



The copy of the Inspector Summation Report (ISR) provided at the conclusion of your inspection is the official listing of deficiencies. 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, 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, 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.
- International laboratories must submit responses to deficiencies in English. Supporting documentation to a deficiency may be submitted in the native language, provided that the key elements, including title and major headings, are in English.

## Helpful Hints

- Include the checklist requirement number on supporting documentation.
- Ensure all documentation is single-sided.
- Do not use staples, page protectors, or binders. (Paper clips are preferred.)
- Underline appropriate details of the response.
- 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.
- Retain copies of all documentation submitted for your laboratory/facility records.

**Note:** Electronic versions of the enclosed Deficiency Response sheet and the Deficiency Response Signature Page are available on the CAP website—e-LAB Solutions Suite > CAP Accreditation Resources > Accreditation Forms and Instructions > Instructions for Deficiency Response

## When to Challenge a Deficiency

If your laboratory was in compliance at the time of inspection, the laboratory may state its intention to challenge the cited deficiency. Comments, such as I wish to challenge this deficiency; Laboratory Challenge, etc, must be noted clearly on the deficiency response sheet, with an explanation for the challenge. Attach required documentation supporting the claim, including records of ongoing compliance dated prior to the inspection. Supporting documentation is required for both Phase I and Phase II deficiencies when challenging.

## 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 for each deficiency.

## 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](mailto:accred@cap.org).

### Mail to:

Technical Specialist  
CAP Accreditation  
Programs

College of American  
Pathologists

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### Any Questions?

- CALL the CAP technical specialists at 800-323-4040 ext. 6065
- SEND an email to [accred@cap.org](mailto:accred@cap.org)
- VISIT [cap.org](http://cap.org)