DEPARTMENT OF HEALTH & HUMAN SERVICES
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**Center for Clinical Standards and Quality/Quality, Safety & Oversight Group**

**Admin Info: 19-05-CLIA**

**DATE:** **January 22, 2019**

**TO:** State Survey Agency Directors

**FROM:** Director
Quality, Safety & Oversight Group

**SUBJECT:** Release of Updated Principles of Documentation (POD) Guidance and CLIA POD Learning Activity (LA) Online Training Available on the Surveyor Training Website On-Demand (24/7, 365 days/year)

**Memorandum Summary**

- **Release of Updated Principles of Documentation (POD)**: The Centers for Medicare & Medicaid Services (CMS) is releasing updated POD Guidance with Appendices and CLIA POD LA Online Training Available on the Surveyor Training Website On-Demand (24/7, 365 days/year) for CLIA surveyors.
- The online POD LA-CLIA course is designed to provide an opportunity for all surveyors to apply and practice the knowledge acquired in the CLIA Surveyor Basic Training POD course.
- All State and Regional Office (RO) CLIA surveyors will be required to complete the course. New surveyors (those with less than two years' experience) will be required to complete within three months of being approved to survey independently. Experienced surveyors have up to six months from the go-live date, to complete the course.
- The new **CLIA POD Learning Activity** online training is now available on the Surveyor Training Website. The goal of the training is to improve the ability of survey staff to properly apply the POD in the documentation of findings. It reviews the proper use of grammar, punctuation, voice, and plain language consistent with the POD.
- **How to Self-Enroll:** Learners may self-register and self-launch the training on the Surveyor Training Website at https://surveyortraining.cms.hhs.gov. The training is available on demand so that learners may access the training at their convenience. It is available 24 hours a day, 7 days a week, 365 days a year.

## Background

The survey and certification of laboratories covered under the Clinical Laboratory Improvement Amendments (CLIA) is a process that must adhere to legal requirements. These programs are administered under extensive laws, regulations, operation manuals, and other guidelines. Surveys and the documentation from surveys may become an important part of potential legal proceedings arising out of the certification process.

The Form CMS-2567 Statement of Deficiencies and Plan of Correction is the official record of the survey where the surveyor(s) documents and justifies the determination of compliance and informs the health care facility of its state of compliance for certification. This information serves as the basis for the laboratory to analyze its deficient practices or system failures and to develop plans of correction or allegations of compliance. It is extremely important for survey staff to utilize proper writing skills to document their findings.

A team from Central Office (CO) and several ROs identified a need for training to help surveyors practice the correct application of the POD in the documentation process. As a result, the Quality, Safety & Oversight Group developed the CLIA POD Learning Activity online training. The online POD LA-CLIA training focuses on teaching learners the knowledge and skills necessary to properly document deficiencies that are identified during surveys. In addition, the course is designed to provide an opportunity for all surveyors to apply and practice the knowledge acquired in the CLIA Surveyor Basic Training POD course.

**Discussion**

The updated POD guidance provides clarification to the previous 2008 guidance based on RO and SA feedback as well as issues identified as part of the State Agency Performance Review (SAPR) and validation processes. Clarification includes the following:

- Updated examples in the guidance document
- Updated language related to extent and sources of evidence
- Added definitions (CFR, condition level deficiency; condition level requirements; immediate jeopardy; State Operations Manual (SOM), Appendix C)
- Expanded number of appendices

The expanded number of appendices are designed to act as surveyor tools and references, and include the following:

- Appendix A: Composing a Deficiency Tag (D-Tag)
- Appendix B: Checklist, Composing D-Tags
- Appendix C: POD Reference Sheet
- Appendix D: Active Voice vs Passive Voice
- Appendix E: Examples, Use of D0000
- Appendix F: Additional Examples for Principles 2-6
- Appendix G: Examples, Use of D8100
- Appendix H: Examples, Lack of Documentation
- Appendix I: Examples, DPS Does Not Match Findings
- Appendix J: Examples, Repeating Regulations in the DPS
- Appendix K: Examples, Writing Condition Statements
- Appendix L: Examples, Multiple Citations under the Same Regulation
- Appendix M: Examples, Cross Referencing
- Appendix N: Examples, PT Desk Review Citations
- Appendix O: Frequently Asked Questions

Finally, the updated POD guidance includes two updates. These include:

- Documentation of date and time for interview(s) as well as observation(s)
- Expanded optional use of D0000

Due to our continued improvement and practical application of the principles of documentation, CLIA policy also allows for the following optional uses of D0000 (see examples in Appendix E):

- Indication of survey type
- Summary of condition-level deficiencies

However, D0000 should not be used for the following:

- List of acronyms used in Form CMS-2567
- Indication of surveyor or names
- Narrative description of the survey and a summary of noncompliance issues

**Training Goal & Description**

The goal of the training is to enable surveyors to properly document evidence that demonstrates specific regulatory noncompliance using language and format consistent with the Principles of Documentation. In addition, the purpose of the training is to improve the ability of survey staff to document findings using proper writing skills consistent with the POD when composing a Form CMS-2567 Statement of Deficiencies. It provides opportunities to practice and demonstrate the correct use of grammar, punctuation, voice, and plain language.

This training course is a web-based, self-paced course that takes approximately three (3) hours to complete. To get the most out of the course, the modules are set up in a particular order for completion. It consists of a Pre-Test, three learning modules with practice questions and case studies, and a Post-Test*.

**Learners are given three attempts to pass the Post-Test with a score of 85 percent or higher. Learners who do not successfully pass the Post-Test within three attempts may reenroll.*

**Target Audience**

All CLIA survey staff who conduct CLIA surveys and complete official survey forms are required to complete this training. The target audience includes surveyors, reviewers, and all other survey staff who are responsible for composing, reviewing, or approving Form CMS-2567, Statement of Deficiencies.

- New State Survey Agency (SA) staff (i.e., less than two years' experience) are expected to complete this required training within three months of being approved to survey independently.
- Experienced surveyors are required to take this training within six months of this memo.

Thereafter, we highly recommend that all surveyors and survey staff review this training annually, or on an as-needed basis, or as directed by their SA or RO to refresh their skills. Non-survey professionals, generalists, managers, supervisors, training coordinators, and other SA or RO support staff responsible for ensuring compliance with regulations are also encouraged to take the training.

**Training Course Prerequisites**

The prerequisites for this course include at least six months of survey experience and successful completion of the following:

- CLIA Virtual Basic Training
- 2018 POD Guidance and appendices
- Basic Writing Skills for Survey Staff
- Orientation Manual
- A working knowledge of the Public Health Service Act, specifically Section 353, Subpart 2 Clinical Laboratories, 42 CFR part 493, the CLIA Regulations, the State Operations Manual (SOM), and SOM Appendix C

All prerequisites are available on demand on the Survey Training Website at https://surveyortraining.cms.hhs.gov.

**Training Access Instructions**

Follow the instructions below to Self-Register and Self-Launch the online training:

Login Instructions:

1. Go to the CMS Surveyor Training Website at **https://surveyortraining.cms.hhs.gov**.
2. Select the "**I AM A SURVEYOR**" link.
3. Enter your username and password into the fields*.
4. Select the "**Submit Logon**" button.
5. Select "**Training Catalog**."
6. Scroll down and search for the **CLIA POD Learning Activity** online training.
7. Select the "**Register for this Training**" button.
8. Select the "**Launch this Training**" button.

** Contact the **Help** desk for assistance if you don't have a username or password.*

**Contact:** For more information about the content of this course, please contact: LabExcellence@cms.hhs.gov.

Technical issues such as logging in, password resets and disabled accounts should be directed to the **CMS Surveyor Training Site Help Desk**, either by phone (1-855-791-8900) or by email at cmstraininghelp@hendall.com.

**Effective Date:** Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
Karen Tritz
Acting Director

Attachment(s): Updated POD Guidance (2018)
POD Appendices

cc: Survey and Certification Regional Office Management

# *Principles of Documentation*

October 2018

# PRINCIPLES OF DOCUMENTATION - 2017
# FOR THE STATEMENT OF DEFICIENCIES (Form CMS-2567)

## Table of Contents

# INTRODUCTION

This manual provides guidance on how to structure a deficiency statement on the Form CMS-2567 after all the necessary information and evidence have been gathered. These guidelines include a general discussion of the legal aspects of the Statements of Deficiencies, and identify and explain the principles considered in the citation of deficiencies to be documented on the Form CMS-2567.

This guide does not replace or supersede the law, regulations, or State Operations Manual (SOM). Rather, this manual is intended to provide guidance for documenting citations. Therefore, this manual does not create additional substantive or procedural requirements that must be present to sustain a valid citation.

The Form CMS-2567 is the record of the survey where the surveyor(s) documents and justifies the determination of compliance and informs the laboratory of its state of compliance for CLIA certification. This information will serve as the basis for the laboratory to analyze its deficient practices or system failures and to develop plans of correction. The Form CMS-2567 may also document deficient practices identified by means other than an on-site survey (e.g., an off-site review of unsuccessful proficiency testing scores).

Each principle is discussed in depth and includes an example of that principle. Each example is identified as being effective and is included to illustrate a particular documentation principle. In each case, there may be other language that may be as effective. The adequacy of any citation can be evaluated only in the context of the particular type and source of evidence, the extent and consequence of deficiency, and other relevant factors.

# DEFINITIONS

Listed below are definitions that will be used throughout these materials.

**CFR:** Code of Federal Regulations

**Condition:** Requirements with which a laboratory must comply in order to be CLIA certified.

**Condition level deficiency** means non-compliance with one or more condition level requirements.

**Condition level requirements** means any of the requirements identified as "conditions" in subparts G through Q of the CLIA regulations at 42 CFR §493.

**Deficiency Citation**: an entry made on the Form CMS-2567 that includes: 1) the alpha prefix and data tag number (D-Tag), 2) the Code of Federal Regulations (CFR), 3) the language from the reference which pinpoints the aspect(s) of the requirement with which the laboratory failed to comply, 4) an explicit statement that the requirement was NOT MET and 5) the evidence (the deficient practice statement and relevant individual findings or facts) to support the decision of noncompliance (see Exhibit 0-1).

**Deficient Practice**: the action(s), error(s), or lack of action on the part of the laboratory relative to a requirement (and to the extent possible, the resulting outcome).

**Deficient Practice Statement (DPS)**: a statement at the beginning of the evidence that sets out why the laboratory was not in compliance with a regulation.

**Evidence**: an integral part of the citation that begins with a description of the deficient practice and identifies the relevant individual findings and facts that substantiate the failure of the laboratory to comply with the regulation.

**Extent of deficient practice**: the prevalence or frequency of a deficient practice.

**Finding**: a generic term used to describe each discrete item of information observed or discovered during the survey about practices of a laboratory relative to the specific requirement being cited as being not met.

**Fact**: an event known to have actually happened. A truth known by actual experience or observation.

**Form CMS-2567 - Statement of Deficiencies and Plan of Correction:** the official document on which citations, and laboratory responses and corrective action are recorded.

**Immediate Jeopardy (IJ):** Means a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public. This term is synonymous with imminent and serious risk to human health and significant hazard to the public health.

**Outcome**: a result/consequence of laboratory practices (e.g., reaction due to receipt of blood of wrong blood type.).

**Requirement**: any structure, process or outcome that is required by the law, regulations.

**State Operations Manual (SOM), Appendix C**: Manual which provides survey interpretive guidance for surveyors and laboratories related to CLIA regulations, and is also known as the "Interpretive Guidelines".

**Universe**: the total number of individuals, records, observations, objects, related to the laboratory practice or patients at risk as a result of a deficient practice. Used as the denominator when determining the extent of a deficient practice.

# LEGAL ASPECTS OF THE STATEMENT OF DEFICIENCIES

The survey and certification of a laboratory that participates in the Clinical Laboratory Improvement Amendments (CLIA) program, is guided by legal requirements. These programs are administered under extensive laws, regulations, operation manuals and other guidelines. Survey documentation can become an important part of legal proceedings arising out of the survey process.

This section is a brief overview of the legal aspects of surveying and the importance of surveyor documentation to the decision making and appeals process. It is not intended to provide complete and detailed information on the mechanics of the process. Please refer to the State Operations Manual (SOM), including Appendix C, for more detailed information.

The survey process determines, and the documentation records, the compliance or noncompliance of CLIA laboratories. The surveyor provides the justification for any resulting enforcement action and the record on which to defend that action in the appeals process. Consistent and accurate documentation is imperative in the entire certification process as it forms the basis for the record and the certification decision. Moreover, the documentation may also be reviewed in any subsequent appeal, i.e., hearing before an Administrative Law Judge (ALJ) of the Departmental Appeals Board (DAB), review by the Board's Appellate Division, and judicial review.

A certification of compliance or noncompliance with the applicable requirements by the State Agency (SA) or the Federal Government is an official finding and determines whether or not a laboratory is issued a certificate to operate under CLIA. It also determines whether a laboratory is subject to sanctions. The decision-making process and subsequent certifications are based on the documentation of the survey in the Statement of Deficiencies (Form CMS-2567), as well as, other documentation such as surveyor worksheets or notes.

If a laboratory is determined to no longer meet the requirements and is subject to CLIA sanctions, the sanction determination may be appealed through an evidentiary hearing before an ALJ. During a hearing, the government has the responsibility to show why a laboratory should be subject to principal and/or alternative sanctions.

The evidence must provide the underlying reason, basis or rationale for the findings of noncompliance with the regulatory requirement(s). Such a hearing is an adversarial proceeding. At the hearing, witnesses testify for both the laboratory and for CMS, and are subject to cross-examination. The primary evidence is the Form CMS-2567, and any other documentation used to make the determination of survey results (e.g., surveyor notes). The ALJ relies on the testimony of witnesses and the documentation from the survey in making a decision. All documentation used at the hearing becomes part of the public record. The ALJ issues a written decision as to whether or not the laboratory should be found in compliance with the requirements of the program. The ALJ

is usually not a health professional, therefore, it is important that the surveyor present the findings in plain language. For this reason, the Form CMS-2567 does not contain technical jargon or abbreviations that would not be readily understood by a lay person.

If either CMS or the laboratory is dissatisfied with an ALJ decision or dismissal, it may file a request for review to the DAB Appellate Division. The DAB considers the evidence introduced at the ALJ hearing to determine whether the ALJ's decision had a sound factual basis. A laboratory dissatisfied with the DAB decision has the right to seek judicial review, CMS does not. The survey documentation again becomes an important document of the proceedings. The review by the Court is limited to the record of the proceedings before the ALJ and the DAB's Appellate Division.

Documentation on the Form CMS-2567 remains the key element in the record to support a determination to certify compliance or noncompliance with applicable requirements and, if necessary, to defend the determination during the administrative appeals process, or in a court during the judicial review process. The documentation of each and every survey should be treated as if it will be subject to close scrutiny. The determination of compliance, as well as noncompliance must be based on objective, factual observations and not vague conclusions. A judge will usually rely on the Form CMS-2567 if the documentation is thorough and comprehensive.

A clear and comprehensive Statement of Deficiencies is necessary to provide the laboratory with the information necessary to analyze its problems, define appropriate corrective action and come into compliance with the requirements. The Form CMS-2567 should tell the complete story in a concise manner while including pertinent facts. The Statement of Deficiencies should focus on the regulatory requirement(s) and how the laboratory failed to meet the requirement(s). The laboratory should be cited at the most appropriate D-Tag(s) for a particular deficient practice so that the laboratory can identify, understand and correct the issue. The same deficient practice should not be cited at multiple D-Tags simply because it can be cited.
For example, if quality control (QC) or quality assessment (QA) issues are already cited under the QC or QA D-Tags it may not be necessary to be cited under personnel or vice versa. It may be more appropriate to cross reference.

Please note that it is not being stated that noncompliance should never be cited more than once. A surveyor may decide that it is appropriate to cite a deficient practice under several D-Tags. For example, the laboratory was not performing QC as well as the laboratory director or technical consultant/technical supervisor was not performing their regulatory responsibilities related to QC. In this case is would seem that the most appropriate way to cite the deficient practice(s) would be to cite at both D-Tags. It is important to look at the regulatory reference and make sure the noncompliance is specific to the regulatory reference cited. Surveyor judgment plays an important role in what and where deficient practices are cited.

# OVERVIEW

Listed below for easy reference are the principles considered in the development and completion of the Form CMS-2567. Each principle is explained in detail in a separate section.

**Principle #1: Laboratory Compliance and Noncompliance**

When a laboratory complies with the requirements applicable to the survey conducted, the Form CMS-2567 should consist of an explicit statement that the laboratory is in compliance. If a laboratory is not in compliance with one or more applicable requirements, the Form CMS-2567 includes corresponding citations of noncompliance.

**Principle #2: Using Plain Language**

The deficiency citation is written clearly, objectively and in a manner that is easily understood. The deficiency citation does not include consultation; advice, comments or direction aimed at the surveyed laboratory.

**Principle #3: Components of a Deficiency Citation**

A deficiency citation consists of (A) a regulatory reference, (B) a deficient practice statement and (C) relevant findings.

A. Regulatory Reference:

A Regulatory Reference includes the following components:

1) A survey data tag (D-Tag) number,
2) The CFR (Code of Federal Regulations),
3) The language from that regulatory reference which specifies the aspect(s) of the requirement with which the laboratory was non-compliant, and
4) An explicit statement that the requirement was "NOT MET".

B. Deficient Practice Statement (DPS)

The statement of deficient practice is one component of the evidence. It includes:

1) The specific action(s), error(s), or lack of action (deficient practice),
2) Outcome(s) relative to the deficient practice, when possible,
3) A description of the extent of the deficient practice or the number of deficient cases relative to the total number of such cases,
4) The identifier of the individuals or situations referenced in the extent of the deficient practice, and
5) The source(s) of the information through which the evidence was obtained.

C. Relevant Facts and Findings

The facts and findings relevant to the deficient practice answer the questions: who, what, where, when, and how. They illustrate the laboratory's noncompliance with the requirement or regulation.

**Principle #4: Relevance of Onsite Correction of Findings**

If, during the survey, the laboratory corrects the situation that resulted in the deficiency, a determination of "NOT MET" must be documented on the Form CMS-2567. The laboratory may indicate its correction in the right-hand column of the Form CMS-2567. If, during the survey, the laboratory initiates corrective action that abates a finding of immediate jeopardy, follow the guidance described in Appendix Q.

**Principle #5: Interpretive Guidelines**

The deficiency citation explains how the laboratory fails to comply with the regulatory requirements, not how it fails to comply with the guidelines for the interpretation of those requirements. Guidelines are not regulatory requirements rather interpretations of regulatory requirements. Deficiencies should only be cited for noncompliance with **regulatory** requirements.

**Principle #6: Citation of State or Local Code Violations**

The laboratory's failure to comply with State or local laws or regulations is not documented in the Form CMS-2567 except when the Federal regulation requires compliance with State or local laws. When the authority having jurisdiction for that State or local law has made a decision of noncompliance which has resulted in an adverse action which has been sustained through the hearing process (such as removal of the license to operate), the Form CMS-2567 should note that the laboratory no longer has a State license.

**Principle # 7: Cross-References**

The cross-referencing of requirements is an acceptable form of documentation on the Form CMS-2567 only when it is applicable and provides additional strength to the linked citations. Cross-referencing is most effective when the linked citations have a direct cause and effect relationship to the deficient practices described in both citations. In all instances, the linked citation must contain sufficient evidence to demonstrate noncompliance for the referenced regulation at the linked site.

**Principle # 8: Condition Deficiencies**

The Condition citation includes deficient practice statements and findings to support the determination of noncompliance with a Condition level requirement. The findings may be incorporated either by cross-references to those requirements which must be corrected to find the Condition to be met or by narrative description of the individual findings.

**Please note: Additional examples for using POD can be found in the appendices attached to this guidance.**

## Principle #1: Laboratory Compliance and Noncompliance

When a laboratory complies with the requirements applicable to the survey conducted, the Form CMS-2567 should consist of an explicit statement that the laboratory is in compliance for that particular survey. If a laboratory is not in compliance with one or more applicable requirements, the Form CMS-2567 includes corresponding citations of noncompliance. The statutes and implementing regulations are the legal authority for determining a laboratory's compliance with Federal requirements for CLIA.

The Form CMS-2567 is the official document that communicates the determination of compliance or noncompliance with the Federal requirements. Also, it is the form a laboratory uses to submit a plan of correction (POC) or an allegation of compliance (AOC). It is an official record and is available to the public on request.

Exhibit 1-1 illustrates how to give official notice to the laboratory or any other interested parties of the compliance status of the laboratory when the surveyor has identified no deficiencies. The specific requirements with which the laboratory must comply, as contained in Title 42 of the Code of Federal Regulations (CFR) Part 493, are included.

Exhibit 1-1: Effective Documentation for Principle #1

| TAG | SUMMARY STATEMENT OF DEFICIENCIES |
|---|---|
| D0000 | An onsite survey conducted, (Date) found the [Name] laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories. |

If a laboratory has no deficiencies identified at the time of the survey, the entry on the Form CMS-2567 would read that the laboratory is in compliance with 42 CFR Part 493 Requirements for Laboratories.

Use of the Tag D0000 should be used judiciously. The original intent for the use of D0000 was to allow for the documentation of compliance. It was not intended to allow commentary, additional narrative information or other documentation not relevant to the use of this tag. Additional applications for the appropriate use of D0000 are: 1) There is no current tag available to cite an existing regulation; 2) There are new regulations in which a D-Tag has not been assigned.

Due to our continued improvement and practical application of the principles of documentation, CLIA policy also allows for the following optional uses of D0000 (see examples in Appendix E):

- Indication of survey type
- Summary of condition-level deficiencies
- Documentation of PT referral for Certificate of Waiver or PT referral for waived tests being performed under other certificate types

D0000 should not be used for the following:

- List of acronyms used in Form CMS-2567
- Indication of surveyor or names
- Narrative to describe the survey and a summary of noncompliance issues

**NOTE: The remainder of the principles of documentation address how to document citations, that is, situations in which the laboratory has been found not to comply with one or more requirements.**

## Principle #2: Using Plain Language

The deficiency citation is written clearly, objectively and in a manner that is easily understood. Each deficiency citation relates to a requirement within the CFR. The deficiency citation should contain only the evidence to support the determination of noncompliance. Exclude the use of consultation, advice, comments or directions aimed at the surveyed laboratory. The deficiency citation should contain only the evidence to support the determination of noncompliance.

Inclusion of extraneous comments or consultative remarks in citations may lead to confusion. The laboratory surveyed and the public may not be able to distinguish between what the surveyor(s) would like to see and what is legitimate evidence of noncompliance. To decrease confusion, documentation in the Form CMS-2567 contains only the citation and evidence to support the determination of noncompliance. Extraneous information that is not relevant to demonstrating noncompliance with the specific requirement should be avoided.

**The following is an example of: "By using the (named) identification system, this deficiency would be corrected."**

The language used to write a deficiency citation should be as clear as possible. Many styles of writing are acceptable, and style is a matter of individual preference, however, surveyors should not use slang, unfamiliar terms and phrases. Best practice is to:

- Put all relevant facts in chronological order.
- Keep sentences short.
- Use simple sentence structure.
- Use active voice (e.g. "The laboratory director stated" not "It was stated by the director")
- Avoid undefined abbreviations, initials and technical jargon.
- Write in layman's terms.
- Write to inform, not impress.
- Avoid unnecessary words.
- Avoid vague terminology (such as, seems, appears, did not always).
- Avoid words that imply or state conclusions without including the facts to support them (e.g., "only", "just", "unsatisfactory", "unnecessary, or "inadequate").
- Ensure the accuracy of quoted material.

According to Strunk and White, "When you become hopelessly mired in a sentence, it is best to start fresh; do not try to fight your way through against the terrible odds of syntax. Usually what is wrong is that the construction has become too involved at some point; the sentence needs to be broken apart and replaced by two or more shorter sentences[2]."

## Principle #3: Components of a Deficiency Citation

A deficiency citation consists of (a) a regulatory reference, (b) a statement of deficient practice, and (c) relevant findings. Since all relevant information demonstrating noncompliance have been provided in the deficiency citation, conclusionary and or summary remarks at the end of the deficiency citation are not necessary and should be avoided.

This principle addresses **all** of the components of a complete citation.

### Regulatory Reference

When the laboratory's practice violates a regulation or requirement, determine the regulation that the laboratory may have violated. Examine the language of the regulation under which a deficiency could be cited. Determine if the requirement addresses the laboratory's policies and procedures, actions, or inaction.

A regulatory reference is composed of: 1) a survey data tag number, 2) the CFR reference, 3) the language from that reference which specifies the aspect(s) of the requirement which the laboratory was non-compliant, and 4) an explicit statement that the requirement was "NOT MET". Regardless of the computer software used to produce the Form CMS-2567, essential components of the citation: survey D-Tag, CFR reference, language of the requirement for that reference and an explicit statement that the requirement was not met are generated automatically on the Form CMS-2567. If a software program is not available and a surveyor must use a handwritten process for developing the Form CMS-2567, each citation must include all of the components. These components are followed by the deficient practice statement and the relevant findings.

If the approved CMS software program for documenting deficiencies does not capture the language of the requirement being cited at a particular D-Tag or the specific regulatory/statutory requirement, incorporate the language for the specific aspect of the requirement being cited as being deficient. In addition, if the approved CMS software program is down for a period of time which requires an alternative methods to document deficiencies, the SA must have a mechanism, including written instructions, on how to complete this activities. If a situation arises that a Form CMS-2567 must be hand written, the SA must ensure that the regulatory language is complete and accurate for the chosen D-Tag.

Federal certification requirements are located at Title 42 of the Code of Federal Regulations (CFR). The requirements are further coded into a series of alpha numeric D-Tags (e.g., D2013, D5293, D6104, etc.) that allow essential survey information to be retrieved and analyzed to determine trends and patterns of noncompliance. The numerical order of survey D-Tags approximates the order of the requirements within the CFR.

Exhibit 3-1: **Regulatory Reference-** Principle #3

| TAG | SUMMARY STATEMENT OF DEFICIENCIES |
|---|---|
| D3007 | 42 CFR 493.1101(b)<br><br>The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.<br><br>This Standard is not met as evidenced by: |

**Requirements**

Federal requirements for participation or coverage can be categorized as follows:

- **Structure-requirements** specify the initial conditions that must be present for a laboratory to be certified to participate and, are expected to remain as is unless there is a need for major renovation, reorganization or expansion of services. Examples of structure requirements include:

**The laboratory must have a director who meets the qualifications OR The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities.....**

- **Process-requirements** that specify the ongoing manner in which a laboratory must operate. They do not allow the laboratory discretion to vary from what is specified. Examples of process requirements include:

**The laboratory must establish and follow written policies and procedures for patient preparation, specimen collection, specimen labeling.... OR The laboratory must check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, anti-sera and identification systems....**

- **Outcome-requirements** that specify the results that must be obtained or events that must occur or not occur following an act. Generally, these requirements are stated in terms of the patient's response to receipt of needed services or conditions that must result from, or are prevented by, implementing one or more processes. Example of outcome requirements include:

**The laboratory must immediately alert the individual or laboratory requesting the test and, if applicable, the individual responsible for using the test results when any result indicates an imminent life-threatening condition, or panic or alert value.**

The outcome oriented survey process places emphasis upon performance or outcome measurements to ensure accurate and reliable test results and other related activities. It directs the surveyor to focus, at least initially, on the services that are being provided and then to examine the

structure and processes contributing to those outcomes or potential outcomes.

Under accepted professional standards, the structures, processes and outcomes required by the regulations are agreed to be necessary for the laboratory to provide accurate and reliable test results. **Failure of the laboratory to meet the requirements, regardless of the presence of outcomes, constitutes evidence of noncompliance and should be cited at the applicable level (i.e., standard or condition).**

Additionally, if the surveyor discovers any practice by the laboratory has a severe or a potentially severe effect on the well being of even one person, the citation should convey the serious outcome in the language of the findings, even if the requirement is a structure or a process regulation.

## Deficient Practice Statement (DPS)

The statement of deficient practice must be written in terms specific enough to allow a reasonably knowledgeable person to understand the aspect(s) of the requirement that is (are) not met. It includes what the laboratory did or did not do which caused the noncompliance. It is also important to ensure that the DPS noncompliance actually speaks to the chosen regulation for which the laboratory is being cited and that the findings support the DPS.

The statement of deficient practice must not merely repeat the regulation, but should state specifically what the facility did that was wrong or failed to do in relation to the regulation and let the reader know what to look for in the findings. Many D-Tags have multiple regulatory requirements. It is important that the DPS speak to the specific portion of the regulation(s) that the laboratory failed to meet. The statement of deficient practice presents the specific action(s), error(s), or lack of action(s) relative to the requirement.

The evidence for a citation begins with a statement of deficient practice summarizing the issues which led to the determination that the laboratory was not in compliance with that requirement and contains all the objective findings. **The statement of deficient practice includes:**

**(1) the specific action(s), error(s), lack of action (deficient practice),**

**(2) when possible, resultant outcome(s) relative to the deficient practice,**

**(3) a description of the extent of the deficient practice or the number of deficient cases relative to the total number of such cases,**

**(4) the code of the individuals or situations referenced in the extent of the practice, and**

**(5) reference to the source(s) of the information through which the evidence was obtained. Note: All sources of evidence must be reflected in the findings.**

Some certification requirements state multiple expectations at a single survey D-Tag. The laboratory must maintain compliance with each facet of the requirement in order to continue participation. The failure to comply with only one expectation may be sufficient evidence for a

citation of the entire requirement. The deficient practice must be described in clear concise terms while balancing the need for the laboratory to determine which part of the regulation it has NOT MET. The deficient practice statement should be organized and presented in a logical manner and should relate to each part of the regulation with which the laboratory failed to comply.

Exhibit 3-2: **Effective** Documentation of Deficient Practice Statement

| | |
|---|---|
| D5763 | 42 CFR 493.1283(a)(1)-(4)<br>The laboratory must maintain an information or record system that includes the following: (1) The positive identification of the specimen. (2) The date and time of specimen receipt into the laboratory. (3) The condition and disposition of specimens that do not meet the lab criteria for specimen acceptability. 4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).<br><br>This Standard is not met as evidenced by:<br><br>Based on surveyor review of test records and interview with the supervisor, the laboratory failed to document the identity of the testing personnel who performed 5 of 10 urine cultures reviewed. (Patient #'s 2331, 2783, 4593, 6946, and 9884) |

Note: In this practice statement, the deficiency is related to only one of the several requirements at this D-Tag.

**Extent**

Extent is the prevalence or frequency of a deficient practice and, when possible, is a numerical quantification of the deficient practice. The extent is expressed in a numerical format by identifying the number of deficient cases within the total number of relevant cases or universe. For example: 4 of 6 staff observed performing testing. The universe of 6 may be all of the staff performing testing on the day of the survey, it may be all the testing personnel from that laboratory department, or it may be all testing personnel employed by the laboratory.

The extent of deficient practice will depend upon whether:

(1) The deficiency is based on the surveyors having knowledge of all situations or cases, to which the requirement applied,

(2) The requirement is based on the review of a sample of applicable situations or the requirement related to a subset of the applicable situations, and

(3) The deficient practice was determined through only random opportunities for discovery.

When the failed practice does not affect all testing personnel employed by the laboratory, the surveyor must attempt to determine the relevant universe or the total number of testing personnel affected by the failed practice. For instance: The technical consultant did not perform competency assessment on two of 10 testing personnel. Therefore, the universe would be all the testing personnel employed by the laboratory (i.e., 10).

The surveyor determines the number of testing personnel performing testing for the laboratory. Did the technical consultant fail to assess competency for all personnel performing testing? If not, how many did not have competency assessed? The total number of testing personnel affected by the deficient practice compared to the total number of testing personnel provides a numerical quantification of the failed practice (i.e.,...2 of 10...).

Another example: The laboratory did not ensure that quality control (QC) was acceptable prior to releasing patient test results. Therefore, the universe would be the total number of days that the surveyor reviewed QC. The extent would be determined by the number of days that the QC was not acceptable.

Depending on how many days the QC was unacceptable, the surveyor can show the extent of the noncompliance. For example: "...2 of 30 days..." versus "...15 of 30 days...". It is clear that the extent of the noncompliance for 2 of 30 days is smaller than the extent reflected in 15 of 30 days.

Knowledge of all cases or situations:

When the deficiency is based on knowledge obtained about all applicable cases or situations, both this total and the number of cases/situations that evidenced the deficiency should be recorded within the body of the citation. The following phrases illustrate a variety of acceptable measures:

**...75 patients to whom transfusions were administered in December XXXX, 11 did not meet the criteria for transfusion...**

**...19 of the 20 Mycology culture records for October XXXX lacked the specimen source.**

**...scored 60% for the first and second total cholesterol proficiency testing events of XXXX...**

**...five testing personnel hired during the last month.....**

Note: In each example, the surveyor describes a specific set of information. December patients receiving transfusion; October Mycology culture records; first and second proficiency testing events; and the five newly hired testing personnel.

Sample of applicable situations:

When the deficiency is based on review of a sample of applicable situations, the extent of the sample for which the requirement is noncompliant should be indicated within the statement of deficient practice. When the requirement is not applicable to all of the situations or cases served by a laboratory, the extent would be developed by using only the situations or cases with a negative outcome as a result of the deficient practice divided by the total number of cases or individuals in the sample that could have been impacted by the deficient practice. The extent of deficiency should be reported in numeric or quantified terms *when possible and applicable.* For example:

**...20 of 35 creatinine test records reviewed...**

**...four of five patient charts reviewed lacked throat culture results...**

**...competency assessments for five testing personnel from a sample of nine...**

**...document the appearance of the blood unit at the time of issuance for 10 of 20 patient's records reviewed....**

**...document the evaluation of three of five complaints received....**

Note: The above examples use quantified extents based on sample reviews of records as compared to the knowledge of all cases in the previous examples.

- Sub-sample: There are also situations where the description of the universe develops a sub-sample. The following is an example of a sub-sample.

**Based on surveyor review of digoxin quality control records and interview with the chemistry supervisor, the laboratory failed to document remedial action for two of three days in October XXXX when the normal digoxin control result was outside the acceptable range.**

Note: In this example, the surveyor reviewed 30 days (i.e., October XXXX) of quality control records. Of the 30 days, 3 days showed unacceptable results for the normal control. The surveyor then continued the review and found that on 1 of the 3 days the laboratory had documented corrective action. The correct description of these findings is the number of days when the laboratory did not take corrective action or 2 of 3. We include the number of days reviewed to give the source of our information and to give magnitude to the problem.

Random opportunities for discovery:

When the deficiency is based on random opportunities for discovery of the problem, all of the

applicable cases or situations may not be known. Surveyors may quantify their observation but may not be able to reference a total number of cases or situations that apply. Even though this procedure does not yield as precise a measure as has been discussed above, the report of measure is valid, particularly when serious outcomes of the deficiency have been observed and reported.

For example:

**Based on observation of urine specimens and interview with the testing personnel, the laboratory failed to label two of four urine specimens with a unique patient identifier. (Accession #443, 445)**

**Based on observation of the cytology laboratory and interview with the laboratory director, the laboratory failed to ensure the ventilation system functioned as the surveyor observed a strong odor during a tour of the cytology laboratory...**

**Based on observation of prothrombin time testing and interview with the testing person on 9/29/2016 at 11:20 am, the laboratory failed to ensure the prothrombin time testing was performed using in date thromboplastin reagent...**

Note: Each of the above deficiencies used an observation as the basis for the deficiency. In many situations, this observation will lead a surveyor to investigate further which may lead to additional information in each practice statement. For example, the third example would lead a surveyor to investigate whether patient results were reported on the day of observation and any days since the reagent expired. Additional investigation may also lead to additional deficiencies related to expired reagents in other areas and quality assurance or personnel responsibilities.

For example,...failed to label and preserve four patient specimens ...

Based on observation of specimen processing, the laboratory failed to label and preserve four patient specimens. Note, in this example, there are two separate expressions of extent. First, the lack of labelling of specimens causing a potential hazard of patients receiving incorrect results and secondly, patient specimens not preserved causing a potential for inaccurate results. The potential impact is on all patients' testing.

## Identifiers

**An individual's name or initials must not appear in the Form CMS-2567**. The identity of the patient included in a deficient practice or any persons, including surveyors, who will be referred to in the report must remain confidential. They are included in the report by using identifiers, which can be letters, numbers, or a combination of both. These identifiers are used in the statement of deficient practice and also in the findings when additional information is added in the findings.

In a laboratory, the unique patient identifier (e.g. accession number, patient identifier list) can be used on the Form CMS-2567 to identify specimens, requisitions, test records and reports provided

the unique patient identifier does not identify the person to the reader without the laboratory's assistance. When the deficient practice references personnel files or staff training, their position, discipline, or job title may be used to identify personnel (e.g., TP2, GS), or a separate coding system (developed by the surveyor) should be developed to identify the staff without using their names.

Identification of each case found to be deficient provides the laboratory with information necessary to evaluate the context of the problem. When the evidence refers to individual patients, the statement of deficient laboratory practice should reference by identifiers.

The coding system used to indicate the patient(s) should be decipherable by the laboratory and retrievable by the RO or SA. If an interviewee does not wish the laboratory to know the source of the information provided to you, that information may be recorded on the Form CMS-2567 without an identifier. The Form CMS-2567 would state, "During a confidential interview...." However, the interviewee must be told that there is no guarantee this information will remain confidential as a court may require that confidential information be disclosed. If an interviewee's identity is not disclosed to the laboratory, the Form CMS-2567 must contain sufficient information for the laboratory to correct the deficient practice and to contest the deficiency, if it desires.

**Examples of identifiers include:**

**Sample Specimen identifiers: ...for three of the five urine culture records reviewed (Culture records 2340, 5496, and 6429)**

**Staff identifiers: Based on an interview with the Technical Supervisor (Title or Position) responsible for Bacteriology, the laboratory failed...**

**Staff Identifier Coding System: Based on review of testing personnel competency records and interview with the laboratory director, the laboratory failed to ensure that competency evaluations were completed for seven of ten testing personnel (Testing persons 11, 12, 14, 17, 19, 20, and 21)...**

**Confidential Interview Identifier: Based on a confidential interview and confirmed by personnel record review...**

## Sources of the Evidence

The source of evidence is the manner through which the evidence was obtained. Sources of evidence may include observation, interview, and record review. They contain specific information regarding who, what, when, where, and how of the event(s) or situation(s) that contributed to the deficiency. It is best to utilize supporting evidence obtained from more than one source of evidence.

The sources of evidence are presented in the statement of deficient practice and are described in detail in the findings portion of the Form CMS 2567 report. Each statement of deficient practice identifies the source(s) through which the evidence was obtained, that is, from observation, interview, or reviews of records or other documents. Sources identified in the deficient practice statement must be represented in the findings. The findings describe the specifics regarding the source.

**Based on surveyor review of quality control records and interview with the laboratory director.....**

**Based on surveyor observation of testing and interview with the general supervisor.....**

Do not identify an individual when using information from an interview with a persons name or initials. Use a generic term or the person's title to identify individuals who are interviewed, (e.g., staff member, director or a client.) It is recommended that if the person appears on the Form CMS-209, that their regulatory position should be reflected in the identifier (e.g., technical consultant would be TC#). If more than one of the same staff types is interviewed, the number of staff should be identified.

## Observations

Observation is the process by which a surveyor gathers information, in accordance with the requirements, based on input obtained from the five senses. It is what the surveyor sees, hears, touches, smells or tastes during the survey that evidences a laboratory's deficient practice. It must answer who, what, where, when, and how questions. A surveyor may observe the actions or outcomes identified in a record review actually occur in the daily operation of the laboratory. Actions or outcomes that are described in a record and observed are also recorded as an observation. For surveys that are performed during the course of one day, the time of the observation must be documented on the CMS-2567. For surveys which take more than one day, the date and time of the observation must be documented on the CMS-2567.

Detailed documentation of observations of deficient practice assists the laboratory in identifying when and where the deficient practice occurred. Time includes the number of observations in which the deficient practice was observed and, as appropriate, the duration of each observation. For example, a series of observations that identify the failure to perform testing from 4:00 P.M. to 6:00 P.M. may help the laboratory identify staffing or supervisory concerns, such as, inadequate supervision or insufficient staffing on a particular shift. Avoid using terms such as "throughout the survey," "during observation on the afternoon of the survey," etc. as they are vague and too general. Exhibit 3-3 illustrates an appropriate manner to document the evidence that was obtained through observation.

Exhibit 3-3: **Effective** documentation of **observation** based findings

| TAG | SUMMARY STATEMENT OF DEFICIENCIES |
|---|---|
| D5417 | 493.1252(d) Standard<br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.<br><br>This Standard is not met as evidenced by:<br><br>Based on surveyor observation of the blood gas analyzer and interview with the general supervisor, the laboratory failed to ensure testing personnel did not use expired reagents. The findings include:<br><br>1. Observation on 8/16/XXXX, at 2PM, showed the pH reference solution (lot number 443XY) expired on 6/XXXX and the pH buffer # 2 solution (lot number 8023UH) expired 7/XXXX. )<br>2. Testing personnel #2 was observed using pH reference solution (lot number 443XY) and a pH buffer # 2 solution (lot number 8023UH) on 8/16/XXXX at 2:10 pm.<br>3. Testing personnel #3 was observed using pH reference solution (lot number 443XY) and a pH buffer # 2 solution (lot number 8023UH) on 8/16/XXXX at 2:15 pm.<br>4. The general supervisor confirmed on 8/16/XX at 3PM the expired outdates of the two solutions and confirmed the laboratory had no unexpired solutions in stock.<br>5. The supervisor stated also the laboratory tested and reported 31 patients since 6/XXXX. |

## Interviews

The interview process largely consists of talking to individuals (e.g., laboratory testing personnel, laboratory director, technical consultants and supervisors, and possibly patients, and requesting physicians, other non-CLIA individuals) to collect information in accordance with requirements about the laboratory practices. Information obtained through interviews can provide evidence to support a deficiency. The surveyor must document who was interviewed and should note the specific date and time of the interview or confirmation.

**For example: Surveyors talk with laboratory staff to determine their technical knowledge of the testing process and knowledge of the laboratory policies and procedures. To the greatest extent possible, the surveyor verifies the information obtained from one source by using a second source (e.g. confirming a finding from observation through interview). In the absence of other objective verification, information may also be confirmed/verified through multiple interview sources.**

For surveys that are performed during the course of one day, the time of the interview must be documented on the CMS-2567. For surveys which take more than one day, the date and time of the interview must be documented on the CMS-2567. Date and/or time is important to document and may appear in the DPS or the findings, but it is not necessary to include in both parts of the citation. The individual who was interviewed must also be identified and documented using a coding system on the CMS-2567.

Exhibit 3-4: Effective Documentation of interview based on findings

| TAG | SUMMARY OF STATEMENT OF DEFICIENCIES |
|---|---|
| D5217 | 42 CFR 493.1236(c)(1)<br><br>At lease twice yearly, the laboratory must verify the accuracy of any test or procedure it performs that is not in subpart I.<br><br>This Standard is not met as evidenced by:<br><br>Based on surveyor review of proficiency testing (PT) records, a lack of any verification records, and interview with the laboratory supervisor, the laboratory failed to have a system for verifying the accuracy of the testing for fetal hemoglobin, cold agglutinins, mumps, and measles test results at least twice yearly for the last two years. The findings include:<br>1. The laboratory's proficiency test results for XXXX did not include testing for fetal hemoglobin, cold agglutinin, mumps or measles.<br>2. On 4/2/XX at 3PM, the general supervisor stated the laboratory had not enrolled in PT for fetal hemoglobin, cold agglutination, mumps or measles, nor had the laboratory performed accuracy verification for these analytes. |

## Review of Records and Other Documents

Evidence discovered during review of the laboratory's documentation is discussed with the staff to determine if additional documentation or other information exists. Record or document review is the process through which administrative (e.g., statements of policy and procedure, competency assessments, consultant reports) and clinical (e.g., assessments of test requests, test records, test reports) documents are read and analyzed. Through review of these records, surveyors determine the practices and procedures of the laboratory and the extent to which the laboratory monitors, identifies and makes changes to its policies, procedures, and practices.

When using information obtained through record review, identify the record that contained the information. If the deficiency results from a lack of documentation, make sure the documentation is requested from the staff member who might or who should know where the documentation could be found.

As necessary, obtain copies of the records that show the deficient practice to prove the deficiency and to show after-the-fact changes that may be made by the laboratory.

If the regulation requires a policy on specific issues, ascertain that the policy fails to address the necessary issues before determining it is deficient.

Examples of documenting information from records may include:

**Based on review of gram stain quality control records and interview with the general supervisor, the laboratory failed to provide documentation staff performed a positive and negative control during the week of testing for the gram stain on culture # 21411.**

**Based on review of digoxin quality control records and interview with the testing personnel, the laboratory failed to provide any documentation to show staff took remedial action when the digoxin abnormal control was out of the acceptable range on 2/27/XX, 3/5/XX, 3/18/XX, 3/20/XX, 4/5/XX, and 4/8/XX.**

**Based on review of the new chemistry analyzer records and interview with the testing person, the laboratory failed to maintain any record of the verification of performance specifications during 02/XX for the newly purchased chemistry analyzer prior to reporting patient results.**

Exhibit 3-5 **Effective** documentation of **record review** based findings

| TAG | SUMMARY STATEMENT OF DEFICIENCIES |
|---|---|
| D5429 | 42 CFR 493.1254(a)(1)<br>Maintenance and function checks<br>Unmodified manufacturer's equipment, instruments, or test systems. The laboratory must perform and document the following: (1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This Standard is not met as evidenced by:<br><br>Based on surveyor record review and interview with the laboratory director, the laboratory failed to ensure staff performed the weekly-required preventive maintenance for the chemistry analyzer 6 of 8 weeks of patient testing reviewed. (First, second and third weeks of May and June, XXXX)<br>The findings include:<br>1. The manufacturer's manual instructed the laboratory to perform weekly maintenance for the chemistry analyzer.<br>2. The laboratory records indicated the laboratory performed the required weekly maintenance once each month. The laboratory tested approximately 60 patients each week.<br>3. On 5/3/XX at 9am, the general supervisor confirmed the laboratory failed to perform the weekly maintenance required by the manufacturer. |

Exhibit 3-6 **Effective** documentation of **record reviews**

| TAG | SUMMARY STATEMENT OF DEFICIENCIES |
|---|---|
| D6104 | 42 CFR 493.1407(e)(3)(iii)<br>The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.<br><br>This Standard is not met as evidenced by:<br><br>Based on surveyor review of test records and interview with the laboratory director, the laboratory failed to follow the manufacturer's instruction for calculating INR (International Normalized Ratio) for 1 of 2 lot numbers reviewed. (Lot # 527011) The findings include:<br><br>1. The laboratory provided no documentation for determining the mean normal range of Dade Behring Thromboplastin C (lot number 527011 ) per the manufacturer's instructions for calculating INR values.<br>2. The laboratory director stated at 11am on 6/4/XX the laboratory used the mean of normal prothrombin time quality control results as the Mean Normal value to calculate the INR.<br>3. The laboratory reported approximately 245 patient results using Lot # 527011. |

Exhibit 3-6. This example reports the evidence in a logical approach. The practice statement includes the sources the surveyor used to find the deficiency (review of test records and the interview with the laboratory director.) The DPS states what the lab failed to do in relation to the regulations: follow the manufacturer's instructions for calculating INR and gives an extent by stating this failure was for one lot number of reagent. The practice statement also includes the identity of the lot number causing the failure (identifier). The findings include additional information from the record review and the second finding provides the information learned from the interview. The third finding expands on the extent and provides some potential outcome by stating the number of patients that were potentially affected.

Exhibit 3-7: **Effective** Documentation of Principle #3

| TAG | SUMMARY STATEMENT OF DEFICIENCIES |
|---|---|
| D5621 | 493.1274((c)(1) Standard: Cytology<br><br>The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following:<br>(1) A review of slides from at least 10 percent of the gynecologic cases interpreted by individuals qualified under §§493.1469 or 493.1483, to be negative for epithelial cell abnormalities and other malignant neoplasms (as defined in paragraph (e)(1) of this section).<br>(i) the review must be performed by an individual who meets one of the following qualifications:<br>(A) A technical supervisor qualified under §§493.1449(b)(or (k).<br>(B) A cytology general supervisor qualified under §493.1469.<br>(C) A cytotechnologist qualified under § 493.1469(b)(2).<br>(ii) Cases must be randomly selected from the total caseload and include negative and those from patients or groups of patients that are identified as having a higher than average probability of developing cervical cancer based on available patient information.<br>(iii) The review of those cases selected must be completed before reporting patient results.<br><br>This Standard is not met as evidenced by:<br><br>Based on surveyor review of quality control and quality assessment records and interview with the laboratory director, the laboratory failed to establish and document a program for the review of at least 10% of negative gynecologic slides for years XXXX and XXXX. The findings include:<br><br>1. The laboratory lacked evidence of a quality control program for documenting the 10% review of negative gynecologic slides.<br>2. The director stated, during an interview on January 23, XXXX at 2 PM, the laboratory had not established or implemented a procedure for a 10% review of negative gynecologic slides. |

Each of the three sources may not be necessary to confirm a deficiency. Regardless of the particular avenue(s) through which information about a laboratory's compliance with requirements

is gathered, the statement should include how the information was obtained. When possible, confirm findings from observations and record review through interview of the appropriate staff.

Outcomes

To the extent possible, especially where described or anticipated in the requirement(s), the deficient practice statement indicates outcome(s). The statement of findings describes the specific results and consequences of the laboratory's deficient practice for the individual cases reported. Negative outcomes include inaccurate test results being reported, delayed turnaround times, etc. Although no negative outcome may be evident from the deficient practice, a failure to comply with a requirement is a deficiency and should be cited. Many requirements are not outcome oriented. Examples of deficiency practices with outcomes include:

**A patient's surgical specimen is discarded prior to testing.**
**Abnormal test results are reported on the wrong patient.**
**Testing performed and reported on an unacceptable specimen.**
**Group A red cells are transfused to a Group O patient due to laboratory clerical error.**

Exhibit 3-8 **Effective** documentation of Deficient Practice Statement

| TAG | SUMMARY STATEMENT OF DEFICIENCIES |
|---|---|
| D3043 | 42 CFR 493.1105(a)(7)(iii)<br>The laboratory must retain its records and, as applicable, slide, blocks, tissues, as follows:<br>(i) Slides<br>(A) Retain cytology slide preparation for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception.)<br>(B) Retain histopathology slides for at least 10 years from the date of examination.<br>(ii) Blocks. Retain pathology specimen blocks for at least 2 years from the date of examination.<br>(iii) Tissue. Preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.<br><br>This Standard is not met as evidenced by:<br><br>Based on surveyor review of tissue records and interview with the laboratory director and testing personnel, the laboratory failed to retain surgical tissue specimen #XX-45332 for pathology examination. The findings include: |

| | |
|---|---|
| | 1. The laboratory accessioning records for July XX showed receipt of specimen XX-45332 was logged at 12:25 pm on 7/1/XX.<br><br>2. The laboratory director confirmed during an interview on 08/09/XX at 10am, the laboratory discarded specimen # XX-45332 prior to testing. He also stated laboratory investigation of the incident showed the laboratory received, numbered and logged the specimen prior to testing.<br>3. The testing person stated, during an interview on 08/09/XX at 4:30pm, the laboratory records showed the laboratory received specimen #XX-45332 on 7/1/XX. The testing person also stated that 7/1/XX was the day the laboratory discarded a large number of specimens from the previous month. The testing person also stated the laboratory was not aware of the discarded specimen prior to surgeon's request for a report. |

This example reports the evidence in a way that the laboratory can understand that the requirement was not met and how the survey team determined that the requirement was not met. The statement identifies the extent of the deficient laboratory practice, includes identifiers for the individuals affected by the deficient laboratory practice, identifies the sources from which the information was obtained, and clearly states the outcomes of the deficient laboratory practice.

## Findings

Findings support or illustrate a laboratory's noncompliance with a requirement. Cite only findings attributable to the laboratory. Each statement of deficient practice is followed by the specific findings **(who, what, where, when, how)** that illustrate the laboratory's noncompliance for each case/issue referenced in the deficient practice statement. The facts are presented in a concise and logical sequence. The findings include the outcomes, descriptions of actions/situations, identifiers, and sources. Any evidence that supports a finding and affects the deficiency determination must be incorporated into the deficiency citation. When details for a number of individual examples have been described to illustrate a particular deficient practice, a final entry may describe additional similar findings and identifiers to demonstrate the magnitude of the problem.

For example, from observation, the surveyor discovers a problem related to specimen processing. Through interview, the surveyor learns this is the routine practice in the laboratory. The procedure manual gives different instructions that, if followed, would meet the requirement. In this example, the information from the interview increased the magnitude of the problem identified by observation.

**Note: All sources of evidence must be reflected in the findings.**

## Facts

A fact is an actual occurrence, something known to exist or have happened. The findings are facts that allow the laboratory to compare what it did or failed to do, against what is required. The findings support the deficient practice statement. For example, if glucose and creatinine testing are discussed in the deficient practice statement, the findings are the facts to support the noncompliance for glucose and creatinine testing. Without the presence of facts, the evidence can be construed to mean that an assumption was made, rather than a known conclusion about the laboratory's practice.

Failure to include pertinent facts may prevent the laboratory from discovering what contributed to the deficient practice. There may be many reasons for the failure. For example, the time the testing was performed may indicate problems related to testing personnel on weekends or evening receiving less training on the laboratory's policies and procedures, courier delivery at different times of day, facility temperature issues which differ by time of day.

Identification of the pertinent facts gives the laboratory the means to examine the failure to comply, in light of the specific circumstances or contexts of the failure.

When writing a deficiency citation, try to provide answers to basic questions--Who?, What?, When?, Where?, and How? Based on the nature of the deficiency, it may be impossible or inappropriate to answer each question. However, this approach facilitates inclusion of the pertinent facts.

Deficiency citations identify:

**How** the deficiency was determined and how the evidence relates to the requirement.
**What** laboratory practice was non-compliant?
**Who** were the patients of the failed practice or the laboratory staff involved?
**Where** the deficient practice occurred, e.g., specific locations in the laboratory documents; and
**When** the problem occurred and for how long. Include the number of records or observations and the duration of the records or observations. Include the specific dates or time period for the noncompliance.

The findings also include documentation of verification or request for additional information through interviews with facility staff.

Exhibit 3-9. The statement of the findings in this example illustrates how the relevant facts answer the basic questions of who, what, when, where and how.

Exhibit 3-9: Documentation of Facts

| TAG | SUMMARY STATEMENT OF DEFICIENCIES |
|---|---|
| D5437 | 42 CFR 493.1255(a)(1)<br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures—<br>(1) Following the manufacturer's instruction using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer.<br>(2) Using the criteria verified or established by the laboratory as specified in §493.1253(b)(3)--<br>(i) Using calibration materials appropriate for the test system and , if possible, traceable to a reference method or reference material of known value; and<br>(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and<br>(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.<br><br>This Standard is not met as evidenced by:<br><br>Based on surveyor review of calibration records and interview with the laboratory supervisor (HOW), the laboratory (WHO) failed to follow and document the calibration procedures (WHAT) according to the manufacturer's instructions for the 14 analytes tested on the chemistry analyzer from January through December XXXX. The findings include:<br>1. The laboratory had no records (HOW) showing calibration performance for alkaline phosphatase, bicarbonate, bilirubin (total and direct), calcium, creatinine, cholesterol (total and HDL), glucose, sodium, potassium, chloride, triglycerides, total protein prior to the current calibrations. (WHAT) (WHERE)<br>2. The laboratory supervisor confirmed (HOW) on 10/03/XX at 10 am the laboratory had not performed calibration for 14 analytes. (HOW) (WHEN)<br>3. The manufacturer's instructions required calibration with each new lot number of reagents, when control materials are unacceptable, following specific major maintenance procedures, and at a minimum of every 3 months. (HOW)<br>4. The laboratory reported approximately 1400 patient results each month during XXXX. (WHO) |

Organization of findings:

The findings should be organized in a chronological and logical order. Grouping related findings and facts under the deficient practice statement assists the laboratory in focusing on the development of plans to correct its deficient practices rather than on correction of the findings. The organization of the findings should clearly convey to the reader the sequential order of events that resulted in a citation. For example, situations or cases are presented in a logical sequence to show individual deterioration over time or date.

When setting forth a series of facts and events, start by setting out the relevant background facts (e.g., Maintenance was performed on the chemistry analyzer on 02/XX.) Then, if possible, set out the events in chronological order. This may or may not be in the order of surveyor's discovery.

Exhibit 3-10 Effective documentation of order of findings.

| TAG | SUMMARY STATEMENT OF DEFICIENCIES |
|---|---|
| D5507 | 42 CFR 493.1261(b)(c) Bacteriology<br>(b)For antimicrobial susceptibility tests, the laboratory must check each batch or media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms.<br>(b)(1)Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.<br>(b)(2)The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results.<br>(c) The laboratory must document all control procedures performed, as specified in this section.<br><br>This Standard is not met as evidenced by:<br><br>Based on surveyor review of microbiology patient testing and quality control(QC) records, microbiology procedure manual, and interview with the technical supervisor, the laboratory failed to perform QC each day of anti-microbial susceptibility patient testing on 7 of 7 patient testing days in September XXXX (09/03, 09/13, 09/16, 09/22, 09/24, 09/27, and 09/28). The findings include:<br><br>1 Review of the September XXXX microbiology patient testing and QC records indicated the laboratory performed antimicrobial susceptibility patient testing on 7 days in September and did not perform QC.<br>2 During an interview at approximately 7:50am on 10/26/08, the |

| | |
|---|---|
| | supervisor confirmed the laboratory did not perform antimicrobial susceptibility QC each day of patient testing.<br>3 The policy titled "Microorganisms Recommended for Quality Control of Media, Stains and Reagents," revised 12/29/XX, in the Microbiology Manual, did not require antimicrobial susceptibility QC performance each day of patient testing. |

Note: In this deficiency, the surveyor listed the findings in a logical sequence, firstly the patient records reviewed, the interview with the supervisor to confirm the finding and then the supporting information from the laboratory's procedure manual.

Exhibit 3-11 **Effective** documentation of **order of findings**.

| TAG | SUMMARY STATEMENT OF DEFICIENCIES |
|---|---|
| D5429 | 42 CFR 493.1252(a)(1) Maintenance and Function Checks<br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This Standard is not met as evidenced by:<br><br>Based on surveyor review of preventive maintenance logs and an interview with the laboratory supervisor, the laboratory failed to conduct and document the weekly and monthly maintenance according to the manufacturer's instructions during XXXX for the chemistry analyzer from January – September XXXX) The findings include:<br>1. Review of chemistry preventive maintenance logs for the year XXXX showed the laboratory did not perform or document the weekly chemistry analyzer maintenance for 39 of 39 weeks as required by the manufacturer.<br>Review of the chemistry preventive maintenance logs showed the laboratory did not perform the monthly chemistry analyzer maintenance for 9 of 9 months as required by the manufacturer.<br>2. The supervisor stated on 5/19/XXXX at 11:30 am that the laboratory did not perform the weekly and monthly maintenance from January XXXX through September XXXX. |

This deficiency lists the findings to cover the two areas (failed to conduct and document the weekly and monthly maintenance) where the deficiencies were found in contrast to the first example, where the findings were organized by the sources, records reviews and interview.

A surveyor may also use more than one practice statement at a single D-Tag when they have more than one deficient practice. This approach can be used when a D-Tag has several requirements and the surveyor has found deficient practices related to more than one of the requirements. See Example 3-12. Note in this deficiency that Practice Statement A refers to the requirement for specimen labeling, while Practice Statement B refers to preservation of specimens.

Exhibit 3-12: Effective Documentation of Two Deficient Practice Statement and their Findings

| TAG | SUMMARY STATEMENT OF DOCUMENTATION |
|---|---|
| D5311 | 42 CFR 493.(a)(1)-(8) Specimen submission, handling, and referral<br><br>The laboratory must establish and follow written policies and procedures for each of the following, if applicable:<br>(1) Patient preparation.<br>(2) Specimen collection.<br>(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source.<br>(4) Specimen storage and preservation.<br>(5) Conditions for specimen transportation.<br>(6) Specimen processing.<br>(7) Specimen acceptability and rejection.<br>(8) Specimen referral.<br><br>This Standard is not met as evidenced by:<br><br>A. Based on surveyor observation of specimen processing, record review, and interview with the specimen processor and general supervisor, the laboratory failed to label 5 of 5 Chemistry specimens observed with the patient's full name, a unique identifier, the date and time of draw and the phlebotomist's initials per the laboratory policy. (# 335, 336, 337, 338, 339)<br>1. During observation on 6/3/XX at 8 AM, staff labeled specimens #335 and #336 from two different individuals with the same last name.<br>2. The written procedure for specimen labeling stated staff are to label specimens with the patient's full name, accession number, date and time of testing and the phlebotomist's initials.<br>3. When interviewed, the specimen processor stated she was unaware of the written policy and labeled specimens as trained.<br>4. The general supervisor confirmed during an interview on 6/3/XX at 8:30am the laboratory did not follow its policy for labeling specimens.<br><br>B. Based on surveyor observation of specimen processing, record review and interview with the general supervisor, the laboratory failed to collect and process specimen # 987 using the reference laboratory's instructions for |

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|---|---|
| | specimen preservation for renin activity testing. The findings include:<br>1. During an observation on 6/3/XX at 11 am, the laboratory staff centrifuged and froze specimen # 987 2 hours (collected 8:30 am, centrifugation began 10:45 am) after collection at room temperature.<br>2. The manual for the reference laboratory stated specimens for renin activity testing required the laboratory to draw blood into a pre-chilled EDTA tube and maintain the specimen in an ice bath until centrifugation. After centrifugation, separate plasma and freeze immediately.<br>3. When interviewed on XX at 11:30 am, the individual processing specimens at 11 am indicated she was aware specimens for renin activity must be frozen but was not aware of the specific collection and processing requirements.<br>4. The general supervisor confirmed the laboratory did not follow the reference laboratory's procedures for specimen processing for rennin activity testing. |

This organizational approach can also be used when the surveyor finds more than one deficient practice related to a single regulation. See 3-12. If there is more than one noncompliance issue under the same D-Tag, it is important that they are clearly delineated. Consider the evidence and how to organize the evidence so that the deficient practices are clearly written. In some cases, each deficient practice will have a separate DPS and findings (if applicable).

Exhibit 3-13 **Effective** documentation of **organizing with numerous practice statements**.

| TAG | SUMMARY STATEMENT OF DEFICIENCIES |
|---|---|
| D5429 | 42 CFR 493.1254(a)(1)<br>For unmodified manufacturer's equipment, instruments, or test systems. The laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer<br><br>This Standard is not met as evidenced by:<br><br>A. Based on surveyor review of preventive maintenance records, manufacturer user manual and interview with the laboratory supervisor, the laboratory failed to perform and document the weekly Dimension chemistry analyzer preventive maintenance according to the manufacturer's instructions during 12 of 12 weeks of January, February and March XXXX. The findings include:<br>1. The Dimension User's Manual, Rev X, requires performance of weekly preventative maintenance. |

| | |
|---|---|
| | 2. The laboratory preventive maintenance records for the Dimension Chemistry analyzer showed the laboratory did not document the performance of preventive maintenance for the 12 weeks during January, February, and March of XXXX.<br>3. The laboratory supervisor stated on 9/9/xx at 3pm the laboratory decided it was not necessary as the service tech performed Imaintenance during quarterly visits.<br><br>B. Based on surveyor review of preventive maintenance records, review of manufacturer instruction manual and interview with the laboratory supervisor, the laboratory failed to perform the monthly cell counter preventive maintenance on 3 of 5 months reviewed as specified by the manufacturer. (May July and August XXXX)<br><br>1. The cell counter user manual, Version X, required monthly maintenance be performed.<br><br>2. Review of cell counter preventive maintenance records showed the laboratory staff failed to perform and document the monthly cell-counter maintenance.<br><br>3. During an interview on 9/9/XXXX at 4pm, the supervisor stated the laboratory staff did not perform the required preventive maintenance. |

## Principle #4: Relevance of Onsite Correction of Findings

If during the survey a deficiency is found and the laboratory corrects the situation during the survey, a determination of "NOT MET" must be documented on the Form CMS-2567. The laboratory may indicate its correction in the right-hand column of the Form CMS-2567. If the laboratory initiates corrective actions that abate a finding of immediate jeopardy during the survey, follow the guidance described in the SOM. The laboratory may indicate its correction in the right-hand column of the Form CMS-2567 when received.

If a laboratory demonstrates practices that cause it to be out of compliance, there may be a system failure. The findings used as part of the evidence illustrate the result of that failure, not the cause. Mere correction of the findings reported to the laboratory prior to the exit conference would not necessarily assure that the cause of the finding had been addressed. The laboratory, not the survey team, must ascertain the cause and correct the systems failure that caused the deficient laboratory practice.

Exhibit 4-1 demonstrates how to document a deficient practice even though the laboratory may have addressed the effects of the practice during the survey. As stated above, mere correction of the findings does not assure that necessary corrections at the system level have taken place. The laboratory needs to address whether it had a system in place to ensure expired reagents are not used for patient testing and what failure in the system must be corrected to ensure the deficient practice does not recur.

Exhibit 4-1: **Effective** Documentation for Principle #4

| TAG | SUMMARY STATEMENT OF DEFICIENCIES |
|---|---|
| D5417 | 493.1252(d) Standard<br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.<br><br>This Standard is not met as evidenced by;<br><br>Based on record review and staff interview, the laboratory failed to ensure testing personnel did not use outdated reagents to perform cholesterol testing for 5 weeks and Immunohematology A, B, and O cells for 1 week. The laboratory tested and reported 53 patient cholesterol patient results and 15 ABO group patient results during these time frames.<br><br>Findings include:<br><br>1. The laboratory used cholesterol reagent which outdated on 5/XX for patient testing until July XXXX.<br>2. The laboratory used A, B, and O cells that expired on September 23, XXXX for testing through September 30, XXXX. The laboratory started a new lot number of unexpired reagents after the surveyor inquired about the expired reagent.<br>3. Staff confirmed during an interview on 6/4/XX at 8am the laboratory used both of the expired reagents. |

## Correction of Immediate Jeopardy during Survey

Exhibit 4-2 documents noncompliance with a participation requirement that resulted in a situation of immediate jeopardy. The Form CMS-2567 includes the laboratory's actions to remove the immediate jeopardy while the survey team was onsite; however, as stated above, mere correction of the findings does not assure that necessary corrections at the systems level have taken place.

Exhibit 4-2: **Effective** Documentation for Correction of **IJ** during Survey- Principle #4

| TAG | SUMMARY STATEMENT OF DEFICIENCIES |
|---|---|
| D5813 | 42 CFR 493.1291(g)<br>The laboratory must immediately alert the individual or laboratory requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminent life-threatening condition or panic or alert values.<br><br>The Standard is not met as evidenced by:<br><br>Based on surveyor review of policies and procedures and interview with the testing personnel and the laboratory director, the laboratory failed to follow its policy for reporting life threatening test results as staff failed to notify the requesting physician for 3 of 3 life-threatening Potassium results reviewed. (#338, 432, 701)<br><br>The findings include:<br><br>1. Three randomly selected potassium reports with results above 6.5 Milliequivalents per liter (Meq/l) lacked documentation of alerting the requesting physician.<br>#338 – 8.7 Meq/l on 9/3/XX<br>#432 – 7.3 Meq/l on 9/7/XX<br>#701 - 7.0 Meq/l on 9/30/XX<br>2. The general supervisor and director confirmed the laboratory staff did not call the physician with these results.<br>3. Upon further investigation, the supervisor found the flagging mechanism for life-threatening values was off on the analyzer. The laboratory relied on this mechanism to identify life threatening results.<br>4. The laboratory policy stated potassium results over 6.5 Meq/l were life threatening, and the lab must notify the requesting physician. |

## Principle #5: Interpretive Guidelines

The deficiency citation demonstrates how the laboratory fails to comply with the regulatory requirements, not how it fails to comply with the guidelines for interpreting those requirements. Appendix C, of the SOM, contains "Interpretive Guidelines" or "Guidance to Surveyors." These Guidelines were designed to assist surveyors develop a better understanding of the requirements, apply these requirements in a consistent manner across entities, and suggest pathways for inquiry.

Although surveyors use the information contained in the Interpretive Guidelines, they should be cautious in their use. Guidelines do not replace or supersede the law or regulation. Guidelines may not be used as the basis for a citation. However, they do contain authoritative interpretations and clarifications of statutory and regulatory requirements. Interpretive guidelines can include professionally recognized standards and assist surveyors in making determinations about a laboratory's compliance with requirements. When a laboratory is found to violate a requirement because of its connection to a professionally recognized standard, the surveyor must indicate such on the Form CMS-2567.

Surveyors should carefully consider how the laboratory practices relate to the illustrations within the Interpretive Guidelines and then compare the laboratory's practice to the specific language and requirement of the regulation before determining that a deficiency exists.

Exhibit 5-1: Interpretive Guidelines

| REGULATION | GUIDANCE TO SURVEYORS |
|---|---|
| 42 CFR 493.1256(d)(3)(iii)<br>Control Procedures<br>Unless CMS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must at least once each day patient specimens are assayed or examined perform the following for test procedures producing graded or titered results, include a negative control material and a control material with graded or titered reactivity, respectively. | EXCEPTIONS:<br>A negative control is not required for anti-streptolysin O titer, anti-hyaluronidase titer tests. A positive control is not required for cold agglutination tests. For radial-immuno-diffusion, one control or standard is required on each plate. |

Exhibit 5-2 illustrates how material in Interpretive Guidelines can be used to support the citation. The critical factor is whether or not the evidence relates directly to the language and requirement within the regulation.

**Exhibit 5-2: Effective Documentation for Principle #5**

| TAG | SUMMARY STATEMENT OF DEFICIENCIES |
|---|---|
| D5457 | 42 CFR 493.1256(d)(4)<br><br>Unless CMS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must perform control procedures as defined in this section. For thin layer chromatography, Spot each plate or card, as applicable, with a calibrator containing all known substances or drug groups, as appropriate, which are identified by thin layer chromatography and reported by the laboratory; and include at least one control material on each plate or card, as applicable, which must be processed through each step of patient testing, including extraction processes.<br><br>This Standard is not met as evidenced by:<br><br>Based on surveyor review of quality control records and interview with the technical consultant, the laboratory failed to include a control for each drug group reported for 9 of 10 qualitative urine drug screens performed. The laboratory performed drug screen testing on accession numbers xx-344-xx-349 and xx-350-xx-351. (A negative control is not required.)<br><br>The findings include:<br><br>1. Qualitative urine drug screen records showed the laboratory did not perform a control with each drug screen patient card that included all drugs tested for the 9 of 10 patient records reviewed.<br>2. The technical consultant confirmed during an interview 3/6/XX at 9am the laboratory staff did not perform a control with each patient test card, but ran a control at the start of each month. |

The above example shows a deficiency where there is an exception in the guidelines not requiring a negative control. To assist the reader in understanding the exception, a note has been included stating that a negative is not required.

## Principle #6: Citation of State or Local Code Violations

When the Federal regulation requires compliance with State or local laws, the laboratory's failure to comply with State or local laws or regulations is documented on the CMS-2567. When the authority having jurisdiction for that State or local law has made a decision of noncompliance and has effectuated an adverse action which has been sustained through the hearing process (such as removal of the license to operate), the Form CMS-2567 should note that the laboratory no longer has a license.

Federal certification requirements are uniform throughout the United States. However, States and localities may have additional requirements that the laboratory must meet in order to continue to operate within those jurisdictions. Some licensing requirements may be more stringent or prescriptive than Federal requirements. Licensure surveys are conducted to determine a laboratory's compliance with Specific State or local laws and regulations.

In the event of a difference in the stringency of a Federal certification requirement and a corresponding State or local (e.g., licensing) requirement, the laboratory is to comply with the more stringent of the two. However, when enforcement of the more stringent requirement comes from an authority other than the Federal requirement, the evidence may be recorded on the Form CMS-2567 only in the manner prescribed by CMS.

Failure of the laboratory to meet State or local requirements is recorded on the Form CMS-2567 at a Federal D-Tag for one of two reasons:

1) The language of the Federal regulation explicitly requires compliance with State or local laws and codes. Deficiency citations made under these requirements should include a reference to the particular State or local code with which the laboratory is non-compliant. This insures that there is legal authority to describe any conditions or practices described as deficient. Surveyors should always review their findings relative to the specific Federal requirement to determine if and when a laboratory's failure to achieve compliance with a licensure requirement is sufficient evidence to cite noncompliance with a Federal certification requirement.

Exhibit 6-1 is consistent with Principle #6. The laboratory's practice of using non-licensed personnel to perform patient testing was deficient specifically relative to the requirement.

Exhibit 6-1: **Effective** Documentation for Principle #6

| TAG | SUMMARY STATEMENT OF DEFICIENCIES |
|---|---|
| D6170 | 42 CFR 493.1489(a)<br>Each individual performing high complexity testing must possess a current license issued by the State, in which the laboratory is located, if such licensing is required.<br><br>This Standard was not met as evidenced by:<br><br>Based on surveyor review of personnel records and interview with the laboratory director, the laboratory failed to ensure the sole individual performing testing between 7/1/XX and 9/30/XX held a current State license to perform laboratory testing. Section 76543 of the Code of Professional Health Practices (State Requirement) requires performance of laboratory testing by a licensed clinical laboratory scientist or medical technologists. |

2) The authority having jurisdiction has made a determination of noncompliance with State or local law, has taken and sustained an adverse action (See Exhibit 6-2.).

An adverse action is any procedure taken by a State Agency that goes beyond the approval of a plan of correction, such as fines, loss of license, etc. The authority having jurisdiction is the person or persons who have the authority to make a final determination of noncompliance and are responsible for signing the correspondence notifying the facility of the adverse action. A final determination means the determination has not been appealed or is no longer being appealed by the laboratory.

Exhibit 6-2: **Effective** Documentation for Principle #6

| TAG | SUMMARY STATEMENT OF DEFICIENCIES |
|---|---|
| D3009 | 42CFR493.1101(c)<br>The laboratory must be in compliance with Federal, State, and local laboratory requirements.<br><br>This Standard is not met as evidenced by:<br><br>Based on evidence in the attached notice of determination of noncompliance, the laboratory did not meet (state or local) Law # XXX. (Authority having jurisdiction) took adverse action against the laboratory. See attached. |

## Principle #7: Cross References

The cross-referencing of requirements is an acceptable form of documentation on the Form CMS-2567 when it is applicable and provides additional strength to the linked citations. Descriptive evidence (facts and findings) from one citation may be linked into the evidence for a citation at another requirement. The evidence being linked into that requirement must support the determination of noncompliance with that requirement. Each citation must contain all components described in this document independent of the additional information being linked into that citation. Cross-referencing is most effective when the linked citations have a direct cause and effect relationship to the deficient practices described in both citations. In all instances, each citation must contain sufficient evidence to demonstrate noncompliance for the referenced regulation.

It is not necessary to repeat lists of patient information, specimen accession numbers, etc. in each D-Tag. The list can simply be cross referenced.

Additional guidance for cross-referencing Condition level citations is provided in Principle #8.

Exhibit 7-1: **Effective** Documentation for Principle #7

| TAG | SUMMARY STATEMENT OF DEFICIENCIES |
|---|---|
| D6020 | 42 CFR 493.1407(e)(5)<br>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided.<br><br>This Standard is not met as evidenced by:<br><br>Based on staff interview and review of quality control records, the laboratory director failed to ensure the laboratory maintained the quality control (QC) program when testing personnel changed in June XXXX. The findings include:<br>1. The laboratory hired the Testing Person 2 (TP2) on June 2, XXXX and trained the person to perform Complete Blood Counts (CBC). Refer to D6029.<br>2. The laboratory had no documentation that TP2 had been trained on the laboratory's QC procedure, including what should be done when controls failed to be acceptable. Refer to D6072<br>3. QC records showed that 15 of 30 white blood cell counts and 8 of 30 platelet results were unacceptable in August XXXX. 235 patients were reported in August XXXX.<br>4. The director stated during an interview on 8/7/XX at 1pm the previous testing person trained the current person, and the director did not participate in the training or test monitoring. |

Exhibit 7-2: **Effective** Documentation for Principle #7

| TAG | SUMMARY STATEMENT OF DEFICIENCIES |
|---|---|
| D5891 | 42 CFR 493.1299(a)<br>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic system specified in §493.1291<br><br>This Standard is not met as evidenced by:<br><br>Based on surveyor review of test reports and interview with the technical consultant, the laboratory failed to evaluate and correct the test reporting problems identified during the March and April XXXX assessment. Refer to D5821 |

## Principle #8: Condition Deficiencies

The evidence for the citation of noncompliance with a Condition explains how the extent or severity of deficient practices justifies a conclusion of noncompliance at the Condition level. The Condition citation includes a statement(s) of deficient practice(s) and findings to support the determination of noncompliance with a Condition level requirement. The findings may be incorporated either by cross-references to those requirements which must be corrected to find the Condition is met or by narrative description of the individual findings. The Condition citation includes ONLY those requirements that must be corrected to achieve compliance with the Condition. The determination that a laboratory is not in compliance with an applicable Condition is one of the most serious decisions the RO or SA can make. The decision as to whether there is compliance with a particular Condition depends upon the manner and degree to which the laboratory satisfies the various requirements and standards within each Condition. If a Condition is determined to be deficient, the Form CMS-2567 should identify the specific practices that must be corrected before the laboratory can be in compliance. .

Some Conditions may stand alone at a single survey D-Tag without accompanying standards or other requirements. Other Conditions may have multiple components. Based on the evaluation of the evidence, a laboratory can be cited at a Condition level even if it violates only one component of multi-component regulations. Only standards found within the condition must be used in the condition statement; however, within those standard citations listed in the condition, standards outside the condition may be cross referenced

For example, if citing D6000 (moderate complexity laboratory director), the text states to meet this condition D6003 through D6032 must be in compliance. Therefore only, D6003 through D6032 can be reasons D6000 is out of compliance and only these tags can be included in the condition statement. The evidence causing one or more of these tags (D6003-D6032) to be out of compliance may be cross-referenced to other sections of the regulations. For example, the surveyor cites D6015 - PT enrollment and within the body of the deficiency cross refers to D2000 - PT Enrollment. The additional information at D2000 is linked supporting D6015 and D2000 does not appear in the condition statement under D6000.

There may be deficiencies cited at the standard D-Tag not essential for a determination of noncompliance with the Condition. Most likely it is because the nature of these practices, individually or collectively, does not justify a conclusion of noncompliance and warrant adverse action. Such standards are not referenced at the Condition citation. They are included at the appropriate tag number and corresponding CFR reference in the Form CMS-2567.

For example, if a laboratory was cited for the following standard-level citations: D6004 (competent personnel), D6010 (physical plant), and D6014 (accurate and reliable test results), D6015 (PT enrollment). The surveyor may determine that only D6004, D6014, and D6015 should be included in the D6000 (condition, moderate complexity LD) as they decide prompt correction is

required. The Form CMS-2567 would include these 3 D-Tags in the D6000 citation, but D6010 would not appear in D6000 as the surveyor determined that they did not justify noncompliance at the condition-level.

Exhibit 8-1: **Effective** Documentation for Principle #8

| TAG | SUMMARY STATEMENT OF DEFICIENCIES |
|---|---|
| D5002 | 493.1201 Condition<br>Bacteriology<br>If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, §493.1261, and §§493.1281 through 1299.<br><br>This Condition is not met as evidenced by;<br><br>Based on surveyor review of Bacteriology records and staff interviews, the laboratory failed to ensure the information on the culture test requisitions included the specimen source (refer to D5305); failed to check each batch of media for its ability to support growth (refer to D5477); failed to perform control procedures for Gram stain testing (refer to D5503); and failed to ensure zone sizes for susceptibility testing were within the acceptable ranges prior to reporting patient testing (refer to D5507). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results. |

Exhibit 8-2: **Effective** Documentation for Principle #8

| TAG | SUMMARY STATEMENT OF DEFICIENCIES |
|---|---|
| D5300 | 493.1240 Condition Preanalytic Systems<br>Each laboratory that performs nonwaived testing must meet the applicable preanlytic system(s) requirements in §§493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in §493.1249 for each specialty and subspecialty of testing performed.<br><br>This Condition is not met as evidenced by;<br><br>Based on surveyor record review and staff interviews, the laboratory failed to ensure test requisitions solicited the specimen source for Bacteriology cultures, the date and time of collection of gentamicin levels, and the |

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|---|---|
| | patient's last menstrual period for Pap smears (D5305); failed to ensure the labeling of specimens with a unique patient identifier (D5311); and failed to monitor the corrective actions taken for test requisition and specimen labeling issues (D5393). |

Exhibit 8-3: **Effective** Documentation for Principle #8

| TAG | SUMMARY STATEMENT OF DEFICIENCIES |
|---|---|
| D2000 | 493.801 Condition – Proficiency Testing<br>Enrollment and testing of samples.<br>Each laboratory must enroll in proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patient specimens.<br><br>This Condition is not met as evidenced by;<br><br>Based on surveyor review of Virology test records, proficiency testing records and staff interviews, the laboratory failed to enroll in an approved proficiency testing program for Virology. The laboratory director and Virology technical supervisor confirmed the laboratory started virology culture testing during May XXXX and did not enrolled in an approved proficiency testing program for XXXX. |

## Proofreading

It is very important that once the deficiencies are written that the surveyor proofread the citations. For example, proofreading should include such items as:

- Grammar
- Spelling
- Inclusion of all sources from the Deficient Practice Statement (DPS) in the findings
- Written in active voice,
- Two (2) sources of evidence (if possible)
- Clear and concise
- DPS is related to regulatory citation
- Findings support the DPS
- Verifying that all cross referenced D-Tags are actually cited on the 2567
- All observation(s)/interview(s) have date and time

Tip: have another person read for clarity and understandability

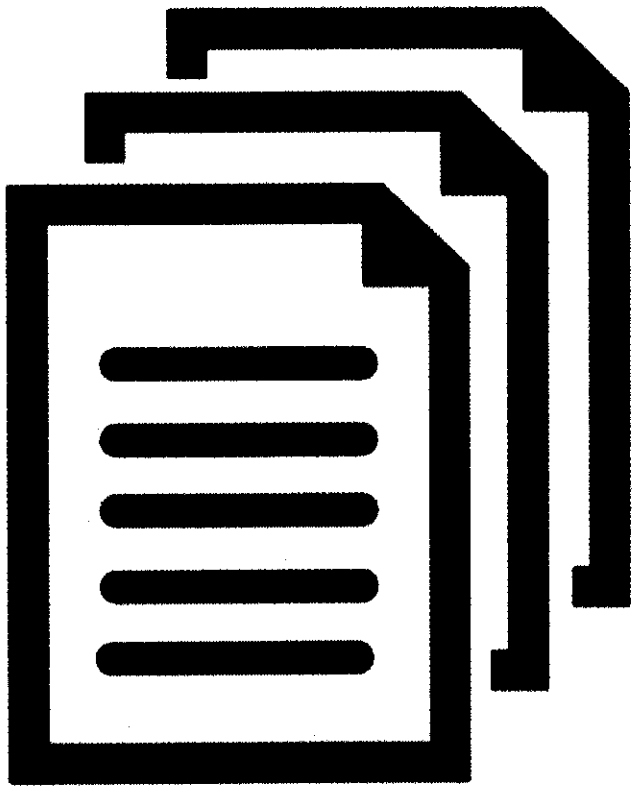
## Conclusion:

The structures, processes and outcomes required by the regulations are necessary for the laboratory to provide quality care, prevent negative outcomes, and facilitate positive outcomes. Failure of the laboratory to meet the CLIA requirements constitutes evidence of noncompliance regardless of the presence of outcomes.

The purpose of these Principles of Documentation is to provide organization and consistency to the construction of a citation. Correctly documenting the Statement of Deficiencies (Form CMS-2567) is the key to the success of the survey and certification process. Keep in mind that one of the roles of the surveyor is to ensure that quality health care is provided. It is the surveyor's knowledge of the regulations and how to interpret and apply these regulations in a consistent manner during the survey that will produce a clear description of the laboratory's deficient practice. When the laboratory corrects the deficient practices, the quality of laboratory results can be assured.

Notes:

# Principles of Documentation Appendices



# Guide to Writing a Deficiency Tag (D-Tag)

Definitions (2008 POD manual)

*Deficient Practice Statement:* A summary statement at the beginning of the evidence that sets out why the laboratory was not in compliance with a regulation.

*Finding:* A generic term used to describe each discrete item of information observed or discovered during the survey about practices of a laboratory relative to the specific requirement being cited as not being met.

Outline for writing a deficiency citation (D-tag)

A. Deficient Practice Statement

1. Begin with your sources (interview, observations, record review).

   *Based on* _____, _____, *and* _____...

   a. Whenever possible, specify what type of records, observations, or whom the interview was with (by title).
   b. Each source in listed in the DPS must be supported in the findings.

   *Example: Based on interview with the technical consultant and proficiency testing (PT) record review, the laboratory director failed to ensure that the laboratory was enrolled in proficiency testing for total iron from 2013 to the date of the survey.*

2. Add what the laboratory did/did not do to cause the noncompliance.

   a. Be specific about actions lab did/did not do, but don't just restate the regulation.

      *Example: Based on interview with the technical consultant and proficiency testing (PT) record review, the laboratory director failed to ensure that the laboratory was enrolled in proficiency testing for total iron from 2013 to the date of the survey.*

3. Describe extent.

   *Example: The laboratory failed to perform weekly maintenance on the Coulter AcT*2 for 6 of 20 weeks from March 2014 through September 2014.*

4. Define acronyms & identifiers.

   *Example: The laboratory failed to perform Quality Control (QC) each day of testing on the Coulter AcT*2 ...*

   *Example: Based on interview with the technical consultant (TC)...*

*Example: ...three of four patient final reports (014563, 145093, 145322)...*

5. Include outcomes, when relevant.

*Examples:*

- Testing performed and reported on an unacceptable specimen
- Results are reported on the wrong patient
- Group A pRBC transfused to Group O patient due to clerical error
- Surgical specimen discarded prior to testing

*Example:* Based on review of specimen logs records, laboratory specimen acceptability procedures and interview with the laboratory director, the laboratory performed and reported potassium (K) results on 2 of 4 hemolyzed specimens (Specimen numbers: 07111410, 07111418)

The findings include:

1. The laboratory procedure titled "Specimen Acceptability" (CH2.1, Section 1.3) stated "...hemolyzed specimens for potassium shall be rejected due to falsely elevated results...a new specimen must be drawn..."
2. Specimen logs from July 11, 2014 showed a total of 20 specimens were received requesting potassium.
3. The specimen log showed 4 of 20 specimens had a note that they were "hemolyzed".
4. 2 of 4 hemolyzed specimens (specimen numbers 07111410, 07111418) were run and results were reported without redrawing the specimens or noting hemolysis.
5. The laboratory's normal range for K is 3.5 to 5.2 mmol/L.
6. 07111410 had a K reported as 6.2 mmol/L and 07111418 had a K reported as 5.7 mmol/L.
7. The laboratory director verified the above findings on 9/2/14 at 1:25 pm.

B. Findings (who, what, where, when, how)

1. Use very specific detail(s).

D5783
Based on review of Chemistry quality control records and procedure manual and interview with the general supervisor (HOW), the laboratory( WHO) failed to take corrective actions (WHAT) when the normal control was outside the acceptable range on five of 30 days of Potassium testing in April 2016 (WHEN). (4/2/2016, 4/7/2016, 4/11/2016, 4/18/2016, and 4/25/2016) The findings include:
1. The Chemistry procedure manual (HOW)(WHERE) stated all control values outside the acceptable range would be repeated. If the second testing of the controls were not within the acceptable range, the testing person would follow the investigative protocol and contact the supervisor.(WHAT)
2. Quality Control records (HOW)(WHERE) showed the following Potassium normal control values with no indication of any repeat testing or corrective action. (WHAT) The acceptable range for the normal control material was 3.5-3.7 mEq/L.
a. 4/2/2016 – 3.3 mEq/L (WHEN)
b. 4/7/2016 – 3.3 mEq/L (WHEN)
c. 4/11/2016 – 3.4 mEq/L (WHEN)
d. 4/18/2016- 3.4 mEq/L (WHEN)

3. The general supervisor(HOW)(WHO) reviewed the April (WHEN) Potassium control records and confirmed the out of range control values and the records did not indicate any repeat testing or corrective actions taken. (WHAT)
4. The laboratory reported 435 patient Potassium values in April 2016. (WHAT)(WHEN)

2. Use extent/universe, when possible.

   *Example:* "...15 of 36 complete blood count (CBC) quality control (QC) values..."

3. *May* contain a "confirmed..." or "verified..." statement.

   *Example #1:* The laboratory director verified the above findings on 9/2/14 at 1:25 pm.

   *Example #2:* The technical consultant confirmed on 9/2/2014 at 2:15 pm that the laboratory did not perform calibration procedures as required for the 2 analytes.

Once the D-Tag is written can you answer the questions below?

a. What did the laboratory fail to do? What regulation or part of a regulation did they not meet?
b. What are your sources of evidence? Are there at least 2?
c. What is the extent of the problem?
d. Are identifiers included?
e. Did you define all acronyms the first time they are used?
f. Did you confirm the evidence? If so, did you include the confirmation in your findings?
g. Do your findings support the DPS?
h. Did the findings include each source listed in the DPS?
i. Did you give any advice or directions to the lab?

Appendix B

# Checklist, Components Documented in a Deficiency Citation

| D-Tags Reviewed | |
|---|---|

| General | | | | |
|---|---|---|---|---|
| | **Yes (Y)** | **No (N)** | **N/A** | **Comments, include D-Tag(s) not meeting POD** |
| Statement that requirement "Not Met" | | | | |
| Applicable to the requirement cited | | | | |
| Free of extraneous remarks and advice | | | | |
| Written in plain language | | | | |
| **Deficient Practice Statement (DPS)** | | | | |
| Description of violation of regulation clearly stated (specific action(s), error(s), lack of action) | | | | |
| Extent of deficient practice | | | | |
| Source(s) of evidence | | | | |
| • Observations | | | | |
| • Interview | | | | |
| • Record review | | | | |
| Identifier(s) | | | | |
| State/Local code reference, if applicable | | | | |
| **Findings/Facts, if applicable** | | | | |
| Support DPS | | | | |
| Concise, chronological, and logical order of facts | | | | |
| Who | | | | |
| What | | | | |
| When | | | | |
| Where | | | | |
| How | | | | |
| Outcome | | | | |
| Observations: date, time, location | | | | |
| Interview: date, time, identifier | | | | |
| Record review: date(s), record type | | | | |
| Extent | | | | |
| Coding system used | | | | |
| Unique identifier system used | | | | |

Appendix C

# Principles of Documentation (POD) Cheat Sheet

| Principle | Key Points |
|---|---|
| 1, Lab Compliance and Noncompliance | ♦ Compliance → D0000<br>♦ Additional uses of D0000 as outlined in POD guidance document<br>♦ Noncompliance → includes specific citations |
| 2, Using Plain Language | ♦ Written clearly, objectively in active voice and in layman's terms<br>♦ Avoid words such as: seems, appears, inadequate, unnecessary<br>♦ No extraneous information or advice, comments, directions, slang<br>♦ Should contain only evidence to support noncompliance<br>♦ Define acronyms, abbreviations 1st time used<br>♦ Ensure accuracy of cited/quoted material |
| 3, Composition of a Deficiency Statement | ♦ Deficient Practice Statement:<br>◦ Clearly states what lab did/did not do to cause noncompliance<br>◦ Do not merely repeat the regulation<br>◦ Includes: specific action(s) or lack of action(s), outcome(s) when possible, extent, sources (2 if possible) and identifiers<br>◦ Name of individuals/patients should never be used<br>♦ Findings Statement:<br>◦ Supports/illustrates lab's noncompliance<br>◦ Who, what, where, when, how<br>◦ Citations specific to lab, in concise and chronological or logical order<br>◦ Date and time for observations |
| 4, Relevance of Onsite Correction Findings | ♦ Must be documented on CMS-2567 as "NOT MET" |
| 5, Interpretive Guidelines (IG) | ♦ May not be used as a basis for citation(s)<br>♦ IGs do not replace/supercede statute or regs |
| 6, Citation of State/Local Code Violation | ♦ Only used for 2 reasons, see POD guidance document |
| 7, Cross References | ♦ Applicable and provides additional strength to linked citation(s)<br>♦ Must support noncompliance with requirement |
| 8, Condition Deficiencies | ♦ Includes only requirements to be corrected to achieve condition-level compliance<br>♦ May stand alone as single cite or include accompanying standards<br>♦ Condition statement is written as a practice statement. Findings are listed or cress-referenced<br>♦ Standards supporting the out of compliance Condition must be requirements for the cited Condition |

# ACTIVE / PASSIVE VOICE

Active voice describes a sentence where the subject performs the action by the verb. Passive voice, the subject does not act, but is the object or receiver of the action. Active voice should be used in both the deficient practice statement (DPS) and the findings.

## Active voice

In most English sentences with an action verb, the subject performs the action expressed by the verb that is the subject is *doing* the verb's action.

Because the subject does or "acts upon" the verb in such sentences, the sentences are said to be in the **active voice.**

Please note: *Active voice is not the same as present tense*. Active voice speaks to the relationship between a subject and a verb (i.e., the subject of the sentence is the actor or is acted upon) whereas tense indicates the relationship between the verb and time (e.g., current action vs past action). As soon as the surveyor exits the survey, the laboratory's actions are in the past tense.

## Passive voice

One can change the normal word order of many active sentences so that the subject is no longer *active*, but is, instead, being *acted upon* by the verb, that is the *subject* is acted upon.

Because the subject is being "acted upon" (or is *passive*), such sentences are said to be in the **passive voice**.

Passive voice sentences can add words which may make the reader work harder to understand the intended meaning.

**Table 1: Examples: Active Voice vs Passive Voice**

| Active Voice | | Passive Voice |
|---|---|---|
| Based on…. the technical supervisor (subject) failed to perform (verb) competency assessment… | vs | Based…It was stated (verb) by the technical supervisor (subject) that competency assessment… |
| Based…The technical supervisor failed to perform competency assessment for 2 of 3 testing personnel annually in 2015 and 2016. | vs | Based…It was stated by the technical supervisor that competency assessment was not performed annually on 2 of 3 testing personnel for 2015 and 2016 |
| Based…the laboratory (subject) failed to retain (verb) documentation of performance verification for… | vs | Based…Verification of performance specification documentation (subject) was not retained (verb) by the laboratory… |
| Based…The laboratory failed to retain documentation of performance verification for the Siemens Advia XPT. | vs | Based…Verification of performance specification documentation for the Siemens Advia XPT was not retained by the laboratory. |

Note: A sentence in active voice flows more smoothly and is easier to understand than the same sentence in passive voice.

**Table 2: Example of Deficiency Statement (DPS + Findings) Using Active Voice**

Based on review of the performance specification verification documentation and interview with the general supervisor and technical supervisor, the laboratory failed to maintain any documentation that the laboratory had participated in conducting the verification of the performance specifications on the Advia XPT. Findings include:

1. The general supervisor and technical supervisor stated on 6/2/16 at 11:50 am that the manufacturer performed all of the performance specification verification activities on the Advia XPT.
2. Review of performance specification verification documentation revealed that the manufacturer had performed the studies on 5/31/16.
3. They further stated that the laboratory staff were available to prepare quality control material and gathering patient samples for the manufacturer representative to perform the verification.
4. The Director of Assays confirmed on 6/2/16 at 2:30 pm that the manufacturer had performed the verification of performance specifications on the Advia XPT.

**Table 3: Helpful Hints to Help With Active Voice**

| |
|---|
| ➢ Active voice sentences are generally clearer, more direct, and easier to understand |
| ➢ Emphasizes the "doer" of the action |
| ➢ Subject = Doer<br>➢ Verb = "Doing" word |
| ➢ Avoid starting a sentence in active voice and then shifting to passive voice<br>For example, "…. the technical supervisor (subject) failed to perform (verb) competency assessment…, but it was stated by TP2 that they had competency assessment performed on their one year anniversary date." |

# Examples for the Uses of D0000*

***Please note that these are only examples, and are not the only ways to write citations at D0000. In addition, please refer to page 11 for appropriate uses of D0000.**

## Required Use - No Deficiencies are Cited

- The laboratory was found to be in substantial compliance with CLIA regulations (42 CFR Part 493, effective April 24, 2003). No deficiencies were cited.

- An onsite survey conducted, (Date) found the [Name] laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.

## Additional Optional Uses

Indication of Survey Type

- An announced CLIA Recertification survey was conducted at the [Laboratory Name] on [Date(s)] by the [State Agency name]. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:

Summary of Condition-Level Deficiencies

- During a recertification survey on [Date], the laboratory was found out of compliance with the following conditions [List applicable Conditions as below]:

  42 CFR §493.803 Proficiency Testing, Successful Participation
  42 CFR §493.1403, Laboratory Director, Moderate Complexity
  42 CFR §493.1409, Technical Consultant, Moderate Complexity

- A validation survey was conducted by the [insert SA] at the facility on [insert date]. The laboratory was found out of compliance with the following conditions:

  [List applicable Conditions as above]

PT Referral for Laboratories Performing Waived Testing

PT Referral occurs very rarely in laboratories performing waived tests. Should PT referral be discovered at a Certificate of Waiver (CoW) or at a laboratory performing PT on waived tests, please contact your RO for guidance in citing the PT referral.

# Additional Examples for Each Principles 2 - 6

Disclaimer: Please note these are just examples taken from actual CMS-2567s and for Principles 3, 4, 5 and 6 are not the only way to follow the principles of documentation.

## Principle #2: Using Plain Language

The deficiency citation should not include advice, conclusions, extraneous comments or direction (i.e., consultation) aimed at the surveyed laboratory. The following are examples of statements which should not appear in the CMS-2567 (see verbiage in italics).

- "...Failure to include the address of the testing laboratory *limited the ability of the individual ordering the test to contact the laboratory.*" (CONCLUSION)

- "The LD confirmed the procedures in the SOP and the QA plan were currently in use by the laboratory. *They should have been signed off by the director when he took the position.*" (ADVICE)

- "...failed to review and evaluate the instrument calculated routine chemistry ratios using an alternative method *(manual calculation, electronic calculation)* since October 2016." (ADVICE)

- "Review of the urine culture policy...failed to contain step-by-step procedures on how to interpret the results of the test on each type of media. *For example how many colonies are seen on EMB, PEA, and BAP and how is that reported?.*" (CONSULTATION)

- "Based on quality assessment records reviewed, lack of documentation, and interview with the testing person, the laboratory failed to...The laboratory tested approximately 10 specimens per year using Potassium Hydroxide (KOH) *to dissolve skin and nail cells for the detection of the presence or absence of fungal elements.* Findings include:

  ...The testing person also stated the laboratory did not perform or document they verified KOH test accuracy *to perform, identify, and record the presence or absence of fungal elements using KOH to digest extraneous cells* at least twice a year." (EXTRANEOUS)

- "...it was determined that the laboratory failed to implement a mechanism, *such as a chart audit (instrument printout result compared to the transcribed entry into eClinical EMR)* to ensure the accuracy of manual recording and transcribing of patient results..." (ADVICE)

- "Based on the review of 2014-2017 quality control records, manufacturer's instructions, shipping invoices and observation of laboratory supplies, the laboratory failed to verify the acceptable criteria for new lots of chemistry quality control materials prior to use. *This deficient practice could result in the laboratory unable to identify quality control failures as they occur.*

# Principle #3: Composition of a Deficiency Citation

A deficiency citation consists of (A) a regulatory reference, (B) a deficient practice statement and (C) relevant findings. Please note that regulatory text is in italics.

## EXAMPLE 1 - LACKED EXTENT AND IDENTIFIERS, REGULATORY REFERENCE

D2015 493.801(b)(5)(6) TESTING OF PROFICIENCY SAMPLES

> *The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.*

Original Citation

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory did not process the proficiency testing (PT) samples in the same manner as the patients. Findings:

1. The PT records from 2016 (3 events) did not include the initials of the testing person on the instrument printout.
2. The testing personnel are required to initial the instrument print outs, therefore, they should be initialing the instrument printouts for the PT samples

Comment: The deficient practice statement lacked an extent and identifiers along with it merely repeated the regulation. In the corrected deficiency, we have added an extent and the identifiers - 3 PT events in 2016. It could also be written as 3 of 3 PT events in 2016. Since the extent is 3 of 3, we know the identifiers are Events 1, 2 and 3 without writing them.
To provide more information about what the lab did not do, we added to the regulatory words that lab did not process PT samples like patients by saying how the instrument printouts for PT samples were not initialed by the testing person.

Principle 3 speaks to not merely repeating the regulation in the DPS and also the need to describe the extent of the deficiency and the identifying (identifiers) of the documents reviewed to cause the deficiency.

Appendix F

Possible Rewrite

Based on Proficiency testing (PT) record review, instrument printouts, and interview with the testing person, the laboratory did not process 3 of 3 Hematology proficiency testing (PT) events in 2016 in the same manner as patients as instrument printouts were not initialed by testing personnel to show which personnel performed the testing. Findings:

1. The Hematology PT records for 2016 (all 3 events) did not include the initials of the testing person. Instrument printouts for patient testing showed the testing persons initials.
2. Testing person #1 stated the practice of the laboratory was that each testing person initialed the instrument printouts as they reviewed the results. Testing person #1 also confirmed that the instrument printouts for the 2016 PT events showed no initials by the testing personnel.

**EXAMPLE 2 - LACKED EXTENT AND IDENTIFIERS**

D5801 493.1291(a) TEST REPORT

*The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (1) Results reported from calculated data. (2) Results and patient-specific data electronically reported to network or interfaced systems. (3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.*

This STANDARD is not met as evidenced by:
Based on record review and staff interview it was determined that the final results recorded on the test log sheet were different from the results found in the Electronic Medical Record (EMR) in the specialty of Bacteriology. Findings include:

1. Record review of the EMR final report in patient charts revealed that test results for bacterial cultures were inconsistent and unmatched on the following patient test reports.
a. Medical record number 31005
b. Medical record number 46852
c. Medical record number 62558
2. Interview with the general supervisor on 2/11/15 at 11:10 am confirmed that discrepancies exist between the EMR final report in the patient's chart and the laboratory log sheet.
3. The laboratory performs 8,027 tests in the specialty of Bacteriology annually.

Comment: The original deficiency lacked an extent, identifiers and also did not use active voice in finding #3. The extent of 3 Medical records was added to the practice statement along with the identifying Medical record numbers. This information was in the findings in the original deficiency but needs to be in the DPS according to Principle 3. Also note finding #3 was reworded to active voice where the subject (general supervisor) confirms information. We also added the discrepancies noted between the log sheet and EMR to show the seriousness of the deficiency.

Appendix F

Possible Rewrite

Based on review of Bacteriology culture records and Electronic Medical Record (EMR) final reports and interview with the general supervisor, it was determined that the final results recorded for 3 patients on the test log sheet were different from the results found in the EMR in the specialty of Bacteriology. (Medical record (MR) numbers 31005, 46852, and 62558) Findings include:

1. Record review of the EMR final report in patient charts revealed that test results for bacterial cultures were inconsistent and unmatched on the following patient test reports.
a. MR number 31005 - Log sheet stated >100,000 E. coli. EMR final report stated no pathogens found.
b. MR number 46852 - Log sheet stated large amount Group A Streptococcus. EMR stated no pathogens found.
c. MR number 62558 – Log sheet stated large amount Group B Streptococcus. EMR stated large amount of Group A Streptococcus.
2. The general supervisor confirmed on 2/11/17 at 11:10 am these discrepancies existed between the EMR final report in the patient's chart and the laboratory log sheet.
3. The laboratory performs 8,027 tests in the specialty of Bacteriology annually.

**EXAMPLE 3 - LACKED REFERENCE TO REGULATION**

D6128 493.1451(b)(9) TECHNICAL SUPERVISOR RESPONSIBILITIES

> *The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.*

This STANDARD is not met as evidenced by:
Based on personnel records review and laboratory testing personnel interview at 11:00 a.m. on 6/9/15, it was determined that the laboratory director failed to establish written procedures to monitor and ensure the competency evaluations of the testing personnel since 2013.

Comment: This original deficiency is not fitted to the regulation where it is written. The regulation is about Technical Supervisor responsibilities but the deficiency is about the failure of the laboratory director. Also the regulation speaks to competency of testing personnel, not the clinical consultant. The corrected version changed to the technical supervisor to fit the regulation and also the interview with the technical supervisor. When determining whether a technical supervisor (or other personnel) fulfilled their responsibilities, it is best to interview the technical supervisor.

Suggested Rewrite

Based on review of personnel records and the personnel manual, and testing personnel interview, it was determined the technical supervisor failed to establish written procedures to monitor and ensure the competency of 5 of 5 testing persons since 2015. (Testing persons #1-5) The findings include:

1. No competency evaluations were found in the personnel records and no competency procedures were found in the personnel manual.
2. The testing personnel confirmed during an interview 04/05/2017, that the technical supervisor had not performed competency assessments and there was no procedure developed.

**EXAMPLE 4 - LACKED FINDINGS**

D6053 493.1413(b)(9) TECHNICAL CONSULTANT RESPONSIBILITIES

*The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.*

This STANDARD is not met as evidenced by:
Based on surveyor's review of the personnel records, laboratory records and an interview with the technical supervisor, the technical consultant failed to follow the laboratory's competency policy and perform the semi-annual evaluation for three of five testing personnel during the first year of patient testing in calendar year 2016.

Comment: The original deficiency included a DPS with sources, who was deficient, the lack of action that caused the deficient practice related to the regulation, and an extent. It lacked identifiers for the testing persons listed. The original deficiency lacked any findings to provide the information that was learned from the sources and also the information that showed how the laboratory was deficient. The rewritten deficiency has added the identifiers to the practice statement and also the findings providing what was learned from the record review and the interview.

Possible Rewrite

Based on surveyor's review of the personnel records, laboratory policy and procedures and an interview with the technical consultant, the technical consultant failed to follow the laboratory's competency policy and perform the semi-annual evaluation for the three of five testing personnel during the first year of patient testing in calendar year 2016. (Testing persons 3, 4 and 5) The findings include:

1. The laboratory policy and procedures related to competency stated each new testing person would be evaluated semi-annually during their first year of employment.
2. Personnel and laboratory records showed no competency evaluations performed in calendar year 2016 for Testing persons 3, 4, and 5 who started working for this laboratory 12/2/2016.
3. The technical supervisor stated during an interview on 1/31/2017 that no semi-annul evaluations were performed on the three testing personnel.

**EXAMPLE 5 - LACKED FINDINGS FOR ALL SOURCES AND ADEQUATE INFORMATION**

D5401 493.1251(a) PROCEDURE MANUAL

*A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.*

This STANDARD is not met as evidenced by:
Based on the surveyor's review of the written laboratory procedure manual, observation of a staining procedure posted on the wall in the MOHS laboratory, and an interview with the testing person, the laboratory failed to have one functioning staining procedure or provide instruction when to two differing procedures. Findings:
The staining procedure in the MOHS laboratory did not correspond with the staining procedure in the laboratory procedure manual.

Comment: The original deficiency lacked findings related to what was learned from the sources: the interview, the procedures, when the interview was held, when the procedure on the wall was observed and differences between the procedures.

Possible Rewrite

Based on the surveyor's review of the written laboratory procedure manual, observation of staining procedures posted on the wall in the MOHS laboratory, and an interview with the testing person, the laboratory failed to have one functioning staining procedure or provide instruction when to use the two differing procedures. Findings:

1. The written laboratory procedure manual included a procedure for staining tissue from a MOHs procedure.
2. A written staining procedure posted on the wall in the MOHS laboratory was observed at 2PM, 10/4/16. This staining procedure in the MOHS laboratory did not correspond with the staining procedure in the laboratory procedure manual. No instruction was noted to indicate when to use either procedure.
3. The testing person (who conducts the MOHs staining procedures) stated she uses the procedure on the wall as that one was used in her training. She also stated she was not aware that the procedure in the manual was different but noted the differences in staining times when shown.

**EXAMPLE 6 - ADDITIONAL SOURCE, NEEDED FINDINGS, LACKED EXTENT & IDENTIFIERS**

D5405 493.1251(c) PROCEDURE MANUAL

*Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.*

This STANDARD is not met as evidenced by:
Based on review of records, observation and laboratory general supervisor interview on 12/2/14 at 10:40 A.M., it was determined that the laboratory failed to follow the manufacturer's instructions for performing RPR (rapid plasma reagent) quality control procedures. The findings include:

a. The manufacturer establishes that three levels of control material of different reactivity (reactive, non-reactive and weakly reactive) must be included each day of testing.
b. Syphilis serology quality control records were reviewed since 1/2014.
c. Since 11/3/14, the laboratory did not include nor document the three levels of control material of different reactivity (reactive, non-reactive and weakly reactive.
d. The laboratory reported and processed 22 RPR patient samples from 11/3/14 to 12/1/14.

Comment: The original deficiency included the sources of review of records, observation and general supervisor interview. There was no observation noted in the findings, so that source was deleted. The review of records was expanded to include the types of records reviewed as noted in the findings – manufacturer's procedures and quality control records. The extent of the deficiency was added - 4 of 4 days, along with the dates to give identifier the specific dates when quality control was not documented.
A finding was added to provide what was learned from the review of the quality control records. This finding replaced finding b. in the original deficiency and the information of the time period reviewed was removed. In the deficiency, the timeframe reviewed gave no valuable information. We also added in finding c. to include what was learned from the interview with the general supervisor.
In reviewing the deficiency, the sources in the DPS also have specific information of what was learned from each source in the findings.

Possible Rewrite

Based on review of quality control records, manufacturer quality control procedures and laboratory general supervisor interview, the laboratory failed to follow the manufacturer's instructions for documenting the RPR (rapid plasma reagent) quality control values for 4 of 4 days of testing reviewed. (11/8/16, 11/15/16, 11/22/16, and 11/29/16) The findings include:

a. The manufacturer establishes that three levels of control material of different reactivity (reactive, non-reactive and weakly reactive) must be included each day of testing.
b. Review of the RPR quality control records showed no entries for the three levels of control for the four testing days in November 2016. (11/8/16, 11/15/16, 11/22/16, and 11/29/16)
c. The general supervisor stated during an interview 12/6/2016 at 10am that she was not aware the controls had not been documented as done.
d. The laboratory reported and processed 22 RPR patient samples from 11/3/14 to 12/1/14.

**EXAMPLE 7 - ADDITIONAL SOURCES, LACKED EXTENT & IDENTIFIERS**

D5413 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 observations, quality control records, procedures manual review and laboratory director interview on 10/21/2014 at 10:48 AM, it was determined that the laboratory failed to monitor and document the laboratory's room temperature and relative humidity. The findings include:

1. The laboratory procedures manual establishes that the laboratory must monitor and document the bacteriology area room temperature (18°C - 30° C) and relative humidity (30% - 80%) daily.
2. The laboratory director confirmed that the laboratory did not monitor nor document the room temperature and relative humidity readings since January 9, 2014.

Comment: The original deficiency included observation as one of the sources but there is no information related to what was learned from an observation. The observation was removed from the rewritten deficiency. The original deficiency lacked any extent of the deficiency practice or any identifying information related to the extent. Both were added in the rewritten version. A finding was added to show what was learned from the review of the quality control records. The date and time of the interview with the director was moved from the DPS to the finding speaking of what was learned in the interview.

Possible Rewrite

Based on quality control records and procedure manual review and laboratory director interview, it was determined that the laboratory failed to monitor and document the laboratory's room temperature and relative humidity daily from January 9, 2016 thru October 21, 2016 . (285 days)
The findings include:

1. The laboratory procedure manual established that the laboratory must monitor and document the bacteriology area room temperature (18°C - 30° C) and relative humidity (30% - 80%) daily.
2. Bacteriology quality control records showed no documentation for temperature or humidity since January 9, 2016.
3. The laboratory director confirmed during an interview October 21, 2016 at 10am that the laboratory did not monitor nor document the room temperature and relative humidity readings since January 9, 2016.

# Principle #4: Relevance of Onsite Correction of Findings

**EXAMPLE 1- SERIOUS FINDINGS**

D6025 - §493.1407(e)(7) STANDARD LABORATORY DIRECTOR RESPONSIBLITIES

*The laboratory director must ensure that patient test results are reported only when the system is functioning properly.*

This STANDARD is not met as evidenced by:

Based on observation of the laboratory refrigerator and storage areas, review of the laboratory test volume records, test requisitions, testing records and test reports, and interview with the testing person and laboratory director, the laboratory director failed to ensure that A1c reagents, calibration materials and control materials were available to conduct hemoglobin A1C testing on the (name) chemistry analyzer. The findings include:

a. The testing person stated during the entrance interview (1PM, 7/12/2017) that the laboratory conducted all tests listed on the test volume document provided to the surveyor.
b. Observation of the laboratory refrigerator at 3PM on 7/12/2017 revealed no A1C reagents, calibration materials or control materials.
c. Review of test requisitions and reports for June 2017 showed 24 A1C tests requested and results reported.
d. Review of testing records for the A1C analyzer showed no testing records for June 2017 and showed the last test records for the instrument to be October 2016. No records of calibration were available.
e. When asked about the lack of reagents, calibration materials and control materials, the testing person stated that "Yes, we are out of reagents but we are waiting for a new shipment".
f. When asked when the laboratory ran out of A1c reagents, the testing person said, I cannot remember but the reagents had been on back order for quite some time." No reagent shipment records were available for review.
g. When asked about testing records for the A1c results reported during the June 2017 including the previous day, the testing person gave no response.
h. The laboratory director was contacted via telephone to report the findings prior to the exit conference at 2PM, 7/13/2017. He stated he was not aware of any problems associated with the A1c testing, shipments of reagents or lack of testing. He stated he would be visiting with the testing person immediately.

Comment: This deficiency covers several areas the surveyor would review and follow when serious and questionable information is discovered. Note we have used all three sources including two interviews, several different records reviewed and observations of more than one location. In many situations this information may be expanded with more specific information. This could be decided to be a deficiency with Immediate Jeopardy.

**EXAMPLE 2 - CORRECTED ONSITE**

D5205 - §493.1233 COMPLAINT INVESTIGATIONS

*The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.*

This STANDARD is not met as evidenced by:

Based on record review and technical consultant interview, the laboratory did not have a system in place describing how the laboratory will document, investigate, track and resolve complaints including laboratory related problems it receives. Findings:

1. The technical consultant confirmed the lab did not address complaints and lab related problems including having a policy and procedure.

2. The technical consultant said that he was unaware of the requirement and had not conducted any investigations.

Comment: This deficiency was corrected onsite when the technical consultant provided a new policy and procedure for documenting complaints. Considering, the staff had not been trained on the new policy and no investigations had been completed, the deficiency was not really corrected. A quick fix during they survey is just that, a quick fix. It does not address the systemic problem that caused the deficiency. In this case, the lack of awareness to respond and investigate problems and complaints throughout the laboratory.

## Principle #5: Interpretive Guidelines

The deficiency citation explains how the laboratory fails to comply with the regulatory requirements, not how it fails to comply with the guidelines for the interpretation of those requirements. Guidelines are not regulatory requirements rather interpretations of regulatory requirements. Deficiencies should only be cited for noncompliance with regulatory requirements.

D5445 §493.1256 CONTROL PROCEDURES

> *Unless CMS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must (1)Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at §§493.1278. (2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section.*

This STANDARD is not as evidenced by:
Based on review of urinalysis microscopic procedures, urinalysis quality control records and interview with the testing person, the laboratory failed to have any control procedures including photomicrographs or charts of all possible urine sediment components. The findings include:

1. The manual urinalysis microscopic procedures did not include any instruction about quality control including reference materials such as photomicrographs or charts of all possible urine sediment components.
2. The testing person stated that the laboratory had no instruction for controls for manual urine microscopic testing and had no reference materials to aid testing personnel in identifying sediment components.

Comment: This deficiency is written using information from the guidelines giving the laboratory the option to use the photomicrographs or charts of all possible urine sediment components as a control procedure. See 5449.

## Principle #6: Citation of State or Local Code Violation

The laboratory's failure to comply with State or local laws or regulations is not documented in the Form CMS-2567 except when the Federal regulation requires compliance with State or local laws. When the authority having jurisdiction for that State or local law has made a decision of noncompliance which has resulted in an adverse action which has been sustained through the hearing process (such as removal of the license to operate), the Form CMS-2567 should note that the laboratory no longer has a State license.

EXAMPLE 1 - CURRENT STATE LICENSE REQUIRED

This could be used for any of the personnel D-Tags that require State licensure.

- Based on review of personnel records and interview with the laboratory director, the laboratory failed to ensure that 1 of 1 testing personnel held a current XX State license to perform laboratory testing from mm/dd/yy to mm/dd/yy. Section YYY of State requirement requires laboratory testing to be performed by a licensed ZZZ.

- Based on review of personnel records and interview with the clinical consultant, the laboratory failed to ensure the clinical consultant, hired 18 months prior to the survey (January 11, 2016) held a license to practice medicine in the State where the laboratory was located. The findings include:
  a. Personnel records indicated the clinical consultant held a license to practice medicine in the State where he resides (Kansas) and not in the State of the laboratory (Nebraska).
  b. The clinical consultant confirmed he is licensed to practice medicine in Kansas where he lives and not in Nebraska where the laboratory was located.

EXAMPLE 2 - STATE/LOCAL ADVERSE ACTION

Typically this would be used for noncompliance with 42 CFR 493.1101(c).

D3009 §493.1101(c) Standard: Facilities

*The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.*

- Based on evidence in the attached notice of determination of noncompliance, the laboratory did not meet (State or local) Law/Regulation #XXX. The State of (State) took adverse action against the laboratory. See attached.

EXAMPLE 3 – NOT FOLLOWING LOCAL LAWS - DEFICIENCY SHOULD NOT BE WRITTEN.

D3011 §493.1101(d) Standard: Facilities

*Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.*

Based on review of laboratory fire drill records related to fire safety and interview with the laboratory directory and fire department personnel, the laboratory failed to ensure they followed the local fire safety practices. The findings include:

1. Local fire practices required a monthly fire drill for all businesses. The laboratory had no records to show these fire drills were taking place.
2. The laboratory director stated he was unaware of this requirement and the laboratory had not conducted any fire drills.
3. Fire department personnel visited the laboratory during the survey to remind the laboratory of this requirement.

Comment: Although there are local laws requiring fire drills, it is the responsibility of the local authorities, not CLIA to monitor the laboratory and take action should it be necessary. If the surveyor noted safety issues in the future, it may be appropriate to notify the local authorities as noted in D3011.

## Uses of D8100

D8100 493.1771 INSPECTION REQUIREMENTS

*Each laboratory issued a CLIA certificate must meet the requirements in §493.1773 and the specific requirements for its certificate type, as specified in §§493.1775 through 493.1780. All CUA-exempt laboratories must comply with the inspection requirements in §§493.1773 and 493.1780, when applicable.*

D8101 493.1773(a) BASIC INSPECTION REQUIREMENTS FOR ALL LABORATORIES ISSUED A CLIA CERTIFICATE AND CLIA-EXEMPT LABORATORIES

*(a) A laboratory issued a certificate must permit CMS or a CMS agent to conduct an inspection to assess the laboratory's compliance with the requirements of this part. A CLIA-exempt laboratory and a laboratory that requests, or is issued a certificate of accreditation, must permit CMS or a CMS agent to conduct validation and complaint inspections.*

D8103 493.1773(d) REQUIREMENT TO PROVIDE INFORMATION AND DATA

*A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.*

D8201 493.1775(b) INSPECTION OF COW OR PPMP LABS

*If necessary, CMS or a CMS agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at anytime during the laboratory's hours of operation to do the following:*
*(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health.*
*(2) Evaluate a complaint from the public.*
*(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory.*
*(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures.*

D8301 493.1777(a) INSPECTION OF LABORATORIES THAT HAVE REQUESTED OR HAVE BEEN ISSUED A CERTIFICATE OF COMPLIANCE

*(a) Initial inspection. (a)(1) A laboratory issued a registration certificate must permit an initial inspection to assess the laboratory's compliance with the requirements of this part before CMS issues a certificate of compliance.*
*(a)(2) The inspection may occur at any time during the laboratory's hours of operation.*

## CoW, TESTING OUTSIDE OF CERTIFICATE

Example 1

D8100 This CONDITION is not met as evidenced by:
Based on interview with the Manager of Ears, Ears, Ears Otolaryngology and the Chief of Ambulatory Operations at 3:00 pm on 6/26/17 and review of a patient result log book, it was determined that the laboratory was performing testing outside of the scope of their Certificate of Waiver (CoW). Refer to D8201.

D8201 This STANDARD is not met as evidenced by:
Based on interview with the Manager of Ears, Ears, Ears Otolaryngology and the Chief of Ambulatory Operations at 3:00 pm on 6/26/17 and review of a patient result log book, it was determined the laboratory was performing Tzanck smear testing. Findings:

1. The laboratory was issued a CoW on 10/28/15.
2. Review of the patient result log book for June 2016 and May 2017 revealed that the laboratory performed and reported results for Tzanck smears for ten patients:

| Date | Patient ID |
|---|---|
| 6/2/16 | 06021604 |
| 6/3/16 | 06031615 |
| 6/11/16 | 06111609 |
| 6/28/16 | 06281609 |
| 5/8/17 | 05081704 |
| 5/8/17 | 05081718 |
| 5/15/17 | 05151712 |
| 5/23/17 | 05231703 |
| 5/26/17 | 05251716 |
| 5/29/17 | 05291707 |

3. Interviews with the Manager and Chief of Ambulatory Operations at 3:00 pm on 6/26/17 confirmed that the laboratory was performing Tzanck smears.
4. Refer to D1000.

Example 2

D8100 This CONDITION is not met as evidenced by:
Through observation and interview, it was determined the laboratory failed to meet the requirements for its Certificate of Waiver as it was performing provider-performed microscopy testing. Cross refer to D8201.

D8201 This STANDARD is not met as evidenced by:
Through observation and interview, it was determined the laboratory was performing microscopic wet prep examinations, KOH examinations, and urine microscopic examinations which are non-waived tests. Findings follow:
A. The surveyor observed a microscope on the counter in the laboratory area.
B. In an interview on 3/27/13 at 11:30, the Testing Person confirmed the physicians were performing microscopic wet prep examinations, KOH examinations, and urine microscopic examinations. Refer to D1000.

## PPM, TESTING OUTSIDE OF CERTIFICATE

Example 1

D8100 This CONDITION is not met as evidenced by:
Based on receipt of a complaint concerning tests performed beyond the scope of the PPMP certificate currently held by the laboratory, and a subsequent onsite inspection, it was determined that the laboratory was not in compliance with the specific requirements for the certificate type issued. See D8201.

D8201 This STANDARD is not met as evidenced by:
Based on receipt of a complaint concerning tests performed beyond the scope of the certificate held by the laboratory, a subsequent onsite investigation, and interview with the director and testing personnel, it was determined that the laboratory, was performing non-waived tests that were classified beyond the scope of the current Provider-Performed Microscopy· Procedure (PPMP) certificate held. Findings included:

a. At the time of the Investigation, the laboratory held a valid PPMP certificate which permitted performance of all tests classified as CLIA Waived and the following lists of provider performed microscopy procedures:
b. An unannounced on site investigation was conducted on 7/25/2017.
c. The following moderate complexity test kits and materials were available for use:
   1) Nova Diagnostics Biokit HSV-2 (Herpes) Rapid Test Lot Number 02975, Expiration 2/2014
   2) Diagnostics Direct Syphilis Health Check (Anti-Treponemal EIA) Lot Number 08111, Expiration 11/2013

d. The laboratory director stated that the tests identified in above were currently in use and confirmed that patient testing began for both HSV-2 and Syphilis in 2015, but the laboratory was unaware that these tests were beyond the scope of the PPMP certificate type.
e. For the period reviewed, covering tests performed from 3/2015 through 7/2017, approximately 1,500 patients were tested for HSV-2 and Syphilis.

Example 2

D8100 This CONDITION is not met as evidenced by:
Based on surveyor observation, review of laboratory records and acknowledged by interview, the laboratory failed to restrict the tests performed to the testing allowed under a Certificate of Provider-Performed Microscopy Procedures (PPMP). (Refer to D8201)

D8201 This STANDARD is not met as evidenced by:
Based on surveyor observation, review of laboratory records and acknowledged by interview, the laboratory failed to restrict the tests performed to the testing allowed under a Certificate of Provider-Performed Microscopy Procedures (PPMP) for the time period of 05/23/2016 to 02/22/2017.
Findings include:

1. A review of patient testing logs available for review revealed the facility performed moderate complexity testing serum pregnancy tests. Records revealed that two (2) serum pregnancy tests (Serum Human Chorionic Gonadotropin (HCG)) were performed in October 2016.
2. A review of Clinitek Status test reports available for review revealed that microscopic urine examinations were done by testing personnel who were not a physician, midlevel practitioner or dentist. Records revealed that 10 urine microscopic tests were documented in October and December 2016.
3. An interview of the owner on 02/22/2017 at 1220 hours confirmed that medical technologists performed serum pregnancy tests and urine microscopics. He stated they were unaware that their CLIA certificate did not authorize them to perform the microscopic urine examination and serum pregnancy tests.

Please refer to patient alias lists.

## REFUSAL OF ACCESS, DOCUMENTS, STAFF

Example 1, Access

D8100 This CONDITION is not met as evidenced by:
Based on interview with the laboratory director and the laboratory's attorney, the laboratory failed to permit the [##] State Agency ([##] SA) access to the laboratory to perform an initial survey. Refer to D8101

D8101 This STANDARD is not met as evidenced by:
Based on interview with the technical supervisor (TS) and the laboratory's attorney, the laboratory failed to allow the [Add State] State Agency (## SA) access to the laboratory to perform an initial survey on July 9, 2017. Findings include:

a. The [##] SA surveyor arrived at the laboratory for an announced survey on 7/9/17 at 9:00 am.
b. The laboratory's hours of operation were Monday-Friday from 8:30 am through 5:00 pm.
c. The TS stated through a closed door that "the laboratory director is unavailable for the survey, you need to contact our attorney".
d. The attorney was contacted and stated that "the laboratory director was ill and unavailable for the survey scheduled today" and "would contact the State Agency when she was available".
e. The [##] SA surveyor explained to the attorney that the laboratory director did not need to be present; that they had the authority to perform a survey at any time during the laboratory's operating hours to determine compliance; and if refused, would need to inform the Regional Office of the refusal to permit the survey.
f. The laboratory's attorney refused to allow the [##] SA surveyors to perform the initial survey.

Example 2, Documents

D8100 This CONDITION is not met as evidenced by:
Based on interview with the laboratory director and the technical consultant, the laboratory refused to provide personnel qualification documentation, establishment of performance specification documentation and quality control (QC) data. Refer to D8103

D8103 This STANDARD is not met as evidenced by:
Based on interview with the laboratory director (LD) and the technical consultant (TC), the laboratory refused to provide personnel qualification documentation for five of five laboratory personnel as well as documentation of establishment of performance specification and quality control (QC) for an FDA-modified toxicology test. Findings include:

1. The surveyor requested personnel qualification documentation for three testing personnel, one laboratory director and one technical consultant.
2. The laboratory was performing toxicology testing on the [insert instrument].
3. The laboratory modified the test system by testing a non-FDA approved or cleared specimen type (serum).
4. The surveyor requested documentation for establishment of performance specifications and QC for [insert instrument].
5. The LD and TC both refused to allow the surveyor to review the requested documentation on 6/19/18 at 10:35 am as the owner instructed them that it was proprietary information and they did not need to show the surveyor the documentation.

# Examples – Lack of Documentation

Example 1

D6046 §493.1413(b)(8) TECHNICAL CONSULTANT RESPONSIBILITIES

*(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to—*

This STANDARD is not met as evidenced by:
Based on *lack of documentation* and interview with the technical consultant, the laboratory failed to document competency assessment (CA) for four of four testing personnel (TP). Findings include:

1. The procedure, "Competency Assessment, v. 2.0" was reviewed.
2. Section 2.4 stated that CA should be "evaluated and documented at 6 months during the first year of employment and annually thereafter."
3. TP #1 and #2 were hired on 9/5/15, TP #3 was hired 1/3/16 and TP#4 was hired 4/25/16.
4. No documentation was found that CA was performed from September 2014 through the date of the survey.
5. The TC confirmed on 11/18/17 at 2:05 pm that CA had not been performed or documented.

Example 2

D3033 493.1105(a)(3)(i) RETENTION REQUIREMENTS
*In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under §493.1253 for the period of time the laboratory uses the test system but no less than 2 years.*

This STANDARD is not met as evidenced by:
Based on the review of shipping invoices, patient reports, interviews with laboratory staff and a manufacturer representative, and *lack of documentation*, the laboratory failed to maintain documentation of verification studies for the ACE Alera chemistry analyzer and the TOSOH A1Aimmunoassay analyzer.
Findings are:

1. Record review of shipping records indicated that the ACE Alera and TOSOH AIA were installed in October 2016.
2. The technical consultant, TC#1, stated during a phone interview on 7/12/17 at 9:45 am that the records were located at the back of the instrument manuals.
3. No verification records were found during the survey.

# Examples – DPS and Findings Do Not Match

Example #1

D5481 §493.1256(f)(g) CONTROL PROCEDURES

*(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results.*
*§493.1256(g) The laboratory must document all control procedures performed.*

Based on review of the laboratory's instrument printouts, quality control (QC) records, and interviews with the Office Manager (OM) and Technical Consultant (TC), the laboratory failed to retain failed QC instrument printouts from 2016 and 2017 for the complete blood count (CBC) testing performed. Findings Include:

1. Review of the laboratory's 2015 Beckman Coulter AcTDiff instrument printouts did not find any failed or unacceptable QC printouts.
2. The Surveyor requested the laboratory's 2016 and 2017 instrument printouts for all QC testing performed on the Beckman Coulter AcTDiff instrument. The OM stated the failed or unacceptable QC records are trashed or erased in the analyzer and the actual instrument printouts are shredded.
3. The TC confirmed on 3/16/2017 at 5 pm that the laboratory did retain all instrument printouts for at least 2 years, but was unable to provide the requested documentation.

*Comments: In this example the DPS cites a different time frame than Finding #1 which leaves the reader confused about what documents were missing, if any. Finding #3 directly conflicts with the DPS as the TC stated that the lab did retain the instrument printouts.*

Example #2

D5791 493.1289(a) ANALYTIC SYSTEMS QUALITY ASSESSMENT

*(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified at §§493.1251 through 493.1283.*

This STANDARD is not met as evidenced by:
Based on review of quality assessment (QA) and QA documentation, and interview with the laboratory director, the laboratory failed to follow the QA procedure for 2017. Findings include:

1. The laboratory's quality control (QC) procedure, Quality Control (QC-001), stated in section 4.3 that "QC must be run each day of patient testing and acceptable prior to release of patient test results".
2. Two levels of Bio-Rad controls were used each day of patient testing on the Siemens XPT.
3. Review of the QC data from April 2017, July 2017, and October 2017 revealed the following number of days QC was unacceptable:

a. Glucose, Level 1: 20 of 60 days
b. Glucose, Level 2: 12 of 60 days
c. Calcium, Level 1: 8 of 60 days
d. Total Protein, Level 2: 13 of 60 days
e. Creatinine, Level 1: 11 of 60 days
f. Creatinine, Level 2: 7 of 60 days

4. The laboratory director confirmed the above findings on 12/15/17 at 3:45 pm.

*Comments: The DPS speaks to QA; however, the findings speak to QC.*

# Examples – Repeating Regulations in DPS

The statement of deficient practice must not merely repeat the regulation, but should state specifically what the facility did that was wrong or failed to do in relation to the regulation and let the reader know what to look for in the findings. Many D-Tags have multiple regulatory requirements. It is important that the DPS speak to the specific portion of the regulation(s) that the laboratory failed to meet.

Example 1

D6000 §493.1407 Standard; Laboratory director responsibilities.

*The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations.*

This CONDITION is not met as evidenced by:
Based on review of documentation and interview with the technical consultant, the laboratory director failed to fulfill his responsibility for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations.

*Comments: It is unclear from the DPS what specific requirements the laboratory director did not fulfill. The citation should have included specific "failed to..." statements with cross references or a more specific DPS with findings that cross refer to the appropriate standard(s).*

*Example meeting POD:*

*Based on review of documentation and interview with the technical consultant on 5/13/17 at 3:30 pm, the laboratory director failed to ensure that a quality control (QC) program for chemistry was established (see D6020) and failed to ensure remedial actions were taken when QC was unacceptable for complete blood counts (CBCs) (D6025).*

*OR*

*Based on review of documentation and interview with the technical consultant on 5/13/17 at 3:30 pm, the laboratory director failed to ensure that a quality control (QC) program was established and failed to ensure remedial actions were taken when hematology QC was unacceptable. Findings include:*

1. *The laboratory director failed to ensure that a quality control (QC) program for chemistry was established (see D6020).*
2. *The laboratory director failed to ensure remedial actions were taken when QC was unacceptable for complete blood counts (CBCs) (D6025).*

Example 2

D5793 §493.1289 Standard: Analytic systems quality assessment.

*(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff.*

This STANDARD is not met as evidenced by:
Based on review of quality assessment (QA) documents and interview with laboratory director, the laboratory failed to include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff.

*Comments: It is unclear from the DPS what specific requirements of analytic quality assessment were not met. The citation should have included a more specific "failed to..." statement.*

*Example meeting POD:*

*Based on laboratory personnel interviews and WBC differential flow cytometer performance report record review on February 17, 2016, the laboratory failed to have an analytic systems quality assessment mechanism that included a review of the effectiveness of flow cytometer corrective actions taken to resolve problems. Findings include:*

a. *For patient capillary specimens, it was the practice of the laboratory to use flow cytometry instrumentation to perform and report patient WBC differentials.*
b. *On August 23, 2015, in which the flow cytometer was used to perform and report patient WBC differentials, laboratory "Cytometer Performance Reports" indicated that at 09:30 the flow cytometer performance check failed. The performance check was repeated and again failed at 10:18. At 12:49, laboratory documentation indicated that the flow cytometer performance check passed.*
c. *The laboratory maintained no documentation to indicate that the actions taken on August 23, 2015 to "pass" the flow cytometer performance check had been reviewed for the effectiveness of the actions under the laboratory's quality assessment mechanism.*

# Examples – Writing Condition Statements

Please Note: Below are examples of the same condition-level deficiency writing in several ways (i.e., narrative or with findings). This illustrates the different ways that condition-level deficiencies may be written according to the POD.

D5024 493.1215 HEMATOLOGY

*If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, §493.1269, and §§493.1281 through 493.1299.*

D5024 This CONDITION is not met as evidenced by:

Based on record review and interview with the laboratory director and technical supervisor, the laboratory failed to have a procedure manual which included the corrective action to take when complete blood counts (CBC) calibration and quality control (QC) results failed to meet the laboratory's criteria for acceptability (see D5403); document CBC calibrations (see D5437); failed to verify stated values of commercially assayed CBC controls (see D5469); failed to ensure QC for PT/INR was acceptable prior to reporting patient test results (see D5481); failed to follow corrective action policies and procedures as necessary to maintain the laboratory operation for testing patient CBC specimens in a manner that ensured accurate and reliable patient test results and reports (see D5779); failed to have an analytic systems quality assessment mechanism that included a review of the effectiveness of the laboratory's corrective actions for CBCs (see D5779); and failed to ensure that the calculated International Normalized Ratio (INR) results were accurate prior to reporting final patient results (see D5801).

OR

Based on the number and severity of the deficiencies cited herein, the Condition: Hematology was not met. The laboratory failed to have a procedure manual which included the corrective action to take when complete blood counts (CBC) calibration and quality control (QC) results failed to meet the laboratory's criteria for acceptability (see D5403); document CBC calibrations (see D5437); verify stated values of commercially assayed CBC controls (see D5469); ensure QC for PT/INR was acceptable prior to reporting patient test results (see D5481); follow corrective action policies and procedures as necessary to maintain the laboratory operation for testing patient CBC specimens in a manner that ensured accurate and reliable patient test results and reports (see D5779); have an analytic systems quality assessment mechanism that included a review of the effectiveness of the laboratory's corrective actions for CBCs (see D5779); and ensure that the calculated International Normalized Ratio (INR) results were accurate prior to reporting final patient results (see D5801).

OR

Based on the number and severity of the deficiencies cited herein, the Condition: Hematology was not met...Findings include:

1. The laboratory failed to have a procedure manual which included the corrective action to take when complete blood counts (CBC) calibration and quality control (QC) results failed to meet the laboratory's criteria for acceptability (see D5403).
2. The laboratory failed to document CBC calibrations (see D5437); verify stated values of commercially assayed CBC controls (see D5469).

**Examples – Multiple Citations Cited Under Same Regulation**

## EXAMPLE 1

D5791 493.1289(a) ANALYTIC SYSTEMS QUALITY ASSESSMENT

*The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in §§493.1251 through 493.1283.*

This STANDARD is not met as evidenced by:

1. Based on surveyor review of the Quality Control (QC) Records, Procedure Manual (PM) and interview with the Laboratory Director (LD), the laboratory failed to monitor that the New QC verification procedures were followed for 4 of 4 lots of New QC materials from January 5, 2016 thru May 10, 2017. (Lot #s 46X31, 56X32, 66X33, 76X34.) The findings include:

   a) The procedure manual included a procedure on how to verify new lots of QC materials.
   b) Quality control record reviews showed the laboratory did not perform and document the verification of the 4 new lots received for Hematology Quality Control materials before putting in use as per their procedure. Lot numbers 46X31, 56X32, 66X33, and 76X34.
   c) The LD confirmed on 10/23/16 at 1:30 PM that the procedure for verifying new lots of QC materials was not followed.

2. Based on surveyor review of calibration records, manufacturer's Instructions and interview with the Laboratory Director (LD), the laboratory failed to monitor hematology calibration to ensure the laboratory followed the manufacturer's instructions for times of "Needed" calibration. "Needed" calibrations were noted and not completed on 8/25/2016, 10/14/2016 and 1/5/2017. The findings include:

   a) Calibration records showed calibration performed on 8/25/14 with a "Platelets" status 'Needed'. The laboratory did not follow the manufacturer's procedure to adjust the calibration factor.
   b) Calibration records for 10/14/2016 and 1/5/2017 showed the laboratory had not reprinted the calibration after adjusting the calibration factor.
   c) The LD confirmed on 10/23/14 at 1:00 PM that the calibration procedures were not followed.

Comment: This regulation addresses the analytic systems and relates to all specialties of testing. A surveyor may have deficiencies at this tag with no similarity hence writing different deficient practice statements with findings is probable. Note that the two deficient practice statements are about monitoring practices but are both very different in substance. One is monitoring the verification of new lots of QC materials and the other monitoring that calibration is competed as needed according to manufacturer's instruction.

**EXAMPLE 2**

D5413 493.1252(b) TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENTS

*(b) 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:

1. Based on observation and document review, the laboratory failed to define ten of ten freezer temperature ranges that were consistent with the manufacturer's instructions for freezers which stored reference materials and patient specimens. Findings include:
   a. A tour of the laboratory on 11/15/2016 at 10:35 am where the freezers were kept showed that the freezer doors were labeled with the laboratory's acceptable temperature ranges.
   b. Four of four -80 C freezers were marked with a temperature range of -60 to -90C.
   c. Six of six -20 C freezers were marked with a temperature range of -17 to -25C.
   d. Review of two manufacturer instructions for samples stored in the -80 C freezers required that the samples be kept at "at least -80 C."
   e. Review of three manufacturer instructions for samples stored in the -20 C freezers required that the samples be kept at "at least -20 C."
   f. The Technical Supervisor confirmed on 11/15/2016 at 11 am that the freezers were labeled with the above ranges and that the ranges did not meet manufacturer instructions.
2. Based on review of the procedure, manufacturer package insert (PI), interview with the general supervisor and observation, the laboratory failed to follow the manufacturer's instructions for expiration date of Innovin (thromboplastin) used for Prothrombin Time/International Normalized Ratio (PT/INR) testing. Findings include:
   a. Dade Innovin (thromboplastin) lot number 539280 was put into use by the laboratory at the end of March 2016.
   b. The general supervisor stated that the PIs were usually white.
   c. The PI for lot number 539280 was pink.
   d. Review of the PI revealed an "important note" that this specific lot number was only stable for 2 days instead of 10 days after reconstitution when stored at 2-8 C.
   e. The current vial of Innovin reagent was observed in the 2-8 C refrigerator with a 5 day expiration date on 11/16/2016 at 2:15 pm.
   f. PT SOP-1001, Version A, "Measuring Prothrombin Time" stated on page 6, section 4.2 that "the package insert for a new lot must be reviewed for any changes before use."
   g. The general supervisor confirmed on 11/16/2016 that the change in storage and stability of the Innovin reagent had not been identified from March 2016 through November 2016.

Comment: This regulation addresses the test system, equipment. Instruments, and reagents. A surveyor may have deficiencies at this tag with no similarity hence writing different deficient practice statements with findings is probable. Note that the two deficient practice statements are about defining freezer temperatures and appropriate expiration date of reagents and are both very different in substance.

Appendix L

**EXAMPLE 3**

D5805 493.1291(c) TEST REPORT

*The test report must indicate the following: (1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (2) The name and address of the laboratory location where the test was performed. (3) The test report date. (4) The test performed. (5) Specimen source, when appropriate. (6) The test result and, if applicable, the units of measurement or interpretation, or both. (7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.*

This STANDARD is not met as evidenced by:
A. Name and Address of the Laboratory where tests performed and reported:
Based on electronic medical record (EMR) review and interview with the general supervisor, the laboratory failed to ensure 2 of 2 laboratory test results documented in the EMR did not contain the required information as to the name and address of the laboratory location where the test was performed. (EMR #s 1690 and 2122) Findings include:

1. EMR record review of the following patient test reports from the Sheridan EMR on 2/11/17 revealed that the laboratory failed to inscribe the name and address of the facility where testing took place.
   a. Test report for MR# 1690
   b. Test report for MR# 2122
2. The general supervisor stated in an interview on 2/11/17 at 12:15 pm the name and address of the laboratory had been left out of the EMR database.
3. The laboratory performs 64,247 tests annually.

B. Incorrect reference ranges and units of measurement (UOM):
Based on EMR record review and general supervisor interview, the laboratory failed to ensure the reference ranges and units of measurements (UOM) from the analyzer printout and the Electronic Medical Record (EMR) match on 2 of 2 records reviewed. (EMR #s 1690 and 2122) Findings include:

1. Review of the final CBC test reports from EMR and the Horiba hematology analyzer on 2/11/17 revealed that the reference ranges and UOM's for CBC parameters were inconsistent and unmatched on the following patient test reports.
   a. Test report for EMR# 1690
   b. Test report for EMR# 2122
2. The general supervisor stated in an interview on 2/11/17 at 12:20 pm that discrepancies exist between the EMR final report and the Horiba instrument printout. The general supervisor also stated that EMR reference ranges and UOM's for CBC parameters were overlooked following last computer system upgrade.
3. Laboratory performs 10,044 CBC's annually.

Comment: This regulation has several different requirements therefore a surveyor may have more than one deficiency at this tag requiring the more organization. More than one DPS with findings may be the best route to organizing the information for more clarity as noted in this example. One deficiency is related to the name and address of the testing location on reports and the other deficiency related to the reference ranges and units of measure not matching between the EMR and instrument. Note the surveyor has organized the two different deficiencies into two practice statements, each with findings. Each deficiency has a separated DPS and findings that can stand alone.

## Cross Referencing

### Example 1

**D6021** §493.1407(e)(5) Standard; Laboratory director responsibilities

*Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and*

This STANDARD is not met as evidenced by:
Based on lack of quality assessment (QA) documentation, the laboratory director failed to ensure that General Laboratory System QA program was established and maintained to ensure the quality of laboratory services provided for Chemistry testing. Refer to D5291.

**D5291** §493.1239(a) General Laboratory Systems Quality Assessment

*The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at §§493.1231 through 493.1236.*

This STANDARD is not met as evidenced by:
Based on lack of Quality Assessment (QA) documentation and interview with the facility personnel, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the general laboratory systems for the specialty of chemistry. Findings include:
1. No QA policies for the general lab system (GLS) were presented for review during the survey, including but not limited to, policies and procedures specific to proficiency testing and personnel competency.
2. The laboratory provided documentation of a blank form titled "I-stat Audit Tool", however there was no documentation to indicate the laboratory completed the form.
3. The "I-State Audit Tool" did not include proficiency testing or competency assessment.
4. The facility personnel confirmed that the laboratory did not have an established QA policy.
5. The laboratory performed approximately of 600 blood gas annually.

**Example 2**

**D5791** §493.1289(a) Analytic systems quality assessment

*The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in §§493.1251 through 493.1283.*

STANDARD is not met as evidenced by:
Based on laboratory personnel interviews and complete blood count (CBC) quality control and calibration record review, the laboratory failed to have an analytic systems quality assessment mechanism that included a review of procedures to include actions to be taken when calibration and quality control results fail, ensure calibration documentation is maintained, and ensure the verification of commercially assayed quality control materials. Finding include:

a. The laboratory's Siemens Advia 2120i and Advia XPT procedures failed to include the corrective actions to be taken when calibration or quality control results failed to meet the laboratory's criteria for acceptability. See D5403.
b. The laboratory's quality assessment mechanism failed to ensure that all CBC calibration documentation was maintained. See D5437.
c. The laboratory's quality assessment mechanism failed to ensure that the stated values of commercially assayed CBC and chemistry quality control materials were verified. See D5469.

**D5403** Procedure Manual

*§493.1251 Procedure manual*
*(b) The procedure manual must include the following when applicable to the test procedure:*
*(b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in §493.1242.*

This STANDARD is not met as evidenced by:
1. Based on interviews with laboratory testing personnel and review of the laboratory's hematology Advia 2120i procedure manual, the laboratory failed to have a procedure manual that included the corrective action to take when calibration or quality control results failed to meet the laboratory's criteria for acceptability. Findings include:

    a. It was the practice of the laboratory to test patient venous complete blood counts (CBC) specimens using a Siemens Advia 2120i instrument.
    b. In the laboratory's procedure titled "SOP Advia 2120i Operation and Maintenance," there was no written protocol for the corrective action to be taken when calibration or quality control failed to meet the laboratory's criteria for acceptability.
    c. Between February 1, 2016 and September 28, 2016, the laboratory performed and reported 5,395 patient CBC test results using the Advia 2120i.
    d. Review of calibration and control logs showed out of range controls were approached differently by each of the testing personnel and there was no consistent approach.

Some out of range controls were repeated, others were logged as only control out this week, and others documented as within three standard deviations.

e. e. Testing person # 1 stated the practice by testing personnel was to address the control failures but no consistent approach was decided or written. Testing person #1 also confirmed there was no written procedure for corrective action to take when controls or calibration failed.

2. Based on review of the quality control (QC) procedure for the Siemens Advia XPT and interview with the testing personnel, the laboratory failed to have control procedures prior to beginning patient testing on 2/6/2016. Findings include:

   a. SOP-C100, Revision A, "Advia XPT System Daily QC Procedure" revealed an effective date of 10/15/2016.
   b. A chart provided by the laboratory indicated that eight of twenty analytes run on the above system were put into use for patient testing prior to 10/15/2016. The initial use dates of the eight analytes ranged from 2/6/2015 through 5/9/2016.
   c. Testing personnel confirmed there was no approved control procedure prior to 10/15/2016.

**D5437** §493.1255 Calibration and Calibration Verification

*(a) Perform and document calibration procedures -*
*(a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer;*
*(a)(2) Using the criteria verified or established by the laboratory as specified in §493.1253(b)(3)--*
*(a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and*
*(a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and*
*(a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.*

This STANDARD is not met as evidenced by:
Based on laboratory personnel interviews and complete blood count (CBC) calibration documentation record reviews, the laboratory failed to document two of two CBC instrument calibrations performed using the Drew 3 instruments, and failed to document calibrations performed on two of two Advia 2120i.

1. Based on laboratory personnel interviews and complete blood counts (CBC) calibration documentation record reviews on September 23, 2015, the laboratory failed to document all CBC instrument calibrations performed using the Drew 3 instruments. Findings included:

   a. It was the practice of the laboratory to test patient capillary CBC specimens using two Drew 3 instruments the laboratory designated as "Drew #2" and "Drew #3." On September 28, 2016, information recorded on "Drew #2" indicated that the "Drew #2" was calibrated on August 24, 2016, and information recorded on "Drew #3" indicated that the "Drew #3" was calibrated on August 31, 2016.

b. The laboratory maintained no documentation of the August 24, 2016 and August 31, 2016 calibrations of the laboratory's two Drew 3 CBC instruments.
c. According to laboratory personnel, between August 24, 2016 and September 28, 2016, the laboratory performed and reported 523 patient CBC specimens using the two Drew 3 instruments.

2. Based on laboratory personnel interviews and complete blood count (CBC) calibration documentation record reviews, the laboratory failed to document CBC instrument calibrations performed using two of two Advia 2120i instruments from the date of installation, 10/5/14 through 9/28/16. Findings included:

a. It was the practice of the laboratory to test patient venous CBC specimens using two Siemens Advia 2120i instruments, designated as
#1 and #2.
b. For Advia 2120i #1, the laboratory maintained no documentation of any calibrations prior to May 21, 2016. For Advia 21201 #2, the laboratory maintained no documentation of any calibrations performed.
c. Between October 2014 and May 21, 2016, the laboratory performed and reported 2,005 patient CBC test results using the Advia 2120i #1. From 10/5/14 to 9/28/16, the laboratory performed and reported 1,067 patient CBC test results using the Advia 21201 #2.

**D5469** §493.1256(d)(10) Control Procedures

*Establish or verify the criteria for acceptability of all control materials.*
*(d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available.*
*(d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory.*
*(d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.*

This STANDARD is not met as evidenced by:
1. Based on interview with the laboratory personnel and review of Complete Blood Count (CBC) records, the laboratory failed to verify the stated values of the commercially assayed CBC quality control materials in use from June 27, 2016 thru the date of the survey. Findings include:

a. It was the practice of the laboratory to use commercially assayed CBC quality control materials to monitor patient CBC testing using two Drew 3 instruments.
b. Laboratory CBC quality control records indicated that on June 27, 2016 the laboratory changed the lot of quality control material from lot number TD048 to TD051.
c. The laboratory maintained no documentation to indicate that the stated values of CBC quality control material lot number TD051 had been verified by the laboratory.
d. According to laboratory personnel, between June 27, 2016 and September 28, 2016, the laboratory used one of the Drew 3 instruments on 30 different days to perform and report patient CBC specimens, and used the other Drew 3 instrument on 87 different days to perform and report patient CBC specimens.

2. Based on interview with the general supervisor and review of chemistry quality control (QC) records, the laboratory failed to verify the stated values of the commercially assayed QC materials used on the Advia 1800 and Advia XPT from June 2016 thru the survey date. Findings include:

a. The general supervisor stated that when a new lot number of QC was started, the QC ranges were entered into the chemistry analyzers (Advia 1800 and Advia XPT) from the manufacturer's package insert just prior to use.

b. The general supervisor further stated that the new lot number of QC was run on time prior to patient testing.

c. QC records show that MultiQual lot number 45660 was put into use in 2015 and discontinued in August 2016.

d. The general supervisor confirmed on 9/28/16 at 9:40 am that manufacturer's QC ranges for new lot numbers of chemistry controls were not verified.

Examples, PT Desk Review Citations

**D2016 (mandatory citation) + specialty/subspecialty specific D-Tag must be cited. Laboratory Director D-Tag is optional.**

*D2016 493.803(a)(b)(c) SUCCESSFUL PARTICIPATION*

*(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA.*
*(b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part.*
*(c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists:*
*(1) There is immediate jeopardy to patient health and safety.*
*(2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance.*
*(3) The laboratory has a poor compliance history.*

**Initial Unsuccessful**

Example 1

D2016 This CONDITION is not met as evidenced by:
Based on an off-site desk review of the laboratory's 2016 and 2017 Medical Laboratory evaluation (MLE) proficiency testing (PT) records and an email and telephone interview with the laboratory coordinator on April 11, 2017, it was determined that the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for Hematology Cell Identification in two (2) out of three (3) Hematology testing events resulting in unsuccessful PT performance. See 2130

D2130 *493.851(f) HEMATOLOGY*
*Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.*

D2130 This STANDARD is not met as evidenced by:
Based on an off-site desk review of the laboratory's 2016 and 2017 Medical Laboratory Evaluation (MLE) proficiency testing (PT) records, and an email and telephone interview with the laboratory coordinator on April 11, 2017 it was determined that the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for White Blood Cell (WBC) Differential Identification in two (2) out of three (3) Hematology testing events. Findings include:

1. Desk review of the laboratory's 2016 and 2017 MLE PT records revealed WBC Differential Identification scores of less than eighty percent for the following Hematology events:

2016 MLE M2 -score of 60%,
2017 MLE M1- score of 60%

2. In an email and telephone interview with the laboratory coordinator on 4/11/17, it was confirmed that the laboratory was unsuccessful in the PT events listed above.

Example 2

D2016 This CONDITION is not met as evidenced by:
Based on review of 2016 hematology proficiency testing (PT) results reported to the CLIA database by the PT provider and phone interview with the technical supervisor, the laboratory failed to successfully participate in PT. See D-tag 2130, unsatisfactory performance for the same analyte in two consecutive hematology PT testing events. Refer to D2130.

D2130 *493.851(f) HEMATOLOGY*
*Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.*

D2130 This STANDARD is not met as evidenced by:
Based on review of 2016 hematology proficiency test (PT) performance reported to the CLIA data base by the PT provider and phone interview with the technical supervisor, the laboratory failed to achieve satisfactory performance for the fibrinogen analyte in two consecutive testing events. Findings:
1. The laboratory obtained an unsatisfactory score of 0 percent for the fibrinogen analyte in the first testing event of 2016.
2. The laboratory obtained an unsatisfactory score of 20 percent for the fibrinogen in the second testing event of 2016.
3. Phone interview with the technical supervisor on September 19, 2016 at 12:30 PM confirmed the laboratory failed to achieve satisfactory performance for the fibrinogen analyte in the first and second PT events for 2016.

Example 3

D2016 This CONDITION is not met as evidenced by:
Based on proficiency testing desk review, the laboratory failed to successfully participate in proficiency testing for the analyte Free Thyroxine (Free TY). Refer to D2107.

D2107 *493.843(f) ENDOCRINOLOGY*
*Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.*

D2107 This STANDARD is not met as evidenced by:
Based on proficiency testing (PT) desk review and the laboratory's graded PT results from American Proficiency Institute (API), the laboratory failed to achieve successful performance for the analyte, Free Thyroxine (Free TY), in two out of three testing events. Findings:

| Analyte | Year | Event | Score |
|---|---|---|---|
| Free TY | 2017 | 1 | 60% |
| Free TY | 2017 | 2 | 20% |

**Non-Initial (or Subsequent) Unsuccessful**

Example 1

D2016 This CONDITION is not met as evidenced by:
Based on review of the Proficiency Testing (PT) data report (Report 155) report and graded results from, American Proficiency Institute (API), the laboratory failed to successfully participate in a Cell Identification. The laboratory had unsatisfactory scores for the 1st event of 2014, the 2nd event of 2014 and 3rd event 2014. See D2130.

D2130 *493.851(f) HEMATOLOGY*
*Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.*

D2130 This STANDARD is not met as evidenced by:
Based on a review of the Proficiency Testing (PT) data report (CASPER Report 155) and graded results from the proficiency testing organization American Proficiency Institute (API), the laboratory failed to successfully participate in Cell Identification. The laboratory had unsatisfactory scores for the 1st event of 2014, the 2nd event of 2014 and 3rd event 2014 for the analyte listed above. Findings include:

1. API 2014 Event 1 for Cell Identification the score was 53% and was unsatisfactory.
2. API 2014 Event 2 for Cell Identification the score was 67% and was unsatisfactory.
3. API 2014 Event 3 for Cell Identification the score was 27% and was unsatisfactory.

Example 2

D2016 This CONDITION is not met as evidenced by:
Based on review of 2016 and 2017 hematology proficiency testing (PT) results reported to the CLIA database by the PT provider and phone interview with the technical supervisor, the laboratory failed to successfully participate in PT. Refer to D2130

D2130 *493.851(f) HEMATOLOGY*
*Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.*

D2130 This STANDARD is not met as evidenced by:
Based on review of 2016 and 2017 hematology proficiency test (PT) results reported to the CLIA database by the PT provider and phone interview with the technical supervisor, the laboratory failed to achieve satisfactory performance for the fibrinogen analyte in two consecutive testing events. Findings:
1. The laboratory obtained an unsatisfactory score of 0 percent for the fibrinogen analyte in the first testing event of 2016.

2. The laboratory obtained an unsatisfactory score of 20 percent for the fibrinogen analyte in the second testing event of 2016.
3. The laboratory obtained an unsatisfactory score of 40 percent for the fibrinogen analyte in the first testing event of 2017.
4. Phone interview with the technical supervisor on May 15, 2017 at 2:00 PM confirmed the laboratory failed to achieve satisfactory performance for the fibrinogen analyte in the first and second testing PT events for 2016 and first testing event of 2017.

Example 3

D2016 This CONDITION is not met as evidenced by:
Based on proficiency testing desk review, the laboratory repeatedly failed to successfully participate in proficiency testing for the subspecialty of Bacteriology. Refer to D2028

D2028 *493.823(e) BACTERIOLOGY*
*Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.*

D2028 This STANDARD is not met as evidenced by:
Based on review of data from proficiency testing (PT) reports and the laboratory 's PT results from American Association of Bioanalysts (AAB), the laboratory failed to achieve satisfactory performance in the subspecialty of Bacteriology and has sustained a subsequent occurrence of unsuccessful participation in PT. Findings:

| Subspecialty | Year | Event | Score |
|---|---|---|---|
| Bacteriology | 2016 | 1 | 20 |
| Bacteriology | 2016 | 2 | 60 |
| Bacteriology | 2016 | 3 | 60 |

# Frequently Asked Questions (FAQs), POD

Q1. Can D0000 be used for anything else besides compliance, if no D-Tag is available or if there are new regulations which don't have a D-Tag assigned yet?

A1. Due to our continued improvement and practical application of the principles of documentation, CLIA policy also allows for the following additional uses of D0000:

- Indication of survey type
- Summary of condition-level deficiencies
- Documentation of PT referral for Certificate of Waiver or PT referral for waived tests being performed under other certificate types

D0000 should not be used for the following:

- List of acronyms used in Form CMS-2567
- Indication of surveyor or names
- Narrative to describe the survey and a summary of noncompliance issues

Q2. Is it ok if the laboratory needs additional paper to respond? Is "see attached" acceptable for an AOC or POC?

A2. It is perfectly acceptable for a laboratory to refer to additional documents when responding to the CMS-2567, especially if their response cannot fit on the CMS-2567 of if they choose to respond with "see attached" in the correction column, as long as it is clearly indicated what and where those documents are found in their submission. **The CMS-2567 must always include: laboratory director or representative signature, title, and date.**

Q3. What is the difference between "extent" and "universe"?

A3. Extent is the prevalence or frequency of a deficient practice. Universe is one way to describe extent. Universe is defined as the total number of individuals, records, observations, objects, related to the laboratory practice or patients at risk as a result of a deficient practice, and is used as the denominator when determining the extent of a deficient practice. Both extent and universe should be reflected in a numerical format, if at all possible.

Extent and universe are very important in order to accurately reflect the degree of a specific deficient practice. It is up to the surveyor to determine the relevant universe.

Q4. If the laboratory director and technical consultant or technical supervisor is the same person, can we say "laboratory director/technical consultant (or supervisor) in all of the personnel D-Tags?

A4. It is important when citing personnel D-tags that your deficient practice statement and/or findings only reference the specific position (e.g., laboratory director (LD), technical consultant (TC), technical supervisor (TS), etc.) that is being cited on the CMS-2567. Many laboratories, especially POLs, will have one person filling more than one position – LD/clinical consultant/TC. You may also find that the LD of a high complexity laboratory is also acting as the TS. However, if the regulatory reference speaks to non-compliance with a LD responsibility, the D-tag citation on the CMS-2567 should only contain a reference to the LD. This is true for all personnel citations. The CMS-209 will reflect that one person is fulfilling more than one position.

Q5. Why do we have to use POD?

A5. PODs provide a consistent framework on how to document a laboratory's compliance or noncompliance. Many styles of writing are acceptable and style is a matter of personal preference. Just remember to follow the POD while injecting your own personal style.

Q6. Why do we need to review the CMS-2567 before we send it to the laboratory?

A6. The CMS-2567 is the record of the survey and the key element in supporting, or not supporting, a determination of compliance. It is important that this document be legally defensible. In addition, this document is used by the laboratory to analyze and correct its deficient practice(s). So, it is very important that you proofread the CMS-2567 after it is written, and before it is sent to the laboratory, to ensure that the principles of documentation are being followed and that it makes sense. This is especially true if you are copying and pasting information into the CMS-2567. Some examples of items to check are:

- Spelling and grammar
- Transposed numbers in D-tags cross references (e.g., D5217 not D5127)
- Cross referenced D-tags are actually cited on the CMS-2567
- DPS/findings speak to the citation (e,g., QC tag with DPS/findings speaking about QA)
- Findings support the DPS (e.g., lab cited for QC problems with BUN and glucose in the DPS and only BUN in addressed in the findings, lab cited for not monitoring temperature and humidity in DPS and findings speak about temperature and centrifuge rpms)
- No advice or directions
- Acronyms are defined the first time they are used
- Write in complete sentences