Please use this link to watch a recording of this training:

https://bacwa.box.com/s/pk9bulupfzvzf9fqu8mxp8w4k9ufcti1

INTERACTIVE PANEL WORKSHOP

Root Cause Analysis: Effective CAPA Writing & Implementation

Survey participants' laboratory scenarios, worked through live with our panel

Compiled by Payal Sarkar, City of San Jose

PANELISTS

Robin Cook ◆ Maria Friedman ◆ Tony Francis, PhD

AGENDA OVERVIEW · 2 HOURS

Agenda Overview

10:00–10:10 10 min	**Panelist introductions** Meet the panel, what the survey told us, this meeting will be recorded
10:10–10:30 20 min	**Root Cause Analysis Fundamentals and Challenges** Kickoff presentation · Robin Cook
10:30–10:50 10 min	**CA ELAP update** Maria Friedman
10:50–11:55 65 min	**Scenarios 01–13 with audience Q&A** About 5 min each; paired cases 05B and 10B, bonus 14–16 if time allows
1:55–2:00 5 min	**Wrap-up & final questions** Closing thoughts from the panel

PANELISTS Robin Cook ◆ Maria Friedman ◆ Tony Francis, PhD

MEET THE PANEL

Our panelists

RC

Robin Cook

Compliance Manager
City of Daytona Beach

Vice Chair of the TNI Microbiology Expert Committee · presenting today's kickoff

MF

Maria Friedman

Sr. Environmental Scientist
California ELAP

Supervisor of the CA-ELAP Assessment Unit · presenting an update from ELAP

TF

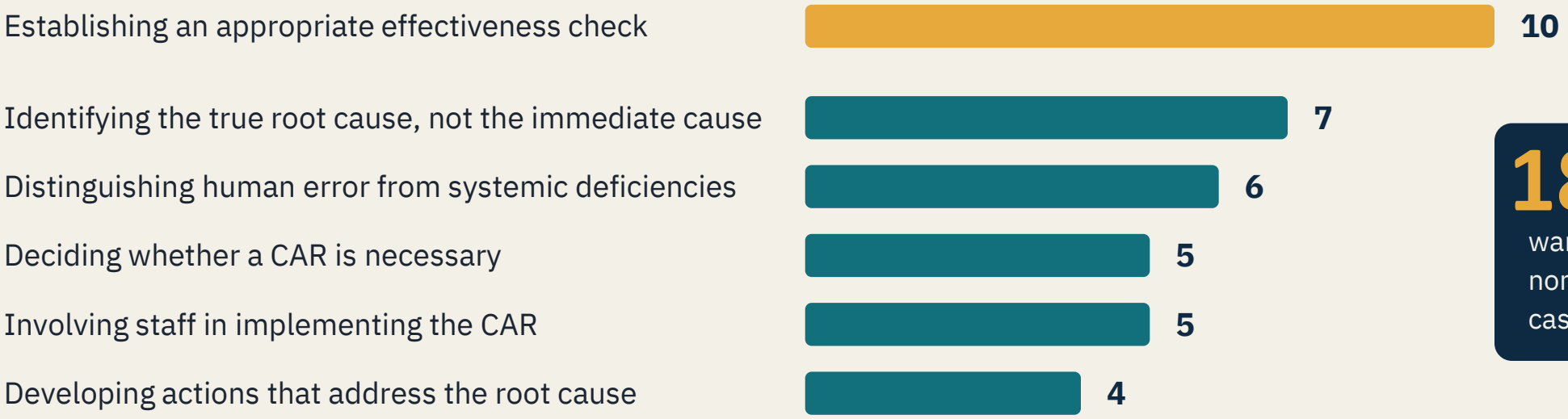
Tony Francis, PhD

Owner
SAW Environmental Consulting

Assessor and Consultant

WHAT YOU TOLD US · 37 SURVEY RESPONSES

Your biggest RCA challenges



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want real-world nonconformance case studies

PANELISTS

Robin Cook ◆ Maria Friedman ◆ Tony Francis, PhD

KICKOFF PRESENTATION

Root Cause Analysis Fundamentals and Challenges

Robin Cook · Compliance Manager, City of Daytona Beach · Current Vice Chair and Former Inaugural Chair of the TNI Microbiology Expert Committee

PANELISTS

Robin Cook ◆ Maria Friedman ◆ Tony Francis, PhD

UPDATE

CA ELAP update

Maria Friedman · Sr. Environmental Scientist, Supervisor of the CA-ELAP Assessment Unit

PANELISTS

Robin Cook ◆ Maria Friedman ◆ Tony Francis, PhD

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SCENARIOS

From the participants

Anonymized nonconformance examples submitted in the pre-workshop survey

DISCLAIMER

The views and opinions expressed by the panelists are their own and are intended for educational and discussion purposes only. They should not be interpreted as official regulatory guidance or prescribed practices. While the panelists may offer recommendations based on their professional experience, the California Environmental Laboratory Accreditation Program(ELAP) remains the accrediting authority and has the final say in determining whether a laboratory's root cause analysis and corrective actions meet applicable accreditation requirements.

SCENARIO 1: DOCUMENT CONTROL

An old worksheet still online

An analyst notices the Enterolert worksheet in use is missing fields for the UV light box and UV light ID. It is a revision from about 2½ years earlier. A newer revision was approved four months ago and printed, but its electronic copy never reached the shared library, so staff kept printing the old one.

Worksheets skip the signature process, so there was no approval record to check against. The CAR named the missed upload with no verification afterwards and was re-opened seven months later to add an upload check, an SOP revision and a lab-wide audit.

DISCUSS

Retraining vs. an upload check. check. Which fix will reach the the root cause?

AUDIENCE Q&A ~5 mins

SCENARIO 02 · PARTICIPANT SUBMISSION

Intermittent method blank contamination (EPA 245.1)

A lab sees a recurring, intermittent contamination in its EPA 245.1 method blanks. Maintenance and other efforts haven't fixed it, and it eventually clears up on its own. In the past, once blanks passed, the lab moved on without a corrective action record, because it didn't know what had fixed the problem. No single root cause can be identified.

DISCUSS

Should a nonconformance be issued, and what goes in the RCA section when there is no definitive single root cause or hard to determine root cause as it maybe a multitude of factors leading to the contamination?

AUDIENCE Q&A ~5 mins

SCENARIO 03 · PARTICIPANT SUBMISSION

Turnaround time and staff performance

A lab repeatedly misses its analytical turnaround time; reminders from management haven't helped. A CAPA found no staffing gaps and only a slight increase in sample volume. Staff are trained to handle the additional workload, prioritization has been discussed, and overtime is available. The root cause points to individual performance and resistance among 3 of 6 staff. Lab policy is to discuss every CAPA openly as a group.

DISCUSS

What measurable indicators show effectiveness, and how do you handle a CAPA that is also a confidential performance issue?

AUDIENCE Q&A ~5 mins

SCENARIO 04 · PARTICIPANT SUBMISSION

Missed incubation reading window

An analyst missed the required incubation reading window for a microbiology sample. They were reportedly juggling several activities that day. The data was qualified accordingly, and the client was appropriately notified. During the RCA investigation, it was found that the analyst is trained and knows the incubation window; checklists and calendar reminders are already in place. Despite reminders, the analyst got distracted and forgot to read the sample. It is this analyst's first occurrence. The RCA cites limited staffing, lack of time, and a lapse in monitoring due to forgetfulness.

DISCUSS

Human error vs system error? Can this be a preventive action that documents the event if this is established as a human error? If it is a CAR, how do you track and measure effectiveness?

AUDIENCE Q&A ~5 mins

SCENARIO 05 · PARTICIPANT SUBMISSION

Outdated SOP saved to a desktop

During an audit, the assessor finds an analyst following an outdated SOP. The current version is on SharePoint, but the analyst had downloaded the previous approved version and saved it locally. The lab's earlier corrective action for a similar finding was retraining staff on document control requirements.

DISCUSS

Is this a repeat finding, and what does it say about the earlier corrective action?

AUDIENCE Q&A ~5 mins

SCENARIO 06 · PARTICIPANT SUBMISSION

Lead in a drinking fountain

A drinking water fountain sample exceeded the lead action level by ICP-MS (EPA 200.8). A resample four days later was below the reporting limit, and the district wants to know which result is real. The high sample ran right after a very-high-lead customer sample. Three weeks earlier, rinse time was cut from 60 to 30 seconds for throughput, with no change-control record. The SOP doesn't require evaluating the rinse blank, so it wasn’t done. The original sample bottle was not stored so a re-run is not possible.

DISCUSS

How would you investigate carryover into clean samples, and what is the root cause?

AUDIENCE Q&A ~5 mins

SCENARIO 07 · PARTICIPANT SUBMISSION

Colilert blanks and the autoclave

Tuesday's Colilert sterility blank turned yellow; all samples in the batch were negative. The analyst reran the blank, got a clean result, and reported the samples. On Thursday, another blank was positive.

Both blanks used dilution water from the same 4 L bottle, autoclaved the week before with a large glassware load. The autoclave chart shows the chamber held 121°C for 15 minutes. Since then, the bottle has been opened at the bench each day and the water poured as needed.

The SOP doesn't define load configurations or how long an opened bottle of sterile water can be used. The monthly spore test was last run 5 weeks ago.

DISCUSS

What would you ask while performing the root cause analysis?

AUDIENCE Q&A ~5 mins

SCENARIO 08 · PARTICIPANT SUBMISSION

Missed incubator temperature readings

A wastewater lab records micro incubator temperatures twice daily. In six months, two readings were missed, by two different trained analysts, on routine workload days (one morning, one afternoon). Ownership is clearly assigned. After the first miss, the lab added a second-person check and computer alarms; the reviewer caught one miss but not the other. Misses were noted on the bench sheet. Data loggers are under consideration, but budget and staffing are tight.

DISCUSS

Is this a repeat finding, and is it reasonable to call the root cause human error?

AUDIENCE Q&A ~5 mins

PANELISTS Robin Cook ◆ Maria Friedman ◆ Tony Francis, PhD

SCENARIO 09 · PARTICIPANT SUBMISSION

A DOC signed before the data existed

A small accredited lab with eight staff analyzes drinking water and wastewater for municipal clients. An internal audit pulls the training file for an analyst who has reported nitrate/nitrite results on 41 client batches over the past three months.

The Demonstration of Capability form is blank: no reviewer signature, no approval date. The four DOC replicate results are in the raw data, but no one has reviewed them against acceptance criteria. LIMS shows that the analyst has been assigned to the method for the full three months.

The analyst is experienced in other methods but new to nitrate/nitrite.

DISCUSS

Where would you start the investigation?

AUDIENCE Q&A ~5 mins

SCENARIO 10 · PARTICIPANT SUBMISSION

Chlorine residual: 0.2 entered as 2.0

A distribution system chlorine residual was recorded on the field sheet as 0.2 mg/L but entered in LIMS as 2.0 mg/L. A state sanitary survey caught it six weeks later; the true low residual should have triggered an operational response. One person did both the field work and the LIMS entry at the end of a 10-hour shift. The older LIMS can't flag excursions. This agency does not have the budget to upgrade their LIMS. Second-person review exists, but they only confirmed whether fields are filled in, not compare values.

DISCUSS

What should the root cause be?

What would an auditor think?

AUDIENCE Q&A ~5 mins

SCENARIO 11 · PARTICIPANT SUBMISSION

TKN dilution factor and ignored LIMS flags

An influent TKN result was reported at 85.4 mg/L, above the LIMS control limits of 35–60 mg/L. LIMS flagged it, but neither the analyst nor the reviewer investigated. The dilution factor had first been left out (8.54 mg/L, a low flag also missed), then entered as 10 instead of 5, undocumented and unverified, after an ammonia-vs-TKN check tripped.

It was found five weeks later, past holding time; the correct value was about 42.7 mg/L. It repeats an earlier CAR whose fixes were those same LIMS limits and the ammonia-vs-TKN check.

DISCUSS

Here the flags worked but no one acted. Was the earlier CAR effective?

AUDIENCE Q&A ~5 mins

SCENARIO 12 · PARTICIPANT SUBMISSION

pH calibration check missed, again

For the third time this year, a pH meter calibration check was missed before analysis, each time by a different analyst. All three CARs were closed as “human error, analyst retrained,” each with a defined effectiveness check. The check sits on page 7 of an 11-page SOP and on the bench worksheet. Checklists are in place, and a supervisor reviews them every Friday for completeness.

DISCUSS

What does this recurrence tell you, and were the earlier CAPAs effective? Is there a permanent fix to this problem?

AUDIENCE Q&A ~5 mins

SCENARIO 13 · PARTICIPANT SUBMISSION

Failed fluoride PT, nothing found

The lab failed a fluoride PT, 18% high and outside limits. The investigation checked calibration, standards, the ISE electrode, TISAB, training, calculations and transcription, and found nothing. The same analyst and standards passed internal QC all week. The PT arrived on a Friday and wasn't analyzed until Thursday; routine samples run within 48 hours. A make-up PT passed. A fluoride PT from two years ago passed, but near the upper limit.

DISCUSS

Can you close this CAPA? Does the passing make-up PT satisfy root cause?

AUDIENCE Q&A ~5 mins

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BONUS SCENARIOS 14–17

If time allows

Real corrective action reports, anonymized

PANELISTS

Robin Cook ◆ Maria Friedman ◆ Tony Francis, PhD

SCENARIO 14

A spreadsheet formula one row off (BOD)

During an annual data review, the Technical Manager finds the BOD bench sheet's DO meter check pulling theoretical DO from one row below the correct one (9.18 instead of 9.20 mg/L). The error began with a new sheet version about five months earlier.

Recovery shifted by only 0.06–0.11%, and every check stayed within 95–105%, so no data was affected.

The lab named incomplete spreadsheet validation as the root cause, no written procedure, and each sheet's builder validated it alone. Root cause Actions: fix and re-validate the sheet, train staff, add a written verification procedure and checklist.

DISCUSSION QUESTIONS

1. Analyst error, or no validation procedure and no independent review? Why does the distinction matter?
2. No data was affected. Does that change whether a CAR was needed, or how deep to investigate?
3. Training and a checklist are the corrective actions. What effectiveness check would show they work?
4. Re-validate every existing spreadsheet, or only new and revised ones?

AUDIENCE Q&A ~5 mins

SCENARIO 15

Checked “ yes,” but not done

Three different nonconformances at one lab:

- A DO meter was calibrated after samples were already run and reported, yet the form's “meter calibrated” box was marked “yes.”
- A pH meter was not calibrated before analysis; the BOD form's “pH meter calibrated” box was marked “yes” without checking the calibration log.
- TSS filters were not dried to constant weight before moving to the next step.

Each was classified as individual performance: a slip or lapse. The corrective action was monitoring and having analysts double-check calibration logbooks, but the double-check doesn't always happen and is hard to prove.

DISCUSSION QUESTIONS

1. How do you track nonconformances in one place so you can tell a systemic problem from an individual performance issue?
2. LCS, method and equipment failures get a correction only. When does a nonconformance on a reported value also need a CAPA?
3. Three events, one pattern: a box that can be checked without proof. Human error, or a form design problem?
4. If the double-check can't be proven, how do you show effectiveness, or what CAPA would be verifiable?

AUDIENCE Q&A ~5 mins

SCENARIO 16

Ceriodaphnia dilutions swapped

On day 5 of a chronic C. dubia effluent test, 25% effluent shows much lower reproduction than 50%, an impossible dose-response. The analyst realizes they poured the 25% and 50% dilutions into each other's cups at the day 4 renewal. Containers were clearly labeled and cups color-coded. Four years on this test, no prior errors, a normal workload, no interruptions, and they self-reported immediately. The SOP is clear; no one else has made this error. The test is invalid and must be rerun within the permit timeframe.

DISCUSS

Does human error hold up as up as the RCA here?

AUDIENCE Q&A ~5 mins

PANELISTS Robin Cook ◆ Maria Friedman ◆ Tony Francis, PhD

SCENARIO 17

WET DMR-QA: NOEC Survival out of range

A lab's DMR-QA for WET testing reported NOEC Survival at 12.5%, outside the acceptable range of 25–100% (assigned value 50%). The other two endpoints passed: NOEC Growth 12.5% (limit 12.5–50%) and IC25 Growth 33.9% (limit 23.4–71%). A thorough investigation and review of the reference toxicant control chart found no obvious issue affecting organism sensitivity, which made the RCA and corrective actions hard to define.

DISCUSS

When a thorough investigation finds nothing, what does a defensible RCA and corrective action look like?

AUDIENCE Q&A ~5 mins

PANELISTS Robin Cook ◆ Maria Friedman ◆ Tony Francis, PhD

SCENARIO 15

A deleted log column with no backup

The Follow Up column in the lab's online Preventive Action Log disappears. The lab, the document system vendor and IT all fail to restore it; the backup provider confirms the log was never backed up because its custom-grid format is excluded.

IT records later show an analyst deleted the column. The analyst has no memory of it.

The lab named two root causes: insufficient record control, and users able to delete structural elements without controls. IT turned on version history and is rebuilding the column “as memory allows.” No dates or effectiveness check are recorded yet.

DISCUSSION QUESTIONS

1. Is this a human error or system error?
2. Access is a root cause, yet no action restricts who can delete columns. What is missing?
3. How should records rebuilt “as memory allows” be marked, and how much weight can they carry?
4. The extent of condition reaches other agency records. Who owns that, and how is it documented?
5. With no dates or effectiveness check, is this CAR ready to close?

AUDIENCE Q&A ~5 mins

PANELISTS Robin Cook ◆ Maria Friedman ◆ Tony Francis, PhD

WRAP-UP

Final questions

Thank you for joining this BACWA workshop.

Email me at payal.sarkar@sanjoseca.gov for a copy of these slides. The slides will also be posted on the BACWA library

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