Responding to Deficiencies Cited During Your CAP Inspection

At the conclusion of your inspection, you will receive a copy of the Inspector Summation Report (ISR) which includes the official listing of deficiencies for your laboratory. The College of American Pathologists (CAP) will not send an additional report of deficiencies cited.

Responses to this report must be submitted online to the CAP within 30 calendar days of the date of the inspection. Failure to meet this deadline and/or adhere to the instructions will delay the accreditation process and may affect the laboratory's/facility's accreditation decision.

Start by logging into e-LAB Solutions Suite (ELSS) on cap.org and select Deficiency Response.

Decide who is entering the deficiencies into ELSS: the CAP or your laboratory.

**CAP Enters**
1. Laboratory is notified by the CAP that deficiencies are ready for response.
2. Laboratory enters a description of the corrective action taken and attaches supporting document(s) (phase II) for each deficiency.
3. Once all deficiencies have a response and attachment(s), the laboratory director reviews and approves. Responses are submitted to the CAP.
4. If additional information is needed, the laboratory will be notified by email with a link to ELSS. You will have 10 days to respond.

**Laboratory Enters**
1. Begin entering deficiencies any time after your inspection is complete (do not enter recommendations). If the CAP has started deficiency entry, the system will not allow you to enter deficiencies. Note: Laboratories cannot enter deficiencies for AABB, initial, and nonroutine inspections; these will be entered by the CAP.
2. Enter the following fields:
   - Section
   - Checklist Requirement
   - Inspector's Comments
3. Once deficiency entry is complete, you can enter your corrective action responses and supporting document(s) for each deficiency. Follow steps 2–4 under “CAP Enters” to complete the response process.

**Overview of the Steps After a CAP Inspection**

- **Deficiencies Recorded** (Lab or CAP)
- **Responses Recorded** (Lab)
- **Responses Approved** (Lab)
- **Responses Submitted** (Lab)
- **CAP Review Completed** (CAP)
- **Lab is Accredited** (CAP)

If you have any questions, call 800-323-4040 or send an email to accred@cap.org.
How to Respond

• **Phase I** deficiencies require a response indicating corrective action taken.
• **Phase II** deficiencies require a response and supporting documentation demonstrating compliance.
• The response should explain the purpose of the documentation submitted. If the same supporting documentation will be used for multiple responses, attach a copy to each deficiency. Examples of appropriate documentation include, but are not limited to:
  - New or revised policies and procedures with evidence of review and approval
  - Sections (or underlined portions) of policies/procedures that pertain to a deficiency
  - QC, calibration, maintenance records, or instrument printouts
  - Log sheets, including recorded data (blank logs are unacceptable)
  - Purchase orders, work orders, photos, diagrams, or floor plans
  - Evidence of staff review or retraining on new, revised, or existing procedures

Helpful Hints

• Underline or highlight the pertinent section of attached document(s).
• Include the specific page number of the updated policy/procedure.
• The deficiency response must be signed by the laboratory director. Directors should review all deficiency responses by clicking the Approve and Sign Responses button, and enter their name on the signature page. The individual deficiencies do not require signature.
• Recommendations do not require a written response unless requested by the CAP.
• The final step of deficiency response is to click the Submit Approved Responses button.

International Laboratory Requirements

• International laboratories must submit responses in English.
• Supporting documentation to a deficiency may be submitted in your native language, provided that the key elements, including title and major headings, are in English.

Corrected During Inspection Deficiencies

• All laboratories must go online to the deficiency response dashboard and complete the submission process for any corrected during inspection deficiencies, whether they are challenging them or not.
• If a laboratory does not wish to challenge any corrected during inspection deficiencies, the laboratory director must approve and sign the response(s) in the action item box on the deficiency response dashboard.
• If a laboratory wishes to challenge any deficiencies, see “When to Challenge a Deficiency” below.

When to Challenge a Deficiency

• If your laboratory was in compliance at the time of inspection, you may challenge the cited deficiency by clicking the challenge deficiency checkbox.
• Provide a detailed explanation for the challenge in the response text box.
• Supporting documentation is required for both Phase I and Phase II deficiencies when challenging.

HIPAA Compliance

• Documentation submitted to the CAP must not include any protected health information (PHI).
• Any patient information must be de-identified in accordance with the requirements under HIPAA. See 45 CFR §164.514(b)(2).

Please note that accreditation is a continual process. A laboratory/facility will remain accredited until otherwise notified. Accreditation does not necessarily terminate on the date of the accreditation certificate. Should you need further documentation of your laboratory’s/facility’s accreditation status, please email accred@cap.org.

FOR QUESTIONS:
Call the CAP technical specialists at 800-323-4040, ext. 6065; email accred@cap.org; or visit cap.org.