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**TECHNICAL INSTRUCTIONS FOR THE DoD CLINICAL LABORATORY  
IMPROVEMENT PROGRAM**

The numbers following each paragraph title in this document correspond to the Code of Federal Regulations (CFR) 42 CFR Part 493 section number, and therefore do not run sequentially. For example, Chapter 2, paragraph 2-4, Test Categorization (§493.17) corresponds to section 17 of 42 CFR Part 493.

Authority: Sec. 353 of the Public Health Service Act and secs. 1102 and 1861 of the Social Security Act (42 U.S.C. 263a, 1302, and 1395hh).

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**CHAPTER 1****INTRODUCTION****1-1. BASIS AND SCOPE (§493.1)**

This document sets forth the technical provisions of the Department of Defense (DoD) Clinical Laboratory Improvement Program (CLIP) policy mandated by DoDI 6440.2, dated 20 April 1994. The CLIP is administered by the Center for Clinical Laboratory Medicine (CCLM). CCLM is also responsible for maintaining this document. The document states the minimal conditions that all laboratories must meet to be certified to perform testing on human specimens under the DoD CLIP. CLIP applies to all laboratories as defined under "laboratory" in the Glossary, Appendix B.

**1-2. REFERENCES**

Required and related publications are listed in Appendix A.

**1-3. EXPLANATION OF ABBREVIATIONS AND TERMS**

Abbreviations and special terms used in this publication are explained in the Glossary, Appendix B.

## CHAPTER 2

## GENERAL PROVISIONS

## 2-1. APPLICABILITY (§493.3)

a. Basic rule. Except as specified in paragraph b below, a laboratory will be cited as out of compliance with these regulations unless it has a current, unrevoked or unsuspended DoD certificate for minimal complexity, a DoD certificate of registration, a DoD certificate of compliance, a DoD certificate for provider-performed microscopy (PPM), or a DoD certificate of accreditation issued by the Service's Surgeon General (TSG) or their designee under the authority of the Office of Assistant Secretary of Defense (Health Affairs) (OASD(HA)) applicable to the category of examinations or procedures performed by the laboratory. These rules are applicable to laboratories located outside of the United States except where modified by Status of Forces agreements.

b. Exception. These rules do not apply to components or functions of:

(1) Any facility or component of a facility that only performs testing for forensic purposes;

(2) Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of, the health of individual patients;

(3) Laboratories that are regulated by Department of Defense Instruction (DoDI) 1010.16, or are certified by the National Laboratory Certification Program (NLCP) of the Substance Abuse and Mental Health Services Administration (SAMHSA) of Health and Human Services (HHS), in which drug testing is performed which meets HHS guidelines and regulations. However, all other testing conducted by a HHS NLCP-certified laboratory, or one governed by DoDI 1010.16, is subject to this rule.

(4) Deployable medical units, or medical laboratories assigned to field medical units that may perform limited human testing in a field environment for military training purposes (see Chapter 16 for guidance regarding specific requirements for deployable medical units).

c. Laboratories under DoD jurisdiction are subject to the rules of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), except, after consultation with HHS, as modified by OASD(HA). The rules, as modified, are specified in this Pamphlet. DoD shall be responsible for

the implementation of, and compliance with, the rules (as modified) with respect to the laboratories under DoD jurisdiction.

(1) During declared or undeclared wars, or when under a period of mobilization, OASD(HA), the Service's Surgeons General (TSG), or subordinate medical commanders may temporarily modify these rules as required.

(2) OASD(HA) or TSG may modify these rules as required for laboratories which are components of deployable operational forces.

(3) OASD(HA) or TSG may modify these rules as required for laboratories which are located in overseas locations.

## 2-2. CATEGORIES OF TESTS BY COMPLEXITY (§493.5)

a. Laboratory tests are categorized as one of the following:

(1) Minimal complexity (waived).

(2) Tests of moderate complexity, including the subcategory of Provider-Performed Microscopy (PPM) procedures.

(3) High complexity.

b. A laboratory may perform only minimal complexity tests, only PPM tests, only tests of moderate complexity, only tests of high complexity, or any combination of these tests depending upon the laboratory's CLIP certificate.

c. Each laboratory must possess one of the following, as defined in the Glossary, Appendix B:

(1) Certificate of registration

(2) Certificate for minimal complexity testing

(3) Certificate for provider-performed microscopy

(4) Certificate of compliance

(5) Certificate of accreditation.

## 2-3. LABORATORIES PERFORMING MINIMAL COMPLEXITY TESTS (§493.15)

a. Tests for certificate for minimal complexity (waived) must meet the descriptive criteria specified in paragraph b below.

b. Test systems are simple laboratory examinations and procedures which:

- (1) Are cleared by the Food and Drug Administration (FDA) for home use;
- (2) Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or
- (3) Pose no reasonable risk of harm to the patient if the test is performed incorrectly.

c. A laboratory may qualify for a certificate to perform tests of minimal complexity under CLIP if it restricts the tests that it performs to one or more of the following minimal complexity tests or examinations (or additional tests added to this category as provided under paragraph d below) and no others.

(1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following:

- Bilirubin
- Glucose
- Hemoglobin
- Ketone
- Leukocytes
- Nitrite
- pH
- Protein
- Specific Gravity
- Urobilinogen

(2) Fecal occult blood.

(3) Ovulation tests - visual color comparison tests for human luteinizing hormone.

(4) Urine pregnancy tests - visual color comparison tests.

(5) Erythrocyte sedimentation rate - non-automated.

(6) Hemoglobin - copper sulfate - non-automated.

(7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use.

(8) Spun microhematocrit.

(9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.

d. HHS will determine whether a laboratory test meets the criteria listed under paragraph b above for a minimal complexity test. Revisions to the list of minimal complexity tests approved by HHS will be published in the FEDERAL REGISTER in a notice with opportunity for comment.

e. Laboratories eligible for a certificate for minimal complexity must:

(1) Follow manufacturers' instructions for performing the test;

(2) Meet the requirements in Chapter 3, Certificate for Minimal Complexity;

(3) Analyze and document the results of controls for the tests as recommended by the test manufacturer;

(4) Ensure that training to properly perform the test(s) is documented for each employee; and

(5) Participate in a proficiency testing program when proficiency testing is commercially available from a CMS approved program for the tests performed. **The proficiency testing program guidance contained in Chapter 7 is applicable to any proficiency testing performed for minimal complexity tests.**

#### 2-4. TEST CATEGORIZATION (§493.17)

a. Notices will be published in the FEDERAL REGISTER which list each specific test system, assay, and examination categorized by complexity. The seven criteria used to categorize tests may be found at 42 CFR 493.17. An on-line database of approved tests and their complexity can be found at <http://www.fda.gov/cdrh/CLIA/index.html>

b. For new commercial test systems, assays, or examinations, the manufacturer, as part of its 510(k) and Pre-Market Approval (PMA) application to the FDA, will submit supporting data for device/test categorization. The FDA will determine the complexity category, notify the manufacturers directly, and will simultaneously inform both the Centers for Medicare and Medicaid Services (CMS) and Centers for Disease Control and Prevention (CDC) of the device/test category.

(1) FDA will consult with the CDC concerning test categorization in the following three situations:

(a) When categorizing previously uncategorized new technology;

(b) When FDA determines it to be necessary in cases involving a request for a change in categorization; and

(c) If a manufacturer requests review of a categorization decision by FDA in accordance with 21 CFR 10.75.

(2) Test categorization will be effective as of the notification of the applicant.

c. For test systems, assays, or examinations not commercially available, DoD laboratories may submit a written request for categorization through TSG and DoD to the Public Health Service (PHS). These requests will be forwarded to the CDC for evaluation; CDC will determine the complexity category and notify the applicant, CMS, and the FDA of the categorization decision. Test categorization will be effective as of the notification to the applicant. In the case of a request for a change of category or for previously uncategorized new technology, PHS will receive the request application and forward it to the CDC for categorization.

d. A request for recategorization will be accepted for review if it is based on new information not previously submitted in a request for categorization or recategorization by the same applicant and will not be considered more frequently than once per year.

e. If a laboratory test system, assay or examination does not appear on the lists of tests in the FEDERAL REGISTER notices, it is considered to be a test of high complexity until PHS, upon request, reviews the matter and notifies the applicant of its decision. Test categorization is effective as of the notification to the applicant.

f. PHS will publish revisions periodically to the list of moderate and high complexity tests in the FEDERAL REGISTER in a notice with opportunity for comment.

**2-5. PROVIDER-PERFORMED MICROSCOPY PROCEDURES (§493.19)**

a. Procedures to be categorized as provider-performed microscopy procedures must meet the criteria specified in paragraph b below.

b. Procedures must meet the following specifications:

(1) The examination must be personally performed by one of the following practitioners:

(a) A physician during the patient's visit, on a specimen obtained from his or her own patient or from a patient of a clinic or group medical practice of which the physician is a member or an employee.

(b) A midlevel practitioner (nurse practitioner, nurse midwife, or physician assistant) under the supervision of a physician, or in independent practice (only if licensed by the recognized licensing agency of a State, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands) and credentialed to practice their specialty in a DoD medical treatment facility (MTF), during the patient's visit, on a specimen obtained from his or her own patient or from a patient of a clinic, group medical practice, or other health care provider of which the midlevel practitioner is a member or an employee.

(c) A dentist during the patient's visit, on a specimen obtained from his or her own patient or from a patient of a clinic or group dental practice of which the dentist is a member or an employee.

(2) The procedure must be categorized as moderately complex.

(3) The primary instrument for performing the test is the microscope, limited to bright-field or phase-contrast microscopy.

(4) The specimen is labile or delay in performing the test could compromise the accuracy of the test result.

(5) Control materials are not available to monitor the entire testing process.

(6) Limited specimen handling or processing is required.

c. A laboratory may qualify to perform tests under this provision if it restricts provider-performed microscopy examinations to one or more of the following procedures (or additional procedures added to this list as provided at paragraph d below), minimal complexity tests, and no others;

(1) All direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular

elements.

- (2) All potassium hydroxide (KOH) preparations
- (3) Pinworm examinations
- (4) Fern tests
- (5) Post-coital direct, qualitative examinations of vaginal or cervical mucous
- (6) Urine sediment examinations
- (7) Nasal smears for granulocytes
- (8) Fecal leukocyte examinations
- (9) Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility).

d. Revisions to criteria and the list of provider-performed microscopy procedures.

(1) The Clinical Laboratory Improvement Advisory Committee (CLIAAC) will conduct reviews upon request of HHS and recommend to HHS revisions to the criteria for categorization of procedures.

(2) HHS will determine whether a laboratory procedure meets the criteria listed under paragraph b above for a provider-performed microscopy procedure. Revisions to the list of provider-performed microscopy procedures proposed by HHS will be published in the FEDERAL REGISTER as a notice with an opportunity for public comment.

e. Laboratories eligible for test performance under the provider-performed microscopy examination provision must:

- (1) Meet the applicable requirements in Chapters 4, 5, 7, 10, 11, and 12.
- (2) Be subject to inspection as specified under Chapter 13.

**2-6. LABORATORIES PERFORMING TESTS OF MODERATE COMPLEXITY (§493.20)**

a. A laboratory may qualify for a certificate to perform tests of moderate complexity provided that it restricts its test performance to minimal complexity tests or examinations and one or more tests or examinations meeting criteria for tests of moderate complexity, including the subcategory of PPM procedures.

b. A laboratory that performs tests or examinations of moderate complexity must meet the applicable requirements in Chapters 4, 5, 7, 10, 11, 12, and 13. Under a registration certificate or certificate of compliance, laboratories also performing PPM procedures must meet the inspection requirements at paragraphs 13-2 and 13-4.

c. If the laboratory also performs minimal complexity tests listed in paragraph 2-3, compliance with Chapters 3, 10, 11, and 12 is not applicable to the minimal complexity tests. However, the laboratory must comply with the requirements in paragraph 2-3e and paragraphs 13-2 and 13-3.

**2-7. LABORATORIES PERFORMING TESTS OF HIGH COMPLEXITY (§493.25)**

a. A laboratory must obtain a certificate for tests of high complexity if it performs one or more tests that meet the criteria for tests of high complexity as specified in paragraph 2-4a.

b. A laboratory performing one or more tests of high complexity must meet the applicable requirements of Chapters 4, 5, 7, 10, 11, 12, and 13.

c. If the laboratory also performs tests of moderate complexity, the applicable requirements of Chapters 4, 5, 7, 10, 11, 12, and 13 must be met. Under a registration certificate or certificate of compliance, PPM procedures must meet the inspection requirements at paragraphs 13-2 and 13-4.

d. If the laboratory also performs minimal complexity tests, the requirements of Chapters 3, 10, 11, and 12 are not applicable for the minimal complexity tests. However, the laboratory must comply with the requirements in paragraph 2-3e and paragraphs 13-2 and 13-3.

CHAPTER 3

CERTIFICATE FOR MINIMAL COMPLEXITY

3-1. APPLICATION FOR A CERTIFICATE FOR MINIMAL COMPLEXITY TESTING (§493.35)

a. Filing of application. Except as specified in paragraph b below, a laboratory performing only one or more minimal complexity tests, listed in paragraph 2-3, must file a separate application for each laboratory location.

b. Exceptions

(1) Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.

(2) DoD laboratories that engage in limited (not more than a combination of 15 moderate or minimal complexity tests per certificate) public health testing may file a single application.

(3) DoD laboratories under the jurisdiction of a single hospital or clinic commander that provide services limited to minimal complexity tests may file a single application or multiple applications for the minimal complexity laboratory testing sites under their command.

c. Application format and contents. The application must:

(1) Be made to TSG or their designee on a form or forms prescribed by OASD(HA).

(2) Be signed by the laboratory director and the commander of the hospital or clinic who attest that the laboratory will be operated in accordance with the requirements established in this Pamphlet.

(3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including:

(a) The name and the total number of test procedures and examinations performed annually (excluding tests the laboratory may run for quality control, quality assurance or proficiency

testing purposes).

(b) The methodologies for each laboratory test procedure or examination performed, or both.

(c) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.

d. Laboratories that perform one or more minimal complexity tests listed in paragraph 2-3 and no other tests must:

(1) Make records available and submit reports through command channels to TSG or their designee as TSG or their designee may reasonably require to determine compliance with this paragraph and paragraph 2-3e.

(2) Agree to permit announced and unannounced inspections by TSG or their designee in accordance with Chapter 13 under the following circumstances:

(a) When TSG or their designee has substantive reason to believe that the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health.

(b) To evaluate complaints from health care beneficiaries or MTF/Clinic commanders.

(c) On a random basis to determine whether the laboratory is performing tests not listed in paragraph 2-3.

e. If TSG determines that the application for a certificate for minimal complexity testing is to be denied, TSG will, through command channels, provide the laboratory with a written statement of the grounds on which the denial is based and an opportunity for appeal, in accordance with Chapter 14.

### **3-2. REQUIREMENTS FOR A CERTIFICATE FOR MINIMAL COMPLEXITY TESTING (§493.37)**

a. TSG or their designee will issue a certificate for minimal complexity testing to a laboratory only if the laboratory meets the requirements of paragraph 3-1.

b. Laboratories issued a certificate for minimal complexity testing:

(1) Are subject to the requirements of this chapter and paragraph 2-3e.

(2) Must permit announced or unannounced inspections by TSG or their designee in accordance with Chapter 13.

c. In accordance with Chapter 14, TSG will, through command channels, suspend, revoke, or limit a laboratory's certificate for minimal complexity testing for failure to comply with the requirements of this chapter.

d. A certificate for minimal complexity testing issued under this chapter is valid for no more than 2 years. In the event of a noncompliance determination resulting in TSG action to revoke, suspend, or limit the laboratory's certificate for minimal complexity testing, TSG will, through command channels, provide the laboratory with a statement of grounds on which the determination of noncompliance is based, and offer an opportunity for appeal as provided in Chapter 14.

e. A laboratory seeking to renew its certificate for minimal complexity testing must:

(1) Complete the renewal application prescribed by OASD(HA) and return it through command channels to TSG or their designee not less than 1 month nor more than 3 months before the expiration of the certificate.

(2) Submit verification of CLIP compliance with the renewal application. Acceptable verification is either a copy of the letter from a deemed accrediting organization granting accreditation, or a memorandum of compliance with the provisions of the CLIP from the facility commander or designee (e.g., acting facility commander, chief of the medical staff, or laboratory director) and a completed compliance self-assessment checklist form. An example of the memorandum of compliance and the compliance self assessment checklist form can be downloaded from the CCLM web page at: <http://www.afip.org/OCLAB/index.html>.

(3) Meet the requirements of paragraphs 3-1 and 3-2.

f. A laboratory with a certificate for minimal complexity testing that wishes to perform examinations or test procedures not listed in the minimal complexity test category must meet the requirements set forth in Chapter 4 or Chapter 5, as applicable.

**3-3. NOTIFICATION REQUIREMENTS FOR LABORATORIES ISSUED A CERTIFICATE FOR MINIMAL COMPLEXITY TESTING (§493.39)**

Laboratories performing one or more tests listed in paragraph 2-3 and no others must notify TSG or their designee if any of the following occur:

a. Before performing and reporting results for any test or examination that is not specified under paragraph 2-3 for which it does not have the appropriate certificate as required in Chapter 4 or Chapter 5.

b. Within 30 days of any change(s) in:

(1) Name;

(2) Location; or

(3) Director.

CHAPTER 4

REGISTRATION CERTIFICATE, CERTIFICATE FOR PROVIDER-PERFORMED  
MICROSCOPY PROCEDURES, AND CERTIFICATE OF COMPLIANCE

4-1. APPLICATION FOR REGISTRATION CERTIFICATE, CERTIFICATE FOR PROVIDER-PERFORMED  
MICROSCOPY (PPM) PROCEDURES, AND CERTIFICATE OF COMPLIANCE (§493.43)

a. Except as specified in paragraph b below, all laboratories performing tests of moderate complexity (including the subcategory of provider performed microscopy procedures), or high complexity, or any combination of these tests, must file a separate application for each laboratory location.

b. Exceptions:

(1) Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.

(2) DoD laboratories that engage in limited (not more than a combination of 15 moderate or minimal complexity tests per certificate) public health testing may file a single application.

(3) DoD laboratories under the jurisdiction of a single hospital or clinic commander and that are supervised by a single laboratory director may file a single application or multiple applications for the laboratory sites under their command.

c. The application must:

(1) Be made to TSG or their designee on a form or forms prescribed by OASD(HA).

(2) Be signed by the laboratory director and the commander of the hospital or clinic who attest that the laboratory will be operated in accordance with the requirements established in this Pamphlet.

(3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including:

(a) The name and total number of test procedures and examinations performed annually (excluding

minimal complexity tests or tests for quality control, quality assurance or proficiency testing purposes).

(b) The methodologies for each laboratory test procedure or examination performed, or both.

(c) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.

d. All laboratories must make records available and submit reports through command channels to TSG or their designee as TSG or their designee may reasonably require to determine compliance with this paragraph.

#### 4-2. REQUIREMENTS FOR A REGISTRATION CERTIFICATE (§493.45)

Laboratories performing only minimal complexity tests, PPM procedures, or any combination of these tests, are not required to obtain a registration certificate.

a. A registration certificate issued by TSG or their designee is required in the following cases:

(1) Initially for all laboratories performing test procedures of moderate complexity (other than the subcategory of PPM procedures) or high complexity, or both.

(2) For all laboratories that have been issued a certificate for minimal complexity testing or certificate for PPM procedures that intend to perform tests of moderate or high complexity, or both, in addition to those tests listed in paragraph 2-3 or specified as PPM procedures.

b. TSG or their designee will issue a registration certificate if the laboratory:

(1) Complies with the requirements of paragraph 4-1.

(2) Agrees to notify TSG or their designee within 30 days of any changes in name, location or director.

(3) Agrees to treat proficiency testing samples in the same manner as it treats patient specimens.

c. Prior to the expiration of the registration certificate, a laboratory must:

(1) Be inspected as specified in Chapter 13 by TSG or their designee, or by a private, nonprofit accrediting agency approved by HHS.

(2) Demonstrate compliance with the applicable requirements of this chapter and Chapters 7, 10, 11, 12 and 13.

d. In accordance with Chapter 14, TSG will, through command channels, initiate suspension or revocation of a laboratory's registration certificate, and will deny the laboratory's application for a certificate of compliance, for failure to comply with the requirements set forth in this chapter. TSG, or their designee, may also impose certain alternative sanctions.

e. A registration certificate is:

(1) Valid for a period of no more than two years or until such time as an inspection to determine program compliance can be conducted, whichever is shorter.

(2) Not renewable; however, a registration certificate may be extended if compliance has not been determined by TSG or their designee prior to the expiration date of the registration certificate.

f. In the event of a non-compliance determination resulting in a TSG denial of a laboratory's certificate of compliance application, TSG will, through command channels, provide the laboratory with a statement of grounds on which the non-compliance determination is based and offer an opportunity for appeal as provided in Chapter 14. If a laboratory appeals within the time specified by TSG, it retains its registration certificate or extended registration certificate until an appeal decision is made as provided in Chapter 14, except when TSG finds that conditions at the laboratory pose an imminent and serious risk to human health.

**4-3. REQUIREMENTS FOR A CERTIFICATE FOR PROVIDER-PERFORMED MICROSCOPY (PPM) PROCEDURES (§493.47)**

a. A certificate for provider-performed microscopy procedures is required:

(1) Initially for all laboratories performing test procedures specified as PPM procedures.

(2) For all certificate for minimal complexity laboratories that intend to perform only test procedures specified as

PPM procedures in addition to those listed in paragraph 2-3.

b. TSG or their designee will issue a certificate for provider-performed microscopy procedures if the laboratory complies with the requirements of paragraph 4-1.

c. Laboratories issued a certificate for provider-performed microscopy procedures are subject to:

(1) The notification requirements of paragraph 4-6.

(2) The applicable requirements of this chapter and Chapters 7, 10, 11, and 12.

(3) Inspection only under the circumstances specified under paragraphs 13-2 and 13-3, but are not routinely inspected to determine compliance with the requirements specified in paragraphs c(1) and (2) above.

d. In accordance with Chapter 14, TSG will, through command channels, initiate suspension, limitation, or revocation of a laboratory's certificate for provider-performed microscopy procedures for failure to comply with the applicable requirements set forth in this chapter. TSG, or their designee, may also impose certain alternative sanctions.

e. A certificate for provider-performed microscopy (PPM) procedures is valid for a period of no more than 2 years.

#### 4-4. REQUIREMENTS FOR A CERTIFICATE OF COMPLIANCE (§493.49)

A certificate of compliance may include any combination of tests categorized as moderate complexity or high complexity or listed in paragraph 2-3 as minimal complexity tests. Moderate complexity tests may include those specified as PPM procedures.

a. TSG or their designee will issue a certificate of compliance to a laboratory only if the laboratory:

(1) Meets the requirements of paragraphs 4-1 and 4-2.

(2) Meets the applicable requirements of this chapter and Chapters 7, 10, 11, 12, and 13.

b. Laboratories issued a certificate of compliance:

(1) Are subject to the notification requirements of paragraph 4-5.

(2) Must permit announced or unannounced inspections by TSG, or their designee, in accordance with Chapter 13:

(a) To determine compliance with the applicable requirements of this Pamphlet.

(b) To evaluate complaints from health care beneficiaries or MTF/Clinic commanders;

(c) When TSG or their designee has substantive reason to believe that any test is being performed, or the laboratory is being operated, in a manner that constitutes an imminent and serious risk to human health.

c. Failure to comply with the requirements of this chapter will result in suspension, revocation or limitation of a laboratory's certificate of compliance in accordance with Chapter 14.

d. A certificate of compliance issued under this chapter is valid for no more than 2 years.

e. In the event of a non-compliance determination resulting in a TSG action to revoke, suspend or limit the laboratory's certificate of compliance, TSG will, through command channels:

(1) Provide the laboratory with a statement of grounds on which the determination of non-compliance is based.

(2) Offer an opportunity for appeal as provided in Chapter 14. If the laboratory appeals within 30 days of the notice of sanction, it retains its certificate of compliance or extended certificate of compliance until an appeal decision is made by TSG, except when TSG finds that conditions at the laboratory pose an imminent and serious risk to human health, or when criteria at paragraphs 14-12a(4) and (5) are met.

f. A laboratory seeking to renew its certificate of compliance must:

(1) Complete and return the renewal application through command channels to TSG or their designee not less than 1 month, nor more than 3 months, prior to the expiration date of the certificate.

(2) Meet the requirements of paragraph 4-1 and paragraph b(2) above.

g. If TSG determines that the application for the renewal of a certificate of compliance is to be denied or limited, TSG will, utilizing command channels, notify the laboratory in writing of the:

- (1) Basis for denial of the application.
- (2) Opportunity for appeal as provided in Chapter 14.
- (3) If a laboratory appeals within the time period specified by TSG, it retains its certificate of compliance or extended certificate of compliance until an appeal decision is made as provided in Chapter 14, except when TSG finds that conditions at the laboratory pose an imminent and serious risk to human health.

**4-5. NOTIFICATION REQUIREMENTS FOR LABORATORIES ISSUED A CERTIFICATE OF COMPLIANCE (§493.51)**

Laboratories issued a certificate of compliance must:

a. Notify TSG or their designee within 30 days of any change in:

- (1) Name;
- (2) Location; or
- (3) Director.

b. Notify TSG or their designee no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory's certificate of compliance, so that compliance with requirements can be determined.

c. Notify TSG or their designee no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance.

**4-6. NOTIFICATION REQUIREMENTS FOR LABORATORIES ISSUED A CERTIFICATE FOR PROVIDER-PERFORMED MICROSCOPY PROCEDURES (§493.53)**

Laboratories issued a certificate for provider-performed microscopy (PPM) procedures must notify TSG or their designee:

a. Before performing and reporting results for any test of moderate or high complexity, or both, in addition to tests specified as PPM procedures or any test or examination that is not specified in paragraph 2-3, for which it does not have a registration certificate as required in Chapter 4 or Chapter 5.

b. Within 30 days of any change in:

(1) Name;

(2) Location; or

(3) Director.

## CHAPTER 5

## CERTIFICATE OF ACCREDITATION

5-1. APPLICATION FOR REGISTRATION CERTIFICATE AND CERTIFICATE OF ACCREDITATION  
(§493.55)

a. A laboratory may be issued a certificate of accreditation in lieu of the applicable certificate specified in Chapter 3 or Chapter 4 provided the laboratory:

(1) Meets the standards of a private, non-profit accreditation program approved by HHS.

(2) Files a separate application for each location, except as specified in paragraph b below.

b. Exceptions

(1) Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.

(2) DoD laboratories that engage in limited (not more than a combination of 15 moderate or minimal complexity tests per certificate) public health testing may file a single application.

(3) DoD laboratories under the jurisdiction of a single hospital or clinic commander and that are supervised by a single laboratory director may file a single application or multiple applications for the laboratory sites under their command.

c. The application must:

(1) Be made to TSG or their designee on a form or forms prescribed by OASD(HA).

(2) Be signed by the laboratory director and the commander of the hospital or clinic who attest that the laboratory will be operated in accordance with the requirements established in this Pamphlet.

(3) Describe the characteristics of the laboratory

operation and the examinations and other test procedures performed by the laboratory including:

(a) The name and total number of tests and examinations performed annually (excluding minimal complexity tests and tests for quality control, quality assurance or proficiency testing purposes).

(b) The methodologies for each laboratory test procedure or examination performed, or both.

(c) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.

d. All laboratories must make records available and submit reports through command channels to TSG or their designee as TSG or their designee may reasonably require to determine compliance with this paragraph.

**5-2. REQUIREMENTS FOR A REGISTRATION CERTIFICATE (§493.57)**

A registration certificate is required for all laboratories seeking a certificate of accreditation, unless the laboratory holds a valid certificate of compliance issued by TSG or their designee.

a. TSG or their designee will issue a registration certificate if the laboratory:

(1) Complies with the requirements of paragraph 5-1.

(2) Agrees to notify TSG or their designee within 30 days of any changes in name, location, or director.

(3) Agrees to treat proficiency testing samples in the same manner as it treats patient specimens.

b. The laboratory must provide TSG or their designee with proof of accreditation by an approved accreditation program:

(1) Within 11 months of issuance of the registration certificate; or

(2) Prior to the expiration of the certificate of compliance.

c. If such proof of accreditation is not supplied within a time frame specified in b above, the laboratory must meet, or continue to meet,

the requirements of paragraph 4-4.

d. In accordance with Chapter 14, TSG will, through command channels, initiate suspension, revocation, or limitation of a laboratory's registration certificate and will deny the laboratory's application for a certificate of accreditation for failure to comply with the requirements set forth in this chapter. TSG, or their designee, may also impose certain alternative sanctions.

e. A registration certificate is valid for a period of no more than 2 years. However, it may be extended if the laboratory is subject to Chapter 4, as specified in paragraph c above, and compliance has not been determined by TSG or their designee before the expiration date of the registration certificate.

f. In the event that the laboratory does not meet the requirements of this chapter, TSG will, through command channels:

(1) Deny a laboratory's request for a certificate of accreditation.

(2) Notify the laboratory if it must meet the requirements for a certificate as defined in Chapter 4.

(3) Provide the laboratory with a statement of grounds on which the application denial is based.

(4) Offer an opportunity for appeal on the application denial as provided in Chapter 14. If the laboratory appeals within the time specified by TSG, the laboratory will retain its registration certificate or extended registration certificate until an appeal decision is made by TSG as provided in Chapter 14, unless TSG finds that conditions at the laboratory pose an imminent and serious risk to human health.

#### 5-3. REQUIREMENTS FOR A CERTIFICATE OF ACCREDITATION (§493.61)

a. TSG or their designee will issue a certificate of accreditation to a laboratory if the laboratory meets the requirements of paragraph 5-2 or, if applicable, paragraph 4-4.

b. Laboratories issued a certificate of accreditation must:

(1) Treat proficiency testing samples in the same manner as patient samples.

(2) Meet the requirements of paragraph 5-4.

(3) Comply with the requirements of the approved accreditation program.

(4) Permit random sample validation and complaint inspections as required in Chapter 13.

(5) Permit TSG or their designee to monitor the correction of any deficiencies found through the inspections specified in paragraph b(4) above.

(6) Authorize the accreditation program to release to TSG or their designee the laboratory's inspection findings whenever TSG or their designee conducts random sample or complaint inspections; and

(7) Authorize the accreditation program to submit to TSG or their designee the laboratory's proficiency testing results.

c. A laboratory failing to meet the requirements of this paragraph:

(1) Will no longer meet the requirements of CLIP by virtue of its accreditation in an approved accreditation program;

(2) Will be subject to full determination of compliance by TSG or their designee;

(3) May be subject to suspension, revocation, or limitation of the laboratory's certificate of accreditation, or to certain alternative sanctions.

d. A certificate of accreditation issued under this chapter is valid for no more than 2 years. In the event of a non-compliance determination as a result of a random sample validation or complaint inspection, a laboratory will be subject to a full review by TSG or their designee.

e. Failure to meet the applicable requirements of the CLIP will result in an action by TSG to suspend, revoke or limit the certificate of accreditation. TSG will, through command channels:

(1) Provide the laboratory with a statement of grounds on which the determination of noncompliance is based.

(2) Notify the laboratory if it is eligible to apply for a certificate as defined in Chapter 4.

(3) Offer an opportunity for appeal as provided in Chapter 14.

(4) If the laboratory appeals within the time frame specified by TSG, it retains its certificate of accreditation or extended certificate of accreditation

until an appeal decision is made by TSG as provided in Chapter 14, unless TSG finds that conditions at the laboratory pose an imminent and serious risk to human health.

f. In the event the accreditation organization's approval is removed by HHS, the laboratory will be subject to the applicable requirements of Chapter 4 or paragraph 5-2.

g. A laboratory seeking to renew its certificate of accreditation must:

(1) Complete and return the renewal application through command channels to TSG or their designee 1 to 3 months prior to the expiration of the certificate of accreditation.

(2) Submit a copy of the letter from CAP, JCAHO or other agency granting accreditation with the application or within 30 days of receipt of the accreditation notice.

(3) Meet the requirements of this chapter.

h. If TSG determines that the renewal application for a certificate of accreditation is to be denied or limited, TSG will, utilizing command channels, notify the laboratory in writing of:

(1) The basis for denial of the application.

(2) Whether the laboratory is eligible for a certificate as defined in Chapter 4.

(3) The opportunity for appeal of TSG's action to deny the renewal application for a certificate of accreditation as provided in Chapter 14.

(4) If the laboratory appeals within the time frame specified by TSG, it retains its certificate of accreditation or extended certificate of accreditation until an appeal decision is made by TSG as provided in Chapter 14, unless TSG finds that conditions at the laboratory pose an imminent and serious risk to human health.

5-4. NOTIFICATION REQUIREMENTS FOR LABORATORIES ISSUED A CERTIFICATE OF ACCREDITATION  
(§493.63)

Laboratories issued a certificate of accreditation must:

a. Notify TSG or their designee and the approved accreditation program within 30 days of any changes in:

- (1) Name.
- (2) Location.
- (3) Director.

b. Notify the approved accreditation program no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included in the laboratory's accreditation, so that the accreditation organization can determine compliance and the certificate of accreditation can be amended.

c. Notify the accreditation program no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of accreditation.

## CHAPTER 6

## Accreditation by a Private, Nonprofit Accreditation Organization

## 6-1. GENERAL REQUIREMENTS FOR LABORATORIES (§493.551)

a. Applicability. TSG or their designee may deem a laboratory to meet all applicable DoD CLIP requirements through accreditation by a private, nonprofit accreditation program (that is, grant deemed status) if the following conditions are met:

(1) The requirements of the accreditation organization are equal to, or more stringent than, the DoD CLIP condition-level requirements specified in this Pamphlet, and the laboratory would meet the condition-level requirements if it were inspected against these requirements.

(2) The accreditation program is approved by CMS.

(3) The laboratory authorizes the approved accreditation organization to release to TSG or their designee all records and information required and permits inspections as outlined in this Pamphlet.

b. A laboratory seeking to meet DoD CLIP requirements through accreditation by an approved accreditation organization must do the following:

(1) Obtain a certificate of accreditation as required in Chapter 5.

(2) Meet the proficiency testing (PT) requirements in Chapter 7.

(3) Authorize its PT organization to furnish to its accreditation organization the results of the laboratory's participation in an approved PT program for the purpose of monitoring the laboratory's PT and for making the annual PT results, along with explanatory information required to interpret the PT results, available on a reasonable basis, upon request of any person. A laboratory that refuses to authorize release of its PT results is no longer deemed to meet the condition-level requirements and is subject to a full review by TSG or their designee, in accordance with Chapter 13, and may be subject to the suspension or revocation of its certificate of accreditation under paragraph 14-12.

(4) Authorize its accreditation organization to release to TSG or their designee the laboratory's PT results that constitute unsuccessful participation in an approved PT

program, in accordance with the definition of "unsuccessful participation in an approved PT program" as specified in the Glossary (Appendix B), when the laboratory has failed to achieve successful participation in an approved PT program.

(5) Authorize its accreditation organization to release to TSG or their designee a notification of the actions taken by the organization as a result of the unsuccessful participation in a PT program within 30 days of the initiation of the action. Based on this notification, TSG or their designee may take an adverse action against a laboratory that fails to participate successfully in an approved PT program.

c. After an accreditation organization has withdrawn or revoked its accreditation of a laboratory, the laboratory retains its certificate of accreditation for 45 days after the laboratory receives notice of the withdrawal or revocation of the accreditation, or the effective date of any action taken by TSG, whichever is earlier.

**6-2 VALIDATION INSPECTIONS - BASIS AND FOCUS (§493.563)**

a. TSG or their designee may conduct an inspection of an accredited laboratory that has been issued a certificate of accreditation on a representative sample basis or in response to a substantial allegation of noncompliance.

b. Validation inspection conducted on a representative sample basis.

(1) If TSG or their designee conducts a validation inspection on a representative sample basis, the inspection is comprehensive, addressing all condition-level requirements, or it may be focused on a specific condition-level requirement.

(2) The number of laboratories sampled is sufficient to allow a reasonable estimate of the performance of the accreditation organization.

c. Validation inspection conducted in response to a substantial allegation of noncompliance.

(1) If TSG or their designee conducts a validation inspection in response to a substantial allegation of noncompliance, the inspection focuses on any condition-level requirement that TSG or their designee determines to be related to the allegation.

(2) If TSG or their designee substantiates a deficiency and determines that the laboratory is out of compliance with any condition-level requirement, TSG or their designee conducts a full DoD CLIP inspection.

**6-3 SELECTION FOR VALIDATION INSPECTION - LABORATORY RESPONSIBILITIES (§493.565)**

A laboratory selected for a validation inspection must do the following:

- a. Authorize its accreditation organization to release to TSG or their designee, on a confidential basis, a copy of the laboratory's most recent full, and any subsequent partial, inspection.
- b. Authorize TSG or their designee to conduct a validation inspection.
- c. Provide TSG or their designee with access to all facilities, equipment, materials, records, and information that TSG or their designee determines have a bearing on whether the laboratory is being operated in accordance with the requirements of this Pamphlet, and permit TSG or their designee to copy material or require the laboratory to submit material.
- d. If the laboratory possesses a valid certificate of accreditation, authorize TSG or their designee to monitor the correction of any deficiencies found through the validation inspection.

**6-4 REFUSAL TO COOPERATE WITH VALIDATION INSPECTION (§493.567)**

Laboratory with a certificate of accreditation.

(1) A laboratory with a certificate of accreditation that refuses to cooperate with a validation inspection by failing to comply with the requirements in paragraph 6-3 -

(a) Is subject to full review by TSG or their designee, in accordance with this Pamphlet; and

(b) May be subject to suspension, revocation, or limitation of its certificate of accreditation under Chapter 14.

(2) A laboratory with a certificate of accreditation is again deemed to meet the condition-level requirements by virtue of its accreditation when the following conditions exist:

(a) The laboratory withdraws any prior refusal to authorize its accreditation organization to release a copy of the laboratory's current accreditation inspection, PT results, or notification of any adverse actions resulting from PT failure.

(b) The laboratory withdraws any prior refusal to allow a validation inspection.

(c) TSG or their designee finds that the laboratory meets all the condition-level requirements.

**6-5 CONSEQUENCES OF A FINDING OF NONCOMPLIANCE AS A RESULT OF A VALIDATION INSPECTION (§493.569)**

If a validation inspection results in a finding that an accredited laboratory is out of compliance with one or more condition-level requirements, the laboratory is subject to -

(1) The same requirements and survey and enforcement processes applied to laboratories that are not accredited and that are found out of compliance following an inspection under this Pamphlet; and

(2) Full review by TSG or their designee, in accordance with this Pamphlet; that is, the laboratory is subject to the principal and alternative sanctions in paragraph 14-3.

**6-6 DISCLOSURE OF ACCREDITATION OR VALIDATION INSPECTION RESULTS (§493.571)**

a. TSG may disclose accreditation organization inspection results to the public only if the results are related to an enforcement action taken by TSG or their designee.

b. TSG may disclose the results of all validation inspections conducted by TSG or their designee.

**6-7 REMOVAL OF DEEMING AUTHORITY (§493.575)**

a. The DoD CLIAC will review all CMS deeming authority removal actions and forward a recommendation for action to the OASD(HA).

b. Withdrawal of deeming authority approval - effect on laboratory status -

(1) Accredited laboratory. After CMS withdraws approval of an accreditation organization's deeming authority, the certificate of accreditation of each affected laboratory continues in effect for 60 days after it receives notification of the withdrawal of approval.

(2) Extension. After CMS withdraws approval of an accreditation organization, TSG or their designee may extend the period for an additional 60 days for a laboratory if it determines that the laboratory submitted an application for accreditation to an approved accreditation organization or an application for the appropriate certificate to TSG or their designee before the initial 60-day period ends.

## CHAPTER 7

PARTICIPATION IN PROFICIENCY TESTING FOR LABORATORIES PERFORMING  
\*NONWAIVED TESTING

## 7-1. CONDITION: ENROLLMENT AND TESTING OF SAMPLES (§493.801)

Each laboratory, unless otherwise exempt as listed in paragraph 2-1b, must enroll in a proficiency testing (PT) program that meets the criteria in Chapters 8 and 9 and is approved by HHS. Laboratories must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. A laboratory must test the samples in the same manner as patient specimens.

**\*NOTES:**

Due to the proliferation of tests categorized as minimal complexity tests, DoD CLIP Certificate for Minimal Complexity laboratories and laboratories performing minimal complexity testing under other types of CLIP certificates are also required to participate in proficiency testing when proficiency testing for the minimal complexity tests performed is commercially available from a CMS-approved proficiency testing program.

DoD medical laboratories/personnel participating in military contingency operations, operating in an active theater of operations, or otherwise considered deployed (as defined in paragraph 16-2) are exempt from participation in an approved PT program. Overseas laboratories, except in time of war or mobilization, will not be exempt from performance of proficiency testing.

## a. The laboratory must:

(1) Notify TSG or their designee of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this chapter.

(2) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this chapter if the laboratory participates in more than one proficiency testing program approved by CMS. For those tests performed by the laboratory that are not included in Chapter 9, a laboratory must establish and maintain the accuracy and reliability of its testing procedures, in accordance with paragraph 11-27c(1)

(3) For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or

programs for one year before designating a different program and must notify TSG or their designee before any change in designation.

(4) Authorize the proficiency testing program to release to TSG or their designee all data required to:

(a) Determine the laboratory's compliance with this chapter.

(b) Make PT results available to DoD authorized health care beneficiaries as required in section 353(f)(3)(F) of the Public Health Service Act.

b. The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens.

(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

(2) The laboratory must test samples the same number of times that it routinely tests patient samples.

(3) Laboratories that perform tests on proficiency testing samples must not engage in any interlaboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

(4) The laboratory will not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory. Any laboratory that TSG or their designee determines intentionally referred its proficiency testing samples to another laboratory for analysis will be subject to appropriate sanctions in accordance with Chapter 14. Any DoD laboratory

that receives proficiency testing samples from another laboratory for testing must notify TSG or its designee of the receipt of those samples.

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all PT samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.

(6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

**7-2. CONDITION: SUCCESSFUL PARTICIPATION (§493.803)**

a. Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in Chapters 8 and 9 for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIP.

**NOTES:**

Due to the proliferation of tests categorized as minimal complexity tests, DoD CLIP Certificate for Minimal Complexity laboratories and laboratories performing minimal complexity testing under other types of CLIP certificates are also required to participate in proficiency testing when proficiency testing for the minimal complexity tests performed is commercially available from a CMS-approved PT program.

(Disclaimer: CMS approves proficiency testing programs for nonwaived testing based on the criteria specified in Subpart I, 42 CFR 493. The inclusion of proficiency testing for minimal complexity (waived) tests and nonwaived analytes and/or tests not specified in Subpart I (i.e., non-PT regulated analytes) is solely at the discretion of a proficiency testing provider. *The CLIA statute prohibits requiring PT for waived tests.* Consequently, such analytes and or tests are not formally assessed by CMS during the proficiency testing program approval process. A prescriptive mechanism of setting proficiency testing performance criteria for minimal complexity (waived) tests

and non-PT regulated nonwaived analytes and/or tests that are included in a proficiency testing program is not specified by CMS and is solely at the discretion of the proficiency testing provider(s) and, for DoD, the Service representatives within the DoD's Center for Clinical Laboratory Medicine. Within DoD, the determination of unsatisfactory proficiency testing performance for minimal complexity testing will generally be defined in the same manner as for nonwaived testing, e.g., failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. Unsatisfactory analyte performance in 2 of 3 or 3 of 4 consecutive testing events will be considered unsuccessful analyte performance. Unsatisfactory or unsuccessful analyte performance will be addressed per the respective Service's failed proficiency testing policy/procedure.)

- b. The scores from each test in a proficiency testing program will be graded with equal emphasis. That is, there will be no distinction made between regulated and unregulated analytes when grading PT.
- c. Each test analyte will be graded individually rather than combining certain procedures into subspecialty groups (for example: Gram Stain, Organism ID and Sensitivity will be graded as three separate tests rather than a combined subspecialty procedure).
- d. Except as specified in paragraph e below, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this chapter, or fails to take remedial action when an individual fails gynecologic cytology, sanctions will be taken as defined in Chapter 14.
- e. If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, TSG or their designee may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists:
- (1) There is immediate jeopardy to patient health and safety.
  - (2) The laboratory fails to provide TSG or their designee with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance.
  - (3) The laboratory has a poor compliance history.

**7-3. CONDITION: REINSTATEMENT OF LABORATORIES PERFORMING NONWAIVED TESTING AFTER FAILURE TO PARTICIPATE SUCCESSFULLY (§493.807)**

- a. If a laboratory's certificate is suspended or limited because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIP for the failed specialty, subspecialty, or analyte, the laboratory must take corrective action, to include technical assistance and/or training, and demonstrate sustained satisfactory performance on two consecutive proficiency remedial recertification events. CCLM will provide for recertification support and provide recommendations to the TSG, who will consider all corrective actions taken and the CCLM recommendations when reviewing the laboratory's request for reinstatement for certification.
- b. If a laboratory's certificate is suspended or revoked in gynecologic cytology, the laboratory must take corrective action and reapply for certification.

**7-4. PROFICIENCY TESTING FOR LABORATORIES PERFORMING NONWAIVED TESTING FOR THE SPECIALTY AND SUBSPECIALTIES OF MICROBIOLOGY (§493.821)**

- a. The specialty of microbiology includes, for purposes of proficiency testing, the subspecialties of bacteriology (§493.823), mycobacteriology (§493.825), mycology (§493.827), parasitology (§493.829) and virology (§493.831).
- b. The following Proficiency Testing Standards apply to the specialty and subspecialties of Microbiology.

- (1) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

- (2) Failure to attain an overall testing event score of at least 80 percent in each subspecialty is unsatisfactory performance.

- (3) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if:

- (a) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results.

- (b) The laboratory notifies the inspecting agency and the proficiency testing program within the

time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples.

(c) The laboratory participated in the previous two proficiency testing events.

(4) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(5) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. For any unacceptable/unsatisfactory analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for 2 years from the date of participation in the proficiency testing event.

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

(7) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

**7-5. PROFICIENCY TESTING FOR LABORATORIES PERFORMING NONWAIVED TESTING FOR THE SPECIALTY AND SUBSPECIALTIES OF DIAGNOSTIC IMMUNOLOGY (§493.833)**

a. The specialty of diagnostic immunology includes, for purposes of proficiency testing, the subspecialties of syphilis serology (§493.835) and general immunology (§493.837).

b. The Proficiency Testing Standards of paragraphs 7-4b(1) through 7-4b(7) apply to the subspecialty of syphilis serology.

c. The Proficiency Testing Standards of paragraphs 7-4b(1) through 7-4b(7) apply to the subspecialty of general immunology.

**7-6. PROFICIENCY TESTING FOR LABORATORIES PERFORMING NONWAIVED TESTING FOR THE SPECIALTY AND SUBSPECIALTIES OF CHEMISTRY (§493.839)**

a. The specialty of chemistry includes, for the purposes of proficiency

testing, the subspecialties of routine chemistry (§493.841), endocrinology (§493.843), and toxicology (§493.845).

b. The Proficiency Testing Standards of paragraphs 7-4b(1) through 7-4b(7) apply to the subspecialties of routine chemistry, endocrinology and toxicology.

**7-7. PROFICIENCY TESTING FOR LABORATORIES PERFORMING NONWAIVED TESTING FOR THE SPECIALTY OF HEMATOLOGY (§493.849) & (§493.851)**

a. The specialty of hematology, for the purpose of proficiency testing, is not subdivided into subspecialties of testing.

b. The Proficiency Testing Standards of paragraphs 7-4b(1) through 7-4b(7) apply to the specialty of hematology.

**7-8. PROFICIENCY TESTING FOR LABORATORIES PERFORMING NONWAIVED TESTING FOR THE SPECIALTY AND SUBSPECIALTIES OF PATHOLOGY (§493.853)**

a. The specialty of pathology includes, for purposes of proficiency testing, the subspecialty of cytology limited to gynecologic examinations (§493.855).

b. To participate successfully in a cytology proficiency testing program for gynecologic examinations (Pap smears), the laboratory must meet the following requirements:

(1) The laboratory **MUST** ensure that each individual engaged in the examination of gynecologic preparations is enrolled in a proficiency testing program approved by CMS. (**NOTE:** Pathologists and military cytotechnologists who are deployed for greater than 7 months of any calendar year are exempt from participation in cytology proficiency testing during that calendar year if the normally scheduled annual gynecological cytology proficiency testing date for the fixed medical treatment facility laboratory has passed and testing would require rescheduling a testing date with payment of the base enrollment fee only for the individual(s) who has (have) returned from deployment.) The laboratory must ensure that each individual is tested at least once per year and obtains a passing score. To ensure this annual testing of individuals, an announced or unannounced testing event will be conducted on-site in each laboratory at least once each year. (**NOTE:** Individuals being tested must adhere to the prohibition on any communications or discussions concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the proficiency testing program for the testing event in which the samples were sent. See paragraph 7-1b(3).) The annual testing event may be conducted by mailing survey materials

to the installation training and testing authority for monitored on-site testing. Laboratories will be notified of the time of each announced testing event at least 30 days prior to each event. Additional testing events will be conducted as necessary, as above, for the purpose of testing individuals who miss the on-site testing event and for retesting individuals as described in paragraph (2) below.

(2) The laboratory must ensure that each individual participates in an annual testing event that involves the examination of a 10-slide test set. Individuals who fail this testing event are retested with another 10-slide test set as described in paragraphs (a) and (b) below. Individuals who fail this second test are subsequently retested with a 20-slide test set as described in paragraphs (b) and (c) below. Individuals are given not more than 2 hours to complete a 10-slide test and not more than 4 hours to complete a 20-slide test. Unexcused failure by an individual to take a retest will result in test failure with resulting remediation and limitations on slide examinations as specified in (a), (b) and (c) below.

(a) An individual is determined to have failed the annual testing event if he or she scores less than 90 percent on a 10-slide test set. For an individual who fails an annual proficiency testing event, the laboratory must schedule a retesting event which must take place not more than 45 days after receipt of the notification of failure.

(b) An individual is determined to have failed the second testing event if he or she scores less than 90 percent on a 10-slide test set. For an individual who fails a second testing event, the laboratory must provide him or her with documented, remedial training and education in the area of failure, and must assure that all gynecologic slides evaluated subsequent to the notice of failure are reexamined until the individual is again retested with a 20-slide test set and scores at least 90 percent. Reexamination of slides must be documented.

(c) An individual is determined to have failed the third testing event if he or she scores less than 90 percent on a 20-slide test set. An individual who fails the third testing event must cease examining gynecologic slide preparations immediately upon notification of test failure and

may not resume examining gynecologic slides until the laboratory assures that the individual obtains at least 35 hours of documented, formally structured, continuing education in diagnostic cytopathology that focuses on the examination of gynecologic preparations, and until he or she is retested with a 20-slide test set and scores at least 90 percent.

c. If a laboratory fails to ensure that individuals are tested or those who fail a testing event are retested, or fails to take required remedial actions as described in paragraph b above, TSG or its designee will initiate alternative sanctions or limit the laboratory's certificate to exclude gynecologic cytology testing under DoD CLIP in accordance with Chapter 14.

**7-9. PROFICIENCY TESTING FOR LABORATORIES PERFORMING NONWAIVED TESTING FOR THE SPECIALTY AND SUBSPECIALTIES OF IMMUNOHEMATOLOGY (§493.857)**

a. The specialty of immunohematology, for the purposes of proficiency testing, includes the subspecialties: ABO group and D (Rho) typing (§493.859); unexpected antibody detection (§493.861); compatibility testing (§493.863); and antibody identification (§493.865).

b. The Proficiency Testing Standards of paragraphs 7-4b(1) through 7-4b(7) apply to the subspecialty of ABO group and D (Rho) typing, except failure to attain a score of 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event (rather than 80 percent performance) and failure to attain an overall testing event score of 100 percent is unsatisfactory performance (rather than 80 percent performance)

c. The Proficiency Testing Standards of paragraphs 7-4b(2) through 7-4b(5) and 7-4b(7) apply to the subspecialty of unexpected antibody detection.

d. The Proficiency Testing Standards of paragraphs 7-4b(2) through 7-4b(5) and 7-4b(7) apply to the subspecialty of compatibility testing, except failure to attain an overall testing event score of 100 percent is unsatisfactory performance (rather than 80 percent performance).

e. The Proficiency Testing Standards of paragraphs 7-4b(2) through 7-4b(5) and 7-4b(7) apply to the subspecialty of antibody identification. In addition, failure to identify the same antibody in two consecutive or two out of three consecutive testing events is unsuccessful performance.

## CHAPTER 8

## PROFICIENCY TESTING PROGRAMS FOR NONWAIVED TESTING

## 8-1. APPROVAL OF PROFICIENCY TESTING PROGRAMS (§493.901)

In order for a proficiency testing program to receive HHS approval, the program must be offered by a private, nonprofit organization or a Federal or State agency, or entity acting as a designated agent for a State. Laboratory directors in overseas laboratories, with the concurrence of the respective Service's CCLM representative, may approve the use of specific proficiency testing materials from a non-CMS approved proficiency testing program when consistent problems with the quality of testing materials shipped from a CMS-approved program in the United States are encountered. For analytes or tests specified in Subpart I, 42 CFR 493, use of proficiency testing materials from a non-CMS approved program will be in addition to, not in lieu of, the use of proficiency testing materials from a CMS-approved program.

## 8-2. ADMINISTRATIVE RESPONSIBILITIES (§493.903)

The proficiency testing program must (if there are any DoD users of the specific proficiency testing program):

- a. Provide TSG or their designee and participating laboratories with an electronic or a hard copy, or both, of reports of proficiency testing results and all scores for each laboratory's performance in a format as required by and approved by CMS for each certified specialty, subspecialty, and analyte or test within 60 days after the date by which the laboratory must report proficiency testing results to the proficiency testing program.
- b. Provide TSG or their designee with reports of PT results and scores of individual performance in cytology and provide copies of reports to participating individuals, and to all laboratories that employ the individuals, within 15 working days of the testing event;
- c. Provide to TSG or their designee cumulative reports on an individual laboratory's performance and aggregate data on DoD CLIP-certified laboratories for the purpose of establishing a system to make the proficiency testing results available, on a reasonable basis, upon request of any person, and include such explanatory information as may be appropriate to assist in the interpretation of the proficiency testing results;
- d. Maintain records of laboratories' performance for a period of five years or such time as may be necessary for any legal proceedings; and
- e. Provide TSG or their designee with an annual report and, if needed, an interim report which identifies any previously unrecognized

sources of variability in kits, instruments, methods, or PT samples, which adversely affect the program's ability to evaluate laboratory performance.

**8-3. NON-APPROVED PROFICIENCY TESTING PROGRAMS (§493.905)**

If a CMS approved proficiency testing program is determined by HHS to fail to meet any criteria contained in sections 493.901 through 493.959 for approval of the proficiency testing program, CMS will notify the program and the program must notify TSG or their designee and all laboratories enrolled of the non-approval and the reasons for non-approval within 30 days of the notification.

## CHAPTER 9

## REGULATED ANALYTES

## 9-1. INTRODUCTION

Sections §493.909 through §493.959 of 42 CFR 493 explain the content of approved proficiency test programs. The following paragraphs summarize the referenced CLIA sections to provide a concise list of regulated analytes. The CLIA reference section is noted for each subspecialty. For a more comprehensive description, the reader is directed to the Code of Federal Regulations (sections §493.909 through §493.959).

## 9-2. MICROBIOLOGY (§463.909)

The subspecialties under the specialty of microbiology for which a proficiency testing program may offer proficiency testing are bacteriology, mycobacteriology, mycology, parasitology, and virology. Specific criteria for these subspecialties are listed below.

## a. Bacteriology (§493.911)

(1) The annual program must include samples that contain organisms that are representative of the six major groups of bacteria - anaerobes, Enterobacteriaceae, gram-positive bacilli, gram-positive cocci, gram-negative cocci, miscellaneous gram-negative bacteria. The program must include other important emerging pathogens (as determined by HHS) and either organisms commonly occurring in patient specimens or opportunistic pathogens. Specific organisms included may vary from year to year. The program must provide a minimum of five samples per testing event and must include samples for bacterial antigen detection, bacterial isolation and identification, Gram stain, and antimicrobial susceptibility testing. For antimicrobial susceptibility testing, the program must provide at least one sample per testing event that includes gram-positive or gram-negative strains that have a pre-determined pattern of sensitivity or resistance to the common antimicrobial agents. There must be at least three testing events at approximately equal intervals per year. Examples of the types of organisms that might be included over time are:

## (a) Anaerobes:

- Bacteroides fragilis group
- Clostridium perfringens
- Peptostreptococcus anaerobius

## (b) Enterobacteriaceae:

- Citrobacter freundii
- Enterobacter aerogenes
- Escherichia coli
- Klebsiella pneumoniae
- Proteus mirabilis
- Salmonella typhimurium
- Serratia marcescens
- Shigella sonnei
- Yersinia enterocolitica

## (c) Gram-positive bacilli:

- Listeria monocytogenes
- Corynebacterium species CDC group JK

## (d) Gram-positive cocci:

- Staphylococcus aureus
- Streptococcus Group A
- Streptococcus Group B
- Streptococcus Group D (S. bovis and enterococcus)
- Streptococcus pneumoniae

## (e) Gram-negative cocci:

- Branhamella catarrhalis
- Neisseria gonorrhoeae
- Neisseria meningitidis

## (f). Miscellaneous Gram-negative bacteria:

- Campylobacter jejuni
- Haemophilis influenza, Type B
- Pseudomonas aeruginosa.

(2) Evaluation of laboratory responses for particular samples is dependent upon the types of services offered by the laboratory for this subspecialty. Bacteriology services are classified into five types. A laboratory must isolate and identify the organisms to the same extent it performs these procedures on patient specimens. For antimicrobial susceptibility testing, a laboratory must indicate which drugs are routinely included in its test panel when testing patient specimens. A laboratory's performance will be evaluated for only those antibiotics for which service is offered.

## b. Mycobacteriology (§493.913)

(1) The annual program must include samples that contain organisms that are representative of the five major groups (complexes) of mycobacteria encountered in human specimens. The program must include mycobacteria commonly occurring in patient specimens and other important emerging mycobacteria (as determined by HHS). Specific organisms included may vary from year to year. The program must provide a minimum of five samples per testing event. For antimycobacterial susceptibility testing, the program must provide at least one sample per testing event that includes mycobacterium tuberculosis that has a predetermined pattern of sensitivity or resistance to the common antimycobacterial agents. For acid-fast stain interpretation, the program must provide at least 5 samples per testing event that includes challenges that are acid-fast and challenges which do not contain acid-fast organisms. There must be at least two testing events per year. Examples of the types of organisms that might be included over time are:

## (a) TB

- Mycobacterium tuberculosis
- Mycobacterium bovis

## (b) Group I

- Mycobacterium kansasii

## (c) Group II

- Mycobacterium szulgai

## (d) Group III

- Mycobacterium avium-intracellulare
- Mycobacterium terrae

## (e) Group IV

- Mycobacterium fortuitum

(2) Evaluation of laboratory responses for particular samples is dependent upon the types of services offered by the laboratory for this subspecialty. Mycobacteriology services are classified into five types. A laboratory must interpret acid-fast stains and isolate and identify the organisms to the same extent it performs these procedures on patient specimens. For antimycobacterial susceptibility testing, a laboratory must indicate which drugs are routinely included in its test panel when testing patient

samples. A laboratory's performance will be evaluated for only those antibiotics for which susceptibility testing is routinely performed on patient specimens.

c. Mycology (§493.915)

(1) The annual program must include samples that contain organisms that are representative of the five major groups of fungi: Yeast or yeast-like fungi, dimorphic fungi, dematiaceous fungi, dermatophytes, and saprophytes, including opportunistic fungi. Other important emerging pathogens (as determined by HHS) and organisms commonly occurring in patient specimens must be included periodically in the program. Specific organisms may vary from year to year. The program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. Examples of the types of organisms that might be included over time are:

- *Candida albicans*
- *Candida* (other species)
- *Cryptococcus neoformans*
- *Sporothrix schenckii*
- *Exophiala jeanselmei*
- *Fonsecaea pedrosoi*
- *Microsporium* sp.
- *Acremonium* sp.
- *Trichophyton* sp.
- *Aspergillus fumigatus*
- *Nocardia* sp.
- *Blastomyces dermatitidis*
- *Zygomycetes* sp.

(2) Evaluation of laboratory responses for particular samples is dependent upon the types of services offered by the laboratory for this subspecialty. Mycology services are classified into four types. A laboratory must isolate and identify the organisms to the same extent it performs these procedures on patient specimens.

d. Parasitology (§493.917)

(1) The annual program must include samples that contain parasites that are commonly encountered in the United States as well as those recently introduced into the United States. Other important emerging pathogens (as determined by HHS) and parasites commonly occurring in patient specimens must be included periodically in the program. Specific organisms may vary from year to year. The program must provide a minimum of five samples per testing event. There must be at least three testing events at

approximately equal intervals per year. Examples of the types of organisms that might be included over time are:

- Enterobius vermicularis
- Entamoeba histolytica
- Entamoeba coli
- Giardia lamblia
- Endolimax nana
- Dientamoeba fragilis
- Iodamoeba butschli
- Chilomastix mesnili
- Hookworm
- Ascaris lumbricoides
- Strongyloides stercoralis
- Trichuris trichiura
- Diphyllbothrium latum
- Cryptosporidium sp.
- Plasmodium falciparum

(2) Evaluation of laboratory responses for particular samples is dependent upon the types of services offered by the laboratory for this subspecialty. Parasitology services are classified into two types. A laboratory must determine the presence or absence of a parasite(s) or concentrate and identify the parasite(s) to the same extent it performs these procedures on patient specimens.

e. Virology (§493.919)

(1) The annual program must include viral species that are the more commonly identified viruses. The program must include other important emerging viruses (as determined by HHS) and viruses commonly occurring in patient specimens. Specific organisms included may vary from year to year. The annual program must include samples for viral antigen detection and viral isolation and identification. The program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The types of viruses that might be included over time are the more commonly identified viruses such as:

- Herpes simplex
- Respiratory syncytial virus
- Adenoviruses
- Enteroviruses
- Cytomegaloviruses

(2) Evaluation of laboratory responses for particular samples is dependent upon the types of services offered by the laboratory for this subspecialty. Virology services are classified into two types. A laboratory must isolate and identify the viruses to the same extent it performs these procedures on patient specimens.

## 9-3. DIAGNOSTIC IMMUNOLOGY (§493.921)

Proficiency testing programs for this specialty are found under syphilis serology (§493.923) and general immunology (§493.927).

a. Syphilis Serology (§493.923) The annual program must include samples that cover the full range of reactivity from highly reactive to non-reactive. The program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. No examples are provided.

b. General Immunology (§493.927) The annual program must include samples that cover the full range of reactivity from highly reactive to non-reactive. The program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The minimum number of challenges per testing event the program must provide for each analyte or test procedure is five. Analytes or tests for which laboratory performance is to be evaluated include:

Analyte or test

Acceptable Performance

Alpha-1 antitrypsin

Target value +/- 3 SD

Alpha-fetoprotein (tumor marker)

Target value +/- 3 SD

Antinuclear antibody

Target value +/- 2 dilutions or + or -

Antistreptolysin O

Target value +/- 2 dilutions or + or -

Anti-human immunodeficiency virus (HIV)

Reactive or nonreactive

Complement C3

Target value +/- 3 SD

Complement C4

Target value +/- 3 SD

Hepatitis markers (HbsAg, anti-HBc, HbeAg)

Reactive (positive) or nonreactive (negative)

IgA

Target value +/- 3 SD

IgG

Target value +/- 25%

IgE

Target value +/- 3 SD

IgM

Target value +/- 3 SD

Infectious mononucleosis

Target value +/- 2 dilutions or + or -

Rheumatoid factor

Target value +/- 2 dilutions or + or -

Rubella

Target value +/- 2 dilutions or + or - or immune or nonimmune.

**9-4. CHEMISTRY (§493.929)**

The subspecialties under the specialty of chemistry for which a proficiency testing program may offer proficiency testing are routine chemistry, endocrinology, and toxicology. Specific criteria for these subspecialties are listed in §493.931 through §493.937.

a. Routine Chemistry (§493.931) The annual program must include samples that cover the clinically relevant range of values that would be expected in patient specimens. The program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The minimum number of challenges per testing event a program must provide for each analyte or test procedure listed below is five serum, plasma, or blood samples. Analytes or tests for which laboratory performance is to be evaluated include:

Analyte or test

Acceptable performance

Alanine aminotransferase (ALT/SGPT)

Target value +/- 20%

Albumin

Target value +/- 10%

Alkaline Phosphatase

Target value +/- 30%

Amylase

Target value +/- 30%

Aspartate aminotransferase (AST/SGOT)

Target value +/- 20%

Bilirubin, total  
Target value +/- 20% or 0.4 mg/dL (greater)

Blood gas (pO<sub>2</sub>)  
Target value +/- 3 SD

Blood Gas (pCO<sub>2</sub>)  
Target value +/- 8% or 5 mm Hg (greater)

Blood Gas (pH)  
Target value +/- 0.04

Calcium, total  
Target value +/- 1.0 mg/dL

Chloride  
Target value +/- 5%

Cholesterol, total  
Target value +/- 10%

Cholesterol, high density lipoprotein  
Target value +/- 30%

Creatine kinase  
Target value +/- 30%

Creatine kinase isoenzymes  
Target value +/- 3 SD or MB elevated (presence or absence)

Creatinine  
Target value +/- 15% or 0.3 mg/dL (greater)

Glucose (excluding glucose performed on monitoring devices cleared by  
FDA for home use)  
Target value +/- 10% or 6 mg/dL (greater)

Iron, total  
Target value +/- 20%

Lactate dehydrogenase (LDH)  
Target value +/- 20%

Lactate dehydrogenase isoenzymes  
Target value +/- 30% or LDH1/LDH2 (+ or -)

Magnesium  
Target value +/- 25%

Potassium  
Target value +/- 0.5 mmol/L

Sodium

Target value +/- 4 mmol/L

Total protein

Target value +/- 10%

Triglycerides

Target value +/- 25%

Urea nitrogen

Target value +/- 9% or 2 mg/dL (greater)

Uric Acid

Target value +/- 17%

b. Endocrinology (§493.933) The annual program must include samples that cover the clinically relevant range of values that would be expected in patient specimens. The program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five serum, plasma, blood, or urine samples. Analytes or tests for which laboratory performance is to be evaluated include:

Analyte or test

Acceptable Performance

Cortisol

Target value +/- 25%

Free Thyroxine

Target value +/- 3 SD

Human chorionic gonadotropin (excluding urine pregnancy tests done by visual color comparison categorized as minimal complexity tests)

Target value +/- 3 SD or + or -

T3 uptake

Target value +/- 3 SD

Triiodothyronine

Target value +/- 3 SD

Thyroid-stimulating hormone

Target value +/- 3 SD

Thyroxine

Target value +/- 20% or 1.0 mcg/dL (greater)

c. Toxicology (§493.937) The annual program must include samples that cover the clinically relevant range of values that would be expected

in specimens of patients on drug therapy and that cover the level of clinical significance for the particular drug. The program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five serum, plasma, or blood samples. Analytes or tests for which laboratory performance is to be evaluated include:

Analyte or test  
Acceptable performance

Alcohol, blood  
Target value +/- 25%

Blood lead  
Target value +/- 10% or 4 mcg/dL (greater)

Carbamazepine  
Target value +/- 25%

Digoxin  
Target value +/- 20% or 0.2 ng/mL (greater)

Ethosuximide  
Target value +/- 20%

Gentamicin  
Target value +/- 25%

Lithium  
Target value +/- 20% or 0.3 mmol/L (greater)

Phenobarbital  
Target value +/- 20%

Phenytoin  
Target value +/- 25%

Primidone  
Target value +/- 25%

Procainamide (and metabolite)  
Target value +/- 25%

Quinidine  
Target value +/- 25%

Tobramycin  
Target value +/- 25%

Theophylline  
Target value +/- 25%

Valproic acid  
Target value +/- 25%

9-5. HEMATOLOGY (INCLUDING ROUTINE HEMATOLOGY AND COAGULATION) (\$493.941)

The annual program must include samples that cover the full range of values that would be expected in patient specimens. For cell identification, the types of cells that might be included may vary over time. The types of cells that may be included are neutrophilic granulocytes, eosinophilic granulocytes, basophilic granulocytes, lymphocytes, monocytes, major red and white blood cell abnormalities, and immature red and white blood cells. The program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five. Analytes or tests for which laboratory performance is to be evaluated include:

Analyte or test  
Acceptable performance

Cell identification  
90% or greater consensus on identification

White blood cell differential  
Target +/- 3 SD based on the percentage of different types of white blood cells in the samples

Erythrocyte count  
Target +/- 6%

Hematocrit (excluding spun hematocrits)  
Target +/- 6%

Hemoglobin  
Target +/- 7%

Leukocyte count  
Target +/- 15%

Platelet count  
Target +/- 25%

Fibrinogen  
Target +/- 20%

Partial thromboplastin time  
Target +/- 15%

Prothrombin time  
Target +/- 15%

**9-6. CYTOLOGY; GYNECOLOGIC EXAMINATIONS (\$493.945)**

The annual program must provide test sets composed of 10 and 20 glass slides. Each test set must include at least one slide representative of each of the following response categories:

- a. Unsatisfactory for diagnosis
- b. Normal or benign changes
- c. Low grade squamous intraepithelial lesion
- d. High grade lesion and carcinoma.

The program must provide announced and unannounced on-site testing for each individual at least once per year and must provide an initial retesting event for each individual within 45 days after notification of test failure and subsequent retesting events within 45 days after completion of remedial action. The scoring system rewards or penalizes participants in proportion to the distance of their answers from the correct response or target diagnosis and the penalty or reward is weighted in proportion to the severity of the lesion.

**9-7. IMMUNOHEMATOLOGY (\$493.959)**

The annual program must include samples that cover the full range of interpretation that would be expected in patient specimens. The program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five. Analytes or tests for which laboratory performance is to be evaluated include:

Analyte or test  
Acceptable performance

ABO group (excluding subgroups)  
100% accuracy

D (Rho) typing  
100% accuracy

Unexpected antibody detection  
80% accuracy

Compatibility testing  
100% accuracy

Antibody identification  
80% accuracy

CHAPTER 10

FACILITY ADMINISTRATION FOR NONWAIVED TESTING

10-1. **CONDITION: FACILITY ADMINISTRATION (§493.1100)**

Each laboratory that performs nonwaived testing must meet the applicable requirements under paragraphs 10-2 through 10-4, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7).

10-2. **STANDARD: FACILITIES (§493.1101)**

a. The laboratory must be constructed, arranged, and maintained to ensure the following:

- (1) The space, ventilation, and utilities necessary for conducting all phases of the testing process.
- (2) Contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.
- (3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.

b. The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.

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

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

e. Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation.

10-3. **STANDARD: REQUIREMENTS FOR TRANSFUSION SERVICES (§493.1103)**

A facility that provides transfusion services must meet all of the requirements of this paragraph and document all transfusion-related activities.

- a. The facility must have a transfusion service agreement reviewed and approved by the responsible party(ies) that govern the procurement, transfer, and availability of blood and blood products.
- b. The facility must provide prompt ABO grouping, D(Rho) typing, unexpected antibody detection, compatibility testing, and laboratory investigation of transfusion reactions on a continuous basis through a CLIP- or CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS, or, at overseas sites, by the laboratory director.
- c. Blood and blood products storage and distribution.
  - (1) If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.
  - (2) The facility must establish and follow policies to ensure positive identification of a blood or blood product recipient.
- d. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal authorities.

10-4. **STANDARD: RETENTION REQUIREMENTS (§493.1105)**

- a. The laboratory must retain its records and, as applicable, slides, blocks, and tissues as follows:
  - (1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years.
  - (2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance.
  - (3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in paragraphs 11-35 through 11-55 for at least 2 years. In addition, retain the following:
    - (a) Records of test system performance specifications that the laboratory establishes or verifies under paragraph 11-36 for the period of

time the laboratory uses the test system but no less than 2 years.

(b) Immunohematology records, blood and blood product records, and transfusion records as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v) and (d).

(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years.

(5) Quality system assessment records. Retain all laboratory quality systems assessment records for at least 2 years.

(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. In addition, retain the following:

(a) Immunohematology reports as specified in 21 CFR 606.160(d).

(b) Pathology test reports for at least 10 years after the date of reporting.

(7) Slide, block, and tissue retention –

(a) Slides.

- Retain cytology slide preparations for at least 5 years from the date of examination (see paragraph 11-49f for proficiency testing exception).

- Retain histopathology slides for at least 10 years from the date of examination.

(b) Blocks. Retain pathology specimen blocks for at least 2 years from the date of examination.

(c) Tissue. Preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.

b. If the laboratory ceases operation, the laboratory must make provisions to ensure that all records and, as applicable, slides, blocks, and tissue are retained and available for the time frames specified in this paragraph.

## CHAPTER 11

## QUALITY SYSTEM FOR NONWAIVED TESTING

## 11-1 INTRODUCTION (§493.1200)

a. Each laboratory that performs nonwaived testing must establish and maintain written policies and procedures that implement and monitor a quality system for all phases of the total testing process (that is, preanalytic, analytic, and postanalytic) as well as general laboratory systems.

b. The laboratory's quality systems must include a quality assessment component that ensures continuous improvement of the laboratory's performance and services through ongoing monitoring that identifies, evaluates and resolves problems.

c. The various components of the laboratory's quality system are used to meet the requirements in this Pamphlet and must be appropriate for the specialties and subspecialties of testing the laboratory performs, services it offers, and clients it serves.

## 11-2 CONDITION: BACTERIOLOGY (§493.1201)

If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in paragraphs 11-21 through 11-39, 11-40, and 11-52 through 11-58.

## 11-3 CONDITION: MYCOBACTERIOLOGY (§493.1202)

If the laboratory provides services in the subspecialty of Mycobacteriology, the laboratory must meet the requirements specified in paragraphs 11-21 through 11-39, 11-41, and 11-52 through 11-58.

## 11-4 CONDITION: MYCOLOGY (§493.1203)

If the laboratory provides services in the subspecialty of Mycology, the laboratory must meet the requirements specified in paragraphs 11-21 through 11-39, 11-42, and 11-52 through 11-58.

## 11-5 CONDITION: PARASITOLOGY (§493.1204)

If the laboratory provides services in the subspecialty of Parasitology, the laboratory must meet the requirements specified in paragraphs 11-21 through 11-39, 11-43, and 11-52 through 11-58.

## 11-6 CONDITION: VIROLOGY (§493.1205)

If the laboratory provides services in the subspecialty of Virology, the laboratory must meet the requirements specified in paragraphs 11-21 through 11-39, 11-44, and 11-52 through 11-58.

**11-7 CONDITION: SYPHILIS SEROLOGY (§493.1207)**

If the laboratory provides services in the subspecialty of Syphilis Serology, the laboratory must meet the requirements specified in paragraphs 11-21 through 11-39, and 11-52 through 11-58.

**11-8 CONDITION: GENERAL IMMUNOLOGY (§493.1208)**

If the laboratory provides services in the subspecialty of General Immunology, the laboratory must meet the requirements specified in paragraphs 11-21 through 11-39, and 11-52 through 11-58.

**11-9 CONDITION: ROUTINE CHEMISTRY (§493.1210)**

If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in paragraphs 11-21 through 11-39, 11-45, and 11-52 through 11-58.

**11-10 CONDITION: URINALYSIS (§493.1211)**

If the laboratory provides services in the subspecialty of Urinalysis, the laboratory must meet the requirements specified in paragraphs 11-21 through 11-39, and 11-52 through 11-58.

**11-11 CONDITION: ENDOCRINOLOGY (§493.1212)**

If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in paragraphs 11-21 through 11-39, and 11-52 through 11-58.

**11-12 CONDITION: TOXICOLOGY (§493.1213)**

If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in paragraphs 11-21 through 11-39, and 11-52 through 11-58.

**11-13 CONDITION: HEMATOLOGY (§493.1215)**

If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in paragraphs 11-21 through 11-39, 11-46, and 11-52 through 11-58.

**11-14 CONDITION: IMMUNOHEMATOLOGY (§493.1217)**

If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in paragraphs 11-21 through 11-39, 11-47, and 11-52 through 11-58.

**11-15 CONDITION: HISTOPATHOLOGY (§493.1219)**

If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in paragraphs 11-21 through 11-39, 11-48, and 11-52 through 11-58.

**11-16 CONDITION: ORAL PATHOLOGY (§493.1220)**

If the laboratory provides services in the subspecialty of Oral Pathology, the laboratory must meet the requirements specified in paragraphs 11-21 through 11-39, and 11-52 through 11-58.

**11-17 CONDITION: CYTOLOGY (§493.1221)**

If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in paragraphs 11-21 through 11-39, 11-49, and 11-52 through 11-58.

**11-18 CONDITION: CLINICAL CYTOGENETICS (§493.1225)**

If the laboratory provides services in the specialty of Clinical Cytogenetics, the laboratory must meet the requirements specified in paragraphs 11-21 through 11-39, 11-50, and 11-52 through 11-58.

**11-19 CONDITION: RADIOBIOASSAY (§493.1226)**

If the laboratory provides services in the specialty of Radiobioassay, the laboratory must meet the requirements specified in paragraphs 11-21 through 11-39, and 11-52 through 11-58.

**11-20 CONDITION: HISTOCOMPATIBILITY (§493.1227)**

If the laboratory provides services in the specialty of Histocompatibility, the laboratory must meet the requirements specified in paragraphs 11-21 through 11-39, 11-51, and 11-52 through 11-58.

**GENERAL LABORATORY SYSTEMS****11-21 CONDITION: GENERAL LABORATORY SYSTEMS (§493.1230)**

Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in paragraphs 11-22 through 11-27, 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 general laboratory systems and correct identified problems as specified in paragraph 11-28 for each specialty and subspecialty of testing performed.

11-22 **STANDARD: CONFIDENTIALITY OF PATIENT INFORMATION (§493.1231)**

The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control.

11-23 **STANDARD: SPECIMEN IDENTIFICATION AND INTEGRITY (§493.1232)**

The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

11-24 **STANDARD: COMPLAINT INVESTIGATIONS (§493.1233)**

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

11-25 **STANDARD: COMMUNICATIONS (§493.1234)**

The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results.

11-26 **STANDARD: PERSONNEL COMPETENCY ASSESSMENT POLICIES (§493.1235)**

As specified in the personnel requirements in Chapter 12, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

11-27 **STANDARD: EVALUATION OF PROFICIENCY TESTING PERFORMANCE (§493.1236)**

a. The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in Chapter 7.

b. The laboratory must verify the accuracy of the following:

(1) Any analyte or subspecialty without analytes listed in Chapter 9 that is not evaluated or scored by a CMS-approved proficiency testing program.

(2) Any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring, or the laboratory receives a zero score for nonparticipation, or late return of results).

c. At least twice annually, the laboratory must verify the accuracy of the following:

(1) Any test or procedure it performs that is not included in Chapter 9.

(2) Any test or procedure listed in Chapter 9 for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.

d. All proficiency testing evaluation and verification activities must be documented.

**11-28 STANDARD: GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT (§493.1239)**

a. The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at paragraphs 11-22 through 11-27.

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

c. The laboratory must document all general laboratory systems quality assessment activities.

**PREANALYTIC SYSTEMS**

**11-29 CONDITION: PREANALYTIC SYSTEMS (§493.1240)**

Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in paragraphs 11-30 and 11-31, 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 11-32 for each specialty and subspecialty of testing performed.

**11-30 STANDARD: TEST REQUEST (§493.1241)**

a. The laboratory must have a written or electronic request for patient testing from an authorized person.

b. The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within 30 days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization.

c. The laboratory must ensure the test requisition solicits the following information:

- (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values.
- (2) The patient's name or unique patient identifier.
- (3) The sex and age or date of birth of the patient.
- (4) The test(s) to be performed.
- (5) The source of the specimen, when appropriate.
- (6) The date and, if appropriate, time of specimen collection.
- (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy.
- (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

d. The patient's chart or medical record may be used as the test requisition or authorization but must be available to the laboratory at the time of testing and available to TSG or their designee upon request.

e. If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.

**11-31 STANDARD: SPECIMEN SUBMISSION, HANDLING, AND REFERRAL (§493.1242)**

a. The laboratory must establish and follow written policies and procedures for each of the following, if applicable:

- (1) Patient preparation.
- (2) Specimen collection.
- (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source.

- (4) Specimen storage and preservation.
- (5) Conditions for specimen transportation.
- (6) Specimen processing.
- (7) Specimen acceptability and rejection.
- (8) Specimen referral.

b. The laboratory must document the date and time it receives a specimen.

c. The laboratory must refer a specimen for testing only to a CLIP or CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS, or, at overseas sites, by the laboratory director.

d. If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in a(1) through a(7) of this paragraph.

**11-32 STANDARD: PREANALYTIC SYSTEMS QUALITY ASSESSMENT (§493.1249)**

a. The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at paragraphs 11-30 through 11-31.

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

c. The laboratory must document all preanalytic systems quality assessment activities.

**ANALYTIC SYSTEMS**

**11-33 CONDITION: ANALYTIC SYSTEMS (§493.1250)**

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in paragraphs 11-34 through 11-54, 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 analytic systems and correct identified problems as specified in paragraph 11-55 for each specialty and subspecialty of testing performed.

11-34 STANDARD: PROCEDURE MANUAL (§493.1251)

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

b. The procedure manual must include the following when applicable to the test procedure:

(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in paragraph 11-31.

(2) Microscopic examination, including the detection of inadequately prepared slides.

(3) Step-by-step performance of the procedure, including test calculations and interpretation of results.

(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing.

(5) Calibration and calibration verification procedures.

(6) The reportable range for test results for the test system as established or verified in paragraph 11-36.

(7) Control procedures.

(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability.

(9) Limitations in the test methodology, including interfering substances.

(10) Reference intervals (normal values).

(11) Imminently life-threatening test results, or panic or alert values.

(12) Pertinent literature references.

(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life-threatening results, or panic, or alert values.

(14) Description of the course of action to take if a test system becomes inoperable.

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

d. Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

e. The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in paragraph 10-4a(2).

**11-35 STANDARD: TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENTS, MATERIALS, AND SUPPLIES (§493.1252)**

a. Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under paragraph 11-36.

b. The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following:

(1) Water quality.

(2) Temperature.

(3) Humidity.

(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

c. Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following:

(1) Identity and when significant, titer, strength or concentration.

(2) Storage requirements.

(3) Preparation and expiration dates.

(4) Other pertinent information required for proper use.

d. 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.

e. Components of reagent kits of different lot numbers must not be interchanged unless otherwise specified by the manufacturer.

**11-36 STANDARD: ESTABLISHMENT AND VERIFICATION OF PERFORMANCE SPECIFICATIONS (§493.1253)**

a. Laboratories are required to verify or establish performance specifications for any test system used by the laboratory.

b. Verification/establishment of performance specifications and determination of calibration and control procedures.

(1) Verification of performance specifications. Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results:

(a) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics:

- Accuracy.
- Precision.
- Reportable range of test results for the test system.

(b) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

(2) Establishment of performance specifications. Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable:

(a) Accuracy.

- (b) Precision.
- (c) Analytical sensitivity.
- (d) Analytical specificity to include interfering substances.
- (e) Reportable range of test results for the test system.
- (f) Reference intervals (normal values).
- (g) Any other performance characteristic required for test performance.

(3) Determination of calibration and control procedures. The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under b(1) or b(2) of this paragraph.

c. The laboratory must document all activities specified in this paragraph.

**11-37 STANDARD: MAINTENANCE AND FUNCTION CHECKS (§493.1254)**

a. 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.
- (2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

b. Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:

- (1) Maintenance
  - (a) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting.
  - (b) Perform and document the maintenance activities specified in paragraph b(1)(a) above.

(2) Function checks.

(a) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting.

(b) Perform and document the function checks, including background or baseline checks, specified in paragraph b(2)(a) above. Function checks must be within the laboratory's established limits before patient testing is conducted.

11-38 **STANDARD: CALIBRATION AND CALIBRATION VERIFICATION PROCEDURES (§493.1255)**

Calibration and calibration verification procedures are required to substantiate the continued accuracy of the test system throughout the laboratory's reportable range of test results for the test system. Unless otherwise specified in this chapter, for each applicable test system the laboratory must do the following:

a. Perform and document calibration procedures -

(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer;

(2) Using the criteria verified or established by the laboratory as specified in paragraph 11-36b(3) -

(a) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and

(b) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and

(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

b. Perform and document calibration verification procedures -

(1) Following the manufacturer's calibration verification instructions;

(2) Using the criteria verified or established by the laboratory under paragraph 11-36b(3) -

(a) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and

(b) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and

(3) At least once every 6 months and whenever any of the following occur:

(a) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes.

(b) There is major preventive maintenance or replacement of critical parts that may influence test performance.

(c) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem.

(d) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

**11-39 STANDARD: CONTROL PROCEDURES (§493.1256)**

a. For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process.

b. The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in paragraph 11-36b(3).

c. The control procedures must -

(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance.

(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

d. Unless CMS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must -

(1) Perform control procedures as defined in this paragraph unless otherwise specified in the additional specialty and subspecialty requirements at paragraphs 11-40 through 11-51.

(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in d(3) of this paragraph.

(3) At least once each day patient specimens are assayed or examined perform the following for -

(a) Each quantitative procedure, include two control materials of different concentrations;

(b) Each qualitative procedure, include a negative and positive control material;

(c) Test procedures producing graded or titered results, include a negative control material and a control material with graded or titered reactivity, respectively;

(d) Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; and

(e) Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition.

- (4) For thin layer chromatography -
  - (a) 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
  - (b) 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.
- (5) For each electrophoretic procedure include, concurrent with patient specimens, at least one control material containing the substances being identified or measured.
- (6) Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced.
- (7) Over time, rotate control material testing among all operators who perform the test.
- (8) Test control materials in the same manner as patient specimens.
- (9) When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system.
- (10) Establish or verify the criteria for acceptability of all control materials.
  - (a) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available.
  - (b) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory.
  - (c) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control

materials having previously determined statistical parameters.

e. For reagent, media, and supply checks, the laboratory must do the following:

(1) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in paragraph 11-40a(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable.

(2) Each day of use (unless otherwise specified in this chapter), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.

(3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use.

(4) Before, or concurrent with the initial use -

(a) Check each batch of media for sterility if sterility is required for testing;

(b) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and

(c) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer.

(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results.

f. Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results.

g. The laboratory must document all control procedures performed.

h. If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented.

11-40 **STANDARD: BACTERIOLOGY (§493.1261)**

a. The laboratory must check the following for positive and negative reactivity using control organisms:

(1) Each day of use for beta-lactamase methods other than Cefinase™.

(2) Each week of use for Gram stains.

(3) When each batch (prepared in-house), lot number (commercially prepared), and shipment of antisera is prepared or opened, and once every 6 months thereafter.

b. For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms.

(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.

(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 paragraph.

11-41 **STANDARD: MYCOBACTERIOLOGY (§493.1262)**

a. Each day of use, the laboratory must check all reagents or test procedures used for mycobacteria identification with at least one acid-fast organism that produces a positive reaction and an acid-fast organism that produces a negative reaction.

b. For antimycobacterial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimycobacterial agent(s) before, or concurrent with, initial use, using an appropriate control organism(s).

(1) The laboratory must establish limits for acceptable control results.

(2) Each week tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.

(3) The results for the control organism(s) must be within established limits before reporting patient results.

c. The laboratory must document all control procedures performed, as specified in this paragraph.

11-42 **STANDARD: MYCOLOGY (§493.1263)**

a. The laboratory must check each batch (prepared in-house), lot number (commercially prepared), and shipment of lactophenol cotton blue when prepared or opened for intended reactivity with a control organism(s).

b. For antifungal susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antifungal agent(s) before, or concurrent with, initial use, using an appropriate control organism(s).

(1) The laboratory must establish limits for acceptable control results.

(2) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.

(3) The results for the control organism(s) must be within established limits before reporting patient results.

c. The laboratory must document all control procedures performed, as specified in this paragraph.

11-43 **STANDARD: PARASITOLOGY (§493.1264)**

a. The laboratory must have available a reference collection of slides or photographs and, if available, gross specimens for identification of parasites and use these references in the laboratory for appropriate comparison with diagnostic specimens.

b. The laboratory must calibrate and use the calibrated ocular micrometer for determining the size of ova and parasites, if size is a critical parameter.

c. Each month of use, the laboratory must check permanent stains using a fecal sample control material that will demonstrate staining characteristics.

d. The laboratory must document all control procedures performed, as specified in this paragraph.

11-44 **STANDARD: VIROLOGY (§493.1265)**

a. When using cell culture to isolate or identify viruses, the laboratory must simultaneously incubate a cell substrate control or uninoculated cells as a negative control material.

b. The laboratory must document all control procedures performed, as specified in this paragraph.

**11-45 STANDARD: ROUTINE CHEMISTRY (§493.1267)**

For blood gas analyses, the laboratory must perform the following:

a. Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer.

b. Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing.

c. Test one sample of control material each time specimens are tested unless automated instrumentation internally verifies calibration at least every 30 minutes.

d. Document all control procedures performed, as specified in this paragraph.

**11-46 STANDARD: HEMATOLOGY (§493.1269)**

a. For manual cell counts performed using a hemocytometer -

(1) One control material must be tested each 8 hours of operation; and

(2) Patient specimens and control materials must be tested in duplicate.

b. For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed.

c. For manual coagulation tests -

(1) Each individual performing tests must test two levels of control materials before testing patient samples and each time a reagent is changed; and

(2) Patient specimens and control materials must be tested in duplicate.

d. The laboratory must document all control procedures performed, as specified in this paragraph.

11-47 STANDARD: IMMUNOHEMATOLOGY (§493.1271)

a. Patient testing.

(1) The laboratory must perform ABO grouping, D(Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e).

(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells.

(3) The laboratory must determine the D(Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent.

b. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b).

c. Blood and blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected.

(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period.

(2) Inspections of the alarm system must be documented.

d. According to the laboratory's established procedures, samples of each unit of transfused blood must be retained for further testing in the event of transfusion reactions. The laboratory must promptly dispose of blood not retained for further testing that has passed its expiration date.

e. Investigation of transfusion reactions.

(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures.

(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and

procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused.

f. The laboratory must document all control procedures performed, as specified in this paragraph.

**11-48 STANDARD: HISTOPATHOLOGY (§493.1273)**

a. As specified in paragraph 11-39e(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reaction(s) of the control slide with each special stain must be documented.

b. The laboratory must retain stained slides, specimen blocks, and tissue remnants as specified in paragraph 10-4. The remnants of tissue specimens must be maintained in a manner that ensures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under paragraphs 12-26b, e, f, g, or h.

c. An individual who has successfully completed a training program in neuromuscular pathology approved by HHS may examine and provide reports for neuromuscular pathology.

d. Tissue pathology reports must be signed by an individual qualified as specified in b or, as appropriate, c of this paragraph. If a computer report is generated with an electronic signature, it must be authorized by the individual who performed the examination and made the diagnosis.

e. The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results.

f. The laboratory must document all control procedures performed, as specified in this paragraph.

**11-49 STANDARD: CYTOLOGY (§493.1274)**

a. All cytology slide preparations must be evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology.

b. Staining. The laboratory must have available and follow written policies and procedures for each of the following, if applicable:

- (1) All gynecologic slide preparations must be stained using a Papanicolaou or modified Papanicolaou staining method.

(2) Effective measures to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process must be used.

(3) Nongynecologic specimens that have a high potential for cross-contamination must be stained separately from other nongynecologic specimens, and the stains must be filtered or changed following staining.

c. 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:

(1) A review of slides from at least 10 percent of the gynecologic cases interpreted by individuals qualified under paragraphs 12-36 or 12-39 to be negative for epithelial cell abnormalities and other malignant neoplasms (as defined in e(1) of this paragraph).

(a) The review must be performed by an individual who meets one of the following qualifications:

- A technical supervisor qualified under paragraph 12-26b or d.

- A cytology general supervisor qualified under paragraph 12-36.

- A cytotechnologist qualified under paragraph 12-39 who has the experience specified in paragraph 12-36b.

(b) Cases must be randomly selected from the total caseload and include negatives 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.

(c) The review of those cases selected must be completed before reporting patient results.

(2) Laboratory comparison of clinical information, when available, with cytology reports and comparison of all gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with the histopathology report, if available in the laboratory (either on-site or in storage), and determination of the causes of any discrepancies.

(3) For each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm, laboratory review of all normal or negative gynecologic specimens received within the previous 5 years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that will affect current patient care, the laboratory must notify the patient's physician and issue an amended report.

(4) Records of initial examinations and all rescreening results must be documented.

(5) An annual statistical laboratory evaluation of the number of -

(a) Cytology cases examined;

(b) Specimens processed by specimen type;

(c) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation);

(d) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison;

(e) Gynecologic cases where cytology and histology are discrepant; and

(f) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms.

(6) An evaluation of the case reviews of each individual examining slides against the laboratory's overall statistical values, documentation of any discrepancies, including reasons for the deviation and, if appropriate, corrective actions taken.

d. Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following:

(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening.

(a) The workload limit is based on the individual's performance using evaluations of the following:

- Review of 10 percent of the cases interpreted as negative for the conditions defined in e(1) of this paragraph.
- Comparison of the individual's interpretation with the technical supervisor's confirmation of patient smears specified in e(1) and e(3) of this paragraph.

(b) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.

(2) The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides (one patient specimen per slide; gynecologic, nongynecologic, or both) irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target. In addition -

(a) The maximum number of 100 slides is examined in no less than an 8-hour workday;

(b) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula -

$$\frac{\text{Number of hours examining slides} \times 100}{8}$$

is used to determine maximum slide volume to be examined;

(c) Nongynecologic slide preparations made using liquid-based slide preparatory techniques that result in cell dispersion over one-half or less of the total available slide may be counted as one-half slide; and

(d) Technical supervisors who perform primary screening are not required to include tissue pathology slides and previously examined cytology slides (gynecologic and nongynecologic) in the 100 slide workload limit.

(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory.

(4) Records are available to document the workload limit for each individual.

e. Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following:

(1) A technical supervisor confirms each gynecologic slide preparation interpreted to exhibit reactive or reparative changes or any of the following epithelial cell abnormalities:

(a) Squamous cell.

- Atypical squamous cells of undetermined significance (ASC-US) or cannot exclude HSIL (ASC-H).
- LSIL-Human papillomavirus (HPV)/mild dysplasia/cervical intraepithelial neoplasia 1 (CIN 1).
- HSIL-moderate and severe dysplasia, carcinoma in situ (CIS)/CIN 2 and CIN 3 or with features suspicious for invasion.
- Squamous cell carcinoma.

(b) Glandular cell.

- Atypical cells not otherwise specified (NOS) or specified in comments (endocervical, endometrial, or glandular).
- Atypical cells favor neoplastic (endocervical or glandular).
- Endocervical adenocarcinoma in situ.
- Adenocarcinoma endocervical, adenocarcinoma endometrial, adenocarcinoma extrauterine, and adenocarcinoma NOS.

(c) Other malignant neoplasms.

(2) The report of gynecologic slide preparations with conditions specified in e(1) of this paragraph must be signed to reflect the technical supervisory review or, if a

computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor who performed the review.

(3) All nongynecologic preparations are reviewed by a technical supervisor. The report must be signed to reflect technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor who performed the review.

(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.

(5) The report contains narrative descriptive nomenclature for all results.

(6) Corrected reports issued by the laboratory indicate the basis for correction.

f. Record and slide retention.

(1) The laboratory must retain all records and slide preparations as specified in paragraph 10-4.

(2) Slides may be loaned to proficiency testing programs in lieu of maintaining them for the required time period, provided the laboratory receives written acknowledgment of the receipt of slides by the proficiency testing program and maintains the acknowledgment to document the loan of these slides.

(3) Documentation of slides loaned or referred for purposes other than proficiency testing must be maintained.

(4) All slides must be retrievable upon request.

g. When performing evaluations using automated and semi-automated screening devices, the laboratory must follow manufacturer's instructions for preanalytic, analytic, and postanalytic phases of testing, as applicable, and meet the applicable requirements of this chapter.

h. The laboratory must document all control procedures performed, as specified in this paragraph.

**11-50 STANDARD: CLINICAL CYTOGENETICS (§493.1276)**

a. The laboratory must have policies and procedures for ensuring accurate and reliable patient specimen identification during the process of accessioning, cell preparation, photographing or other

image reproduction technique, photographic printing, and reporting and storage of results, karyotypes, and photographs.

b. The laboratory must have records that document the following:

- (1) The media used, reactions observed, number of cells counted, number of cells karyotyped, number of chromosomes counted for each metaphase spread, and the quality of the banding.
- (2) The resolution is appropriate for the type of tissue or specimen and the type of study required based on the clinical information provided to the laboratory.
- (3) An adequate number of karyotypes are prepared for each patient.

c. Determination of sex must be performed by full chromosome analysis.

d. The laboratory report must include a summary and interpretation of the observations, number of cells counted and analyzed, and use the International System for Human Cytogenetic Nomenclature.

e. The laboratory must document all control procedures performed, as specified in this paragraph.

**11-51 STANDARD: HISTOCOMPATIBILITY (§493.1278)**

a. General. The laboratory must meet the following requirements:

- (1) An audible alarm system must be used to monitor the storage temperature of specimens (donor and recipient) and reagents. The laboratory must have an emergency plan for alternate storage.
- (2) All patient specimens must be easily retrievable.
- (3) Reagent typing sera inventory prepared in-house must indicate source, bleeding date and identification number, reagent specificity, and volume remaining.
- (4) If the laboratory uses immunologic reagents (for example, antibodies, antibody-coated particles, or complement) to facilitate or enhance the isolation of lymphocytes, or lymphocyte subsets, the efficacy of the methods must be monitored with appropriate quality control procedures.
- (5) Participate in at least one national or regional cell exchange program, if available, or develop an exchange system with another laboratory in order to validate interlaboratory reproducibility.

b. HLA typing. The laboratory must do the following:

(1) Use a technique(s) that is established to optimally define, as applicable, HLA Class I and II specificities.

(2) HLA type all potential transplant recipients at a level appropriate to support clinical transplant protocol and donor selection.

(3) HLA type cells from organ donors referred to the laboratory.

(4) Use HLA antigen terminology that conforms to the latest report of the World Health Organization (W.H.O.) Committee on Nomenclature. Potential new antigens not yet approved by this committee must have a designation that cannot be confused with W.H.O. terminology.

(5) Have available and follow written criteria for the following:

(a) The preparation of cells or cellular extracts (for example, solubilized antigens and nucleic acids), as applicable to the HLA typing technique(s) performed.

(b) Selecting typing reagents, whether prepared in-house or commercially.

(c) Ensuring that reagents used for typing are adequate to define all HLA-A, B and DR specificities that are officially recognized by the most recent W.H.O. Committee on Nomenclature and for which reagents are readily available.

(d) The assignment of HLA antigens.

(e) When antigen redefinition and retyping are required.

(6) Check each HLA typing by testing, at a minimum, the following:

(a) A positive control material.

(b) A negative control material in which, if applicable to the technique performed, cell viability at the end of incubation is sufficient to permit accurate interpretation of results. In assays in which cell viability is not required, the negative control result must be sufficiently

different from the positive control result to permit accurate interpretation of results.

(c) Positive control materials for specific cell types when applicable (that is, T cells, B cells, and monocytes).

c. Disease-associated studies. The laboratory must check each typing for disease-associated HLA antigens using control materials to monitor the test components and each phase of the test system to ensure acceptable performance.

d. Antibody Screening. The laboratory must do the following:

(1) Use a technique(s) that detects HLA-specific antibody with a specificity equivalent or superior to that of the basic complement-dependent microlymphocytotoxicity assay.

(2) Use a method that distinguishes antibodies to HLA Class II antigens from antibodies to Class I antigens to detect antibodies to HLA Class II antigens.

(3) Use a panel that contains all the major HLA specificities and common splits. If the laboratory does not use commercial panels, it must maintain a list of individuals for fresh panel bleeding.

(4) Make a reasonable attempt to have available monthly serum specimens for all potential transplant recipients for periodic antibody screening and crossmatch.

(5) Have available and follow a written policy consistent with clinical transplant protocols for the frequency of screening potential transplant recipient sera for preformed HLA-specific antibodies.

(6) Check each antibody screening by testing, at a minimum, the following:

(a) A positive control material containing antibodies of the appropriate isotype for the assay.

(b) A negative control material.

(7) As applicable, have available and follow written criteria and procedures for antibody identification to the level appropriate to support clinical transplant protocol.

e. Crossmatching. The laboratory must do the following:

(1) Use a technique(s) documented to have increased sensitivity in comparison with the basic complement-dependent microlymphocytotoxicity assay.

(2) Have available and follow written criteria for the following:

(a) Selecting appropriate patient serum samples for crossmatching.

(b) The preparation of donor cells or cellular extracts (for example, solubilized antigens and nucleic acids), as applicable to the crossmatch technique(s) performed.

(3) Check each crossmatch and compatibility test for HLA Class II antigenic differences using control materials to monitor the test components and each phase of the test system to ensure acceptable performance.

f. Transplantation. Laboratories performing histocompatibility testing for transfusion and transplantation purposes must do the following:

(1) Have available and follow written policies and protocols specifying the histocompatibility testing (that is, HLA typing, antibody screening, compatibility testing and crossmatching) to be performed for each type of cell, tissue or organ to be transfused or transplanted. The laboratory's policies must include, as applicable -

(a) Testing protocols for cadaver donor, living, living-related, and combined organ and tissue transplants;

(b) Testing protocols for patients at high risk for allograft rejection; and

(c) The level of testing required to support clinical transplant protocols (for example, antigen or allele level).

(2) For renal allotransplantation and combined organ and tissue transplants in which a kidney is to be transplanted, have available results of final crossmatches before the kidney is transplanted.

(3) For nonrenal transplantation, if HLA testing and final crossmatches were not performed prospectively because of an emergency situation, the laboratory must document the circumstances, if known, under which the emergency

transplant was performed, and records of the transplant must reflect any information provided to the laboratory by the patient's physician.

g. The laboratory must document all control procedures performed, as specified in this paragraph.

**11-52 STANDARD: COMPARISON OF TEST RESULTS (§493.1281)**

a. If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

b. The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available:

- (1) Patient age.
- (2) Sex.
- (3) Diagnosis or pertinent clinical data.
- (4) Distribution of patient test results.
- (5) Relationship with other test parameters.

c. The laboratory must document all test result comparison activities.

**11-53 STANDARD: CORRECTIVE ACTIONS (§493.1282)**

a. Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

b. The laboratory must document all corrective actions taken, including actions taken when any of the following occur:

(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in paragraph 11-36b, which include but are not limited to -

(a) Equipment or methodologies that perform outside of established operating parameters or performance specifications;

(b) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and

(c) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

(3) The criteria for proper storage of reagents and specimens, as specified under paragraph 11-35b, are not met.

**11-54 STANDARD: TEST RECORDS (§493.1283)**

a. 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 laboratory's criteria for specimen acceptability.
- (4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

b. Records of patient testing including, if applicable, instrument printouts, must be retained.

**11-55 STANDARD: ANALYTIC SYSTEMS QUALITY ASSESSMENT (§493.1289)**

a. The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in paragraphs 11-34 through 11-54.

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

c. The laboratory must document all analytic systems quality assessment activities.

**POSTANALYTIC SYSTEMS****11-56 CONDITION: POSTANALYTIC SYSTEMS (§493.1290)**

Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in paragraph 11-57 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 postanalytic systems and correct identified problems as specified in paragraph 11-58 for each specialty and subspecialty of testing performed.

**11-57 STANDARD: TEST REPORT (§493.1291)**

a. The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following:

- (1) Results reported from calculated data.
- (2) Results and patient-specific data electronically reported to network or interfaced systems.
- (3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

b. Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to TSG or their designee upon request.

c. The test report must indicate the following:

- (1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number.
- (2) The name and address of the laboratory location where the test was performed.
- (3) The test report date.
- (4) The test performed.
- (5) Specimen source, when appropriate.
- (6) The test result and, if applicable, the units of measurement or interpretation, or both.

(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

d. Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

e. The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in paragraph 11-36. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

f. Test results must be released only to authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test.

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

h. When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing.

i. If a laboratory refers patient specimens for testing -

(1) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory;

(2) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report; and

(3) The authorized person who orders a test must be notified by the referring laboratory of the name and address of each laboratory location where the test was performed.

j. All test reports or records of the information on the test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility.

k. When errors in the reported patient test results are detected, the laboratory must do the following:

- (1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors.
- (2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results.
- (3) Maintain duplicates of the original report, as well as the corrected report.

**11-58 STANDARD: POSTANALYTIC SYSTEMS QUALITY ASSESSMENT (§ 493.1299)**

a. The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in paragraph 11-57.

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

c. The laboratory must document all postanalytic systems quality assessment activities.

## CHAPTER 12

## PERSONNEL FOR NONWAIVED TESTING

## 12-1. GENERAL (§493.1351)

This chapter consists of the personnel requirements that must be met by laboratories performing nonwaived testing. As feasible, medical laboratories located outside of the United States will meet these personnel rules to ensure quality laboratory services, but OASD(HA) or TSG may waive specific personnel requirements if necessary for national defense.

## 12-2. LABORATORIES PERFORMING PROVIDER-PERFORMED MICROSCOPY (PPM) PROCEDURES: SCOPE (§493.1353)

In accordance with paragraph 2-5b, the moderate complexity procedures specified as PPM procedures are considered such only when personally performed by a health care provider during a patient visit in the context of a physical examination. PPM procedures are subject to the personnel requirements in paragraphs 12-3 through 12-8.

## 12-3. CONDITION: LABORATORIES PERFORMING PPM PROCEDURES: LABORATORY DIRECTOR (§493.1355)

The laboratory must have a director who meets the qualification requirements of paragraph 12-4 and provides overall management and direction in accordance with paragraph 12-5.

## 12-4. STANDARD: LABORATORIES PERFORMING PPM PROCEDURES: LABORATORY DIRECTOR QUALIFICATIONS (§493.1357)

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of PPM procedures as specified in paragraph 2-5c.

The laboratory director must meet one of the following requirements:

- a. Be a physician, as defined in Appendix B, Glossary, privileged to practice medicine in a DoD medical treatment facility.
- b. Be a midlevel practitioner, as defined in Appendix B, Glossary, privileged to practice independently in a DoD medical treatment facility.
- c. Be a dentist, as defined in Appendix B, Glossary, privileged to practice dentistry in a DoD medical treatment facility.

**12-5. STANDARD: LABORATORIES PERFORMING PPM PROCEDURES: LABORATORY DIRECTOR RESPONSIBILITIES (§493.1359)**

The laboratory director is responsible for the overall operation and administration of the laboratory, including the prompt, accurate, and proficient reporting of test results. The laboratory director must:

- a. Direct no more than five laboratories performing moderate complexity testing (including the subcategory of PPM procedures), high complexity testing, or a combination of moderate (including the subcategory of PPM procedures) and high complexity testing.
- b. Ensure that any procedure listed under paragraph 2-5c is personally performed by an individual who meets the qualification requirements in paragraph 12-7, and is performed in accordance with applicable requirements in Chapters 7, 10, 11, and 12.

**12-6. CONDITION: LABORATORIES PERFORMING PPM PROCEDURES: TESTING PERSONNEL (§493.1361)**

The laboratory must have a sufficient number of individuals who meet the qualification requirements of paragraph 12-7 to perform the functions specified in paragraph 12-8 for the volume and complexity of testing performed.

**12-7. STANDARD: LABORATORIES PERFORMING PPM PROCEDURES: TESTING PERSONNEL QUALIFICATIONS (§493.1363)**

Each individual performing PPM procedures must meet one of the following:

- a. Be a physician, as defined in Appendix B, Glossary, and be privileged to practice medicine in a DoD medical treatment facility.
- b. Be a midlevel practitioner, as defined in Appendix B, Glossary, under the supervision of a physician, or privileged to practice independently in a DoD medical treatment facility.
- c. Be a dentist, as defined in Appendix B, Glossary, privileged to practice dentistry in a DoD medical treatment facility.

**12-8. STANDARD: LABORATORIES PERFORMING PPM PROCEDURES: TESTING PERSONNEL RESPONSIBILITIES (§493.1365).**

The testing personnel are responsible for specimen processing, test performance, and for reporting test results. Any PPM procedure must be:

a. Personally performed by one of the following practitioners:

(1) A physician during the patient's visit on a specimen obtained from his or her own patient or from a patient of a clinic or group medical practice for which the physician is a member or employee.

(2) A midlevel practitioner, under the supervision of a physician or privileged to practice independently in a DoD medical treatment facility, during the patient's visit on a specimen obtained from his or her own patient or from a patient of a clinic, group medical practice, or other health care provider, in which the midlevel practitioner is a member or employee.

(3) A dentist during the patient's visit on a specimen obtained from his or her own patient or from a patient of a clinic or group dental practice for which the dentist is a member or employee.

b. Performed using a microscope limited to a bright field or a phase/contrast microscope.

**12-9. CONDITION: LABORATORIES PERFORMING MODERATE COMPLEXITY TESTING: LABORATORY DIRECTOR (§493.1403)**

The laboratory must have a director who meets the qualification requirements of paragraph 12-10 and provides overall management and direction in accordance with paragraph 12-12.

**12-10. STANDARD: LABORATORIES PERFORMING MODERATE COMPLEXITY TESTING: LABORATORY DIRECTOR QUALIFICATIONS (§493.1405)**

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests.

a. For medical field units deployed during periods of war, mobilization, or national emergency, the qualifications for laboratory director listed in paragraph b below may be modified or waived by OASD(HA) or TSG.

b. The laboratory director must meet one of the following qualifications:

(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy by the recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands, and privileged to practice medicine in a DoD medical treatment facility; and be certified in anatomic or clinical pathology, or both, by the American

Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification.

(2) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine, licensed to practice medicine, osteopathy, or podiatry by the recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands, and privileged to practice medicine in a DoD medical treatment facility; and have had laboratory training or experience consisting of one of the following:

(a) At least one year directing or supervising non-waived laboratory testing.

(b) Beginning 1 September 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in paragraph 12-12, and approved by TSG or their designee.

(c) Laboratory training equivalent to paragraph b(2)(b) above obtained during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine).

(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution and one of the following:

(a) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology.

(b) Have had at least one year experience directing or supervising non-waived laboratory testing.

(4) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution with at least one year of laboratory training or experience, or both, in non-waived testing plus have at least one year of supervisory laboratory experience in non-waived testing.

(5) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from

an accredited institution, with at least 2 years of laboratory training or experience, or both, in non-waived testing plus have at least 2 years of supervisory laboratory experience in non-waived testing.

(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under paragraph 12-11.

**12-11. STANDARD: LABORATORIES PERFORMING MODERATE COMPLEXITY TESTING: LABORATORY DIRECTOR QUALIFICATIONS ON OR BEFORE 28 FEBRUARY 1992 (§493.1406)**

The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. The laboratory director must meet one of the following qualifications:

(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification;

(2) Be a physician who:

(a) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or

(b) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or

(c) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or

(d) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties;

(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification;

(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and:

- (a) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or
  - (b) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties;
- (5) With respect to individuals first qualifying before 1 July 1971, have been responsible for the direction of a laboratory for 12 months between 1 July 1961, and 1 January 1968, and, in addition, either:
- (a) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; or
  - (b) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; or
  - (c) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or
  - (d) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before 1 July 1970.

**12-12. STANDARD: LABORATORIES PERFORMING MODERATE COMPLEXITY TESTING: LABORATORY DIRECTOR RESPONSIBILITIES (§493.1407)**

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

- a. The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of paragraphs 12-14, 12-17 and 12-20, respectively.
- b. If the laboratory director reapportions performance of his or her

responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

c. The laboratory director must be accessible to the laboratory to provide on-site, telephone or electronic consultation as needed.

d. Each individual may direct no more than five laboratories performing moderate complexity testing (including the subcategory of PPM procedures), high complexity testing, or a combination of moderate (including the subcategory of PPM procedures) and high complexity testing.

e. The laboratory director must:

(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the pre-analytic, analytic, and post-analytic phases of testing;

(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards;

(3) Ensure that:

(a) The test methodologies selected have the capability of providing the quality of results required for patient care.

(b) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

(c) Laboratory personnel are performing the test methods as required for accurate and reliable results.

(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed, and that:

(a) The proficiency testing samples are tested as required under Chapter 7.

(b) The results are returned within the time frames established by the proficiency testing program.

(c) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

(d) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and that patient test results are reported only when the system is functioning properly.

(8) Ensure that reports of test results include pertinent information required for interpretation.

(9) Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions.

(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this chapter.

(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test

results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

(14) Specify, in writing, the responsibilities and duties of each consultant and each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

**12-13. CONDITION: LABORATORIES PERFORMING MODERATE COMPLEXITY TESTING: TECHNICAL CONSULTANT (§493.1409)**

The laboratory must have a technical consultant who meets the qualification requirements of paragraph 12-14 and provides technical oversight in accordance with paragraph 12-15.

**12-14. STANDARD: LABORATORIES PERFORMING MODERATE COMPLEXITY TESTING: TECHNICAL CONSULTANT QUALIFICATIONS (§493.1411)**

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this paragraph.

a. For medical field units deployed during periods of war, mobilization, or national emergency, the qualifications for technical consultant listed in paragraph b below may be modified or waived by OASD(HA) or TSG.

b. The technical consultant must meet one of the following qualifications:

- (1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy by the recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands, and privileged to practice medicine in a DoD medical treatment facility; and be certified in

anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification.

(2) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry by the recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands, and privileged to practice medicine in a DoD medical treatment facility; and have at least one year of laboratory training or experience, or both, in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology).

(3) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution, and have at least one year of laboratory training or experience, or both, in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.

(4) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and have at least 2 years of laboratory training or experience, or both, in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.

*Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual, who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.*

12-15. **STANDARD: LABORATORIES PERFORMING MODERATE COMPLEXITY TESTING: TECHNICAL CONSULTANT RESPONSIBILITIES (§493.1413)**

The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be on-site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph a below.

a. The technical consultant must be accessible to the laboratory to provide on-site, telephone, or electronic consultation.

b. The technical consultant is responsible for:

(1) Selection of test methodology appropriate for the clinical use of the test results.

(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

(3) Enrollment and participation in an HHS-approved proficiency testing program commensurate with the services offered.

(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications.

(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly.

(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed.

(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation

of the competency of the staff must include, but are not limited to:

- (a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.
- (b) Monitoring the recording and reporting of test results.
- (c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.
- (d) Direct observation of performance of instrument maintenance and function checks.
- (e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.
- (f) Assessment of problem solving skills.

(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

**12-16. CONDITION: LABORATORIES PERFORMING MODERATE COMPLEXITY TESTING: CLINICAL CONSULTANT (§493.1415)**

The laboratory must have a clinical consultant who meets the qualification requirements of paragraph 12-17 and provides clinical consultation in accordance with paragraph 12-18.

**12-17. STANDARD: LABORATORIES PERFORMING MODERATE COMPLEXITY TESTING: CLINICAL CONSULTANT QUALIFICATIONS (§493.1417)**

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must be:

a. qualified as a laboratory director under paragraph 12-10b(1), (2), or (3)(a); or

b. a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry by the recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands, and privileged to practice medicine in a DoD medical treatment facility.

**12-18. STANDARD: LABORATORIES PERFORMING MODERATE COMPLEXITY TESTING: CLINICAL CONSULTANT RESPONSIBILITIES (§493.1419)**

The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results. The clinical consultant must:

a. Be available to provide clinical consultation to the laboratory's clients.

b. Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations.

c. Ensure that reports of test results include pertinent information required for specific patient interpretation.

d. Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

**12-19. CONDITION: LABORATORIES PERFORMING MODERATE COMPLEXITY TESTING: TESTING PERSONNEL (§493.1421)**

The laboratory must have a sufficient number of individuals who meet the qualification requirements of paragraph 12-20, to perform the functions specified in paragraph 12-21 for the volume and complexity of tests performed.

**12-20. STANDARD: LABORATORIES PERFORMING MODERATE COMPLEXITY TESTING: TESTING PERSONNEL QUALIFICATIONS (§493.1423)**

Each individual performing moderate complexity testing must meet one of the following requirements:

a. Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry by the recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands, and be privileged to practice medicine in a DoD medical treatment facility; or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory

science, or medical technology from an accredited institution.

b. Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution

c. Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).

d. Have earned a high school diploma or equivalent, and have documentation of training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has:

(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens.

(2) The skills required for implementing all standard laboratory procedures.

(3) The skills required for performing each test method and for proper instrument use.

(4) The skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed.

(5) A working knowledge of reagent stability and storage.

(6) The skills required to implement the quality control policies and procedures of the laboratory.

(7) An awareness of the factors that influence test results.

(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient results.

**12-21. STANDARD: LABORATORIES PERFORMING MODERATE COMPLEXITY TESTING: TESTING PERSONNEL RESPONSIBILITIES (§493.1425)**

The testing personnel are responsible for specimen processing, test performance, and for reporting test results.

a. Each individual performs only those moderate complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

b. Each individual performing moderate complexity testing must:

(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples.

(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

(4) Follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance.

(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director.

(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.

**12-22. CONDITION: LABORATORIES PERFORMING HIGH COMPLEXITY TESTING: LABORATORY DIRECTOR (§493.1441)**

The laboratory must have a director who meets the qualification requirements of paragraph 12-23 and provides overall management and direction in accordance with paragraph 12-24.

**12-23. STANDARD: LABORATORIES PERFORMING HIGH COMPLEXITY TESTING: LABORATORY DIRECTOR QUALIFICATIONS (§493.1443)**

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of high complexity tests.

a. For medical field units deployed during periods of war, mobilization, or national emergency, the qualifications for laboratory director listed in paragraph b below may be modified or waived by OASD(HA) or TSG.

b. The laboratory director must meet one of the following qualifications:

(1) Be a doctor of medicine or doctor of osteopathy, licensed to practice medicine or osteopathy by the recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands, and be privileged to practice medicine in a DoD medical treatment facility; and be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification;

(2) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry by the recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands, and be privileged to practice medicine in a DoD medical treatment facility; plus have one of the following:

(a) At least 1 year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or

(b) At least 2 years of experience directing or supervising high complexity testing.

(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and one of the following:

(a) Be certified, and continue to be certified, by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, the American Board of Medical Laboratory Immunology or other board deemed comparable by HHS.

(b) Before February 24, 2003, must have served or be serving as a director of a laboratory performing high complexity testing and must have at least 2 years of laboratory training or experience, or both; and 2 years of laboratory experience directing or supervising high complexity testing.

(4) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

**12-24. STANDARD: LABORATORIES PERFORMING HIGH COMPLEXITY TESTING: LABORATORY DIRECTOR RESPONSIBILITIES (§493.1445)**

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

a. The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under paragraphs 12-26, 12-29, 12-32, and 12-42, respectively.

b. If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

c. The laboratory director must be accessible to the laboratory to provide on-site, telephone or electronic consultation as needed.

d. Each individual may direct no more than five laboratories performing moderate complexity testing (including the subcategory of PPM procedures), high complexity testing, or a combination of moderate (including the subcategory of PPM procedures) and high complexity testing.

e. The laboratory director must:

(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards.

(3) Ensure that:

(a) The test methodologies selected have the

capability of providing the quality of results required for patient care.

(b) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

(c) Laboratory personnel are performing the test methods as required for accurate and reliable results.

(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that:

(a) The proficiency testing samples are tested as required under Chapter 7.

(b) The results are returned within the time frames established by the proficiency testing program.

(c) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

(d) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and that patient test results are reported only when the system is functioning properly.

(8) Ensure that reports of test results include pertinent information required for interpretation.

(9) Ensure that consultation is available to the laboratory's clients on matters relating to the quality of

the test results reported and their interpretation concerning specific patient conditions.

(10) Ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under paragraph 12-42(e) & f (see paragraph 12-34c for exception to this requirement).

(11) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this chapter.

(12) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

**12-25. CONDITION: LABORATORIES PERFORMING HIGH COMPLEXITY TESTING: TECHNICAL SUPERVISOR (§493.1447)**

The laboratory must have a technical supervisor who meets the qualification requirements of paragraph 12-26 and provides technical supervision in accordance with paragraph 12-27.

**12-26. STANDARD: LABORATORIES PERFORMING HIGH COMPLEXITY TESTING: TECHNICAL SUPERVISOR QUALIFICATIONS (§493.1449)**

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this paragraph.

a. For medical field units deployed during periods of war, mobilization, or national emergency, the qualifications for technical supervisor listed in paragraphs b through h and paragraph k below may be modified or waived by OASD(HA) or TSG.

b. The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor meets the following qualifications:

(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy by the recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands, and is privileged to practice medicine in a DoD medical treatment facility.

(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for such certification.

c. If the requirements of paragraph b above are not met and the laboratory performs tests in any of the specialties of Microbiology, Diagnostic Immunology, Chemistry, Hematology, or Radiobioassay, the individual functioning as the technical supervisor must meet one of the following qualifications:

(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy by the recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands, and be privileged to practice medicine in a DoD medical treatment facility; and be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification.

(2) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry by the recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands, and be privileged to practice medicine in a DoD medical treatment facility; and have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty supervised (for example, in the specialty of hematology, physicians certified in either hematology or hematology and medical oncology by the American Board of Internal Medicine). Additionally, supervisors of the subspecialties of Bacteriology, Mycobacteriology, Mycology, Parasitology, or Virology must have a minimum of 6 months experience in high complexity testing within the subspecialty.

(3) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty supervised. Additionally, supervisors of the subspecialties of Bacteriology, Mycobacteriology, Mycology, Parasitology, or Virology must have a minimum of 6 months experience in high complexity testing within the subspecialty.

(4) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty supervised. Additionally, supervisors of the subspecialties of Bacteriology, Mycobacteriology, Mycology, Parasitology, or Virology must have a minimum of 6 months experience in high complexity testing within the subspecialty.

(5) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty supervised. Additionally, supervisors of the subspecialties of Bacteriology, Mycobacteriology, Mycology, Parasitology, or Virology must have a minimum of 6 months experience in high complexity testing within the subspecialty.

**Note: The qualification listed below is military unique and may not be recognized by a laboratory's accreditation organization. It is advisable to check with the**

**accreditation organization before appointing a technical supervisor under this qualification.**

(6) Be a commissioned officer in the Armed Forces, and have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution and meet the following qualifications:

(a) Have at least 3 years of laboratory training or experience, or both, in high complexity testing within the specialty supervised. Additionally, supervisors of the subspecialties of Bacteriology, Mycobacteriology, Mycology, Parasitology, or Virology; must have a minimum of 6 months experience in high complexity testing within the subspecialty.

(b) Be certified by an agency appropriate to the specialty such as the American Board of Medical Microbiology, the American Society of Clinical Pathology, the National Certifying Agency for Medical Laboratory Personnel, or other board deemed comparable by OASD(HA).

*Note: The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.*

d. If the requirements of paragraph b above are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must:

(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy by the recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands, and privileged to practice medicine in a DoD medical treatment facility; and meet one of the following requirements:

(a) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification.

(b) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification.

(2) An individual qualified under paragraph b or paragraph d(1) above may delegate some of the cytology technical supervisor responsibilities to an individual who is in the final year of full-time training leading to certification specified in paragraphs b or d(1)(a) above provided the technical supervisor qualified under paragraph b or paragraph d(1) above remains ultimately responsible for ensuring that all of the responsibilities of the cytology technical supervisor are met.

e. If the requirements of paragraph b above are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must:

(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy by the recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands, and be privileged to practice medicine in a DoD medical treatment facility; and be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification.

(2) An individual qualified under paragraph b or paragraph e(1) above may delegate to an individual who is a resident in a training program leading to certification specified in paragraph b or e(1) above, the responsibility for examination and interpretation of histopathology specimens.

f. If the requirements of paragraph b above are not met and the laboratory performs tests in the subspecialty of dermatopathology, the individual functioning as the technical supervisor must:

(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy by the recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands, and be privileged to practice medicine

in a DoD medical treatment facility; and meet one of the following requirements:

(a) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification.

(b) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification.

(c) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification.

(2) An individual qualified under paragraph b or paragraph f(1) above may delegate to an individual who is a resident in a training program leading to certification specified in paragraph b or f(1) above, the responsibility for examination and interpretation of dermatopathology specimens.

g. If the requirements of paragraph b above are not met and the laboratory performs tests in the subspecialty of ophthalmic pathology, the individual functioning as the technical supervisor must:

(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy by the recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands and be privileged to practice medicine in a DoD medical treatment facility; and must meet one of the following requirements:

(a) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification.

(b) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology.

(2) An individual qualified under paragraph b or paragraph g(1) above may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs b or g(1) above, the responsibility for examination and interpretation of ophthalmic specimens.

h. If the requirements of paragraph b above are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements:

(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy by the recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands, and privileged to practice medicine in a DoD medical treatment facility; and be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification, or be certified in oral pathology by the American Board of Oral Pathology or possess qualifications that are equivalent to those required for such certification.

(2) An individual qualified under paragraph b or paragraph h(1) above may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs b or h(1) above, the responsibility for examination and interpretation of oral pathology specimens.

i. If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either:

(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry by the recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands, and be privileged to practice medicine in a DoD medical treatment facility; and have training or experience that meets one of the following requirements:

(a) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility.

(b) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and have 2 years of laboratory

training or experience, or both, in the specialty of histocompatibility.

(2) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and have training or experience that meets one of the following requirements:

(a) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility.

(b) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility.

j. If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must either:

(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry by the recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands, and be privileged to practice medicine in a DoD medical treatment facility; and have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics.

(2) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics.

k. If the requirements of paragraph b above are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must:

(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy by the recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands, and be privileged to practice medicine in a DoD medical treatment facility; and be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for

such certification

(2) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry by the recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands, and privileged to practice medicine in a DoD medical treatment facility; and have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology.

**Note: The qualifications listed below are military unique and may not be recognized by a laboratory's accreditation organization. It is advisable to check with the accreditation organization before appointing a technical supervisor under one of these qualifications.**

(3) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and have either:

(a) At least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of immunohematology.

(b) Successfully completed a CAHEA accredited school as a Specialist in Blood Banking.

(4) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and have either:

(a) At least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of immunohematology.

(b) Successfully completed a CAHEA accredited school as a Specialist in Blood Banking.

(5) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and have either:

(a) At least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of immunohematology.

(b) Successfully completed a CAHEA accredited school as a Specialist in Blood Banking.

(6) Be a commissioned officer in the Armed Forces, and have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and have at least 3 years of laboratory training or experience, or both, in high complexity testing within the specialty of immunohematology; and be certified by the American Society of Clinical Pathology, the National Certification Agency for Medical Laboratory Personnel, or other board deemed comparable by OASD(HA).

**12-27. STANDARD: LABORATORIES PERFORMING HIGH COMPLEXITY TESTING: TECHNICAL SUPERVISOR RESPONSIBILITIES (§493.1451)**

The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified below.

a. The technical supervisor must be accessible to the laboratory to provide on-site, telephone, or electronic consultation.

b. The technical supervisor is responsible for:

(1) Selection of the test methodology that is appropriate for the clinical use of the test results.

(2) Verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

(3) Enrollment and participation in an HHS-approved proficiency testing program commensurate with the services offered.

(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications.

(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly.

(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed.

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

(a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

(b) Monitoring the recording and reporting of test results.

(c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

(d) Direct observation of performance of instrument maintenance and function checks.

(e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

(f) Assessment of problem solving skills.

(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless the test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

c. In cytology, the technical supervisor or the individual qualified under paragraph 12-26d(2):

(1) May perform the duties of the cytology general supervisor and the cytotechnologist, as specified in paragraph 12-37 and paragraph 12-40, respectively.

- (2) Must establish the workload limit for each individual examining slides.
- (3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary.
- (4) Must perform the functions specified in paragraph 11-49d and e.
- (5) Must ensure that each individual examining gynecologic preparations participates in an HHS-approved cytology proficiency testing program, as specified in paragraph 9-6 and achieves a passing score, as specified in paragraph 7-8.
- (6) If responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24 hour period to screening cytology slides.

**12-28. CONDITION: LABORATORIES PERFORMING HIGH COMPLEXITY TESTING: CLINICAL CONSULTANT (§493.1453)**

The laboratory must have a clinical consultant who meets the requirements of paragraph 12-29 and provides clinical consultation in accordance with paragraph 12-30.

**12-29. STANDARD: LABORATORIES PERFORMING HIGH COMPLEXITY TESTING: CLINICAL CONSULTANT QUALIFICATIONS (§493.1455)**

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must meet one of the following qualifications:

- a. Be qualified as a laboratory director under paragraph 12-23b(1),(2), or (3)(a) or, for the subspecialty of oral pathology, paragraph 12-23b(4).
- b. Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry by a recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands, and privileged to practice medicine in a DoD medical facility.

**12-30. STANDARD: LABORATORIES PERFORMING HIGH COMPLEXITY TESTING: CLINICAL CONSULTANT RESPONSIBILITIES (§493.1457)**

The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results. The clinical consultant must:

- a. Be available to provide consultation to the laboratory's clients.
- b. Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations.
- c. Ensure that reports of test results include pertinent information required for specific patient interpretation.
- d. Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

**12-31. CONDITION: LABORATORIES PERFORMING HIGH COMPLEXITY TESTING: GENERAL SUPERVISOR (§493.1459)**

The laboratory must have one or more general supervisors who are qualified under paragraph 12-32 to provide general supervision in accordance with paragraph 12-34.

**12-32. STANDARD: LABORATORIES PERFORMING HIGH COMPLEXITY TESTING: GENERAL SUPERVISOR QUALIFICATIONS (§493.1461)**

The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results.

- a. For medical field units deployed during periods of war, mobilization, or national emergency, the qualifications for general supervisor listed in paragraph b may be modified or waived by OASD(HA) or TSG.
- b. The general supervisor must be qualified as either:
  - (1) Laboratory director under paragraph 12-23.
  - (2) Technical supervisor under paragraph 12-26.

c. If the requirements of paragraphs b(1) or b(2) above are not met, the individual functioning as the general supervisor must meet one of the following qualifications:

(1) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry by the recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands, and be privileged to practice medicine in a DoD medical treatment facility; or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and have at least 1 year of laboratory training or experience, or both, in high complexity testing.

(2) Qualify as testing personnel under paragraph 12-42b; and have at least 2 years of laboratory training or experience, or both, in high complexity testing.

(3) Have previously qualified as a general supervisor under paragraph 12-33 on or before 28 February 1992. (Exception: An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between 1 March 1986 and 31 December 1987 qualifies as a general supervisor if he or she meets the requirements of paragraph 12-33 on or before 1 January 1994.)

(4) On or before 1 September 1992, have served as a general supervisor of high complexity testing and as of 24 April 1995 meet one of the following requirements and have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing:

(a) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS.

(b) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).

(5) On or before 1 September 1992 have served as a general supervisor of high complexity testing; and be a high school graduate or equivalent; and have at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between 1 September 1982 and 1 September 1992.

d. For blood gas analysis, the individual providing general supervision must meet one of the following qualifications:

(1) Be qualified under paragraph b(1) or (2) above, or paragraph c above.

(2) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and have at least 1 year of laboratory training or experience, or both, in blood gas analysis.

(3) Have earned an associate degree related to pulmonary function from an accredited institution; and have at least 2 years of training or experience, or both, in blood gas analysis.

e. The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations must be performed:

(1) In histopathology, by an individual who is qualified as a technical supervisor under paragraph 12-26b or paragraph 12-26e(1);

(2) In dermatopathology, by an individual who is qualified as a technical supervisor under paragraph 12-26b or paragraph 12-26f(1).

(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under paragraph 12-26b or paragraph 12-26g(1) and

(4) In oral pathology, by an individual who is qualified as a technical supervisor under paragraph 12-26b or paragraph 12-26h(1).

**12-33. STANDARD: LABORATORIES PERFORMING HIGH COMPLEXITY TESTING: GENERAL SUPERVISOR QUALIFICATIONS ON OR BEFORE 28 FEBRUARY 1992 (§493.1462)**

To qualify as a general supervisor under paragraph 12-32c(3), an individual must have met, or could have met, one of the following qualifications as they were in effect on or before 28 February 1992.

## a. The laboratory supervisor:

(1) Who qualifies as a laboratory director under paragraph 12-11(1), (2), (4), or (5) also qualifies as a general supervisor; therefore, depending upon the size and functions of the laboratory, the laboratory director may also serve as the laboratory supervisor.

(2) Is a physician or has earned a doctoral degree from an accredited institution with a major in one of the chemical, physical or biological sciences; and subsequent to graduation, has had at least 2 years experience in one of the lab specialties in a laboratory.

(3) Holds a master's degree from an accredited institution with a major in one of the chemical, physical or biological sciences, and subsequent to graduation has had at least 4 years of pertinent full-time lab experience of which not less than 2 years have been spent working in the designated specialty in a laboratory.

(4) Who qualifies as a laboratory technologist under paragraph 12-43; and after qualifying as a laboratory technologist, has had at least 6 years of pertinent full time laboratory experience of which not less than 2 years have been spent working in the designated specialty in a laboratory.

(5) With respect to individuals first qualifying before 1 July 1971, has had at least 15 years of pertinent full time laboratory experience before 1 January 1968; this required experience may be met by the substitution of education for experience.

**12-34. STANDARD: LABORATORIES PERFORMING HIGH COMPLEXITY TESTING: GENERAL SUPERVISOR RESPONSIBILITIES (§493.1463)**

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

## a. The general supervisor:

(1) Must be accessible to testing personnel at all times testing is performed to provide on-site, telephone or electronic consultation to resolve technical problems in accordance with policies and procedures established either by the laboratory director or technical supervisor.

(2) Is responsible for providing day-to-day supervision of

high complexity test performance by testing personnel qualified under paragraph 12-42.

(3) Except as specified in paragraph c below, must be on-site to provide direct supervision when high complexity testing is performed by any individuals qualified under paragraph 12-42e and f.

(4) Is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.

b. The director or technical supervisor may delegate to the general supervisor the responsibility for:

(1) Assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications.

(2) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning.

(3) Providing orientation to all testing personnel.

(4) Annually evaluating and documenting the performance of all testing personnel.

c. Exception: For individuals qualified under paragraph 12-42e and f, who were performing high complexity testing on or before 19 January 1993, the requirements of paragraph a(3) above are not effective, provided that all high complexity testing performed by the individual in the absence of a general supervisor is reviewed within 24 hours by a general supervisor qualified under paragraph 12-32.

**12-35. CONDITION: LABORATORIES PERFORMING HIGH COMPLEXITY TESTING: CYTOLOGY GENERAL SUPERVISOR (§493.1467)**

For the subspecialty of cytology, the laboratory must have a general supervisor who meets the qualification requirements of paragraph 12-36, and provides supervision in accordance with paragraph 12-37.

**12-36. STANDARD: LABORATORIES PERFORMING HIGH COMPLEXITY TESTING: CYTOLOGY GENERAL SUPERVISOR QUALIFICATIONS (§493.1469)**

The cytology general supervisor must be qualified to supervise cytology services. The general supervisor in cytology must either:

a. Be qualified as a technical supervisor under paragraph 12-26b or d.

b. Be qualified as a cytotechnologist under paragraph 12-39; and have

at least 3 years of full-time (2,080 hours per year) experience as a cytotechnologist within the preceding 10 years.

**12-37. STANDARD: LABORATORIES PERFORMING HIGH COMPLEXITY TESTING: CYTOLOGY GENERAL SUPERVISOR RESPONSIBILITIES (§493.1471)**

The technical supervisor of cytology may perform the duties of the cytology general supervisor or delegate the responsibilities to an individual qualified under paragraph 12-36.

a. The cytology general supervisor is responsible for the day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

b. The cytology general supervisor must:

(1) Be accessible to provide on-site, telephone, or electronic consultation to resolve technical problems in accordance with policies and procedures established by the technical supervisor of cytology.

(2) Document the slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed (as specified under paragraph 11-49c).

(3) For each 24 hour period, document the total number of slides he or she examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer.

(4) Document the number of hours spent examining slides in each 24 hour period.

**12-38. CONDITION: LABORATORIES PERFORMING HIGH COMPLEXITY TESTING: CYTOTECHNOLOGIST (§493.1481)**

For the subspecialty of cytology, the laboratory must have a sufficient number of cytotechnologists who meet the qualifications specified in paragraph 12-39 to perform the functions specified in paragraph 12-40.

**12-39. STANDARD: LABORATORIES PERFORMING HIGH COMPLEXITY TESTING: CYTOTECHNOLOGIST QUALIFICATIONS (§493.1483)**

Each person examining cytology slide preparations must meet the qualifications of paragraph 12-26b or d or meet one of the following requirements:

a. Have graduated from a school of cytotechnology accredited by the CAHEA or other organization approved by HHS.

b. Be certified in cytotechnology by a certifying agency approved by HHS.

c. Before 1 September 1992:

(1) Have successfully completed 2 years in an accredited institution with at least 12 semester hours in science, 8 hours of which are in biology; and have completed 1 of the following:

(a) 12 months of training in a school of cytotechnology accredited by an accrediting agency approved by HHS.

(b) received 6 months of formal training in a school of cytotechnology accredited by an accrediting agency approved by HHS and 6 months of full-time experience in cytotechnology in a laboratory acceptable to the pathologist who directed the formal 6 months of training.

(2) Have achieved a satisfactory grade to qualify as a cytotechnologist in a proficiency examination approved by HHS and designed to qualify persons as cytotechnologists.

d. Before 1 September 1994, have full-time experience of at least 2 years or equivalent within the preceding 5 years examining slide preparations under the supervision of a physician qualified under paragraphs 12-26b or d(1), and before 1 January 1969, must have completed all of the following:

(1) Graduated from high school.

(2) Completed 6 months of training in cytotechnology in a laboratory directed by a pathologist or other physician providing cytology services.

(3) Completed 2 years of full-time supervised experience in cytotechnology.

**12-40. STANDARD: CYTOTECHNOLOGIST RESPONSIBILITIES (§493.1485)**

The cytotechnologist is responsible for documenting:

a. The slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed (as specified in paragraph 11-49c).

b. For each 24-hour period, the total number of slides examined or reviewed in the laboratory as well as the total number of slides

examined or reviewed in any other laboratory or for any other employer.

c. The number of hours spent examining slides in each 24 hour period.

**12-41. CONDITION: LABORATORIES PERFORMING HIGH COMPLEXITY TESTING: TESTING PERSONNEL (§493.1487)**

The laboratory has a sufficient number of individuals who meet the qualification requirements of paragraph 12-42 and perform the functions specified in paragraph 12-44 for the volume and complexity of testing performed.

**12-42. STANDARD: LABORATORIES PERFORMING HIGH COMPLEXITY TESTING: TESTING PERSONNEL QUALIFICATIONS (§493.1489)**

Each individual performing high complexity testing must meet one of the following eight requirements:

a. Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry by the recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands, and privileged to practice medicine in a DoD medical treatment facility; or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution;

b. Have met 1 of the following associate degree or equivalency requirements:

(1) Earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution.

(2) Have education and training equivalent to that specified in paragraph b(1) above that includes both:

(a) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either:

(1) 24 semester hours of medical laboratory technology courses, or

(2) 24 semester hours of science courses that include 6 semester hours of chemistry, 6 semester hours of biology, and 12 semester hours of chemistry, biology, or medical

laboratory technology in any combination.

(b) Laboratory training that includes either:

(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, CAHEA or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph b(2)(a) above), or

(2) Minimum 3 months documented laboratory training in each specialty in which the individual performs high complexity testing.

c. Have previously qualified or could have qualified as a technologist under paragraph 12-43 on or before 28 February 1992.

d. On or before 24 April 1995 be a high school graduate or equivalent and have either:

(1) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA or other organization approved by HHS.

(2) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).

e. Until 1 September 1997, have earned a high school diploma or equivalent; and have documentation of training appropriate to the testing performed before analyzing patient specimens. Such training must ensure that the individual has:

(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens.

(2) The skills required for implementing all standard laboratory procedures.

(3) The skills required for performing each test method and proper instrument use.

(4) The skills required for performing preventive

maintenance, troubleshooting and calibration procedures related to each test performed.

(5) A working knowledge of reagent stability and storage.

(6) The skills required to implement the quality control policies and procedures of the laboratory.

(7) An awareness of the factors that influence test results.

(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

f. On 1 September 1997, testing personnel must meet the qualifications of paragraph a, b or d above, except for those individuals qualified under paragraph e above who were performing high complexity testing on or before 24 April 1995.

g. For blood gas analysis, the individual must:

(1) Be qualified under paragraph 12-42a, b, c, d, e, or f.

(2) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution, or have earned an associate degree related to pulmonary function from an accredited institution;

h. For histopathology, an individual must meet the qualifications of paragraphs 12-26b or 12-26e to perform tissue examinations.

**12-43. LABORATORIES PERFORMING HIGH COMPLEXITY TESTING: TECHNOLOGIST QUALIFICATIONS ON OR BEFORE 28 FEBRUARY 1992 (\$493.1491)**

In order to qualify as high complexity testing personnel under paragraph 12-42c, the individual must have met or could have met, the following qualifications for technologist as they were in effect on or before 28 February 1992. Each technologist must:

Meet one of the following requirements:

(1) Have earned a BS in medical technology from an accredited university.

(2) Have successfully completed 3 years of academic study (minimum 90 semester hours or equivalent) from an accredited college or university, which met the specific requirements for entrance into a school of medical technology accredited by an accrediting agency approved by

the Secretary HHS, and has successfully completed a course of training of at least 12 months in such a school.

(3) Have earned a BS in one of the chemical, physical or biologic sciences and, in addition, has at least 1 year of pertinent full time lab experience or training, or both, in the specialty or subspecialty in which the individual performs tests.

(4) Have successfully completed 3 years (90 semester hours or equivalent) in an accredited college or university with the following distribution of courses; and has experience, training, or both, covering several fields of medical laboratory work of at least 1 year and of such quality as to provide him or her with education and training in medical technology equivalent to that described in paragraphs (1) and (2) above.

(a) For those whose training was completed before 15 September 1963, at least 24 semester hours in chemistry and biology courses of which at least 6 semester hours were in inorganic chemistry, at least 3 semester hours in other chemistry courses and at least 12 semester hours in biology courses pertinent to the medical sciences.

(b) For those whose training was completed after 14 September 1963, at least 16 semester hours in chemistry of which at least 6 semester hours were in inorganic chemistry and that are acceptable toward a major in chemistry, 16 semester hours in biology courses pertinent to the medical sciences and are acceptable toward a major in the biological sciences, and 3 semester hours of mathematics.

(5) With respect to individuals first qualifying before 1 July 1971, the technologist was performing the duties of a lab technologist at any time between 1 July 1961 and 1 January 1968, and has at least 10 years of pertinent lab experience prior to 1 January 1968 (required experience may be met by the substitution of education for experience).

(6) Achieves a satisfactory grade in a proficiency examination approved by HHS.

**12-44. STANDARD: LABORATORIES PERFORMING HIGH COMPLEXITY TESTING: TESTING PERSONNEL RESPONSIBILITIES (§493.1495)**

The testing personnel are responsible for specimen processing, test performance and for reporting test results.

a. Each individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

b. Each individual performing high complexity testing must:

(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens.

(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

(4) Follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance.

(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, technical supervisor, clinical consultant, or director.

(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.

(7) Except as specified in paragraph c below, if qualified under paragraph 12-42e and f, perform high complexity testing only under the on-site, direct supervision of a general supervisor qualified under paragraph 12-32.

c. Exception: For individuals qualified under paragraph 12-42e and f, who were performing high complexity testing on or before 19 January 1993, the requirements of paragraph b(7) above are not effective, provided that all high complexity testing performed by the individual in the absence of a general supervisor is reviewed within 24 hours by a general supervisor qualified under paragraph 12-32.

CHAPTER 13

INSPECTIONS

**13-1. CONDITION: INSPECTION REQUIREMENTS APPLICABLE TO ALL CLIP-CERTIFIED LABORATORIES (§ 493.1771)**

Each laboratory issued a CLIP certificate must meet the requirements in paragraph 13-2 and the specific requirements for its certificate type, as specified in paragraphs 13-3 through 13-5.

**13-2 STANDARD: BASIC INSPECTION REQUIREMENTS FOR ALL LABORATORIES ISSUED A CLIP CERTIFICATE (§ 493.1773)**

a. A laboratory issued a certificate must permit TSG or their designee to conduct an inspection to assess the laboratory's compliance with DoD CLIP. A laboratory that requests, or is issued a certificate of accreditation, must permit TSG or their designee to conduct validation and complaint inspections. Reports of complaint inspections are governed by 10 U.S.C. 1102 as quality assurance documents.

b. General requirements. As part of the inspection process, TSG or their designee may require the laboratory to do the following:

(1) Test samples, including proficiency testing samples, or perform procedures.

(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of DoD CLIP.

(3) Permit laboratory personnel to be observed performing all phases of the total testing process (preanalytic, analytic, and postanalytic).

(4) Permit TSG or their designee access to all areas encompassed under the certificate including, but not limited to, the following:

(a) Specimen procurement and processing areas.

(b) Storage facilities for specimens, reagents, supplies, records, and reports.

(c) Testing and reporting areas.

(5) Provide TSG or their designee with copies or exact duplicates of all records and data it requires.

- c. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection.
- d. A laboratory must provide, upon request, all information and data needed by TSG or their designee to make a determination of the laboratory's compliance with the applicable requirements of DoD CLIP.
- e. TSG or their designee may reinspect a laboratory at any time to evaluate the ability of the laboratory to provide accurate and reliable test results.
- f. TSG or their designee may conduct an inspection when there are complaints alleging noncompliance with any of the requirements of DoD CLIP. Reports of complaint inspections are governed by 10 U.S.C. 1102 as quality assurance documents.
- g. Failure to permit TSG or their designee to conduct an inspection or reinspection results in the suspension or limitation of, or action to revoke the laboratory's CLIP certificate, in accordance with the provisions contained in Chapter 14.

**13-3 STANDARD: INSPECTION OF LABORATORIES ISSUED A CERTIFICATE OF MINIMAL COMPLEXITY OR A CERTIFICATE FOR PROVIDER-PERFORMED MICROSCOPY PROCEDURES (§ 493.1775)**

- a. A laboratory that has been issued a certificate for minimal complexity or a certificate for provider-performed microscopy procedures is not subject to biennial inspections. However, when a medical treatment facility is accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), minimal complexity and PPM testing sites within that facility must be either surveyed by JCAHO in conjunction with the facility's JCAHO accreditation survey or be separately inspected/accredited by an accreditation agency granted deeming authority by JCAHO.
- b. If necessary, TSG or their designee may conduct an inspection of a laboratory issued a certificate for minimal complexity or a certificate for provider-performed microscopy procedures at any time during the laboratory's hours of operation to do the following:
  - (1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to health care beneficiaries.
  - (2) Evaluate a complaint from health care providers, beneficiaries, commanders, or other users of the laboratory. Reports of complaint inspections are governed by 10 U.S.C. 1102 as quality assurance documents.
  - (3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory.

c. The laboratory must comply with the basic inspection requirements of paragraph 13-2.

**13-4 STANDARD: INSPECTION OF LABORATORIES THAT HAVE REQUESTED OR HAVE BEEN ISSUED A CERTIFICATE OF COMPLIANCE (§ 493.1777)**

a. Initial inspection.

(1) A laboratory issued a registration certificate must permit an initial inspection to assess the laboratory's compliance with the requirements of DoD CLIP before TSG or designee issues a certificate of compliance.

(2) The inspection may occur at any time during the laboratory's hours of operation.

b. Subsequent inspections.

(1) TSG or their designee may conduct subsequent inspections on a biennial basis or with such other frequency as TSG or their designee determines to be necessary to ensure compliance with the requirements of DoD CLIP.

(2) TSG or their designee bases the nature of subsequent inspections on the laboratory's compliance history.

c. The inspection sample for review may include testing in the subcategory of provider-performed microscopy procedures.

d. The laboratory must comply with the basic inspection requirements of paragraph 13-2.

**13-5. STANDARD: INSPECTION OF LABORATORIES REQUESTING OR ISSUED A CERTIFICATE OF ACCREDITATION (§ 493.1780)**

a. TSG or their designee may conduct a validation inspection of any accredited laboratory at any time during its hours of operation.

b. TSG or their designee may conduct a complaint inspection of a laboratory requesting or issued a certificate of accreditation at any time during its hours of operation upon receiving a complaint applicable to the requirements of DoD CLIP. Reports of complaint inspections are governed by 10 U.S.C. 1102 as quality assurance documents.

c. If a validation or complaint inspection results in a finding that the laboratory is not in compliance with one or more condition-level requirements, a laboratory issued a certificate of accreditation is subject to a full review by TSG or their designee, in accordance with Chapter 6.

d. Laboratories requesting or issued a certificate of accreditation must comply with the basic inspection requirements in paragraph 13-2.

CHAPTER 14

ENFORCEMENT PROCEDURES

14-1. BASIS AND SCOPE (§493.1800)

a. Under Title 10, US Code, Chapter 55, DoD is given jurisdictional responsibility under law for the operation of its facilities.

b. This chapter sets forth:

(1) The policies and procedures that TSG or their designee follow to enforce the requirements applicable to laboratories under the DoD Clinical Laboratory Improvement Program; and

(2) The appeal rights of laboratories on which sanctions are imposed.

14-2. GENERAL CONSIDERATIONS (§493.1804)

a. Enforcement mechanisms are taken to improve the quality of laboratory services available to beneficiaries. As such, all investigation and complaint reports are governed by 10 U.S.C. 1102. Enforcement mechanisms set forth in this chapter have the following purposes:

(1) To provide accurate and reliable test results.

(2) To protect all individuals served by DoD laboratories against substandard testing of specimens.

(3) To safeguard DoD laboratory staff, health care providers and other medical treatment facility staff, and health care beneficiaries against the health and safety hazards that might result from substandard laboratory activities.

b. Basis for a decision to impose sanctions.

(1) A decision to impose sanctions is based on one or more of the following:

(a) Deficiencies found by TSG or their designee in the conduct of inspections to certify or validate compliance with DoD requirements, or through review of materials submitted by the laboratory (e.g., personnel qualifications).

(b) Unsuccessful participation in proficiency testing.

(2) TSG or their designee imposes one or more of the alternative or principle sanctions specified in paragraph 14-3 when TSG or their designee finds that a laboratory has condition-level deficiencies.

c. Imposition of alternative sanctions.

(1) TSG or their designee may impose alternative sanctions in lieu of, or in addition to, the principle sanctions, including imposing alternative sanctions on laboratories that have certificates of waiver.

(2) TSG or their designee may impose alternative sanctions after the laboratory has had an opportunity to respond through command channels.

d. TSG or their designee bases its choice of sanction or sanctions on consideration of one or more factors that include, but are not limited to, the following, as assessed by TSG or their designee:

(1) Whether the deficiencies pose immediate jeopardy.

(2) The nature, incidence, severity, and duration of the deficiencies or noncompliance.

(3) Whether the same condition-level deficiencies have been identified repeatedly.

(4) The accuracy and extent of laboratory records (e.g. of remedial action) in regard to the noncompliance and their availability to TSG or their designee.

(5) The relationship of one deficiency or group of deficiencies to other deficiencies.

(6) The overall compliance history of the laboratory including, but not limited to, any period of noncompliance that occurred between certifications of compliance.

(7) The corrective and long-term compliance outcomes that TSG or their designee hopes to achieve through application of the sanction.

(8) Whether the laboratory has made any progress toward improvement following a reasonable opportunity to correct deficiencies.

(9) Any recommendations within the chain of command as to which sanctions would be appropriate.

e. TSG or their designee may impose a separate sanction for each condition-level deficiency or a single sanction for all condition-level deficiencies that are interrelated and subject to correction by a single course of action.

f. The appeal process for laboratories is set forth in paragraph 14-13.

**14-3. AVAILABLE SANCTIONS: ALL LABORATORIES (§493.1806)**

a. TSG or their designee may impose one or more of the sanctions specified in this paragraph on a laboratory that is out of compliance with one or more DoD CLIP conditions.

b. TSG may impose any of the three principal sanctions, which are suspension, limitation, or revocation of any type of DoD CLIP certificate.

c. TSG or their designee may impose one or more of the following alternative sanctions in lieu of, or in addition to, imposing a principal sanction (only TSG may impose a principal sanction).

(1) Directed plan of correction, as set forth at paragraph 14-9.

(2) Directed on-site monitoring as set forth at paragraph 14-10.

**14-4. IMPOSITION AND LIFTING OF ALTERNATIVE SANCTIONS (§493.1810)**

a. If TSG or their designee identifies condition-level noncompliance in a laboratory, TSG or their designee gives the laboratory, through command channels, written notice of the following:

(1) The condition-level noncompliance that it has identified.

(2) The sanction or sanctions that TSG or their designee proposes to impose against the laboratory.

(3) The rationale for the proposed sanction or sanctions.

(4) The projected effective date and duration of the proposed sanction or sanctions.

(5) The authority for the proposed sanction or sanctions.

(6) The time allowed for the laboratory to respond to the notice.

b. During the period specified in paragraph a(6) above, the laboratory may submit for review, through command channels to TSG or their designee, written evidence or other information against the imposition of the proposed sanction or sanctions.

c. After evaluation of data submitted in accordance with paragraph b above, laboratories are notified of the final decision in writing. The final decision notice will acknowledge any evidence or information received from the laboratory and, if sanctions are still to be imposed, specifies the following:

(1) The sanction(s) to be imposed against the laboratory.

(2) The authority and rationale for imposing the sanction(s).

(3) The effective date and duration of the sanction(s).

d. Sanctions become effective in the following time frame:

(1) If TSG or their designee determines that the deficiencies pose immediate jeopardy, TSG or their designee provides notice at least 5 days before the effective date of the sanction.

(2) If TSG or their designee determines that the deficiencies do not pose immediate jeopardy, TSG or their designee provides notice at least 15 days before the effective date of the sanction.

e. An alternative sanction continues until the earlier of the following occurs:

(1) The laboratory corrects all condition-level deficiencies.

(2) TSG's suspension, limitation, or revocation of the laboratory's DoD CLIP certificate becomes effective.

f. Alternative sanction(s) are lifted in the following manner:

(1) General rule. Alternative sanctions are not lifted until a laboratory's compliance with all condition-level requirements is verified.

(2) Credible allegation of compliance. When a sanctioned laboratory submits a credible allegation of compliance, TSG or their designee determines whether:

(a) It can certify compliance on the basis of the evidence presented by the laboratory in its allegation.

(b) It must revisit to verify whether the laboratory has, in fact, achieved compliance.

**14-5. ACTION WHEN DEFICIENCIES POSE IMMEDIATE JEOPARDY (§493.1812)**

If a laboratory's deficiencies pose immediate jeopardy, the following rules apply:

a. TSG or their designee requires the laboratory to take immediate action to remove the jeopardy and may impose one or more alternative sanctions to help bring the laboratory into compliance.

b. If the findings of a revisit indicate that a laboratory has not eliminated the jeopardy, TSG suspends or limits the laboratory's DoD CLIP certificate no earlier than 5 days after the date of notice of suspension or limitation. TSG may later revoke the certificate.

c. In addition, if TSG or their designee has reason to believe that the continuation of any activity by any laboratory (either the entire laboratory operation or any specialty or subspecialty of testing) would constitute a significant hazard to the health of DoD beneficiaries, TSG or their designee may direct that the activity be immediately discontinued, regardless of the type of DoD CLIP certificate the laboratory had been previously issued.

**14-6. ACTIONS WHEN DEFICIENCIES ARE AT THE CONDITION-LEVEL BUT DO NOT POSE IMMEDIATE JEOPARDY (§493.1814)**

If a laboratory has condition-level deficiencies that do not pose immediate jeopardy, the following apply:

a. Initial action:

(1) TSG may suspend, limit, or revoke the laboratory's DoD CLIP certificate.

(2) If TSG does not impose a principal sanction under paragraph a(1) above, TSG or their designee may impose one or more alternative sanctions. In the case of unsuccessful participation in proficiency testing, TSG or their designee may impose the training and technical assistance requirement set forth at paragraph 14-11 in lieu of, or in addition to, one or more alternative sanctions.

b. If TSG or their designee imposes alternative sanctions for condition-level deficiencies that do not pose immediate jeopardy, and the laboratory does not correct the condition-level deficiencies

within 12 months after the last day of inspection, TSG or their designee:

(1) Following a revisit which indicates that the laboratory has not corrected its condition-level deficiencies, TSG notifies the laboratory through command channels that it proposes to suspend, limit, or revoke the DoD CLIP certificate, as specified in paragraph 14-7b, and the laboratory's right to respond in writing through command channels within 30 days to TSG; and

(2) May impose (or continue if already imposed) any alternative sanctions.

c. If a final decision upholds a proposed suspension, limitation, or revocation of a laboratory's DoD CLIP certificate, TSG or their designee discontinues any alternative sanctions as of the day the suspension, limitation, or revocation becomes effective.

**14-7. ACTION WHEN DEFICIENCIES ARE NOT AT THE CONDITION LEVEL (§493.1816)**

If a laboratory has deficiencies that are not at the condition-level, the following rules apply:

a. The laboratory must submit, through command channels to TSG or their designee, a plan of correction that is acceptable to TSG or their designee in content and time frames.

b. If, on a revisit, it is found that the laboratory has not corrected the deficiencies within 12 months after the last day of inspection, TSG notifies the laboratory through command channels of its intent to suspend, limit, or revoke the laboratory's DoD CLIP certificate and of the laboratory's right to respond in writing through command channels to TSG or their designee within 30 days.

**14-8. ENSURING TIMELY CORRECTION OF DEFICIENCIES (§493.1820)**

a. TSG or their designee may visit the laboratory at any time to evaluate progress, and at the end of the period to determine whether all corrections have been made.

b. If during a visit it is found that a laboratory has not corrected its deficiencies, TSG may propose to suspend, limit, or revoke the laboratory's DoD CLIP certificate.

c. If at the end of the plan of correction period all condition-level deficiencies have been corrected but deficiencies that are not at the condition level remain, TSG or their designee may require a revised plan of correction. The revised plan may not extend beyond 12 months from the last day of the inspection that originally identified the

cited deficiencies.

d. If at the end of the period covered by the plan of correction the laboratory still has deficiencies, the rules of paragraph 14-6 and paragraph 14-7 apply.

**14-9. DIRECTED PLAN OF CORRECTION AND DIRECTED PORTION OF A PLAN OF CORRECTION (§493.1832)**

a. TSG or their designee may impose a directed plan of correction or a directed portion of a plan of correction as an alternative sanction for any laboratory that has condition-level deficiencies.

b. Procedures for imposing either course of action are:

(1) When imposing a directed plan of correction, TSG or their designee:

(a) Gives the laboratory prior notice of the sanction and opportunity to respond in accordance with paragraph 14-4.

(b) Directs the laboratory to take specific corrective action within specific time frames in order to achieve compliance.

(c) May direct the laboratory to submit the names of laboratory clients for notification purposes, as specified in paragraph b(2) below.

(2) When imposing a directed portion of a plan of correction, TSG may decide to notify clients of a sanctioned laboratory because of the seriousness of the noncompliance (e.g., the existence of immediate jeopardy) or for other reasons. When imposing this sanction, TSG takes the following steps:

(a) Directs the laboratory to submit to TSG or their designee, within 10 calendar days after the notice of the alternative sanction, for all laboratory clients from outside the laboratory's organization, a list of names and addresses of all physicians, providers, suppliers, and other clients who have used some or all of the services of the laboratory since the last certification inspection or within any other time frame specified by TSG. This list will include any civilian health care providers that have been furnished with laboratory test results under the CHAMPUS program, TRICARE, or as a service to eligible beneficiaries utilizing civilian

healthcare providers. Additionally, the names of all laboratories that have sent referred specimens to the sanctioned laboratory, will be provided.

(b) Within 30 calendar days of receipt of the information, TSG or their designee may send to each laboratory client a notice containing the name and address of the laboratory, the nature of the laboratory's noncompliance, and the kind and effective date of the alternative sanction.

(c) Sends to each laboratory client notice of the rescission of an adverse action within 30 days of the rescission.

(3) If TSG imposes a principal sanction following the imposition of an alternative sanction for which TSG has already obtained a list of laboratory clients, TSG may use that list to notify the clients of the imposition of the principal sanction.

c. If TSG or their designee imposes a directed plan of correction, and on revisit it is found that the laboratory has not corrected the deficiencies within 12 months from the last day of inspection, the following rules apply:

(1) TSG notifies the laboratory, through command channels, of its intent to suspend, limit, or revoke the laboratory's DoD CLIP certificate.

(2) The directed plan of correction continues in effect until the day suspension, limitation, or revocation of the laboratory's DoD CLIP certificate becomes effective.

#### 14-10. DIRECTED ON-SITE MONITORING (§493.1836)

a. TSG or their designee may require continuous or intermittent monitoring of a plan of correction by a designated laboratory monitor (an individual or team) to ensure that the laboratory makes the improvements necessary to bring it into compliance with the condition-level requirements. (The monitor does not have management authority, that is, cannot hire or fire staff, obligate funds, or otherwise dictate how the laboratory operates. The monitor's responsibility is to oversee whether corrections are made, and to make recommendations to the laboratory director and the facility commander.)

b. Before imposing this sanction, TSG or their designee, through command channels, provides a notice of sanction and an opportunity to respond in accordance with paragraph 14-4.

c. If TSG or their designee imposes on-site monitoring, the sanction continues until:

(1) TSG or their designee determines that the laboratory has the capability to ensure compliance with all condition-level requirements.

(2) If the laboratory does not correct all deficiencies within 12 months, and a revisit indicates that deficiencies remain, TSG notifies the laboratory, through command channels, of its intent to suspend, limit, or revoke the laboratory's certificate of compliance, registration certificate, certificate of accreditation, certificate for PPM procedures, or certificate for minimal complexity.

**14-11. TRAINING AND TECHNICAL ASSISTANCE FOR UNSUCCESSFUL PARTICIPATION IN PROFICIENCY TESTING (§493.1838)**

a. If a laboratory's participation in proficiency testing is unsuccessful, TSG or their designee may require the laboratory to undertake training of its personnel, or to obtain necessary technical assistance, or both, in order to meet the requirements of the proficiency testing program. This requirement is separate from the principal and alternative sanctions set forth in paragraph 14-3.

b. Upon failure to successfully participate in proficiency testing, as defined in Chapter 7, the laboratory will take immediate action which may include voluntary cessation for the specialty, subspecialty or analyte that was failed. The accuracy of testing will be verified within 5 days of receiving the proficiency results. The remedial action will be documented and sent to TSG or their designee within 30 days of receipt of the proficiency results for review and approval.

**14-12. SUSPENSION, LIMITATION, OR REVOCATION OF ANY TYPE OF DOD CLIP CERTIFICATE (§493.1840)**

a. TSG may initiate adverse action to suspend, limit, or revoke any DoD CLIP certificate if TSG finds that a laboratory's commander, director, or one of its employees has:

(1) Been guilty of misrepresentation in obtaining a DoD CLIP certificate.

(2) Performed, or represented the laboratory as entitled to perform, a laboratory examination or other procedure that is not within a category of laboratory examinations or other procedures authorized by its DoD CLIP certificate.

(3) Failed to comply with the certificate requirements and performance standards.

(4) Failed to comply with reasonable requests by TSG or their designee for any information or work on materials that TSG or their designee concludes is necessary to determine the laboratory's continued eligibility for its DoD CLIP certificate or continued compliance with performance standards set by the DoD CLIP.

(5) Refused a reasonable request by TSG or their designee for permission to inspect the laboratory and its operation and pertinent records during the hours the laboratory is in operation.

(6) Violated or aided and abetted in the violation of any provisions of DoD CLIP.

(7) Failed to comply with an alternative sanction imposed under this chapter.

(8) Within the preceding two-year period, directed a laboratory that had its CLIP certificate revoked. (This provision applies only to the director of the laboratory).

b. If TSG determines that a laboratory has intentionally referred its proficiency testing samples to another laboratory for analysis, TSG shall revoke the laboratory's DoD CLIP certificate. The period of revocation of the CLIP certificate (established with due consideration of DoD health care mission requirements, especially in remote or OCONUS locations) and the corrective alternative sanctions imposed will be of sufficient duration and extent to ensure appropriate policies/procedures are in place to prevent the reoccurrence of intentional referral of proficiency testing. Individuals found to be responsible for such referral(s) shall be held accountable for their actions subject to the provisions of the Uniform Code of Military Justice (UCMJ) or applicable judicial and administrative civilian regulations.

c. Procedures for suspension or limitation of a DoD CLIP certificate:

(1) Except as provided in paragraph c(2) below, TSG will not suspend or limit a DoD CLIP certificate until after personnel responsible for the laboratory have responded to TSG in writing through command channels.

(2) Exceptions. TSG may suspend or limit a DoD CLIP certificate before the written response through command channels in any one of the following circumstances:

(a) The laboratory's deficiencies pose immediate jeopardy.

(b) The laboratory has refused a reasonable request for information or for work on materials.

(c) The laboratory has refused permission for TSG or their designee to inspect the laboratory or its operation.

(d) The laboratory has failed to respond to TSG in writing through command channels within 30 days.

d. TSG may revoke a DoD CLIP certificate even if it had not previously suspended or limited that certificate.

e. TSG must notify OASD(HA) of any DoD CLIP certificate suspended, limited, or revoked under this section within 30 days of the action.

**14-13. FINAL DECISION APPEAL PROCEDURES (§493.1844)**

a. The following actions are initial determinations and therefore are subject to appeal in accordance with this paragraph:

(1) The suspension, limitation, or revocation of the laboratory's DoD CLIP certificate by TSG because of noncompliance with DoD CLIP requirements.

(2) The denial of a DoD CLIP certificate.

(3) The imposition of alternative sanctions under this chapter (but not the determination as to which alternative sanction or sanctions to impose).

b. Actions that are not listed in paragraph a above are not initial determinations and therefore are not subject to appeal under this paragraph. They include, but are not necessarily limited to, the following:

(1) The finding that a laboratory accredited by a CMS-approved accreditation organization is no longer deemed to meet the conditions set forth in chapters 7, 10, 11, 12, and 13 of this Pamphlet. However, the suspension, limitation, or revocation of a certificate of accreditation is an initial determination and is appealable.

(2) The finding that a laboratory is determined to be in compliance with condition-level requirements but has deficiencies that are not at the condition-level.

(3) The determination not to reinstate a suspended DoD CLIP certificate because the reason for the suspension has not been removed or there is insufficient assurance that the

reason will not recur.

(4) The determination as to which alternative sanction or sanctions to impose.

(5) The determination that a laboratory's deficiencies pose immediate jeopardy.

c. Effect of requested appeals of action are:

(1) The effective date of an alternative sanction is not delayed because the laboratory has appealed and the appeal decision is pending.

(2) The effect on suspension, limitation, or revocation of a laboratory's DoD CLIP certificate are:

(a) Except as provided in paragraph c(2)(b) below, suspension, limitation, or revocation of a DoD CLIP certificate is not effective until after an appeal decision by TSG is issued.

(b) Exceptions. If TSG determines that conditions at a laboratory pose immediate jeopardy, the effective date of the suspension or limitation of a DoD CLIP certificate is not delayed because the laboratory has appealed the final decision through command channels. TSG may also suspend or limit a laboratory's DoD CLIP certificate before an appeal decision is issued if the laboratory has refused a reasonable request for information or for work on materials, or has refused permission for TSG or their designee to inspect the laboratory or its operation.

d. Any laboratory or prospective laboratory dissatisfied with a suspension, limitation, revocation, or denial of its DoD CLIP certificate, or with the imposition of an alternative sanction under this chapter, is entitled to an appeal of the action to TSG. Such appeal must be in writing and sent through command channels to reach TSG within 30 days of the receipt of the final decision notice. When more than one of the actions specified in paragraph a above are carried out concurrently, the laboratory has a right to only one appeal on all matters at issue.

e. Notice of adverse action:

(1) If TSG suspends, limits, or revokes a laboratory's DoD CLIP certificate, TSG gives notice to the laboratory, and may give notice to physicians, providers, suppliers, and other laboratory clients, according to the procedures set

forth at paragraph 14-9. In addition, TSG may notify DoD health care beneficiaries each time one of the principal sanctions is imposed.

(2) The notice to the laboratory:

(a) Sets forth the reasons for the adverse action, the effective date and effect of that action, and the response and/or appeal process, if any.

(b) When the certificate is limited, specifies the specialties or subspecialties of tests that the laboratory is no longer authorized to perform.

(3) The notice to other entities includes the same information except the information about the laboratory's response and/or appeal process.

f. Effective date of adverse action:

(1) When the laboratory's deficiencies pose immediate jeopardy, the effective date of the adverse action is no more than 5 days after the date of the notice.

(2) When the laboratory's deficiencies do not pose immediate jeopardy, the effective date of the adverse action is no more than 15 days after the date of the notice.

**14-14. LABORATORY REGISTRY (§493.1850)**

a. Once a year, TSG will make available to OASD (HA), DoD health care beneficiaries, and health care providers who utilize DoD laboratories specific information that is useful in evaluating the performance of laboratories, including the following:

(1) A list of laboratories that have had their DoD CLIP certificates suspended, limited, or revoked, and the reason for the adverse actions.

(2) A list of laboratories on which alternative sanctions have been imposed, showing:

(a) The effective date of the sanctions.

(b) The reasons for imposing the sanctions.

(c) Any corrective action taken by the laboratory.

(d) If the laboratory has achieved compliance, the verified date of compliance.

(3) A list of laboratories whose accreditation has been withdrawn or revoked and the reasons for the withdrawal or revocation.

b. The laboratory registry is compiled for the calendar year preceding the date the information is made available and includes appropriate explanatory information to aid in the interpretation of the data. It also contains corrections of any erroneous statements or information in the previous registry.

c. The laboratory registry will be posted to the CCLM web page at <http://www.afip.org/OCLAB/index.html>.

CHAPTER 15

CONSULTATIONS

15-1. ESTABLISHMENT AND FUNCTION OF THE DOD CLINICAL LABORATORY IMPROVEMENT ADVISORY COMMITTEE (§493.2001)

a. OASD(HA) will establish a DoD Clinical Laboratory Improvement Advisory Committee to advise and make recommendations on technical and scientific aspects of the provisions of this program. The DoD Clinical Laboratory Improvement Advisory Committee will evaluate and establish laboratory standards and practices for laboratory operations within DoD just as the HHS Clinical Laboratory Improvement Advisory Committee will do for the civilian community throughout the United States.

b. The DoD Clinical Laboratory Improvement Advisory Committee will be comprised of individuals from all Services involved in the provision of laboratory services, utilization of laboratory services, development of laboratory testing or methodology, and others as approved by OASD(HA). As a minimum, representatives on the Committee must include board certified physicians who serve as the Pathology Consultant or Pathology Specialty Leader to each Service's Surgeon General, laboratory scientists from each Service who serve as the Laboratory Consultant or Laboratory Specialty Leader to each Service's Surgeon General, and representatives from the Quality Assurance Offices of each Service Surgeon General and from OASD(HA).

c. OASD(HA) will designate specialized subcommittees as necessary.

d. The DoD Clinical Laboratory Improvement Advisory Committee or any designated subcommittees will meet as needed, but not less than once each year.

e. The DoD Clinical Laboratory Improvement Advisory Committee or subcommittee, will review and adopt, with or without modifications, the recommendations of the HHS Clinical Laboratory Improvement Advisory Committee concerning:

- (1) Personnel standards.
- (2) Facility administration and quality systems standards.
- (3) Proficiency testing standards.
- (4) Applicability to the standards of new technology.
- (5) Other issues relevant to DoD CLIP, if requested by OASD(HA), or any Service Surgeon General.

f. OASD(HA) will be responsible for providing the data and information, as necessary, to the members of the DoD Clinical Laboratory Improvement Advisory Committee.

## CHAPTER 16

## DEPLOYABLE MEDICAL UNITS

16-1. **APPLICABILITY**

This chapter is applicable to deployable medical units of the Army, Navy, Air Force and Marines that are designed to operate in non-fixed facilities or perform in contingency operations. Further definition of these units can be found at Appendix B, Glossary.

16-2. **CONCEPT**

a. Deployable medical units performing health care testing on a routine basis while in garrison during peacetime are required to meet the requirements of CLIP except for proficiency testing. Laboratories in these units must obtain CLIP registration. There is no requirement for notification or re-registration when these laboratories deploy. The local medical treatment facility (MTF) laboratory will provide technical assistance.

b. Deployable medical units that do not perform laboratory testing services on a routine basis when in garrison are subject to the minimum CLIP requirements stated at paragraph 16-3a below.

c. Deployment of medical units for training, hostile operations, operations other than war, or national emergency immediately places the unit in a military readiness position. Upon mobilization and deployment, units will adhere to minimum CLIP requirements [described at paragraph 16-3a(1) - (3)] unless they are temporarily modified in writing by OASD(HA), the Service's Surgeons General (TSG), or subordinate medical commanders. **NOTE:** Naval shipboard laboratories (including those on U.S. Coast Guard assets when deployed as a component of Naval Forces), either in port or underway, are considered deployed medical units supporting the ship's operational mission.

d. The local medical treatment facility (MTF) laboratory will provide technical assistance (described at paragraph 16-3b) to deployable medical units to assure CLIP requirements are met. Minimal requirements are stated below.

16-3. **RESPONSIBILITIES**

a. Unit. At a minimum, units will:

(1) Maintain verification of training and competency of personnel in accordance with Chapter 12.

(2) Maintain a standard operating procedure (SOP) for each test performed.

(3) Maintain and document quality control, quality assurance, and maintenance programs.

(4) Validate all procedures with the supporting MTF laboratory.

(5) Participate in continuing education offered by the supporting MTF.

b. Supporting MTF. Minimal support consists of:

(1) Assigning a technical consultant to each unit.

(2) Conducting an annual assistance visit to each unit.

(3) Providing training as necessary.

(4) Establishing internal proficiency testing, as needed.

(5) Verifying a unit's ability to perform all listed procedures.

**APPENDIX A REQUIRED AND RELATED PUBLICATIONS**

Title 42, Code of Federal Regulations, Part 493.

Public Law 100-578, "Clinical Laboratory Improvement Amendments of 1988", October 31, 1988.

Memorandum of Agreement (MOA) between the Department of Defense and Department of Health and Human Services, "Implementation of the Clinical Laboratory Improvement Amendments of 1988 (CLIA'88) within DoD", January 16, 1993.

Department of Defense Instruction 6440.2, "Clinical Laboratory Improvement Program", 20 April 1994.

Title 10, United States Code, section 1102.

**APPENDIX B GLOSSARY**

**ABHES** - Accrediting Bureau of Health Education Schools.

**AFIP** - Armed Forces Institute of Pathology.

**Accredited institution** - a school or program which:

- a. Admits as regular students only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such certificate, such as a GED examination;
- b. Is legally authorized within a State to provide a program of education beyond secondary education;
- c. Provides an educational program for which it awards a bachelor's degree or provides not less than a two-year program which is acceptable toward such a degree, or provides an educational program for which it awards a master's or doctoral degree;
- d. Is accredited by a nationally recognized accrediting agency or association.

This definition includes any foreign institution of higher education that DoD or its designee determines meets substantially equivalent requirements.

**Accredited Laboratory** - a laboratory that has voluntarily applied for and been accredited by a private, non-profit accreditation organization approved by CMS.

**Adverse Action** - the imposition of a principal or alternative sanction by TSG or their designee

**Alternative Sanctions** - any action less than limitation, suspension, or revocation of a CLIP certificate taken in response to a laboratory's deficiencies in meeting CLIP requirements.

**Analyte** - a substance or constituent for which the laboratory conducts testing.

**Authorized person** - an individual authorized under military regulations to order tests or receive test results, or both.

**CAHEA** - Committee on Allied Health Education and Accreditation.

**Calibration** - a process of testing and adjusting an instrument or test system to establish a correlation between the measurement response and the concentration or amount of the substance that is being measured by the test procedure.

**Calibration Verification** - the assaying of materials of known concentration in the same manner as patient samples to substantiate the instrument or test system's calibration throughout the reportable range for patient test results.

**CCLM** - the Center for Clinical Laboratory Medicine located within the Armed Forces Institute of Pathology.

**CDC** - Centers for Disease Control and Prevention, Atlanta, GA.

**Challenge** - for quantitative tests, an assessment of the amount of substance or analyte present or measured in a sample; for qualitative tests, the determination of the presence or the absence of an analyte, organism, or substance in a sample.

**CLIA** - the Clinical Laboratory Improvement Amendments of 1988.

**CLIP** - the DoD Clinical Laboratory Improvement Program.

**CLIP Certificate** - any of the following types of certificates issued by TSG or their designee:

a. Certificate of compliance - issued to a laboratory after an inspection that finds the laboratory to be in compliance with all applicable condition-level requirements.

b. Certificate for provider-performed microscopy (PPM) procedures - issued to a laboratory in which a physician, midlevel practitioner or dentist performs no tests other than PPM procedures and, if desired, minimal complexity tests.

c. Certificate of accreditation - issued on the basis of the laboratory's accreditation by an accrediting organization approved by CMS (indicating that the laboratory is deemed to meet applicable CLIP requirements).

d. Certificate of registration or registration certificate - issued to an entity that enables that entity to conduct moderate or high complexity laboratory testing, or both, until the entity is determined to be in compliance through a survey by CCLM or their designee or is accredited by an approved accreditation organization; or becomes exempt from CLIP.

e. Certificate for minimal complexity (called Certificate

of Waiver under CLIA)- issued to a laboratory to perform only minimal complexity tests.

**CLIPO** - the Clinical Laboratory Improvement Program Office, located within the Center for Clinical Laboratory Medicine (CCLM) at the Armed Forces Institute of Pathology (AFIP) and operated under the auspices of OASD(HA).

**CMS** - Centers for Medicare & Medicaid Services

**Condition-Level Deficiencies** - non-compliance with one or more condition-level requirements.

**Condition-Level Requirements** - any of the requirements identified as "conditions" in chapters 7 and 10 - 13 of this Pamphlet.

**Credential** - written record of individual's ability to perform specified procedures.

**Credible allegation of compliance** - means a statement or documentation that -

- (1) Is made by a representative of a laboratory that has a history of having maintained a commitment to compliance and of taking corrective action when required;
- (2) Is realistic in terms of its being possible to accomplish the required corrective action between the date of the exit conference and the date of the allegation; and
- (3) Indicates that the problem has been resolved.

**DoD** - Department of Defense.

**DoD CLIAC** - Department of Defense Clinical Laboratory Improvement Advisory Committee.

**Dentist** - a doctor of dental medicine or doctor of dental surgery who is licensed by the recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands, and privileged to practice dentistry in a DOD medical treatment facility.

**Deployable medical units** - medical units of the Marines, Navy, Air Force, or Army that are designed to temporarily operate in non-fixed facilities or perform in medical contingency operations.

**FDA** - Food and Drug Administration.

**FDA-cleared or approved Test System** - a test system cleared or approved by the FDA through the premarket notification (510(k)) or premarket approval (PMA) process for in-vitro diagnostic use. Unless otherwise stated, this includes test systems exempt from FDA pre-market clearance or approval.

**Federal Register** - uniform system for making available to the public regulations and legal notices issued by Federal agencies.

**HHS** - the Department of Health and Human Services, or its designee.

**Immediate Jeopardy** - 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 DoD health care beneficiaries. This term is synonymous with imminent and serious risk to human health and significant hazard to the health of DoD health care beneficiaries.

**Intentional Violation** - knowing and willful noncompliance with any DoD CLIP condition.

**Kit** - all components of a test that are packaged together.

**Laboratory** - a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

**Memorandum of compliance** - Verification submitted by a laboratory that they are in compliance with current CLIP regulations. This is indicated by the facility submitting to CCLM a certificate request package which contains: 1) a completed self-evaluation using a checklist from CCLM or a deemed accrediting organization, 2) a letter from the facility commander or designee attesting to CLIP compliance and 3) a completed registration form. Currently this is allowed for Minimal complexity sites only.

**Midlevel practitioner** - a nurse midwife, nurse practitioner or physician assistant who is licensed by the recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands, and privileged to practice his or her specialty in a DOD medical treatment facility.

**NAACLS** - National Accrediting Agency for Clinical Laboratory Sciences.

**OASD(HA)** - Office of the Assistant Secretary of Defense for Health Affairs.

**Nonwaived test** - any test system, assay, or examination that has not been found to meet the statutory criteria for minimal complexity (waived) tests, i.e., moderate complexity tests (including the subcategory of provider-performed microscopy procedures) and high complexity tests

**Performance characteristic** - a property of a test that is used to describe its quality, e.g., accuracy, precision, analytical sensitivity, analytical specificity, reportable range, reference range, etc.

**Performance specification** - a value or range of values for a performance characteristic, established or verified by the laboratory, which is used to describe the quality of patient test results.

**Physician** - an individual with a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine degree who is licensed by the recognized licensing agency of a State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, or the U.S. Virgin Islands, and privileged to practice medicine in a DOD medical treatment facility.

**Principle Sanctions** - limitation, suspension or revocation of a CLIP certificate in response to condition-level deficiencies.

**Referee laboratory** - a laboratory currently in compliance with applicable CLIA requirements, that has had a record of satisfactory proficiency testing performance for all testing events for at least one year for a specific test, analyte, subspecialty, or specialty and has been designated by an HHS-approved proficiency testing program as a referee laboratory for analyzing proficiency testing specimens for the purpose of determining the correct response for the specimens in a testing event for that specific test, analyte, subspecialty, or specialty.

**Reference range** - the range of test values expected for a designated population of individuals, e.g., 95 percent of individuals that are presumed to be healthy (or normal).

**Regulated analyte** - Tests or procedures for which proficiency testing is required by Public Law 100-578. The list and minimal performance in proficiency testing events is stated in Chapter 9.

**Reportable Range** - the span of test result values over which the laboratory can establish or verify the accuracy of the instrument or test system measurement response.

**Sample** (in relation to proficiency testing) - the material that is to be tested by the participants in the proficiency testing program.

**State** - includes any political subdivision to which the State has expressly delegated powers sufficient to enable it to enforce requirements equal to, or more stringent than, CLIA requirements.

**Substantial allegation of noncompliance** - means a complaint from any of a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles, that, if substantiated, would have an impact on the health and safety of the general public or individuals served by a laboratory and raises doubts as to a laboratory's compliance with any condition-level requirement.

**Target value for quantitative tests** - either the mean of all participant responses after removal of outliers (those responses greater than 3 standard deviations from the original mean) or the mean established by definitive or reference methods acceptable for use in the National Reference System for the Clinical Laboratory (NRSCL) by the Clinical and Laboratory Standards Institute (CLSI; previously known as the National Committee for Clinical Laboratory Standards (NCCLS)). In instances where definitive or reference methods are not available or a specific method's results demonstrate bias that is not observed with actual patient specimens, as determined by a defensible scientific protocol, a comparative method or a method group ("peer" group) may be used. If the method group is less than 10 participants, "target value" means the overall mean after outlier removal (as defined above) unless acceptable scientific reasons are available to indicate that such an evaluation is not appropriate.

**Test System** - the instructions and all of the instrumentation, equipment, reagents, and supplies needed to perform an assay or examination and generate test results.

**TSG** - the Service's Surgeons General, i.e., the Surgeon General of the Air Force, the Surgeon General of the Army, and the Surgeon General of the Navy.

**Unsatisfactory proficiency testing performance** - failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event.

**Unsuccessful participation in proficiency testing** - means any of the following:

- (1) Unsatisfactory performance for the same analyte in two consecutive or two out of three testing events.

(2) Repeated unsatisfactory overall testing event scores for two consecutive or two out of three testing events for the same specialty or subspecialty.

(3) An unsatisfactory testing event score for those subspecialties not graded by analyte (that is, bacteriology, mycobacteriology, virology, parasitology, mycology, blood compatibility, immunohematology, or syphilis serology) for the same subspecialty for two consecutive or two out of three testing events. **NOTE:** Per paragraph 7-2c, DoD CLIP requires individual assessment of proficiency testing performance for each analyte rather than following CLIA's practice of combining procedures into subspecialty groups.

(4) Failure of a laboratory performing gynecologic cytology to meet the standard at paragraph 7-8.

**Unsuccessful proficiency testing performance** - failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for two consecutive or two of three consecutive testing events.

**Waived test** (minimal complexity test) - a test system, assay, or examination that HHS has determined meets the CLIA statutory criteria for waiver.

The proponent agency of this regulation is the Center for Clinical Laboratory Medicine. Users are invited to send suggestions and comments on DA Form 2029 (Recommended Changes to Publications and Blank forms) to the Director, AFIP, ATTN: AFIP-ZD, Washington, DC 20306-6000.

//original signed by//  
FLORABEL G. MULLICK, M.D., Sc.D., FCAP  
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