HOW TO RESPOND AFTER YOUR ON-SITE CLIA SURVEY

During the exit conference of your on-site inspection, the surveyor will inform you of any problems you may have in the laboratory with meeting the regulatory requirements. This initial verbal notice will be followed within 10 days of the inspection by a CMS 2567--the official, written report listing any CLIA deficiencies.

Time should be set aside to prepare a written plan to address each deficiency listed on the written report. Some laboratories begin drafting a plan prior to receiving the written report. Preparing the plan shortly after the inspection may be beneficial since this would be the time when deficiencies and corrective actions are most clear.

Taking notes on any suggestions the surveyor makes regarding appropriate corrective action and any follow-up documentation which may be required by the state agency will make writing the plan easier. The plan for correcting any problems must be submitted within 10 days of receiving the written statement of deficiencies.

Once the report is received, review each deficiency and create a detailed plan of correction. Each part of the deficiency must be completely addressed.

Consider how the deficiency may affect multiple testing processes and devise a corrective action plan to address all affected testing processes or systems. An acceptable plan of correction (POC) specifically addresses all of the deficiencies cited, indicating the corrective action, the person(s) responsible for the corrective action, and the date of completion.

Remember that documentation of the corrections made for each deficiency will be requested. If there is documentation showing that corrective action has been taken prior to submitting the plan for approval, include the supportive documentation with the plan.

TIME SHOULD BE SET ASIDE TO PREPARE A WRITTEN PLAN TO ADDRESS EACH DEFICIENCY LISTED ON THE WRITTEN REPORT.

The time frame for taking corrective action must be reasonable and appropriate for the deficiencies identified.

Finally, the person who will be responsible for implementing the plan should be identified by title/position. The laboratory director or authorized representative is required to sign and date the bottom of the plan.

The state inspection agency will review the plan and determine whether it is acceptable. Make sure all entries are legible to ensure a swift and successful approval.

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