



## **Preparing Responses to Nonconformities (Deficiencies) and Comments (Suggestions)**

These instructions are offered to assist laboratories in preparing nonconformity/deficiency responses and to expedite the review of these responses by the Site Assessor, AIHA-LAP, LLC staff and technical reviewers.

**Site Assessor(s):** Please leave this document with the laboratory upon completion of the on-site evaluation and indicate your preferences in receiving responses.

**Laboratories:** One copy of the entire deficiency and suggestion response package must be submitted directly to the Site Assessor and to the Laboratory Accreditation Specialist assigned to your laboratory, as per the Site Assessment Notification. Please discuss submission preferences with your site assessor when reviewing this form at the closing meeting. Laboratories must submit the deficiency response electronically to the AIHA-LAP office. All types of electronic file transfer (email, CD, jump drive, external hard drive, ftp) are acceptable. An email response may be sent to both the Site Assessor and the Laboratory Accreditation Specialist in the same submission, i.e., via Cc or multiple recipients. All attachments must be clearly numbered and assembled in the numerical order of the deficiencies.

### **Section 1: RESPONDING TO NONCONFORMITIES/DEFICIENCIES:**

A response to a nonconformity/deficiency consists of five (5) parts:

1. Statement of the nonconformity/deficiency
2. Results of Root Cause Analysis
3. Statement of action
4. Proof of commitment
5. Objective evidence of compliance

1. **Statement of the nonconformity/deficiency:** The following nonconformity/deficiency is used to illustrate:

Nonconformity/Deficiency 1 (ISO/IEC 17025:2005 Section 5.5.2) The laboratory has not developed a program for calibration and calibration checks of its analytical balances.

2. **Results of Root Cause Analysis:** This is a statement of what gaps or breakdowns in the process allowed the nonconformity/deficiency to occur. This does not include placing blame or pointing fingers at employees. Examples of incorrect results from root cause analysis are: 'Oversight', 'Operator Error', 'Not following procedures', etc. One of the simplest methods to determining the root cause of a problem is the "5 Why's" method, in which the question 'why?' is asked at least five (5) times to ensure that the cause has been correctly identified.

Other methods may include data collection and analysis. It is important that the organization determine the cause so effective action can be taken to eliminate the chance of recurrence. Laboratories are encouraged to use and submit their standard nonconformance/corrective action form for documenting their root cause analysis process.

3. **Statement of Action:** This consists of a statement of the corrective action for each nonconformity/deficiency. Each statement should be brief and succinct.

Nonconformity/Deficiency 1 (ISO/IEC 17025:2005 Section 5.5.2) – We have prepared, issued, and implemented a procedure for the calibration of analytical balances and for daily calibration checks. Attachment 1 shows our SOP, and attachment 2 shows a copy of the first two balance calibration checks.



Note that this must be written in the past tense. The lab must complete the corrective actions in order to become accredited; however, nonconformities/deficiencies involving procurement may be considered complete if the item has been ordered and proof of ordering (e.g., copy of purchase order) is submitted.

**IMPORTANT:** The statements of action must be in a separate signed and dated document or letter, containing the nonconformities/deficiencies and suggestions and a statement of action for each nonconformity/deficiency and concern/suggestion. All attachments (proof of commitment and/or objective evidence of compliance) must be labeled and clearly reference the applicable nonconformity/deficiency to facilitate review of the response. Improperly organized or improperly identified responses will be returned to the laboratory.

4. **Proof of Commitment:** This consists of documented changes in the Quality Manual and/or written quality system documents (policy or procedure). In this case it is attachment 1, a copy of the SOP.

In some cases, submission of written policies or procedures may not apply. For example, if the laboratory has a written procedure that they are not following, other evidence of corrective actions, such as staff training records, is required.

**IMPORTANT:** If only sections of manuals or procedures are revised to address nonconformities/deficiencies, the applicable sections must be indicated in the statement of action. Applicable excerpts from large documents are acceptable and preferred instead of including the entire document. Note that as required by ISO/IEC 17025:2005 Section 4.3.3.2, new or altered text must be identified in controlled documents or their attachments. Assessors will expect all such changes to be clearly identified.

5. **Objective Evidence of Compliance:** This consists of copies of actual laboratory records demonstrating compliance. In this case, it is attachment 2, a copy of the actual calibration check records that have been implemented by the laboratory.

In some cases, this item may not apply. For example, if the laboratory was conducting and recording balance calibration checks, but had not written a procedure, this item is not necessary.

## **Section 2: RESPONDING TO SUGGESTIONS:**

Suggestions are situations where there is no evidence for a nonconformity/deficiency but if not addressed, there is a situation for a potential nonconformity/deficiency. This is an excellent opportunity for the laboratory to initiate preventive action or process improvement. The only requirement for responding to suggestions is the statement of action, and the lab need not agree with the suggestion. The lab does, however, have to state its response to, and intentions regarding the suggestion. The following suggestion is used to illustrate:

Suggestion 1 (ISO/IEC 17025:2005 Section 5.4.7.1) – Consider the use of a checklist to aid in documenting and standardizing calculation and data transfer checks.

The lab would first need to assess the potential nonconformity/deficiency and the need for process improvement.

What problem could potentially occur if we do not initiate a checklist for documenting and standardizing calculation and data transfer checks?

Without documentation, there may not be any indication that the data transfer checks have occurred. Miscommunication could occur if employees think that the data transfers have occurred, but have not. The checklist would serve to demonstrate that the checks have been performed.

The Lab's response might be the following:



Suggestion 1 (ISO/IEC 17025:2005 Section 5.4.7.1) – We have implemented a checklist to document and standardize such checks.

However, after a review of the situation, the lab's response may also be:

Suggestion 1 (ISO/IEC 17025:2005 Section 5.4.7.1) – We have reviewed our data check process, and we feel that the current program is adequate and suitable for our lab's needs.

No corroborating evidence is required for suggestion responses, regardless of the lab's position on the suggestion.