COLLEGE of AMERICAN PATHOLOGISTS

To Cite or Not to Cite?

1. When do you cite a deficiency?

Laboratory practices must meet the intent of the checklist requirement, but the laboratory does not have to follow the exact protocol of the inspector's laboratory. There are many ways to accomplish the same objective. The inspector should cite a deficiency if there is no policy or procedure; if it is not being followed as written or is not being documented; if there is no record of review or corrective action; or if the procedure is an ineffective or bad laboratory practice. In the situation where documentation is incomplete, the inspector must judge whether the degree of partial compliance is likely to have adversely affected patient care or worker safety. If so, a deficiency must be cited. If the checklist item applies but the laboratory does not address it in any way, the laboratory is not in compliance.

The inspector should not be afraid to cite a deficiency and should never give a recommendation instead of a deficiency if the laboratory is not in compliance. When an inspector gives a recommendation instead of a deficiency in a situation where the laboratory is clearly deficient, the CAP may convert the recommendation into a deficiency and ask the laboratory to respond to and correct the deficiency. The goal of the inspection is laboratory improvement.

2. When do you cite a recommendation?

A recommendation is a suggestion for improvement. For instance, when a laboratory is in compliance, but it can improve its process. A recommendation may not always pertain to a specific checklist item, but it could relate to the way the laboratory is doing a specific task or keeping records. The laboratory is not obligated to respond to or implement a recommendation. A recommendation should not be given in place of a deficiency just to be "nice." If a laboratory is not in compliance, it is deficient. A recommendation that should have been cited as a deficiency may be changed to a deficiency by the CAP, and a deficiency response will be required from the laboratory.

3. When do you cite "Corrected on Site"?

Some deficiencies, both phase I and phase II, may be corrected while the inspectors are still on site. Correction on site is a relatively rare occurrence and would include minor corrections such as signing one or two procedures, inserting minimal changes in a procedure, or writing a policy to match existing practice. In all cases, the inspector must indicate on the deficiency form how the deficiency was corrected.

Other more extensive deficiencies, such as the lack of a quality management plan, lapses in performance or review of quality control or proficiency testing, or implementation of a new or significantly changed procedure, cannot be corrected on site. When a change to a process, policy, or procedure requires additional training or retraining of personnel or if previous patient results must be evaluated for any impacts to patient care (eg, when expired reagents are found to be in use or when incorrect result calculations are identified), the deficiency cannot be corrected on site. Recurring deficiencies are of significant concern and, as such, cannot be corrected on site.

Deficiencies corrected on site during the inspection are deficiencies and will remain in the laboratory record. The CAP reserves the right to request documentation from the laboratory concerning how a deficiency was corrected on site; for phase II deficiencies, both a corrective action plan and evidence to support implementation may be requested.

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