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 Site Assessor and to the Laboratory Accreditation Specialist assigned to your laboratory, as per the Site Assessment Notification. 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 are addressed. 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, LLC through our secure site here.

- Please note that when uploading your responses, the file name should not contain any special characters (including &, #, $, %, {, }, and ~).
- For larger submissions, we recommend that you break your submission into multiple smaller files which should be uploaded separately.
- If your upload is successful you will receive a confirmation page. If you did not receive a confirmation page, we did not receive your submission.

If at any time, you should encounter any issues submitting the materials please contact your accreditation specialist.
Deficiency Responses will be accepted via email, however please be aware that email size limitations may be in place, so large files (5MB and greater) will need to be sent in multiple emails. 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. Other types of electronic transfer (CD, jump drive, external hard drive) are acceptable.

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.

> 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 it applicability in their preventive action or process improvement program.

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 Manager** of the request to review the deficiency.

The Quality Systems Manager 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.