



# Heads Up

Issue: 362

Date: 2017/03/09

To: ANAB-Accredited and Applicant CBs and MS Accreditation Assessors

From: Lori Gillespie, Vice President, Management Systems

Re: Corrective Action Responses for NCRs Issued by ANAB


This Heads Up should serve as a reminder for most of us.

The ANAB process for CBs to respond to ANAB-issued nonconformances involves several steps, including correction, root cause analysis, corrective action, evidence of implementation, and verification of effective implementation.

Years ago, ANAB shared its internal procedure with customers so there would be no surprises about what was expected for a corrective action response to be accepted. We are sharing this procedure (PR 5301) again as a reminder for all and to replace the original Heads Up 137.

The attached procedure is a tool that outlines nothing more than basic corrective action responses with ISO/IEC 17021-1 requirements included. It is what is expected of CBs when responding to ANAB-issued NCRs and what is expected of ANAB assessors when reviewing the responses.

We hope you will find value in using this guidance when responding to ANAB-issued NCRs.

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|--|---------------------------|-----------------------|---|
| <b>Corrective Action Review for ANAB-issued NCRs</b> |                           |                       |  |
| <b>PR 5301</b>                                       | Authority: Vice President | Effective: 2016/08/26 |   |

1. NCR responses must be reviewed in four parts that are linked as outlined below: correction, cause analysis, corrective action and evidence.
  - 1.1. In reviewing the parts of an NCR response, make sure the CB has provided ANAB a plan and evidence that the plan is being implemented. The CB may take action but not provide a plan; this is acceptable as long as the detail provided is appropriate in accordance with this procedure and evidence of the action is provided. The CB must also define the methodology for determining the effectiveness of their implemented plan.
  - 1.2. The original NCR statement and requirements referred to must be addressed throughout the responses.
2. To be fully accepted, correction shall include the following:
  - 2.1. The extent of the NCR has been determined and contained.
    - 2.1.1. The NCR has been corrected and the response is written in the past tense (e.g., "The missing record was found" rather than "The missing record will be found").
    - 2.1.2. The CB has examined the system to determine the extent of the issue (i.e., whether or not there are other examples that need to be corrected) and has addressed the extent of the issue in its response.
    - 2.1.3. The response includes correcting the examples (evidence) ANAB found and any other examples the CB has found.
  - 2.2. If correction cannot be immediate, a plan to correct the NCR may be appropriate and shall include:
    - 2.2.1. Identification of parties responsible for the actions.
    - 2.2.2. A schedule (dates) for implementation.
  - 2.3. If applicable, all parties involved have been informed of the problem (internally affected parties, auditors, customers, etc., should be identified).
  - 2.4. Evidence that the correction was implemented or evidence that the plan is being implemented.
3. To be fully accepted, the cause analysis shall:
  - 3.1. Not simply repeat the finding or the direct cause.
  - 3.2. Be an expression of fact that neither explains away the situation nor rationalizes the condition.
  - 3.3. Include a well thought out direct cause and a well thought out analysis to determine the true cause (e.g., someone not following a process would be a direct cause, while determining why that person did not follow the process would lead to the true cause).
  - 3.4. Focus on a single issue.
    - 3.4.1. If more than one cause is identified (e.g., training and inadequate work instructions), then the corrective action plan submitted must address both causes.
  - 3.5. Address a fundamental issue without any obvious "why" questions remaining.
    - 3.5.1. If a "why" question can reasonably be asked about the cause analysis, this indicates the analysis did not go far enough.
4. To be fully accepted, the corrective action or corrective action plan shall include the following:
  - 4.1. Addresses the cause(s) determined through the cause analysis.
  - 4.2. Actions to address the cause(s).

- 4.2. Identification of parties responsible for the actions.
- 4.2. A schedule (dates) for implementation.
- 5.. Evidence of implementation shall be sufficient to show the plan is being implemented as outlined in the response (and on schedule).
  - 5.1. In most cases, evidence in full is not required to close the NCR; additional evidence may be reviewed during a future assessment when verifying the corrective action.
  - 5.2. For the ICOP aerospace programs, NCRs are categorized as AQMS minor or AQMS major. All minor and major NCRs issued during AQMS assessments (e.g., AS9100 witnessed audit) or during ISO/IEC 17021-1 assessments that include AQMS programs or other requirements referring to AS evidence, must include full evidence of the corrective action plan to **verify** the corrective actions prior to closure. Verification may have to be conducted on site.
    - 5.2.1. Closure shall be within 90 calendar days or ANAB shall initiate the suspension process for AQMS accredited CBs or withdraw the application for CB AQMS applicants.
- 6. The methodology for determining the effectiveness of the CB's implemented plan is required. Only the methodology is required; evidence of effectiveness would be provided by the CB at a later date.