

# *Principles of Documentation*



October 2018

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

**Table of Contents**

Introduction	2
Definitions	3
Legal Aspects of the Statement of Deficiencies	5
Principles of Documentation/Overview	7
Principle # 1: Laboratory Compliance and Noncompliance	10
Principle # 2: Using Plain Language	12
Principle # 3: Composition of a Deficiency Citation	13
• Regulatory Reference	13
• Statement of Deficient Practice	15
• Extent	16
• Identifiers	19
• Sources of the Evidence	20
• Outcomes	28
• Findings	29
• Facts	30
• Organization of the Findings	32
Principle #4: Relevance of Onsite Correction of Findings	37
Principle #5: Interpretive Guidelines	40
Principle #6: Citation of State or Local Code Violations	42
Principle #7: Cross References	44
Principle #8: Condition Deficiencies	46
Proofreading	48
Conclusion	49

**Appendices**

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	

## **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 it 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<sup>9</sup>.”

## **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	<p>42 CFR 493.1101(b)</p> <p>The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.</p> <p>This Standard is not met as evidenced by:</p>

**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	<p>42 CFR 493.1283(a)(1)-(4)</p> <p>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).</p> <p>This Standard is not met as evidenced by:</p> <p>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)</p>
-------	---

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 person's 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	<p>493.1252(d) Standard                      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.</p> <p>This Standard is not met as evidenced by:</p> <p>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:</p> <ol style="list-style-type: none"> <li>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. )</li> <li>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.</li> <li>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.</li> <li>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.</li> <li>5. The supervisor stated also the laboratory tested and reported 31 patients since 6/XXXX.</li> </ol>

**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	<p>42 CFR 493.1236(c)(1)</p> <p>At lease twice yearly, the laboratory must verify the accuracy of any test or procedure it performs that is not in subpart I.</p> <p>This Standard is not met as evidenced by:</p> <p>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:</p> <ol style="list-style-type: none"> <li>1. The laboratory’s proficiency test results for XXXX did not include testing for fetal hemoglobin, cold agglutinin, mumps or measles.</li> <li>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.</li> </ol>

### **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	<p>42 CFR 493.1254(a)(1)                      Maintenance and function checks                      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.</p> <p>This Standard is not met as evidenced by:</p> <p>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)                      The findings include:</p> <ol style="list-style-type: none"> <li>1. The manufacturer’s manual instructed the laboratory to perform weekly maintenance for the chemistry analyzer.</li> <li>2. The laboratory records indicated the laboratory performed the required weekly maintenance once each month. The laboratory tested approximately 60 patients each week.</li> <li>3. On 5/3/XX at 9am, the general supervisor confirmed the laboratory failed to perform the weekly maintenance required by the manufacturer.</li> </ol>

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

TAG	SUMMARY STATEMENT OF DEFICIENCIES
D6104	<p>42 CFR 493.1407(e)(3)(iii)                      The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This Standard is not met as evidenced by:</p> <p>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:</p> <ol style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>3. The laboratory reported approximately 245 patient results using Lot # 527011.</li> </ol>

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	<p>493.1274((c)(1) Standard: Cytology</p> <p>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:</p> <p>(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).</p> <p>(i) the review must be performed by an individual who meets one of the following qualifications:</p> <p>(A) A technical supervisor qualified under §§493.1449(b)(or (k).</p> <p>(B) A cytology general supervisor qualified under §493.1469.</p> <p>(C) A cytotechnologist qualified under § 493.1469(b)(2).</p> <p>(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.</p> <p>(iii) The review of those cases selected must be completed before reporting patient results.</p> <p>This Standard is not met as evidenced by:</p> <p>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:</p> <ol style="list-style-type: none"> <li>1. The laboratory lacked evidence of a quality control program for documenting the 10% review of negative gynecologic slides.</li> <li>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.</li> </ol>

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	<p>42 CFR 493.1105(a)(7)(iii)</p> <p>The laboratory must retain its records and, as applicable, slide, blocks, tissues, as follows:</p> <ul style="list-style-type: none"> <li>(i) Slides                             <ul style="list-style-type: none"> <li>(A) Retain cytology slide preparation for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception.)</li> <li>(B) Retain histopathology slides for at least 10 years from the date of examination.</li> </ul> </li> <li>(ii) Blocks. Retain pathology specimen blocks for at least 2 years from the date of examination.</li> <li>(iii) Tissue. Preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.</li> </ul> <p>This Standard is not met as evidenced by:</p> <p>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:</p>

	<ol style="list-style-type: none"><li>1. The laboratory accessioning records for July XX showed receipt of specimen XX-45332 was logged at 12:25 pm on 7/1/XX.</li><li>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.</li><li>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.</li></ol>
--	---

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	<p>42 CFR 493.1255(a)(1)                      Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures—</p> <ul style="list-style-type: none"> <li>(1) Following the manufacturer’s instruction using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer.</li> <li>(2) Using the criteria verified or established by the laboratory as specified in §493.1253(b)(3)—                             <ul style="list-style-type: none"> <li>(i) Using calibration materials appropriate for the test system and , if possible, traceable to a reference method or reference material of known value; and</li> <li>(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and</li> </ul> </li> <li>(3) Whenever calibration verification fails to meet the laboratory’s acceptable limits for calibration verification.</li> </ul> <p>This Standard is not met as evidenced by:</p> <p>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:</p> <ul style="list-style-type: none"> <li>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)</li> <li>2. The laboratory supervisor confirmed (HOW) on 10/03/XX at 10 am the laboratory had not performed calibration for 14 analytes. (HOW) (WHEN)</li> <li>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)</li> <li>4. The laboratory reported approximately 1400 patient results each month during XXXX. (WHO)</li> </ul>

**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	<p>42 CFR 493.1261(b)(c) Bacteriology                      (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.                      (b)(1)Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.                      (b)(2)The laboratory’s zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results.                      (c) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This Standard is not met as evidenced by:</p> <p>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:</p> <ol style="list-style-type: none"> <li>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.</li> <li>2 During an interview at approximately 7:50am on 10/26/08, the</li> </ol>

	<p>supervisor confirmed the laboratory did not perform antimicrobial susceptibility QC each day of patient testing.</p> <p>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.</p>
--	---

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	<p>42 CFR 493.1252(a)(1) Maintenance and Function Checks 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.</p> <p>This Standard is not met as evidenced by:</p> <p>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:</p> <ol style="list-style-type: none"> <li>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. 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.</li> <li>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.</li> </ol>

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	<p>42 CFR 493.(a)(1)-(8) Specimen submission, handling, and referral</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable:</p> <ol style="list-style-type: none"> <li>(1) Patient preparation.</li> <li>(2) Specimen collection.</li> <li>(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source.</li> <li>(4) Specimen storage and preservation.</li> <li>(5) Conditions for specimen transportation.</li> <li>(6) Specimen processing.</li> <li>(7) Specimen acceptability and rejection.</li> <li>(8) Specimen referral.</li> </ol> <p>This Standard is not met as evidenced by:</p> <p><b>A.</b> 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)</p> <ol style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>3. When interviewed, the specimen processor stated she was unaware of the written policy and labeled specimens as trained.</li> <li>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.</li> </ol> <p><b>B.</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</p>

	<p>specimen preservation for renin activity testing. The findings include:</p> <ol style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>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.</li> <li>4. The general supervisor confirmed the laboratory did not follow the reference laboratory's procedures for specimen processing for rennin activity testing.</li> </ol>
--	---

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	<p>42 CFR 493.1254(a)(1) 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</p> <p>This Standard is not met as evidenced by:</p> <ol style="list-style-type: none"> <li>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: <ol style="list-style-type: none"> <li>1. The Dimension User's Manual, Rev X, requires performance of weekly preventative maintenance.</li> </ol> </li> </ol>

	<ol style="list-style-type: none"><li>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.</li><li>3. The laboratory supervisor stated on 9/9/xx at 3pm the laboratory decided it was not necessary as the service tech performed maintenance during quarterly visits.</li></ol> <p><b>B.</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)</p> <ol style="list-style-type: none"><li>1. The cell counter user manual, Version X, required monthly maintenance be performed.</li><li>2. Review of cell counter preventive maintenance records showed the laboratory staff failed to perform and document the monthly cell-counter maintenance.</li><li>3. During an interview on 9/9/XXXX at 4pm, the supervisor stated the laboratory staff did not perform the required preventive maintenance.</li></ol>
--	---

## **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	<p>493.1252(d) Standard                      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.</p> <p>This Standard is not met as evidenced by;</p> <p>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.</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>1. The laboratory used cholesterol reagent which outdated on 5/XX for patient testing until July XXXX.</li> <li>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.</li> <li>3. Staff confirmed during an interview on 6/4/XX at 8am the laboratory used both of the expired reagents.</li> </ol>

**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	<p>42 CFR 493.1291(g)</p> <p>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.</p> <p>The Standard is not met as evidenced by:</p> <p>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)</p> <p>The findings include:</p> <ol style="list-style-type: none"> <li>1. Three randomly selected potassium reports with results above 6.5 Milliequivalents per liter (Meq/l) lacked documentation of alerting the requesting physician.               <ul style="list-style-type: none"> <li>#338 - 8.7 Meq/l on 9/3/XX</li> <li>#432 - 7.3 Meq/l on 9/7/XX</li> <li>#701 - 7.0 Meq/l on 9/30/XX</li> </ul> </li> <li>2. The general supervisor and director confirmed the laboratory staff did not call the physician with these results.</li> <li>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.</li> <li>4. The laboratory policy stated potassium results over 6.5 Meq/l were life threatening, and the lab must notify the requesting physician.</li> </ol>

## 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
<p>42 CFR 493.1256(d)(3)(iii) 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 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.</p>	<p><b>EXCEPTIONS:</b> 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.</p>

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	<p>42 CFR 493.1256(d)(4)</p> <p>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.</p> <p>This Standard is not met as evidenced by:</p> <p>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.)</p> <p>The findings include:</p> <ol style="list-style-type: none"> <li>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.</li> <li>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.</li> </ol>

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	<p>42 CFR 493.1489(a)                      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.</p> <p>This Standard was not met as evidenced by:</p> <p>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.</p>

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	<p>42CFR493.1101(c)                      The laboratory must be in compliance with Federal, State, and local laboratory requirements.</p> <p>This Standard is not met as evidenced by:</p> <p>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.</p>

## **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	<p>42 CFR 493.1407(e)(5)                      The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This Standard is not met as evidenced by:</p> <p>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:</p> <ol style="list-style-type: none"> <li>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.</li> <li>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</li> <li>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.</li> <li>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.</li> </ol>

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

TAG	SUMMARY STATEMENT OF DEFICIENCIES
D5891	<p data-bbox="423 436 683 468">42 CFR 493.1299(a)</p> <p data-bbox="423 474 1425 575">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</p> <p data-bbox="423 617 951 648">This Standard is not met as evidenced by:</p> <p data-bbox="423 690 1403 827">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</p>

## **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	<p>493.1201 Condition  <b>Bacteriology</b>                      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.</p> <p>This Condition is not met as evidenced by;</p> <p>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.</p>

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

TAG	SUMMARY STATEMENT OF DEFICIENCIES
D5300	<p>493.1240 Condition Preanalytic Systems                      Each laboratory that performs nonwaived testing must meet the applicable preanalytic 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.</p> <p>This Condition is not met as evidenced by;</p> <p>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</p>

	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	<p>493.801 Condition - Proficiency Testing Enrollment and testing of samples. 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.</p> <p>This Condition is not met as evidenced by;</p> <p>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.</p>

## **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: