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Management Bulletin

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# How to Respond to CLIA Deficiencies

Let out the breath you have been holding because your CLIA inspection is finally over. Whew! Unfortunately, after all your hard work, you were cited for one or more CLIA deficiencies. Now what?

This issue of the Management Bulletin will explain the different types of CLIA deficiencies and how to properly respond to the CLIA post-survey process.

## Statement of Deficiencies

The goal of a CLIA survey is to assess the laboratory's overall performance, determine compliance with the regulations, and ensure the quality of patient testing. Shortly after your inspection, the laboratory will receive the Statement of Deficiencies (CMS-2567 Statement of Deficiencies) in the mail from the CLIA inspector. During your survey exit conference, the surveyor reviewed the inspection findings with the laboratory. Although the exit conference is not meant to be all-inclusive, it should have provided the laboratory an idea of the deficiencies that will be included in the Statement of Deficiencies. So there should be no surprises.

The Statement of Deficiencies identifies the regulation in violation and describes the finding of non-compliance. The Statement of Deficiencies will include direct references to regulations with a corresponding D-tag number. The summary statement column will include the regulatory citation along with the description of the laboratory's deficient practice.

There are two types of deficiencies an inspector may cite your facility for during a survey: standard-level and condition-level.

**Standard-Level Deficiency:**
A standard-level deficiency constitutes non-compliance with a specific CLIA regulation. For instance, you may have a deficient practice related to quality control procedures.

*Example: A laboratory performs gram-stain testing, but failed to perform minimum quality control testing.*

*§493.1261* ***Standard****: Bacteriology.*
*(a)(2) Each week of use for Gram stains.*

**Condition-Level Deficiency:**
A condition-level deficiency constitutes a significant or a serious problem that adversely affects patient test results or care, or has the potential for adversely affecting patient test results or care. An example would be a deficient practice in the qualification of laboratory leadership.

*Example: A laboratory is performing non-waived testing without a laboratory director or with one that is not properly qualified.*

*§493.1403* ***Condition****: Laboratories performing moderate complexity testing; laboratory director.*

*The laboratory must have a director who meets the qualification requirements of §493.1405 of this subpart and provides overall management and direction in accordance with §493.1407 of this subpart.*

## Plan of Correction

The laboratory is required to submit a written response within 10 working days of receiving the Statement of Deficiencies. This response is known as the Plan of Correction (POC). An acceptable POC must be submitted for all deficiencies noted. The POC must be specific, realistic and complete. If the POC is not properly completed or if additional information is needed, the laboratory will be contacted for clarification or modifications or both.

The POC **must** address:

1. A step-by-step description of how the deficient practice(s) will be corrected or how corrections have already been made

2. Corrective action(s) taken if patients were found to be affected or identified as potentially being affected by the deficient practice
3. The method(s) to be used to maintain and monitor compliance and the position(s) responsible for monitoring the correction
4. A realistic date of correction (month, date, and year)

In addition, the POC must be written in ink or typed directly on the form provided. The plan must be signed and dated by the Laboratory Director or representative of your laboratory.

For any deficiency, a revisit or follow-up is conducted. The time frame depends on the type of deficiency. Evidence of condition-level compliance must be received within 45 days of the survey. Standard-level compliance must be addressed within 12 months of the survey.

## Conclusion

Remember, it is not the end of the world if you receive a deficiency during a CLIA survey. View your survey results, both good and bad, as a learning experience. If your laboratory does have to respond to a deficiency, remember these tips:

1. Don't wait. Initiate corrective action(s) prior to receiving the Statement of Deficiencies.
2. Ensure your plan of corrective action addresses each requirement.
3. Return your POC within the guidelines.
4. Don't be afraid to ask questions. Contact the surveyor or Regional Laboratory Consultant for clarification or assistance.

With a little extra work, both the laboratory and patients will benefit from the experience.

**Submitted by:**

Tracey B. Shives, BS MT ((ASCP)

**References:**

http://www.cms.gov/Regulations-and Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html (Accessed 11/5/14)

Appendix C: Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/apcpolicy.pdf (Accessed 11/5/14)

http://www.shl.uiowa.edu/publications/cliacorner/2007q3.pdf (Accessed 11/4/14)

APHL. 2013 CLIA Update: Tips for a Successful Survey. http://eo2.commpartners.com/users/APHL/downloads/588-909-13-3SlidesPerPage.pdf (Accessed 11/4/14)

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