	<b>AIHA</b> Laboratory Accreditation Programs, LLC	<b>Code:</b> QSD-PR	
		<b>Quality System Document</b>	Revision 12
			02/08/2021
<b>Title:</b> Preparing Responses to Nonconformities (Deficiencies) & Comments		Page 1 of 3	

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 provide this document to the laboratory upon completion of the assessment.

**Laboratories:** One copy of the entire deficiency response package must be submitted directly to the AIHA LAP, LLC secure online data management system (DMS) [here](#). Instructions for this process may be found in the *LAP Document Library*, which can be accessed from your Dashboard in DMS.

Laboratories are encouraged to use their own nonconformity/corrective action forms when responding to deficiencies. However, laboratories should ensure that all 5 parts mentioned in Section 1, below, are addressed. Please discuss submission preferences with your site assessor when reviewing this form at the closing meeting.

If at any time, you should encounter any issues submitting the materials please [contact](#) your assigned accreditation specialist, as noted in your Site Assessment Notification.

All attachments must be clearly numbered and assembled in the numerical order of the deficiencies. If submitting responses in PDF format, do not enable extra security measures or restrictions. This includes setting an expiration date, setting a password, limiting printing and commenting, disabling page extraction, etc. Please contact AIHA LAP, LLC staff if you have any questions about this requirement.

### **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 17025:2017 Section 6.4.7) 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.

	<b>AIHA</b> Laboratory Accreditation Programs, LLC	<b>Quality System Document</b>	<b>Code:</b> QSD-PR
			Revision 12
			02/08/2021
<b>Title:</b> Preparing Responses to Nonconformities (Deficiencies) & Comments			Page 2 of 3

Nonconformity/Deficiency 1 (ISO/IEC 17025:2017 Section 6.4.7) – 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 a statement of action for each nonconformity/deficiency. 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 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 17025:2017 Section 8.3.2.c, changes shall 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 COMMENTS**

Comments are situations where there is no evidence for a nonconformity/deficiency but if not addressed, there is a potential for a nonconformity/deficiency. The laboratory is not required to submit a response for the comments. However, the laboratory is encouraged to review each comment for its applicability in their preventive action or process improvement program.

	<b>AIHA</b> Quality System Document	<b>Code:</b> QSD-PR
		Revision 12
		02/08/2021
<b>Title:</b> Preparing Responses to Nonconformities (Deficiencies) & Comments		Page 3 of 3

**Section 3: DEFICIENCY DISPUTES**

If there is a disagreement between the Site Assessor and the laboratory over the validity of a deficiency, the laboratory or the site assessor must notify the [Quality Systems & Technical Program Director](#) of the request to review the deficiency.

The Quality Systems & Technical Program Director will consult with the Chief Site Assessor, technical expert(s), the AIHA LAP, LLC Managing Director, and/or the Accreditation Manager to evaluate and make the final determination.