CLIA Corner

State Hygienic Laboratory at The University of Iowa

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In This Issue...

How to complete the Statement of Deficiencies and Plan of Correction, Form CMS-2567

Your laboratory recently had its biannual survey (inspection) conducted by your favorite CLIA surveyor from your State Agency (SA). At the time of the survey, the surveyor found several areas of non-compliance with the CLIA regulations in your laboratory. The surveyor formally cites the deficiencies on the Form CMS-2567, Statement of Deficiencies and Plan of Correction.

The Form CMS-2567 serves several important functions, including:

- Documents that specific deficiencies were found, as well as documents when there are no citations;
- Documents the laboratory's receipt of the deficiency notice;
- Discloses to the public the laboratory's deficiencies and what is being done to remedy them;
- Provides an opportunity for the laboratory to refute survey findings and to furnish documentation that requirements are met; and
- Documents the laboratory's plans and time frames for correcting deficiencies.

The surveyor has 10 days from the survey date to complete and mail the Form CMS-2567 to the laboratory. If there are citations, except when immediate jeopardy is identified at the survey, the laboratory has 10 days to complete and return a plan of correction (PoC) or credible allegation of compliance (AoC).

After the laboratory receives the Statement of Deficiencies, Form CMS-2567, the laboratory enters its planned action to correct each deficiency and the expected completion date in the section opposite the appropriate data tag (D-tag) number (Refer to Example CMS-2567). The D-tag number corresponds to the regulation being cited. If a deficiency has been corrected since the survey, the laboratory should indicate this on the form along with the date of correction and include evidence (i.e. documents, photos, procedures, training records, etc.).

As the laboratory completes the plan of correction, the plan must be specific for the deficient practice and use realistic time frames for completion. **The PoC must address each of the following:**

- **How the deficient practice will be corrected or how it was corrected;**
- **What corrective action(s) have been taken for patients found to have been affected by the deficient practice;**
- **How the laboratory has identified other patients having the potential to be affected by the deficient practice and what corrective(s) have been taken;**
- **What measure(s) has been put into place or what systematic changes have been made to ensure that the deficient practice does not recur; and**
- **How the corrective action(s) is being monitored to ensure the deficient practice does not recur.**
- **Indicate the position(s) (e.g. laboratory director, technical supervisor or consultant, laboratory supervisor or manager, testing personnel, etc.) that will be responsible for monitoring**

and ensuring that the correction prevents the recurrence of the deficiency. Do NOT use specific names.

- **For each D-tag include a realistic date of correction by month, day and year.**
- **The laboratory director or other authorized official must sign and date the Form CMS-2567 on which the laboratory's PoC is written.**

If the above items are not included on your plan of correction, it will not be accepted.

After completing the PoC, the laboratory needs to make a copy for their records and return the original to the State Agency (SA) or possibly the Regional Office (RO) within 10 days of receipt. If the laboratory requests additional time to develop the plan, the laboratory must still submit a preliminary PoC within the 10 days and then submit a more specific plan as early as possible.

If the laboratory corrects a cited deficiency, before the completion of the survey, the surveyor documents the deficiency on the Form CMS-2567 and when the laboratory receives the Form CMS-267, it indicates the correction as of that date.

The SA reviews the laboratory's PoC for appropriateness, legibility, completeness, and timeliness. If not properly completed or there is a question about the PoC, the SA contacts the laboratory representative to obtain clarification or appropriate modification of the plan.

The Statement of Deficiencies and Plan of Correction, Form CMS-2567, is a legal document. The survey findings and plan of corrections are subject to public disclosure under the Federal Freedom of Information Act upon request from the SA or RO.

In summary, the Statement of Deficiencies and Plan of Correction, Form CMS-2567, serves the following purposes:

- Serves as the formal record of the survey;
- Documents and justifies the determination of compliance; and
- Aids the facility in (1) analyzing the deficient practices and failures and (2) developing plans of correction.

The overall purpose of the Statement of Deficiencies and Plan of Correction is to ensure that the laboratory takes the steps necessary to resolve a deficient practice and maintain compliance. The goal is for the laboratory to provide accurate and reliable patient test results.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
16D0000000	A. BUILDING _____ B. WING _____	05/28/2015

NAME OF FACILITY	STREET ADDRESS, CITY, STATE, ZIP CODE
EXAMPLE LABORATORY	1000 Example Street, Example, IA 52340

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY SHOULD BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERRED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5413 310M	493.1252(b) TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the laboratory temperature records and confirmed by the laboratory manager, the laboratory failed to monitor and document the temperature of the chemistry reagent refrigerator for 9 out of 31 days in March 2015 (3/2, 3/6, 3/7, 3/8, 3/23, 3/25, 3/27, 3/30 and 3/31).	D5413	For an acceptable Plan of Correction, address each of the following: 1. How deficient practice will be corrected? 2. What corrective action(s) have been taken for patients found to be affected by the deficient practice? 3. How the laboratory has identified other patient(s) having the potential to be affected by the deficient practice and what corrective action(s) has been taken? 4. What measure(s) has been put into place or what system changes have been made to ensure the deficient practice does not recur? 5. How the corrective action(s) is being monitored to ensure the deficient practice does not recur and who is responsible for monitoring (list by position and NOT by name)? 6. Date of completion. D5413-EXAMPLE PLAN OF CORRECTION 1. The testing personnel assigned to the chemistry section each day is responsible for taking the temperature of the reagent refrigerator. The task has been added to the daily maintenance log as of 06/01/2015. 2. The laboratory determined that no patient test results were affected after review of the chemistry control and calibration results. All QC results were acceptable for the dates when temperatures were not taken. 3. No patients have been affected - refer to #4 and #5 for corrective action. 4. An email will be sent to all testing personnel rotating in the chemistry section explaining the additional daily task. Each testing personnel must respond back to the laboratory manager that they have read and understand the email no later than 06/15/2015. 5. The laboratory manager added a monthly review of all temperature records to the quality assessment plan. Corrective action will be taken for omissions and out-of-range temperatures.	07/01/2015

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. *(See reverse for further instructions.)* Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Erin E. Example, MD	Laboratory Director	06/20/2015