date for every action, all within six months
5. **Means to document**
   the specific records that will prove it
6. **Client notification**
   or a stated basis for "not applicable"
7. **Verification of effectiveness**
   how you will know it worked

Name each one in your response. Make the reviewer's job an act of reading, not searching.

THE MOST COMMON FAILURE

A correction is not a corrective action

Correction

Fixes the instance in front of you.

- We reanalyzed the affected samples.
- The analyst was retrained.
- The findings have now been closed.
- The form has been corrected.

Corrective action

Changes the system that produced it.

- The review step that missed it now exists.
- The procedure that allowed it is revised.
- The trigger that should have fired is defined.
- The gap is closed everywhere it occurs.

Do the correction. It is necessary. It is just not a complete corrective action.

THE RESPONSE THAT IS NEVER ACCEPTED

"No corrective action needed" is not an answer

Why it fails every time

- The response form is not the place to dispute a finding.
- By the time the report is issued, the finding is of record.
- It leaves the reviewer nothing to approve — so it is denied, and your 30 days are gone.

When to push back

- During the assessment — while the assessor can still look at evidence you produce.
- At the closing meeting — the last moment a finding can be discussed before it is written.
- Questions on findings go to the assessor within the same 30 days — and the CAP deadline does not move.

The closing meeting is your last low-cost opportunity.

State Water Board third-party assessment MOU

ROOT CAUSE

Three things that are not root causes

"Analyst error"

Names who, not why. Every process depends on people; a process that fails when one person has a bad morning is the finding, not the excuse.

"Oversight"

Names a category of human failure, not a mechanism. Nothing in it can be fixed, because nothing in it is described.

"We were short-staffed"

A condition, not a cause — and one that will still be true next year. If staffing is genuinely the cause, the corrective action has to be a workload or trigger change.

The test: could someone similarly qualified read your root cause and change something? If not, it is a restatement.

ROOT CAUSE

Keep asking until you reach something you control

Example finding: media verifications recorded as pass/fail rather than the observation of growth or no growth.

1	**Why was the observation not recorded?**	The bench form has only a Pass/Fail checkbox.
2	**Why does the form have no observation field?**	It was redesigned in 2024 to streamline the bench.
3	**Why did the redesign remove it?**	Document control review checks format and version — not whether a form captures an original observation.
4	**Why does the review not check that?**	The criterion was never written into the procedure.

The finding surfaced in microbiology. The defect lives in document control. That is the move most plans never make.

SCOPE

Every part of the finding, everywhere it lives

1. **All parts**

   A finding with two clauses needs two answers. Reviewers read it back against your response, sentence by sentence.

2. **All departments**

   If the cause is a procedure, it reaches every bench that procedure touches.

3. **All instruments and forms**

   The same defect usually exists on three more forms nobody looked at.

The repeat-finding trap

A plan that fixes only the audited bench passes review, then fails at the next assessment when the assessor finds the same defect one room over.

A subsequent assessment revealing that the laboratory failed to take the corrective actions specified in a Corrective Action Plan is its own basis to deny, suspend, or revoke.

22 CCR § 64802.20(i)

REPEAT FINDINGS

A repeat finding is answered with proof, not a plan

First-time finding

You may describe what you will do, who will do it, and when it will be finished. The reviewer approves the plan and verifies it at your next assessment.

Repeat finding

The corrective action must already be complete when you submit, and you must attach objective evidence that the issue is resolved. A plan alone is a non-response.

Objective evidence means the record, not the promise

The revised SOP itself, with its approval signatures. The completed training records. The new form, filled in. The data showing the control now works. Attached to the response — not described in it.

Your thirty days on a repeat finding is thirty days of doing, not thirty days of planning.

ACTION TO PREVENT RECURRENCE

Your action to prevent recurrence must be wider, not longer

Corrective action

Removes the cause where it produced this finding.

Action to prevent recurrence

Removes the same cause everywhere else it is waiting.

Worked example

CA: Revise the document control SOP and the microbiology media verification form.

APR: Review every active record form in every department for the same defect, and revise each one found.

Same cause. Different scope. That is what makes them two elements instead of one.

TIMETABLE

A named person, a date, and six months to close

Reads as reasonable

30 to 90 days for most actions, and every corrective action complete within six months of the assessment date. Longer is fine when you say why, if the date lands inside the six months.

Not a date

- "Ongoing"
- "As soon as possible"
- "At the next internal audit"
- "Upon completion of the revision"

Name the person responsible for every action

The instructions ask for the name of the person responsible for completing each corrective action, plus a proposed completion date. "The laboratory will" is not an owner — give the name and the role: Jane Doe, QA Manager. This matters more in small labs, not less: when three people wear nine hats, the unnamed action is the one that does not happen.

MEANS TO DOCUMENT

Name the record, not the intention

1	**Revised procedures**	SOP number and revision, with revision history and approval signatures
2	**Revised forms**	Form number and revision, plus the approval record for each
3	**Training**	Training record with attendance and competency sign-offs
4	**Reviews and assessments**	The memo or review record, by number, that captures what you found

Pointing back at your own corrective action report is not acceptable. The reviewer needs to know what to ask for at the next assessment.

VERIFICATION OF EFFECTIVENESS

The element most often skipped

It is also the one that decides whether you see this finding again. A plan without verification is a promise; a plan with it is a control.

A method

What will be examined, how many, and when. "QA will monitor" is not a method.

A criterion

What result counts as effective. State it before you look, not after.

A consequence

What happens if the criterion is not met. Usually: the corrective action reopens.

QA will review 100% of media verification records for December and January, with the acceptance criterion that every record documents the actual observation. Any record found non-compliant reopens the corrective action.

WORKED EXAMPLE ONE

A records finding, as answered

FINDING 1	
2016 TNI Standard	V1M2 4.13.2.1
Requirement	The laboratory shall retain records of original observations, derived data, and sufficient information to establish an audit trail, calibration records, staff records, and a copy of each test report.
Finding	The laboratory had not retained records of all original observations. Results for microbiology media verifications were recorded as pass or fail rather than the observation of growth or no growth.
Laboratory Response including Root cause analysis	**Root cause:** The document control SOP has no step verifying that a form captures an original observation. This is systemic — not analyst error. **Corrective action:** Add that criterion to the SOP. Rebuild Form QC-M-04 with discrete observation fields. **Action to prevent recurrence:** Review every active record form in every department for the same defect, and revise each one found. **Timetable:** Five actions, each with a named person and a date, 10/15 through 12/31/2026. **Means to document:** SOP QA-002 Rev. 4, Form QC-M-04 Rev. 3, record FRM-2026-01, training TR-2026-11. **Client notification:** Not applicable — basis stated, supporting memo named. **Verification of effectiveness:** 100% review for two months, then ten per department, against a stated criterion. A non-compliant record reopens the action.

WORKED EXAMPLE ONE

Why that one gets approved

✓ The cause is not where the finding was

Microbiology surfaced it; document control owns it. The plan repairs the process that approved a bad form.

✓ Prevention is wider than correction

The corrective action fixes two documents. Prevention sweeps every form in the building for the same defect.

✓ Every action has a name and a date

Five actions, each with a named person and a date, all inside the six-month window.

✓ Verification is allowed to fail

A stated criterion and a consequence: a non-compliant record reopens the corrective action.

Seven elements, seven headings. The reviewer never had to go looking for any of them.

WORKED EXAMPLE TWO

An internal audit finding, as answered

FINDING 2	
2016 TNI Standard	V1M2 4.14.2
Requirement	When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test results, the laboratory shall take timely corrective action.
Finding	The laboratory had not performed corrective actions on internal audit findings (Internal Audit Report, dated 12/16/2025).
Laboratory Response including Root cause analysis	**Root cause:** The laboratory did not perform corrective actions on the internal audit findings identified in the Internal Audit Report dated 12/16/2025. The findings were not addressed in a timely manner. This was an oversight on the part of the laboratory. **Corrective action:** The laboratory will perform corrective actions on the findings identified in the next internal audit.

WORKED EXAMPLE TWO

Why that one comes back

The root cause is the finding	with the verb tense changed. "Oversight" names no mechanism, so there is nothing anyone could fix.
The corrective action defers	It does not close the open findings. It proposes to keep not closing them until some future audit.
"The next internal audit" is not a date	Audits are annual. This is an unbounded delay written to look like a commitment.
Four elements are simply absent	No action to prevent recurrence, no timetable, no documents named, no verification of effectiveness.

The response is itself a second violation of the clause it is answering.

THE DIFFERENCE

Cause, action, dates — not word count

	Approved	Rejected
Cause	Names a mechanism the lab controls	Restates the finding
Action	Changes the system	Defers, or just does the correction
Dates	Named person and date per action	None, or an event instead of a date

Length is not the variable. The rejected plan could be fixed in a third of the approved one's word count. What is missing is structure and a real cause — not volume.

BEFORE YOU HIT SEND

Eight questions to ask yourself

1. Am I answering the finding at all — or arguing that none was needed?
2. Does my root cause explain a mechanism, or does it restate the finding?
3. Would my corrective action have prevented this, had it been in place?
4. Is my action to prevent recurrence wider than my corrective action?
5. Is this a repeat finding — and if so, is the work already done and the evidence attached?
6. Does every action name the person responsible and a date within six months?
7. Have I named the documents by number, so the assessor knows what to ask for?
8. Does my verification have a method, a criterion, and a consequence?

Photograph this one.

Write it once.

The plan that gets approved the first time is not the longest one. It is the one that names a real cause, changes a real system, and tells the assessor exactly what to look for next time.

Questions?

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