CAP Accreditation Programs
Instructions for Responding to Deficiencies

The copy of the Inspector Summation Report (ISR) provided at the conclusion of your inspection is the official listing of deficiencies that require responses. The CAP will not send an additional report of deficiencies cited. Responses are due to the CAP within 30 calendar days from the date of the inspection. Failure to meet response deadlines or adhere to the following instructions will delay the accreditation process and may affect the laboratory’s/facility’s accreditation decision.

How to Respond
• Each deficiency requires a separate Deficiency Response Sheet.
• Phase I deficiencies require a written response indicating corrective action taken.
• Phase II deficiencies require a written response and supporting documentation demonstrating compliance. The response should explain the purpose of the documentation submitted. (Note: If the same supporting documentation will be used for multiple responses, a copy must be attached 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 highlighted portions) of policies/procedures that pertain to a deficiency.
• QC, calibration, maintenance records, and instrument printouts.
• Log sheets including recorded data. Blank logs are unacceptable.
• Purchase orders, work orders, photos, diagrams, and floor plans.
• Evidence of staff review or retraining on new, revised or existing procedures.

• Deficiencies noted as “Corrected On-Site” do not require a written response unless requested by the CAP.
• Recommendations do not require a written response unless requested by the CAP.
• Phase 0 requirements do not require a response to the CAP.
• Electronic versions of the enclosed Deficiency Response sheet and the Deficiency Response Signature Page are available on the CAP website—e-LAB Solutions™ > LAP Resources for Laboratories > Deficiency Responses & Root Cause Analysis Template.

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).

How to Challenge a Deficiency
If a decision is made to challenge a deficiency, state your intention (i.e., I wish to challenge this deficiency...) clearly on the response sheet, and explain the reason for the challenge. Attach required documentation supporting the claim that your laboratory was in compliance prior to the inspection, including records of ongoing implementation dated prior to the inspection. Supporting documentation is required for both Phase I and II deficiencies.

Helpful Hints
• Include the checklist item number on supporting documentation.
• All documentation should be single-sided.
• Do not use staples, page protectors, or binders. (Paper clips are preferred.)
• Retain copies of all documentation submitted for your laboratory/facility records.
• Highlight/underline appropriate details of the response.

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.

What to Send to the CAP
• Send the Deficiency Response Signature Page, signed by the director, attesting that he/she has reviewed and approved the responses.
• Include Deficiency Response Sheets with attached supporting documentation.

Mail to:
Technical Specialist
CAP Accreditation Programs
College of American Pathologists
325 Waukegan Road
Northfield, IL 60093-2750

Any Questions?
• CALL the CAP technical specialists at 800-323-4040 ext. 6065
• SEND an email to accred@cap.org
• VISIT cap.org

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