How to Complete the CAR Form & Monitoring Form

Laboratory Accreditation

05/2025 Rev. 2.0

Why does the laboratory have a nonconformity?

- During the assessment, the laboratory was unable to provide objective evidence to satisfy the TNI standard, Regulation requirement, or Method requirement

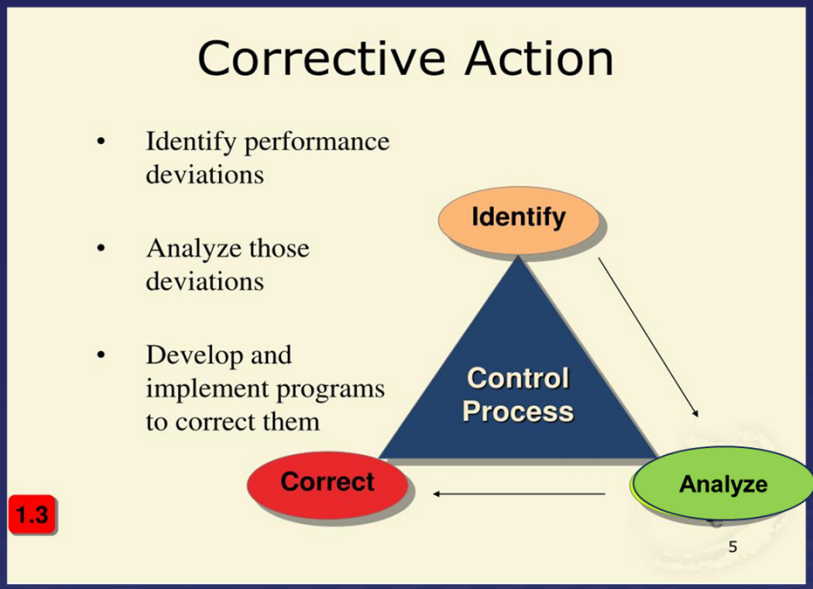
Characteristics	Conformity	Nonconformity
Definition	Refers to the act of matching behaviors to a standard, a specification or a method	Refers to a deviation from a standard, a specification, or method

Appeal Process

If the laboratory does not agree with a nonconformity (NC), the follow the appeal process:

1. Wait until the assessment report has been issued.
2. If the laboratory still does not agree with the nonconformity, then the laboratory will email the lead assessor. In the email, the Laboratory will provide:
   - The NC they do not agree with.
   - Objective evidence the laboratory is meeting the standard for the NC.
3. The lead assessor will forward the appeal to the Program Manager.
4. The Program Manager will decide the outcome of the appeal and notify the laboratory.

What is the purpose of a corrective action (CA)?



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Reminder:

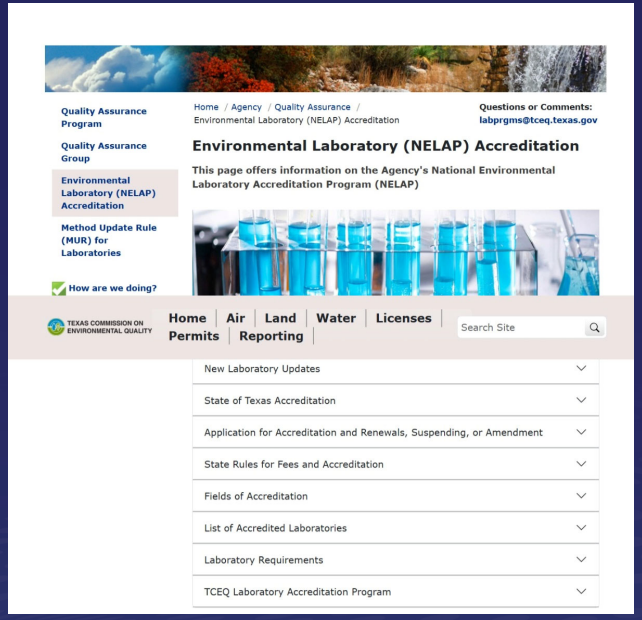
Correction-corrective-action-and-preventive-action.jpg

Step one: Access the CAR form and Monitoring form

Step one: Accessing the CAR form

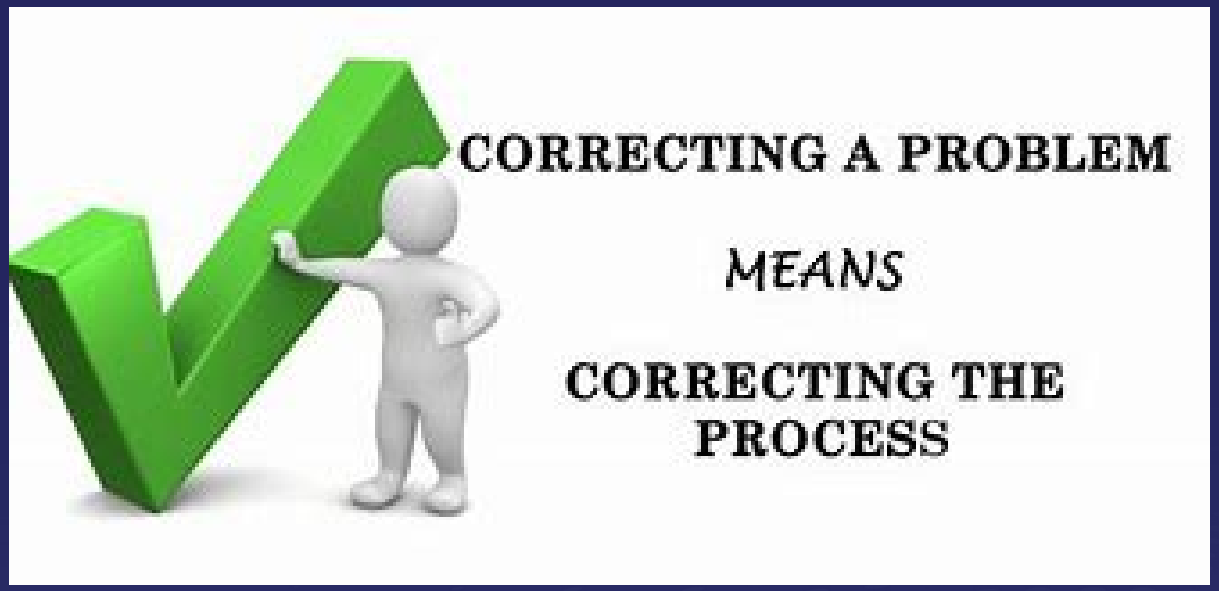
- External CAR form (LQA-FRM-06) and Monitoring form (LQA-FRM-07) can be found on the TCEQ Environmental Laboratory (NELAP) Accreditation Website:
- Click Laboratory Requirements
  - Laboratory Requirements ->
    - Corrective Actions and TCEQ's Corrective Action Response (CAR) Form

[TCEQ National Environmental Laboratory Program Website]



Step 2: Completing the CAR form

- 2a. CA Information
- 2b. Incident Nonconformity
- 2c. Root Cause Analysis
- 2d. Corrective Action Plan
- 2e. Affected Data: Customer Notification
- 2f. Verification of Effectiveness



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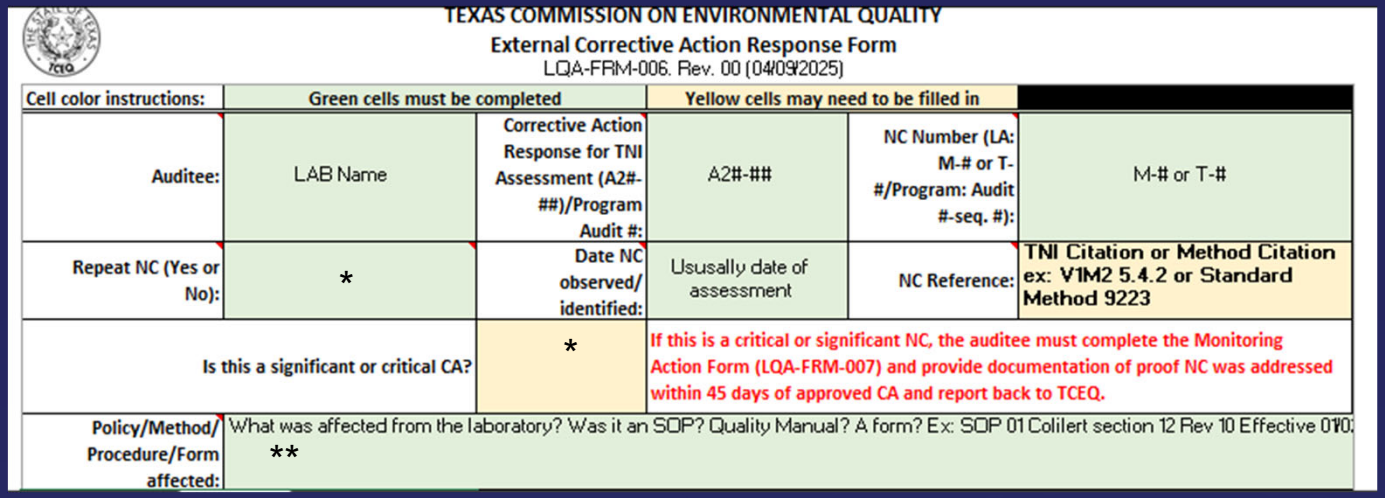
2a. CA Information



TEXAS COMMISSION ON ENVIRONMENTAL QUALITY
External Corrective Action Response Form
LQA-FRM-006, Rev. 00 (04/09/2025)

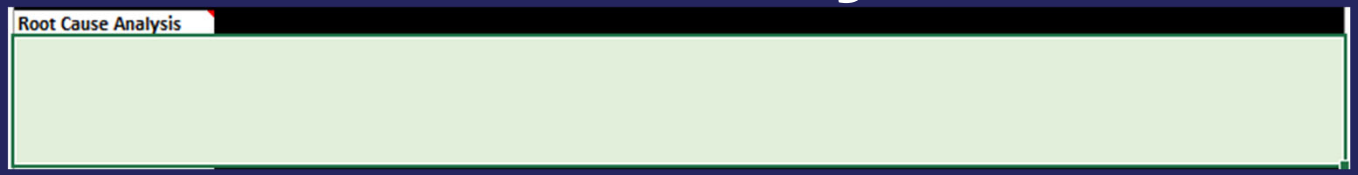
Cell color instructions:	Green cells must be completed		Yellow cells may need to be filled in		
Auditee:	LAB Name	Corrective Action Response for TNI Assessment (A2#-##)/Program Audit #:	A2#-##	NC Number (LA: M-# or T-#/Program: Audit #-seq. #):	M-# or T-#
Repeat NC (Yes or No):	*	Date NC observed/ identified:	Ususally date of assessment	NC Reference:	TNI Citation or Method Citation ex: V1M2 5.4.2 or Standard Method 9223
Is this a significant or critical CA?		*	If this is a critical or significant NC, the auditee must complete the Monitoring Action Form (LQA-FRM-007) and provide documentation of proof NC was addressed within 45 days of approved CA and report back to TCEQ.		
Policy/Method/ Procedure/Form affected:	What was affected from the laboratory? Was it an SOP? Quality Manual? A form? Ex: SOP 01 Colilert section 12 Rev 10 Effective 01/0				
	**				

- * = drop-down
- ** = When investigating non-conformances, be sure to look laboratory-wide to ensure findings are not repeated in other areas

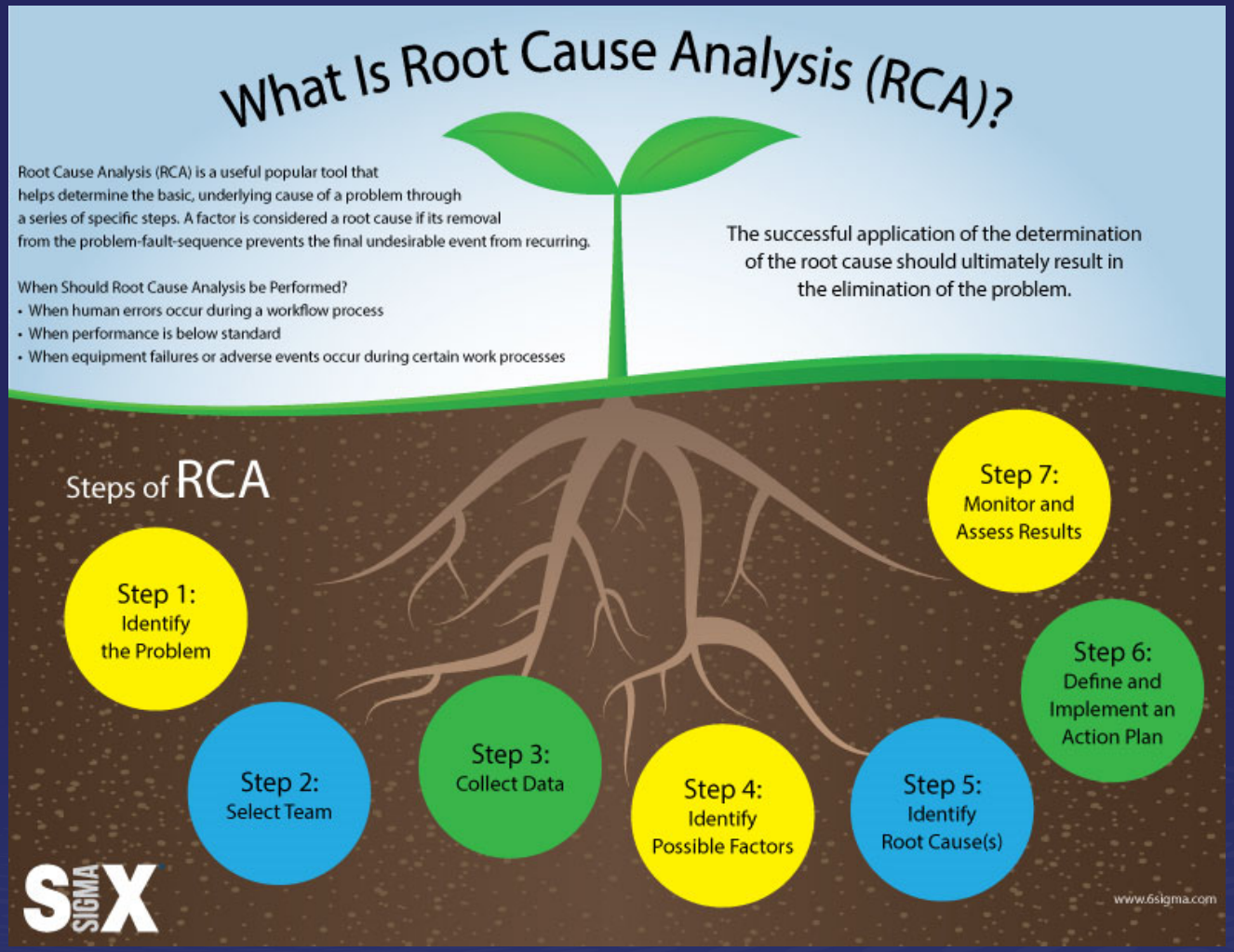
2b. Identified Nonconformity

- Copy and paste from the report. May summarize lengthy nonconformities
- Example 1: Laboratory staff stated that they do not currently evaluate suppliers of critical consumables, supplies and services which affect the quality of testing, nor does the Laboratory maintain records of those evaluations.
- Example 2: The laboratory did not retain all information necessary for the historical reconstruction of the data for all sample preparation, including cleanup, separation protocols, incubation periods or subculture, ID codes, volumes, weights, instrument printouts, meter readings, calculations, reagents. Examples include, but may not be limited to: A. Quality control records associated with sterility verifications for 120 mL vessels used during microbiological testing were not inclusive of the UID of the sterile water used during analysis; and B. Records associated with analysis of samples for COD were inclusive of the digestion end time, but not the digestion start time.

2c. Root Cause Analysis



- Document the outcome of the root cause analysis. It requires the laboratory to ensure the main issue has been. Identified. Usually the “5 Whys” is utilized to get to the root of the issue.
- The response cannot be “error,” “be more careful,” “oversight,” or placing blame on an individual.
- The root cause must be documented. If not, then the CA will be sent back for correction.
- Ex. 1: The Laboratory did have a list of suppliers that was being checked annually to ensure only approved suppliers were being utilized, but the requirements for evaluation were not fully understood, so these requirements were not being applied appropriately.
- Ex. 2: A. The sterile water identification was being written in the data book by some locations sporadically, but it was not consistent. The sterility check for Colilert was being recorded in the data book, which is part of the reason this information was not included as there is not a location to document this. This practice will be discontinued, and all items being tested for sterility will be recorded on the sterility sheet moving forward to ensure all relevant information is included with data records. B. The digestion start time was not included with data records, because a place was not provided to include this information.



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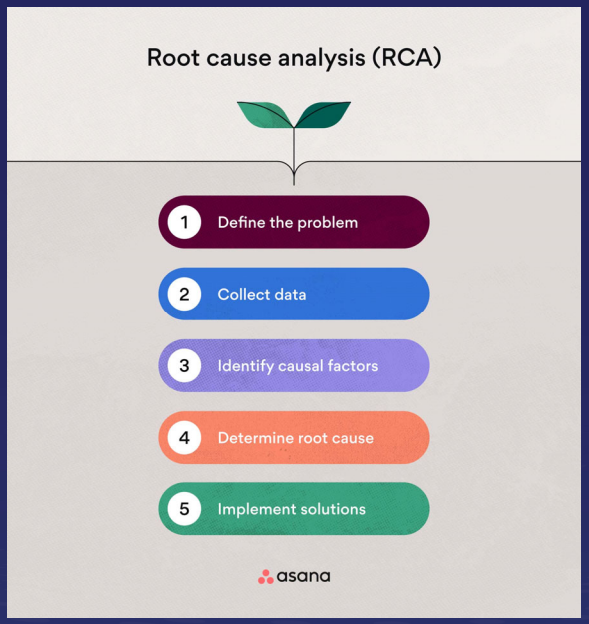
Root Cause Analysis with the 5 Why Analysis Method



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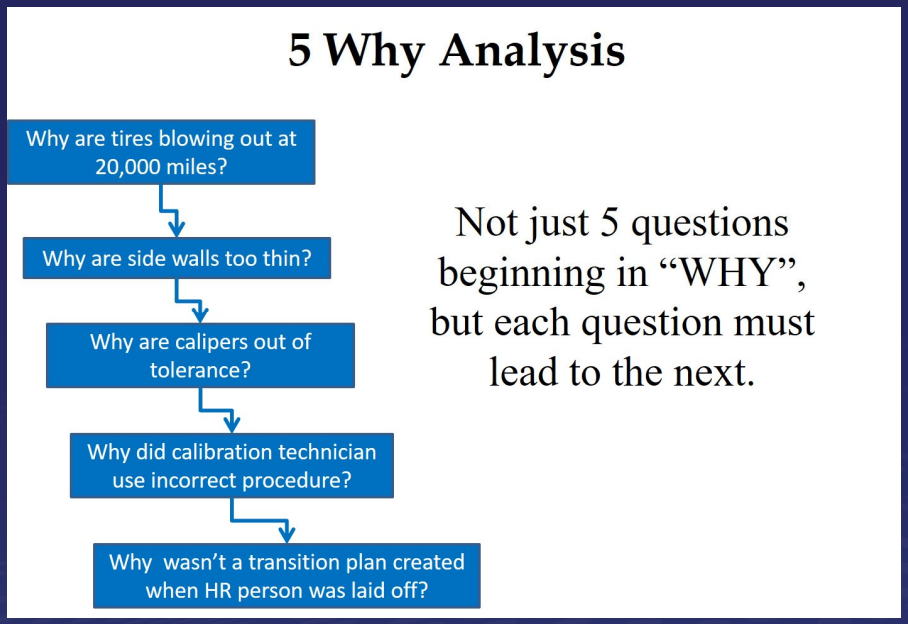


5-why-analysis-for-root-cause-analysis.jpg (1423×973) (medicaldeviceacademy.com)

2d. Corrective Action Items

Corrective Action			
Corrective action items(s) to address the nonconformity (If additional space is needed, provide another page):	**Date for implementation of correction(s) (i.e. MM/YYYY):**	**How was this documented?**	**Will this action prevent reoccurrence?** *
The corrective action must be measurable and able to be documented. Multiple actions are usually required. If procedures or forms are revised or created, staff training is required. This should be noted in the corrective action with a completion date and a way to document the training.	Specify the date for implementation: Completed/estimate future actions. Month/year is acceptable	Specify what records were completed. Make sure the records meet the TNI requirements.	Many of the specified actions may result in "No." At least one action must prevent reoccurrence must be "Yes."

Be sure to include a new line and a date for implementation for each corrective action.
* = Drop-down

2d. Corrective Action Items Suggestions

- Correct the NC
  - Example:
    - Label the thermometer
    - Properly calibrate the volumetrics

- Correct the documentation which supports the action
  - Example:
    - SOP(s)
    - Form(s)

2d. Corrective Action Items Considerations

- When investigating nonconformities, be sure to look laboratory-wide to ensure nonconformities are not repeated in other areas.
  - Check for (and correct) similar occurrences of the issue.
- Train staff who will be performing the tasks routinely
- **NOTE: If procedures or forms are revised or created, staff training is required**
  - This should be noted in the corrective action with:
    - Completion date
    - A form of documentation for the training
- Check back in 1-3 months to make sure this is being done correctly (verification of effectiveness)

2d. Corrective Action Example 1

Corrective Action			
Corrective action items(s) to address the nonconformity (If additional space is needed, provide another page):	**Date for implementation of correction(s) (i.e. MM/YYYY):**	**How was this documented?**	**Will this action prevent reoccurrence?**
The current supplier evaluation form needs to be revised to include criteria to show the evaluation for each of the suppliers used by the laboratory.	12/2024	Supplier evaluation form	Yes
Section 9, Purchasing Section of the Quality Manual needs to be revised to reflect the new procedure for supplier evaluation.	12/2024	Quality Manual revision	Yes
Staff needs to be trained on the new supplier form and revised procedure in Section 9 of the Quality Manual.	12/2024	Training records for new form and revised Quality Manual	Yes
Suppliers need to be evaluated based on the new procedure so the Laboratory can meet the requirement.	12/2024	Supplier evaluation records	Yes
A global review needs to be performed to ensure that all other administrative procedures contained the required elements. If any documents are found that need revision, this will be done ASAP with staff training immediately following the revision.	01/2025	Master File list printed and reviewed, any changes needed documented directly on List If changes are needed, revisions will be made, master list electronically updated, and staff trained on revised documents.	Yes

2d. Corrective Action Example 2

Corrective Action			
Corrective action items(s) to address the nonconformity (If additional space is needed, provide another page):	**Date for implementation of correction(s) (i.e. MM/YYYY):**	**How was this documented?**	**Will this action prevent reoccurrence?**
A. The SOP needs to be revised to ensure that the sterility checks are recorded on the sterility check form and that all relevant information is included such as lot numbers, etc. The master file list will be updated immediately following document revision. Staff needs to be trained on the new SOP.	No later than 01/2025	Enzyme Substrate SOP E. Coli by IDEXX (enumeration) SOP Staff training records Master File List	Yes
A. The sterility form needs to be revised to ensure all relevant information is included in data records moving forward. The master file list will be updated immediately following form revisions. Staff needs to be trained on the new form.	No later than 01/2025	Sterility forms Staff training records Master File List	Yes
A. All technical methods and support tests need to be reviewed to ensure lot numbers for any other items are not missing from data records. A copy of the accreditation list will be used to verify this information for each method with any issues found documented directly on the list so changes can be made if needed. If needed changes are found, it will be done immediately. If SOP or data form revisions are necessary, the master file list will be updated, and staff training will be performed.	12/2025	Method Check Review SOP/Data form revisions if needed Staff Training Records	Yes
B. The Chemical Oxygen Demand SOP needs to be revised to include a requirement that the analyst must record start and end time for digestion. The master file list will be updated immediately following SOP revision. Staff needs to be trained on the new SOP.	12/2025	Chemical Oxygen Demand SOP Staff training records Master File List	Yes
B. The COD data form needs to be revised to add a place to record digestion start and end time. The master file list will be updated immediately following form revision. Staff must be trained on the new data form.	12/2025	Chemical Oxygen Demand data form Staff training records Master File List	Yes
B. All technical methods and support tests need to be reviewed to ensure relevant times are not missing from records. A copy of the accreditation list will be used to verify this information for each method with any issues found documented directly on the list so changes can be made if needed. If SOP or data form revisions are necessary, the master file list will be updated, and staff training will be performed.	No later than 01/2025	Method Check Review SOP/Data form revisions if needed Staff training records Master File List	Yes

2e. Affected Data: Program/Customer Notification

Affected Data			
Program/Customer data affected?	*	**If No, please provide justification to how this was concluded. Then move to Verification of Effectiveness.**	**Example:** Even though the calibration was not conducted properly by the analyst, the subsequent calibrations indicate the instrument remains calibrated
If Yes was selected, the cited nonconformity casts doubt on the validity of results. Complete below.			
What work results were affected? (If a batch or sample affected, list the sample/batch. If no work results were affected, then mark N/A):	Batch or sample affected		
Action(s) for Program/Customer Notification:	**Date for Program/Customer Notification:**	**How was this documented?**	
Required if reported results would have been different if the incident had not occurred. Consider the timeframe needed	This is when the laboratory notified the program/customer	Email, phone call, Teams meeting	

* = Drop-down

2f. Verification of Effectiveness

Verification of Effectiveness		
Action(s) for Effectiveness (If additional space is needed, insert more rows or provide another page):	**Date for Verification (i.e. MM/YYYY):**	**How is this going to be documented?**
Verification involves checking: 1. all proposed corrective actions occurred; 2. fixed and not reoccurring.	Must occur AFTER proposed corrective action date. Usually 1-3 months after.	Usually documented via internal audit records, management review, training forms, new SOP, etc.

- It is critical for each proposed corrective action (CA) from section 2d to have a verification of effectiveness (VOE).
- If a CAR is received without a VOE for each proposed CA, the CAR will be returned.

2f. Verification of Effectiveness Example 1

Verification of Effectiveness		
Action(s) for Effectiveness(If additional space is needed, insert more rows or provide another page):	**Date for Verification (i.e. MM/YYYY):**	**How is this going to be documented?**
The supplier evaluation record will be reviewed after completion to ensure the requirements are met following the supplier evaluation and a schedule will be made for this to be performed annually during the same time period.	01/2025 and subsequent years	Supplier evaluation record review
A question will be added to the internal administative audit regarding the supplier evaluation requiring review of related documents to ensure our procedure continues to meet the requirements of the standard.	04/2025 and annually thereafer	Internal audit records
Revisions to QM have been verified. Completion of global review has been verified	01/2025	Master document list
Training of all staff has been verified.	01/2025	Training forms and management system review

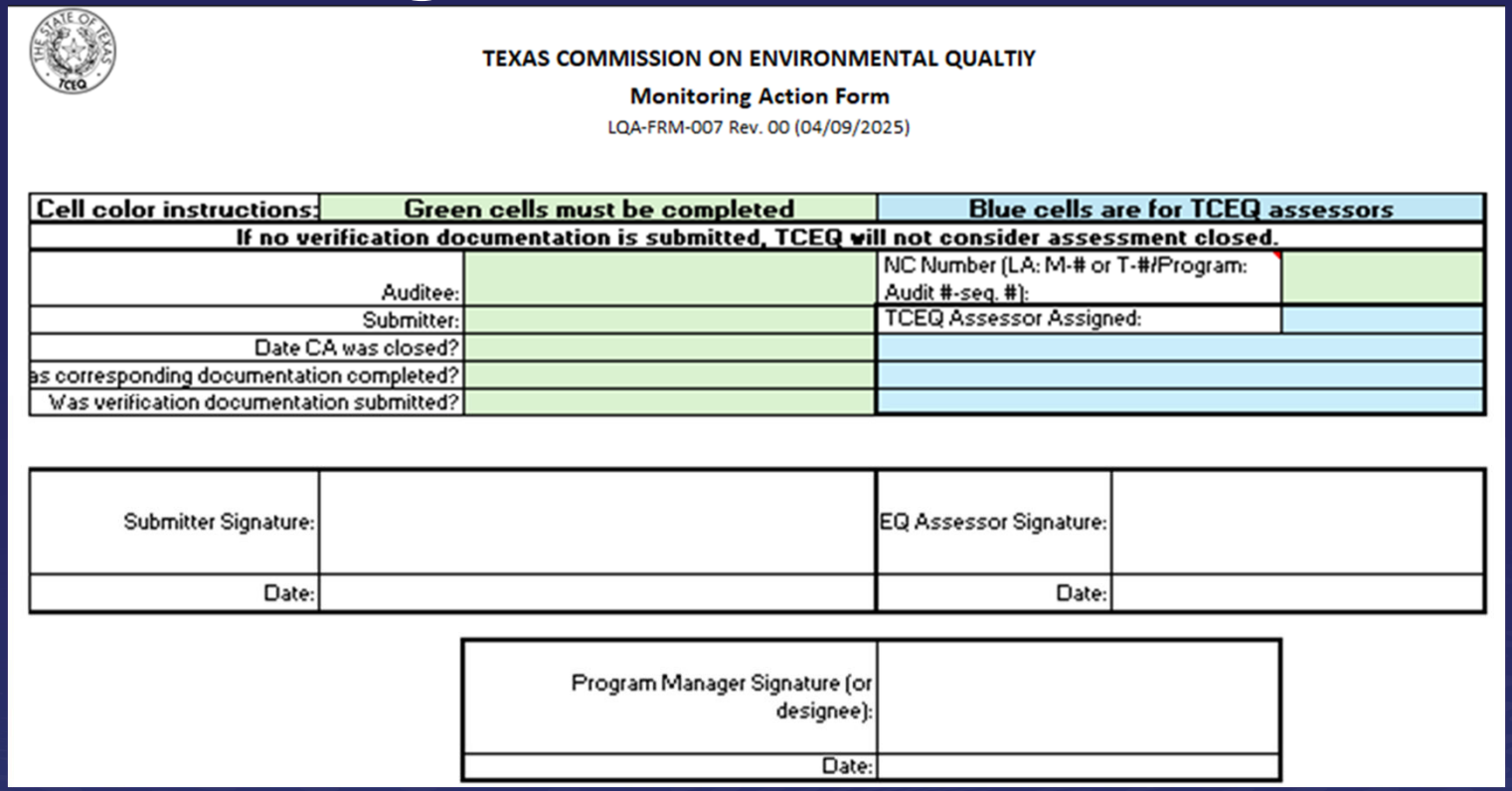
2f. Verification of Effectiveness Example 2

Verification of Effectiveness		
Action(s) for Effectiveness (If additional space is needed, insert more rows or provide another page):	**Date for Verification (i.e. MM/YYYY):**	**How is this going to be documented?**
A. A month after changes have been made, data records will be reviewed to ensure sterile water UID is being included with each sterility check.	02/2025	Sterility check verification form
A. A question will be added to the technical audit for micro methods to ensure this information is included in all future data records and will be monitored moving forward for all locations.	04/2025 and annually thereafter	Internal audit data records
B. Data records for COD will be reviewed weekly for two months to ensure the digestion start and end times are included for each batch until this becomes standard practice.	12/2024-01/2025	COD digestion time review form
B. A question will be added to the technical audit for this method to ensure digestion start and end times are included with every batches records.	04/2025 and annually thereafter	Internal audit data records
Revisions to QM have been verified. Completion of global review has been verified	01/2025	Master document list
Training of all staff has been verified.	01/2025	Training forms and management system review

When does the laboratory need to complete a Monitoring Form

- Must be used by a laboratory to respond to a critical or significant nonconformity identified during their TCEQ assessment.
- Documentation must be provided to TCEQ as proof the NC is addressed within 45 days of the approved CAR.
- This ensures the laboratory is implementing the corrective actions and provides objective proof.

Monitoring Form



TEXAS COMMISSION ON ENVIRONMENTAL QUALTIY

Monitoring Action Form

LQA-FRM-007 Rev. 00 (04/09/2025)

Cell color instructions:	**Green cells must be completed**	**Blue cells are for TCEQ assessors**	
If no verification documentation is submitted, TCEQ will not consider assessment closed.			
Auditee:		NC Number (LA: M-# or T-#/Program: Audit #-seq. #):	
Submitter:		TCEQ Assessor Assigned:	
Date CA was closed?			
as corresponding documentation completed?			
Was verification documentation submitted?			

Submitter Signature:		EQ Assessor Signature:	
Date:		Date:	

Program Manager Signature (or designee):	
Date:	

Questions?

- If you have any questions on how to complete the CAR form:
  - Contact the TCEQ lead assessor who performed your most recent assessment
  - Assigned TCEQ assessor if a 3rd party contractor completed your most recent assessment