# How to Complete the CAR Form

Laboratory Accreditation

11/2023 Rev. 1.0

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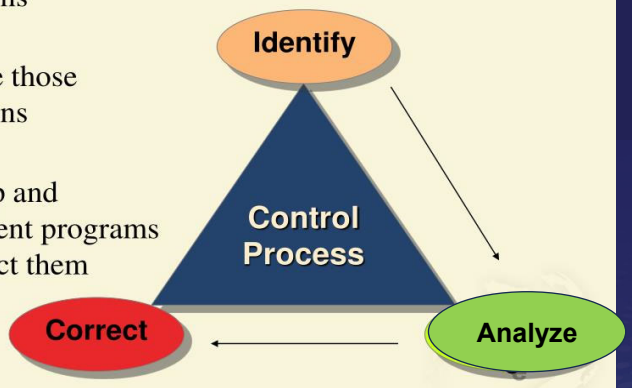
## Corrective Action

- Identify performance deviations
- Analyze those deviations
- Develop and implement programs to correct them

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corrective-action-l.jpg (1024×768) (slideserve.com)

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# Step one: Accessing the CAR form

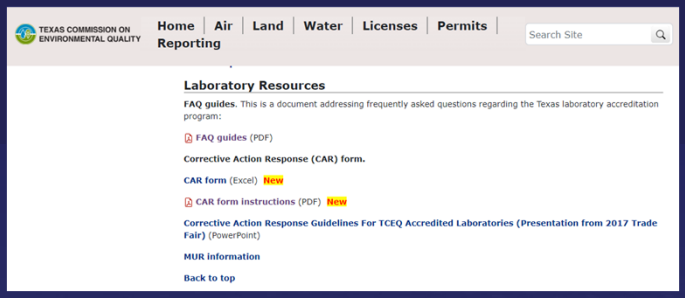
The CAR form (LAPF-012) can be found on the TCEQ Environmental Laboratory (NELAP) Accreditation Website:

Environmental Laboratory (NELAP) Accreditation - Texas Commission on Environmental Quality - www.tceq.texas.gov

Towards the bottom of page under Laboratory resources

Also present:

- CAR form instructions
- CAR guidelines - PowerPoint



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# Step 2: Completing the CAR form

- 2a. Heading
- 2b. Incident Deficiency
- 2c. Root Cause Analysis
- 2d. Corrective Action Items
- 2e. Customer Notification
- 2f. Verification of Effectiveness



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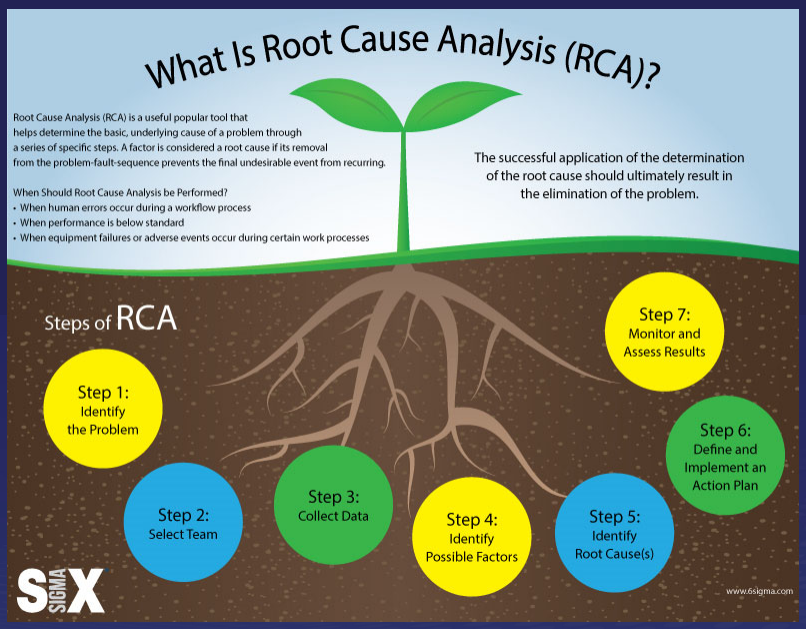


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# 2a. Heading

**Corrective Action Report**

| | Green cells need to be filled in | | | Yellow cells may need to be filled in | |
|---|---|---|---|---|---|
| Laboratory: | LAB NAME | NC Number (M-# or T-#): | M-# or T-# | Repeat NC (Yes or No): | * |
| Corrective Action Response for TNI Assessment # (A2#-##): | | A2#-## | TNI 2016/Method Reference: | TNI Citation - V1M# or Method | |
| Date NC observed/identified: | Typically the date the assessor noted the issue if found on-site | | | | |
| Laboratory Related Policy/Method/Procedure/Form affected: | | | What was affected in the laboratory? ** | | |

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

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# Conformity vs. Nonconformity Table

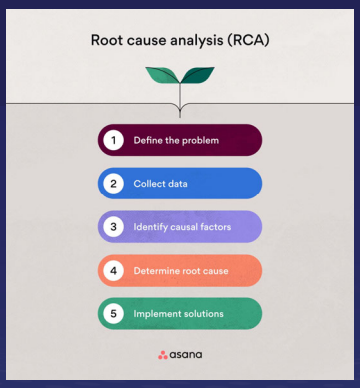
| Characteristics | Conformity | Nonconformity |
|---|---|---|
| Definition | Refers to the act of matching behaviors to a standard, a specification or a method | Refers to a deviation from a standard, a specification, or method |



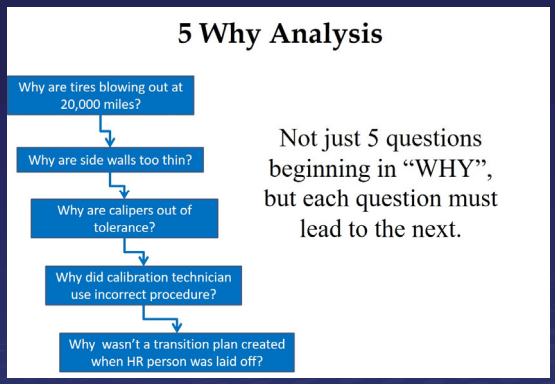
# 2b. Incident Nonconformancy

| Incident Nonconformity |
|---|
| Copy and paste from the report. May summarize lengthy nonconformities.<br>Example 1: The Quality Policy Statement in section 5.3 of the laboratory's QM did not include a commitment by laboratory management to continually improve the management system's effectiveness.<br>Example 2: The following SOPs did not include or reference a procedure for the determination of a measure of relative error (%RE) and acceptance criteria for relative error as required by TNI V1M4-1.7.1.1.k.ii.<br>-SOP Method 200.7<br>-SOP Method 300.0 |

# Root Cause Analysis with the 5 Why Analysis Method




inline-project-planning-root-cause-analysis-1-2x.jpg (1800×1918) (asana.biz)




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



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# 2c. Root Cause Analysis

| 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.<br>Example 1: The Quality Manager utilized the example quality policy statement found in the TNI-QM-2017-v3.1 without reviewing the requirements of the standard.<br>Example 2: The Quality Manager was unaware of the new (2016) requirements for calibration for the root cause. |



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# Reminder:


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



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# 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." |
| Example 1: Quality Manager will update the quality manual to include a commitment by laboratory management to continually improve the management system's effectiveness. | 07/2023 | Quality Manual revision notes and Laboratory Document Master List | Yes |
| Example 1: Train all laboratory personnel on the changes to the Quality Manual. | 07/2023 | Employee Training Sign-Off sheet | Yes |
| Example 2: The lab will revise the SOPs to include the procedure with acceptance criteria by 08/2023 with training completed. | 08/2023 | Updated SOP in Document Master List and Employee training completed | Yes |
| Example 2: The lab will do a lab wide review of other methods and revise them if needed by 10/2023 with training completed. | 10/2023 | Employee Training Sign-Off sheet | Yes |



* = Drop-down



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# 2d. Corrective Action Items Suggestions

- Correct the finding
  - Example:
    - Label the thermometer
    - Properly calibrate the volumetrics
- Correct the documentation which supports the action
  - Example:
    - SOP(s)
    - Form(s)



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# 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)



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# 2e. Customer Notification

| Affected Data | | | |
|---|---|---|---|
| Customer data affected? | * | If Yes, the cited nonconformity casts doubt on the validity of results. Complete below. If No, move to Verification of Effectiveness. | |
| What work affected? (If a batch or sample affected, list the sample/batch. If no client samples affected, then mark N/A): | | Batch or sample #(s) | |
| Action(s) for Client Notification: | | Date for Client 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 clients | |

* = Drop-down



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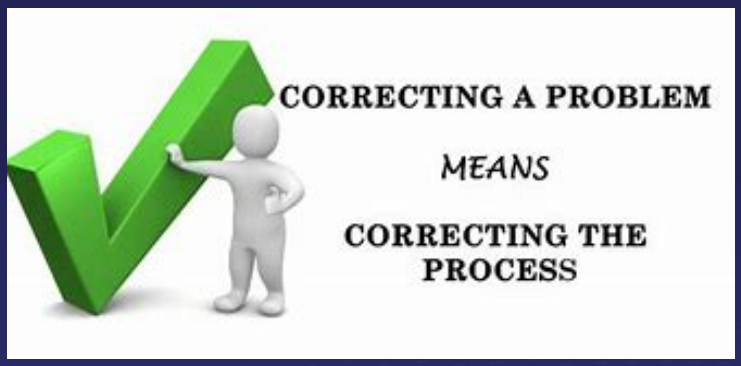




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# 2f. Verification of Effectiveness

| Verification of Effectiveness | | |
|---|---|---|
| **Action(s) for Effectiveness:** | **Date for Verification (i.e. MM/YYYY):** | **How is this going to be documented?** |
| Verification involves checking: 1. all proposed corrective actions that occurred; 2. fixed and not reoccurred. | Must occur AFTER proposed corrective action date. Usually 1-3 months after | Usually documented via internal audit records, management review, training forms, etc. |
| Example 1: Quality Manager will verify the Quality Manual includes a commitment by laboratory management to continually improve the management system's effectiveness during an internal audit of TNI 2016 V1M2 annually in accordance with that year's internal audit schedule. | 09/2023 | TNI 2016 V1M2 internal audit assessment report |
| Example 1: Quality Manager will verify that the Training document has been maintained for all laboratory personnel during an internal audit of TNI 2016 V1M2 annually in accordance with that year's internal audit schedule. | 09/2023 | TNI 2016 V1M2 internal audit assessment report |
| Example 2: The lab (Quality Manager, Tech. Manager, etc.) will review all SOP methods with calibrations to ensure the TNI requirements are included. In addition, the lab will review all calibration data to ensure the requirements are being followed. | 01/2023 | All calibrations for the next 3 months will be verified and checked again during the internal audit. |



# 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