



# Department of Defense MANUAL

NUMBER 6440.02

May 29, 2014

Incorporating Change 1, Effective August 5, 2020

---

---

USD(P&R)

SUBJECT: Clinical Laboratory Improvement Program (CLIP) Procedures

References: See Enclosure 1

1. **PURPOSE.** In accordance with the authority in DoD Directive 5136.01 (Reference (a)) and the policy in DoD Instruction (DoDI) 6440.02 (Reference (b)), this manual implements policy, assigns responsibilities, and provides for standards and procedures for managing the CLIP. This manual states the minimal conditions that all laboratories must meet to be certified to perform testing on human specimens under the CLIP.

2. **APPLICABILITY.** This manual applies to:

a. The OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the DoD, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (referred to in this manual as the “DoD Components”).

b. All medical laboratories as defined in the Glossary. The Center for Clinical Laboratory Medicine (CCLM) issues certificates of accreditation within the DoD in lieu of Department of Health and Human Services (HHS). This manual states the minimal conditions that all laboratories must meet to be certified to perform testing on human specimens.

3. **POLICY.** It is DoD policy according to the Memorandum of Agreement between the Department of Defense and HHS on the Clinical Laboratory Improvement Amendments of 1988 within DoD, Public Law 100-578, and Part 493 of Title 42, Code of Federal Regulations (References (c), (d), (e)):

a. The Clinical Laboratory Improvement Amendments (CLIA) comparable regulations in this manual incorporate, to the maximum extent possible, the regulations issued by HHS in accordance with Reference (e), modified only to meet unique aspects of DoD missions, training, and preparations during peace, contingency, and wartime operations, which preclude compliance with CLIA. Nothing in this manual limits the authority of the DoD Component heads to apply more stringent laboratory standards as commanders or medical directors deem necessary.

b. The DoD will ensure the quality and reliability of laboratory testing at facilities conducting testing on 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 in accordance with Reference (c).

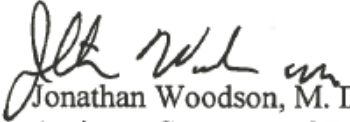
4. RESPONSIBILITIES. See Enclosure 2.

5. PROCEDURES. See Enclosure 3.

6. RELEASABILITY. Cleared for public release. This manual is available on the Directives Division Website at <https://www.esd.whs.mil/DD/>.

7. SUMMARY OF CHANGE 1. The change to this issuance updates references and removes expiration language in accordance with current Chief Management Officer of the Department of Defense direction.

8. EFFECTIVE DATE. This manual is effective May 29, 2014.

  
Jonathan Woodson, M. D.  
Assistant Secretary of Defense  
For Health Affairs

Enclosures

1. References
2. Responsibilities
3. Procedures

Glossary

TABLE OF CONTENTS

ENCLOSURE 1: REFERENCES.....5

ENCLOSURE 2: RESPONSIBILITIES.....6

    ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS (ASD(HA)).....6

    DIRECTOR, DHA.....6

    SECRETARIES OF THE MILITARY DEPARTMENTS.....6

ENCLOSURE 3: PROCEDURES.....8

    GENERAL PROVISIONS .....8

    CERTIFICATE OF WAIVER.....9

    REGISTRATION CERTIFICATE, CERTIFICATE FOR PPM PROCEDURES, AND  
    CERTIFICATE OF COMPLIANCE.....11

    CERTIFICATE OF ACCREDITATION .....15

    ACCREDITATION BY A PRIVATE NONPROFIT ACCREDITATION  
    ORGANIZATION .....19

    PARTICIPATION IN PT .....22

    PT BY SPECIALTY AND SUBSPECIALTY FOR LABORATORIES PERFORMING  
    NON-WAIVED TESTS OF MODERATE COMPLEXITY, HIGH COMPLEXITY,  
    OR ANY COMBINATION OF THESE TESTS.....26

    PT PROGRAMS FOR NON-WAIVED TESTING .....26

    PT PROGRAMS BY SPECIALTY AND SUBSPECIALTY .....26

    FACILITY ADMINISTRATION FOR NON-WAIVED TESTING .....26

    QUALITY SYSTEM FOR NON-WAIVED TESTING INTRODUCTION .....26

    QUALITY SYSTEM FOR NON-WAIVED TESTING – GENERAL LABORATORY  
    SYSTEMS.....27

    QUALITY SYSTEMS FOR NON-WAIVED TESTING – PREANALYTIC SYSTEMS ....28

    QUALITY SYSTEM FOR NON-WAIVED TESTING – ANALYTIC SYSTEMS.....31

    QUALITY SYSTEM FOR NON-WAIVED TESTING – POSTANALYTIC SYSTEMS ....40

    PERSONNEL FOR NON-WAIVED TESTING – GENERAL .....43

    PERSONNEL FOR NON-WAIVED TESTING – LABORATORIES PERFORMING  
    PPM PROCEDURES.....43

    PERSONNEL FOR NON-WAIVED TESTING – LABORATORY PERFORMING  
    MODERATE COMPLEXITY TESTING.....43

    PERSONNEL FOR NON-WAIVED TESTING – LABORATORIES PERFORMING  
    HIGH COMPLEXITY TESTING .....44

    INSPECTIONS .....45

    ENFORCEMENT PROCEDURES .....48

    NON-FIXED MTF LABORATORIES .....59

    LABORATORY JOINT WORKING GROUP (LJWG).....60

GLOSSARY .....63

PART I: ABBREVIATIONS AND ACRONYMS .....63  
PART II: DEFINITIONS.....64

ENCLOSURE 1

REFERENCES

- (a) DoD Directive 5136.01, “Assistant Secretary of Defense for Health Affairs (ASD(HA)),” September 30, 2013, as amended
- (b) DoD Instruction 6440.02, “Clinical Laboratory Improvement Program (CLIP),” May 29, 2014, as amended
- (c) Memorandum of Agreement between the Department of Defense and Department of Health and Human Services on the Clinical Laboratory Improvement Amendments of 1988 within DoD, January 14, 2009
- (d) Public Law 100-578, “Clinical Laboratory Improvement Amendments of 1988,” October 31, 1988
- (e) Title 42, Code of Federal Regulations
- (f) Title 10, United States Code
- (g) DoD Instruction 1010.16, “Technical Procedures for the Military Personnel Drug Abuse Testing Program (MPDATP),” June 15, 2020
- (h) Appendix C of Centers for Medicare & Medicaid Service (CMS) Publication 100-07, Medicare State Operations Manual, 1 June 2004

ENCLOSURE 2

RESPONSIBILITIES

1. ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS (ASD(HA)). Under the authority, direction, and control of the Under Secretary of Defense for Personnel and Readiness, the ASD(HA):

a. Establishes DoD procedures and supporting guidance for CLIP. Exercises authority, oversight, and responsibility for implementation of CLIA-comparable regulations within DoD pursuant to Reference (c) and in accordance with References (d) and (e), and Chapter 55 of Title 10, United States Code (Reference (f)).

b. Directs the establishment the CCLM in the DHA.

2. DIRECTOR, DHA. Under the authority, direction, and control of the ASD(HA), the Director, DHA:

a. Executes those responsibilities and functions pertaining to the day-to-day operations of the CCLM and CLIP as described in Enclosure 3 of this manual.

b. Appoints the Director, CCLM. This position should rotate among the three O-6-level CCLM Military Department directors.

3. SECRETARIES OF THE MILITARY DEPARTMENTS. The Secretaries of the Military Departments:

a. Implement CLIP requirements within their respective Department's Active and Reserve Components and facilities under their supervision to include oversight, inspections, proficiency testing (PT), personnel standards, and training in laboratories performing testing on human specimens as defined under "laboratory" in the Glossary of this manual.

b. Follow CLIP procedures for corrective action on laboratory facilities whose PT or performance criteria fall outside the standards of CLIP policy.

c. In accordance with Reference (f), implement the standards and procedures governing the operation, management, and oversight of clinical laboratory assets assigned to operational forces. Except where operational constraints preclude compliance, the standards governing clinical laboratory assets assigned to operational forces will incorporate the CLIP policy to the maximum extent possible without impeding operational requirements.

d. Recommend changes and revisions to CLIP standards to CCLM.

e. Oversee Surgeon General, laboratory commander, and laboratory medical director implementation of the procedures in Enclosure 3 of this manual.

ENCLOSURE 3

PROCEDURES

1. GENERAL PROVISIONS

a. Basic Rule. Except as specified in the applicability statement of this manual, a laboratory will be cited as out of compliance with these standards unless it has a current, unrevoked, or unsuspended CLIP certificate of waiver, a CLIP certificate of registration, a CLIP certificate of compliance, a CLIP certificate for provider-performed microscopy (PPM) or a CLIP certificate of accreditation, as appropriate, issued by the CCLM under the authority of the ASD(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 a status of forces agreement.

b. Exceptions. These rules do not apply to DoD 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 DoDI 1010.16 (Reference (g)), or are certified by the National Laboratory Certification Program (NLCP) of the Substance Abuse and Mental Health Services Administration of HHS, in which drug testing is performed that meets HHS guidelines and regulations. However, all other testing conducted by an HHS NLCP-certified laboratory, or one governed by Reference (g), is subject to the CLIP.

c. Laboratories. Laboratories under DoD jurisdiction are subject to the rules in References (d) and (e), except as modified by ASD(HA) after consultation with HHS. The CLIA comparable regulations, as modified, are specified in this enclosure. ASD(HA) will be responsible for the implementation of, and compliance with, these regulations with respect to the laboratories under DoD jurisdiction. Under the authority, direction, and control of the Director, DHA, the Director, CLLM is the ASD(HA)'s designee for matters related to CLIP as defined in this manual.

(1) During declared or undeclared wars, or during a period of mobilization, ASD(HA) may temporarily modify the provisions of this manual.

(2) ASD(HA) may modify the provisions of this manual as required for laboratories that are components of deployable operational forces.



(3) ASD(HA) may modify the provisions of this manual as required for laboratories that are located in overseas locations.

d. Categories of Tests By Complexity. Laboratory tests are categorized as: Waived tests; tests of moderate complexity, including the subcategory of PPM procedures; tests of high complexity.

(1) A laboratory may perform only waived tests, tests of moderate complexity, PPM procedures, tests of high complexity, or any combination of these tests.

(2) Each laboratory must possess one of these CLIP certificates:

- (a) Certificate of registration.
- (b) Certificate of waiver.
- (c) Certificate for PPM procedures.
- (d) Certificate of compliance.
- (e) Certificate of accreditation.

(3) DoD laboratories within a single hospital or clinic system that are located on the same campus or military installation, and under common direction, may file, with the CCLM Service Director's concurrence, either a single application or multiple applications for certificates per complexity category.

## 2. CERTIFICATE OF WAIVER

### a. Application for a Certificate of Waiver

(1) Filing of Application. Except as specified in paragraph 2a(2) of this section, a laboratory performing only one or more waived tests must file a separate application for each laboratory location.

### (2) Exceptions

(a) Laboratories that are not at a fixed location (i.e., 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.

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

(3) Application Format and Contents. The application must:

(a) Be made to ASD(HA) through CCLM.

(b) Be signed by the laboratory director and the commander, commanding officer, or officer in charge of the hospital or clinic who attest that the laboratory will be operated in accordance with the requirements established in this enclosure. The laboratory director must be a physician or other personnel approved by ASD(HA) through CCLM.

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

1. 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 PT purposes).

2. The methodologies for each laboratory test procedure or examination performed, or both.

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

(4) Access Requirements. Laboratories that perform one or more waived tests and no tests other than those listed in section 493.15 of Reference (e):

(a) Make records available and submit reports through command channels to the CCLM as may be reasonably required to determine compliance with this section.

(b) Agree to permit announced and unannounced inspections by the CCLM in accordance with section 493.35 of Reference (e):

1. When the CCLM has substantive reason to believe that the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health.

2. To evaluate complaints from health care providers, beneficiaries, commanders or other users of the laboratory.

3. On a random basis to determine whether the laboratory is performing tests not listed in section 493.15 of Reference (e).

(5) Denial of Application. If the CCLM determines that the application for a certificate of waiver is to be denied, the CCLM will, through the Services Surgeons General:

(a) Provide the laboratory with a written statement of the grounds on which the denial is based and an opportunity for appeal, in accordance with section 21 of this enclosure.

(b) Notify the laboratory that it cannot operate as a laboratory for patient testing unless the denial is overturned by CCLM.

b. Requirements for a Certificate of Waiver

(1) The CCLM will issue a certificate of waiver to a laboratory only if the laboratory meets the requirements of section 493.35 of Reference (e).

(2) A laboratory with a certificate of waiver that wishes to perform examinations or test procedures not listed in the waived test category must meet the requirements set forth in section 3 or section 4 of this enclosure, as applicable.

c. Notification Requirements for Laboratories Issued a Certificate for Waiver. Laboratories performing one or more waived tests and no others must notify the CCLM:

(1) Before performing and reporting results for any test or examination that is not specified under section 493.15 of Reference (e) for which it does not have the appropriate certificate as required in section 3 or section 4 of this enclosure.

(2) Within 30 days of any change(s) in name, location, or director.

3. REGISTRATION CERTIFICATE, CERTIFICATE FOR PPM PROCEDURES, AND CERTIFICATE OF COMPLIANCE

a. Application for Registration Certificate, Certificate for PPM Procedures, and Certificate of Compliance. Applications for registration certificate, certificate for PPM procedures, and certificates of compliance will follow section 493.43 of Reference (e). Exceptions follow section 493.43(b) of Reference (e); DoD laboratories within a single hospital or clinic that are located in contiguous buildings on the same campus or military installation and under common direction may, with the CCLM Service Director's concurrence, file a single application or multiple applications for the laboratory sites.

b. Requirements for a Registration Certificate. Application format and contents. The application must be made to CCLM. Laboratories performing only waived tests, PPM procedures, or any combination of these tests are not required to obtain a registration certificate.

(1) A registration certificate issued by the CCLM is required:

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

(b) For all laboratories that have been issued a certificate of waiver or certificate for PPM procedures that intend to perform tests of moderate or high complexity, or both, in addition to waived tests or those specified as PPM procedures.

(c) Non-fixed military treatment facilities (MTFs): If lab operations in a non-fixed MTF are expected to extend beyond 180 days, the MTF must request a registration certificate to be issued by the CCLM.

(2) The CCLM will issue a registration certificate if the laboratory:

(a) Complies with the requirements of this section.

(b) Agrees to notify the CCLM within 30 days of any changes in name, location, or director.

(c) Agrees to treat PT samples in the same manner as it treats patient specimens (non-fixed MTFs as defined in section 22 of this enclosure are exempt from PT).

(3) Prior to the expiration of the registration certificate, a laboratory must:

(a) Be inspected as specified in section 20 of this enclosure by the CCLM, or by a private, nonprofit accrediting agency approved by HHS.

(b) Demonstrate compliance with the applicable requirements of this section and sections 6 through 21 of this enclosure.

(4) In accordance with section 21 of this enclosure, through the MTF's chain of command, the CCLM will initiate suspension or revocation of a laboratory's registration certificate and will deny the laboratory's application for a certificate of compliance or certificate of accreditation, for failure to comply with the requirements set forth in section 3 of this enclosure. The CCLM may also impose certain alternative sanctions.

(5) A registration certificate is:

(a) Valid for a period of no more than 2 years or until such time as an inspection to determine program compliance can be conducted, whichever is shorter.

(b) Not renewable; however, a registration certificate may be extended if compliance has not been determined by the CCLM prior to the expiration date of the registration certificate.

(6) In the event of a non-compliance determination resulting in a denial of a laboratory's certificate of compliance application, the CCLM 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 section 21 of this enclosure. If a laboratory appeals within the time specified by the CCLM, it retains its registration certificate or extended registration certificate until an appeal decision is made as provided in section 21 of this enclosure, except when the CCLM finds that conditions at the laboratory pose an imminent and serious risk to human health.

c. Requirements for a Certificate for PPM Procedures. Follow section 493.47 of Reference (e).

(1) The CCLM will issue a certificate for PPM procedures if the laboratory complies with the requirements of this section.

(2) A certificate for PPM procedures is valid for a period of no more than 2 years.

d. Requirements for a Certificate of Compliance. Follow section 493.49 of Reference (e). A certificate of compliance may include any combination of tests categorized as moderate complexity or high complexity or listed in section 493.15 of Reference (e) as waived tests. Moderate complexity tests may include those specified as PPM procedures.

(1) The CCLM will issue a certificate of compliance to a laboratory only if the laboratory:

(a) Meets the requirements of this section.

(b) Meets the applicable requirements of sections 6 through 20 of this enclosure.

(c) Meets the definition of a non-fixed MTF as described in section 22 of this enclosure.

(2) Laboratories issued a certificate of compliance:

(a) Are subject to the notification requirements of this section.

(b) Must permit announced or unannounced inspections by CCLM, in accordance with section 20 of this enclosure:

1. To determine compliance with the applicable requirements.

2. To evaluate complaints from health care providers, beneficiaries, commanders or other users of the laboratory.

3. When the CCLM 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.

(3) Failure to comply with the requirements of this section will result in suspension, revocation, or limitation of a laboratory's certificate of compliance in accordance with section 21 of this enclosure.

(4) A certificate of compliance issued under this section is valid for no more than 2 years; however, a certificate of compliance may be extended if continued compliance has not been determined by the CCLM prior to the expiration date of the certificate of compliance.

(5) In the event of a non-compliance determination resulting in an action by the CCLM to revoke, suspend, or limit the laboratory's certificate of compliance, the CCLM will, through command channels:

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

(b) Offer an opportunity for appeal as provided in section 21 of this enclosure. 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 the CCLM, except when the CCLM finds that conditions at the laboratory pose an imminent and serious risk to human health, or when criteria in section 21 of this enclosure are met.

(6) A laboratory seeking to renew its certificate of compliance must:

(a) Complete and return the renewal application through command channels to the CCLM not less than 1 month, nor more than 3 months, prior to the expiration date of the certificate. In the event of a non-compliance, the procedures in paragraphs 3d(5)(a) and 3d(5)(b) will be followed.

(b) Meet the requirements of this section.

(7) If the CCLM determines that the application for the renewal of a certificate of compliance is to be denied or limited, the CCLM will, utilizing command channels, notify the laboratory in writing:

(a) The basis for denial of the application.

(b) The opportunity for appeal as provided in section 21 of this enclosure.

(c) Whether a laboratory appeals within the time period specified by the CCLM. It retains its certificate of compliance or extended certificate of compliance until an appeal decision is made in accordance with section 21 of this enclosure, except when the CCLM finds that conditions at the laboratory pose an imminent and serious risk to human health.

e. Notification Requirements for Laboratories Issued a Certificate of Compliance.  
Laboratories issued a certificate of compliance must:

(1) Notify the CCLM within 30 days of any change in name, location, or director.

(2) Notify the CCLM 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.

(3) Notify the CCLM 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.

f. Notification Requirements for Laboratories Issued a Certificate for PPM Procedures.  
Laboratories issued a certificate for PPM procedures must notify the CCLM:

(1) 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 as waived in accordance with section 493.15(c) of Reference (d) for which it does not have a registration certificate as required in this section or section 4 of this enclosure.

(2) Within 30 days of any change in name, location, or director.

#### 4. CERTIFICATE OF ACCREDITATION

##### a. Application for Registration Certificate and Certificate of Accreditation

(1) A laboratory may be issued a certificate of accreditation in lieu of the applicable certificate specified in section 2 or section 3 of this enclosure provided the laboratory:

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

(b) Files a separate application for each location, except as specified in section 2 of this enclosure.

(c) The application process of section 2 of this enclosure applies.

(2) All laboratories must make records available and submit reports through command channels to the CCLM as may reasonably require to determine compliance with this section.

##### b. Requirements for a Registration Certificate

(1) A registration certificate is required for all laboratories seeking a certificate of accreditation unless the laboratory holds a valid certificate of compliance issued by CCLM.

(2) The CCLM will issue a registration certificate if the laboratory:

(a) Complies with the requirements of this section.

(b) Agrees to notify the CCLM within 30 days of any changes in name, location, or director.

(c) Agrees to treat PT samples in the same manner as it treats patient specimens.

(3) The laboratory must provide the CCLM with proof of accreditation by an approved accreditation program (or in the case of non-fixed MTFs, proof of compliance from an inspection by CCLM within 11 months of issuance of the registration certificate or prior to the expiration of the certificate of compliance. If such proof of accreditation or inspection by CCLM is not supplied within a time frame specified in this section, the laboratory must continue to meet, the requirements of section 3 of this enclosure.

(4) In accordance with section 21 of this enclosure, the CCLM 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, if applicable, for failure to comply with the requirements set forth in this section. The CCLM, may also impose certain alternative sanctions.

(5) A registration certificate is valid for a period of no more than 2 years. However, it may be extended if compliance has not been determined by a private, non-profit accreditation program approved by HHS or the CCLM before the expiration date of the registration certificate.

(6) In the event that the laboratory does not meet the requirements of this section, the CCLM will, through command channels:

- (a) Deny a laboratory's request for a certificate of accreditation.
- (b) Notify the laboratory if it must meet the requirements for a certificate as defined in section 3 of this enclosure.
- (c) Provide the laboratory with a statement of grounds on which the application denial is based.
- (d) Offer an opportunity for appeal on the application denial in accordance with section 21 of this enclosure. If the laboratory appeals within the time specified by the CCLM, the laboratory will retain its registration certificate or extended registration certificate until an appeal decision is made by the CCLM in accordance with section 21 of this enclosure, unless the CCLM finds that conditions at the laboratory pose an imminent and serious risk to human health.

c. Requirements for a Certificate of Accreditation

(1) The CCLM will issue a certificate of accreditation to a laboratory if the laboratory meets the requirements of this section or, if applicable, section 3 of this enclosure.

(2) Laboratories issued a certificate of accreditation must:

- (a) Treat PT samples in the same manner as patient samples.
- (b) Meet the requirements of this section.



- (c) Comply with the requirements of an approved accreditation program.
  - (d) Permit random sample validation and complaint inspections as required in section 20 of this enclosure.
  - (e) Permit the CCLM to monitor the correction of any deficiencies found through the inspections specified in this section.
  - (f) Authorize the accreditation program to release to the CCLM the laboratory's inspection findings whenever the CCLM conducts random sample or complaint inspections.
  - (g) Authorize the accreditation program to submit to the CCLM the laboratory's PT results.
- (3) A laboratory failing to meet the requirements of this section:
- (a) Will no longer meet the requirements of CLIP by virtue of its accreditation in an approved accreditation program.
  - (b) Will be subject to full determination of compliance by the CCLM.
  - (c) May be subject to suspension, revocation, or limitation of the laboratory's certificate of accreditation, or to certain alternative sanctions.
- (4) A certificate of accreditation issued under this section is valid for no more than 2 years; however, the certificate may be extended if compliance has not been determined by the CCLM prior to the expiration date of the certificate. 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 the CCLM.
- (5) Failure to meet the applicable requirements of the CLIP will result in an action by the CCLM to suspend, revoke or limit the certificate of accreditation. The CCLM will, through command channels:
- (a) Provide the laboratory with a statement of grounds on which the determination of noncompliance is based.
  - (b) Notify the laboratory if it is eligible to apply for a certificate as defined in section 3 of this enclosure.
  - (c) Offer an opportunity for appeal as provided in section 21 of this enclosure.
  - (d) If the laboratory appeals within the time frame specified by the CCLM, it retains its certificate of accreditation or extended certificate of accreditation until an appeal decision is made by the CCLM as provided in section 21 of this enclosure, unless the CCLM finds that conditions at the laboratory pose an imminent and serious risk to human health.

(6) In the event the accreditation organization's approval is removed by HHS, the laboratory will be subject to the applicable requirements of section 3 or this section of this enclosure.

(7) A laboratory seeking to renew its certificate of accreditation must:

(a) Complete and return the renewal application through command channels to the CCLM 1 to 3 months prior to the expiration of the certificate of accreditation. In the event of a non-compliance the procedures in paragraphs 3d(5)(a) and 3d(5)(b) of this enclosure will be followed.

(b) Submit a copy of the letter from a Centers for Medicare & Medicaid Services (CMS) deemed agency granting accreditation with the application or within 30 days of receipt of the accreditation notice.

(c) Meet the requirements of this section.

(8) If the CCLM determines that the renewal application for a certificate of accreditation is to be denied or limited, the CCLM will, thorough the MTF's chain of command, notify the laboratory in writing of:

(a) The basis for denial of the application.

(b) Whether the laboratory is eligible for a certificate as defined in section 3 of this enclosure.

(c) The opportunity for appeal of the CCLM's action to deny the renewal application for a certificate of accreditation as provided in section 21 of this enclosure.

(d) If the laboratory appeals within the time frame specified by the CCLM, it retains its certificate of accreditation or extended certificate of accreditation until an appeal decision is made by the ASD(HA) as provided in section 21 of this enclosure, unless the ASD(HA) finds that conditions at the laboratory pose an imminent and serious risk to human health.

d. Notification Requirements for Laboratories Issued a Certificate of Accreditation.  
Laboratories issued a certificate of accreditation must:

(1) Notify the CCLM and the approved accreditation program within 30 days of any changes in name, location, or director.

(2) 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.

(3) 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.

## 5. ACCREDITATION BY A PRIVATE, NONPROFIT ACCREDITATION ORGANIZATION

a. General Requirements for Laboratories. The CCLM may deem a laboratory to meet all applicable CLIP requirements through accreditation by a private, nonprofit accreditation program (that has been granted deemed status by CMS) if the following conditions are met:

(1) The requirements of the accreditation organization are equal to or more stringent than the CLIP condition level requirements specified in this enclosure, 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 the CCLM all records and information required and permits inspections as outlined in this enclosure.

### b. Accreditation Policy

(1) All eligible medical laboratories located in a fixed MTF within the DoD MHS will be accredited by the Commission on Inspection and Accreditation of the College of American Pathologists (CAP).

(2) All fixed MTFs, ambulatory care clinics, and troop medical clinics, decentralized laboratories or point-of-care testing sites performing moderate or high complexity testing will be accredited by CAP.

(3) All fixed MTFs, ambulatory care clinics, and troop medical clinics, including their assigned laboratories performing waived or PPM testing may be accredited by and follow the guidelines of The Joint Commission (TJC) or be accredited by CAP.

(4) Laboratories performing high or moderate complexity testing but not associated with an MTF will be inspected biennially and accredited by the CAP, TJC, or the Commission on Office Laboratory Accreditation.

(5) A laboratory seeking to meet CLIP requirements through accreditation by an approved accreditation organization must :

(a) Obtain a certificate of accreditation as required in section 4 of this enclosure.

(b) Meet the PT requirements in section 6 of this enclosure.

(c) 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 the CCLM, in accordance with section 20 of this enclosure, and may be subject to the suspension or revocation of its certificate of accreditation under section 21 of this enclosure.

(d) Authorize its accreditation organization to release to the CCLM the laboratory's PT results.

(e) Authorize its accreditation organization to release to the CCLM 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, the CCLM may take adverse action against a laboratory that fails to participate successfully in an approved PT program.

(6) 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 the CCLM, whichever is earlier.

c. Validation Inspections - Basis and Focus

(1) The CCLM 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.

(2) Validation inspection may be conducted on a representative sample basis.

(a) If the CCLM 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.

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

(3) Validation inspection may be conducted in response to a substantial allegation of noncompliance.

(a) If the CCLM conducts a validation inspection in response to a substantial allegation of noncompliance, the inspection focuses on any condition level requirement that the CCLM determines to be related to the allegation.

(b) If the CCLM substantiates a deficiency and determines that the laboratory is out of compliance with any condition level requirement, the CCLM may conduct a full CLIP inspection. CCLM may choose to use the CMS-deemed agency's inspection standards, guidelines, or protocols to evaluate the quality of the inspection process.

d. Selection for Validation Inspection - Laboratory Responsibilities. A laboratory selected for a validation inspection must:

(1) Authorize its accreditation organization to release to the CCLM, on a confidential basis, a copy of the laboratory's most recent full, and any subsequent partial, inspection.

(2) Authorize the CCLM to conduct a validation inspection.

(3) Provide the CCLM with access to all facilities, equipment, materials, records, and information that the CCLM determines have a bearing on whether the laboratory is being operated in accordance with the requirements in section 4 of this enclosure and permit the CCLM to copy material or require the laboratory to submit material.

(4) If the laboratory possesses a valid certificate of accreditation, authorize the CCLM to monitor the correction of any deficiencies found through the validation inspection.

e. Refusal to Cooperate with Validation Inspection

(1) A laboratory with a certificate of accreditation that refuses to cooperate with a validation inspection by failing to comply with the requirements in this section:

(a) Is subject to full review by the CCLM.

(b) May be subject to suspension, revocation, or limitation of its certificate of accreditation under section 21 of this enclosure.

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

(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) CCLM finds that the laboratory meets all the condition level requirements.

f. Consequences of a Finding of Noncompliance as a Result of a Validation Inspection. 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 enclosure.

(2) Full review by the CCLM, in accordance with this enclosure; that is, the laboratory is subject to the principal and alternative sanctions in section 21 of this enclosure.

g. Disclosure of Accreditation or Validation Inspection Results

(1) CCLM may disclose accreditation organization inspection results to the public only if the results are related to an enforcement action taken by the CCLM.

(2) CCLM may disclose the results of all validation inspections conducted by the CCLM.

h. Removal of Deeming Authority

(1) The CCLM will review all CMS deeming authority removal actions and forward a recommendation for action to OCCLM.

(2) The effect on laboratory status of withdrawal of deeming authority approval:

(a) 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.

(b) Extension. After CMS withdraws approval of an accreditation organization, the CCLM 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 the CCLM before the initial 60-day period ends.

6. PARTICIPATION IN PT

a. Condition: Enrollment and Testing of Samples

(1) Each laboratory, unless otherwise exempt as specified in the applicability statement of this manual, must enroll in a PT program that meets the criteria in sections 8 and 9 of this enclosure 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.

(2) Non-fixed DoD medical laboratories and personnel participating in military contingency operations, operating in an active theater of operations, or otherwise considered deployed (as defined in section 22 of this enclosure) are exempt from participation in an external

PT program. Fixed laboratories located overseas must participate in a CMS-approved PT program.

(3) The laboratory must:

(a) Notify the CCLM of the approved program or programs in which it chooses to participate to meet the PT requirements of this section.

(b) Designate the program or programs to be used for each specialty, subspecialty, and analyte or test to determine compliance with this section if the laboratory participates in more than one PT program approved by CMS. For those tests performed by the laboratory that are not included in section 9 of this enclosure, a laboratory must establish and maintain the accuracy and reliability of its testing procedures, in accordance with section 12 of this enclosure.

(c) For each specialty, subspecialty, and analyte or test, participate in one approved PT program or programs for 1 year before designating a different program and must notify the CCLM before any change in designation.

(d) Authorize the PT program to release to the CCLM all data required to:

1. Determine the laboratory's compliance with this section.

2. Make PT results available to DoD authorized health care beneficiaries as required in section 493.801 of Reference (d).

(4) The laboratory must examine or test, as applicable, the PT samples it receives from the PT program in the same manner it tests patient specimens.

(a) 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.

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

(c) Laboratories that perform tests on PT samples must not engage in any inter-laboratory communications pertaining to the results of PT sample(s) until after the date by which the laboratory must report PT 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 or locations concerning PT sample results until after the date by which the laboratory must report PT results to the program.

(d) The laboratory will not send PT samples or portions of samples to another laboratory for any analysis that it is certified to perform in its own laboratory. Any laboratory

that the CCLM determines intentionally referred its PT samples to another laboratory for analysis will be subject to appropriate sanctions in accordance with section 21 of this enclosure. Any DoD laboratory that receives PT samples from another laboratory for testing must notify the CCLM of the receipt of those samples.

(e) 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 PT program report forms used by the laboratory to record PT results. These reports include the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that PT samples were tested in the same manner as patient specimens, for a minimum of 2 years from the date of the PT event.

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

b. Condition: Successful Participation For Laboratories Performing Non-Waived Testing

(1) Each laboratory performing non-waived testing must successfully participate in a PT program approved by CMS, if applicable, as described in sections 8 and 9 of this enclosure for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIP.

(2) The scores from each test in a PT program will be graded with equal emphasis. There will be no distinction made between regulated and unregulated analytes when grading PT.

(3) Each test analyte will be graded individually rather than combining certain procedures into subspecialty groups (e.g., gram stain, organism identification, and sensitivity will be graded as three separate tests rather than a combined subspecialty procedure).

(4) Except as specified in this section, if a laboratory fails to participate successfully in PT for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology PT, sanctions will be taken as defined in section 21 of this enclosure.

(5) If a laboratory fails to perform successfully in a CMS-approved PT program, for the initial unsuccessful performance, the CCLM may, through Service's Surgeon General, direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both. This may be done rather than imposing alternative or principle sanctions except when:

- (a) There is immediate jeopardy to patient health and safety.
- (b) The laboratory fails to provide the CCLM with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful PT performance.
- (c) The laboratory has a poor compliance history.



c. Condition: Successful Participation For Laboratories Performing Waived Testing

(1) Due to the proliferation of tests categorized as waived, DoD CLIP certificate of waiver laboratories and laboratories performing waived complexity testing under other types of CLIP certificates are also required to participate in PT when commercially available from a CMS-approved PT program. A prescriptive mechanism of setting PT performance criteria for waived tests and non-PT regulated non-waived analytes or tests that are included in a PT program is not specified by CMS and is solely at the discretion of the PT provider(s) and, for DoD, the Service Directors within the CCLM. Within the DoD, the determination of unsatisfactory PT performance for waived testing will generally be defined in the same manner as for non-waived 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.

(2) The scores from each test in a PT program will be graded with equal emphasis. There will be no distinction made between regulated and unregulated analytes when grading PT.

(3) Each test analyte will be graded individually rather than combining certain procedures into subspecialty groups (e.g., gram stain, organism identification, and sensitivity will be graded as three separate tests rather than a combined subspecialty procedure).

(4) Except as specified in this section, if a laboratory fails to participate successfully in PT for a given specialty, subspecialty, analyte or test, or fails to take remedial action when an individual fails gynecologic cytology PT, sanctions will be taken in accordance with section 21 of this enclosure.

(5) If a laboratory fails to perform successfully in a CMS-approved PT program, for the initial unsuccessful performance, the CCLM may, through Service's Surgeon General, 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:

- (a) There is immediate jeopardy to patient health and safety.
- (b) The laboratory fails to provide the CCLM with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful PT performance.
- (c) The laboratory has a poor compliance history.

d. Condition: Reinstatement of Laboratories. If a laboratory's certificate is suspended or limited by CCLM or the accrediting agency because it fails to participate successfully in PT 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. The laboratory must seek technical assistance or training, and demonstrate sustained satisfactory performance on two consecutive proficiency remedial recertification events; one of

which may be on site. CCLM will then consider all corrective actions taken when reviewing the laboratory's request for reinstatement of patient testing.

7. PT BY SPECIALTY AND SUBSPECIALTY. The various laboratory specialties for purposes of PT are as described in sections 493.821 through 493.865 of Reference (e).

8. PT PROGRAMS FOR NON-WAIVED TESTING

a. Approval of PT Programs. For a PT 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 director, may approve the use of specific PT materials from a non-CMS approved PT 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 Reference (d), use of PT materials from a non-CMS approved program will be in addition to, not in lieu of, the use of PT materials from a CMS-approved program.

b. Administrative Responsibilities. The PT program must follow section 493.903 of Reference (e):

c. Non-Approved PT Programs. If a CMS approved PT program is determined by HHS to fail to meet any criteria contained in sections 493.901 through 493.959 of Reference (e) for approval of the PT program, CMS will notify the program and the program must notify the CCLM and all laboratories enrolled of the non-approval and the reasons for non-approval within 30 days of the notification.

9. PT PROGRAMS BY SPECIALTY AND SUBSPECIALTY. The content of approved PT programs is explained in sections 493.909 through 493.959 of Reference (e).

10. FACILITY ADMINISTRATION FOR NON-WAIVED TESTING. Each laboratory that performs non-waived testing must meet the applicable requirements in sections 493.1101 through 493.1105 of Reference (e) unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of Centers for Medicare & Medicaid Service Publication 100-07 (Reference (h)).

11. QUALITY SYSTEM FOR NON-WAIVED TESTING INTRODUCTION

a. Each laboratory that performs non-waived testing must establish and maintain written policies and procedures that implement and monitor a quality system for all phases of the total testing process (preanalytic phase, analytic phase, and postanalytic phase) 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 enclosure and must be appropriate for the specialties and subspecialties of testing the laboratory performs, services it offers, and clients it serves.

d. For each subspecialty the laboratory must follow the applicable conditions found in sections 493.1201 through 493.1227 of Reference (e).

## 12. QUALITY SYSTEM FOR NON-WAIVED TESTING - GENERAL LABORATORY SYSTEMS

a. Condition: General Laboratory Systems. Each laboratory that performs non-waived testing must meet the applicable general laboratory systems requirements in sections 493.1231 through 493.1236 of Reference (e) unless HHS approves a procedure, specified in Reference (h) 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 section 493.1239 of Reference (e) for each specialty and subspecialty of testing performed.

b. Standard: Confidentiality of Patient Information. The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that is under the laboratory's control.

c. Standard: Specimen Identification and Integrity. 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.

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

e. Standard: Communications. 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 (i.e., physician/doctor, physician's assistant, nurse practitioner) who orders or receives test results.

f. Standard: Personnel Competency Assessment Policies. As specified in the personnel requirements in sections 16, 17, 18, and 19 of this enclosure, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

g. Standard: Evaluation of PT Performance

(1) The laboratory must review and evaluate the results obtained on PT performed as specified in section 6 of this enclosure.

(2) The laboratory must verify the accuracy of:

(a) Any analyte or subspecialty without analytes listed in section 9 of this enclosure that is not evaluated or scored by a CMS-approved PT program.

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

(3) At least twice annually, the laboratory must verify the accuracy of:

(a) Any test or procedure it performs that is not included in section 9 of this enclosure.

(b) Any test or procedure listed in section 9 of this enclosure for which compatible PT samples are not offered by a CMS-approved PT program.

(4) All PT evaluation and verification activities must be documented.

h. Standard: General Laboratory Systems Quality Assessment

(1) 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 in this section.

(2) 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.

(3) The laboratory must document all general laboratory systems quality assessment activities.

13. QUALITY SYSTEMS FOR NON-WAIVED TESTING - PREANALYTIC SYSTEMS

a. Condition: Preanalytic Systems. Each laboratory that performs non-waived testing must meet the applicable preanalytic system(s) requirements in this section, unless HHS approves a procedure, specified in Reference (h) 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 section 13 of this enclosure for each specialty and subspecialty of testing performed.

b. Standard: Test Request

(1) The laboratory must have a written or electronic request for patient testing from an authorized person (i.e., physician or doctor, physician's assistant, nurse practitioner).

(2) 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.

(3) The laboratory must ensure the test requisition solicits:

(a) The name and address or other suitable identifiers of the authorized person (i.e., physician/doctor, physician's assistant, nurse practitioner) requesting the test and, if appropriate, the individual responsible for using the test results. Alternatively, the name and address of the laboratory submitting the specimen, including a contact person to enable the reporting of imminently life threatening laboratory results or critical or alert values.

(b) The patient's name or unique patient identifier.

(c) The sex and age or date of birth of the patient.

(d) The test(s) to be performed.

(e) The source of the specimen, when appropriate.

(f) The date and, if appropriate, time of specimen collection.

(g) For pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy.

(h) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

(4) 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 the CCLM upon request.

(5) 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.

c. Standard: Specimen Submission, Handling, and Referral

(1) The laboratory must establish and follow written policies and procedures for each of the following, if applicable:

- (a) Patient preparation.
  - (b) Specimen collection.
  - (c) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source.
  - (d) Specimen storage and preservation.
  - (e) Conditions for specimen transportation.
  - (f) Specimen processing.
  - (g) Specimen acceptability and rejection.
  - (h) Specimen referral.
- (2) The laboratory must document the date and time it receives a specimen.
- (3) 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.
- (4) 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 this section.

d. Standard: Preanalytic Systems Quality Assessment

- (1) 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 in this section.
- (2) 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.
- (3) The laboratory must document all preanalytic systems quality assessment activities.

14. QUALITY SYSTEM FOR NON-WAIVED TESTING - ANALYTIC SYSTEMS

a. Condition: Analytic Systems. Each laboratory that performs non-waived testing must meet the applicable analytic systems requirements in this section, unless HHS approves a procedure, specified in Reference (h) 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 this section for each specialty and subspecialty of testing performed.

b. Standard: Procedure Manual

(1) 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.

(2) The procedure manual must include the following when applicable to the test procedure:

(a) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in section 13 of this enclosure.

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

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

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

(e) Calibration and calibration verification procedures.

(f) The reportable range for test results for the test system as established or verified.

(g) Control procedures.

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

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

(j) Reference intervals (normal values).

(k) Imminently life-threatening test results, or critical or alert values.

(l) Pertinent literature references.

(m) 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 critical or alert values.

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

(3) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of this section. Any of the items under section 14 not provided by the manufacturer must be provided by the laboratory.

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

(5) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in section 10 of this enclosure.

c. Standard: Test Systems, Equipment, Instruments, Reagents, Materials, and Supplies

(1) 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 in accordance with this section.

(2) 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:

(a) Water quality.

(b) Temperature.

(c) Humidity.

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

(3) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate:

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

(b) Storage requirements.

(c) Preparation and expiration dates.



(d) Other pertinent information required for proper use.

(4) 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. For DoD laboratories located outside the United States, expired reagents may be used only when delivery of new shipments of reagents is delayed through causes not under the control of the laboratory. The laboratory must document validation of the performance of expired reagents in accordance with a written laboratory policy.

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

d. Standard: Establishment and Verification of Performance Specifications. Laboratories are required to verify or establish performance specifications; determine calibration and control procedures, and document all activities specified in this section.

(1) Verification of performance specifications. Before reporting patient test results, each laboratory that introduces an unmodified, Food and Drug Administration (FDA)-cleared or approved test system or method must:

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

1. Accuracy.
2. Precision.
3. 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. A laboratory may modify 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 textbook procedures), or uses a test system in which performance specifications are not provided by the manufacturer. However, before reporting patient test results the laboratory must establish the performance specifications for each test system using 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 this section.

e. Standard: Maintenance and Function Checks

(1) Unmodified manufacturer's equipment, instruments, or test systems. The laboratory must perform and document:

(a) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

(b) 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.

(2) When equipment, instruments, or test systems or methods are developed in-house or commercially available and modified by the laboratory or maintenance and function check protocols are not provided by the manufacturer, the laboratory must do:

(a) Maintenance.

1. 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.

2. Perform and document the maintenance activities specified in this section.

(b) Function checks.

1. 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.

2. Perform and document the function checks, including background or baseline checks, specified in this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

f. Standard: Calibration and Calibration Verification Procedures. 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 section, for each applicable test system the laboratory must:

(1) Perform and document calibration procedures

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

(b) Using the criteria verified or established by the laboratory as specified in this section:

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

2. Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration.

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

(2) Perform and document calibration verification procedures

(a) Following the manufacturer's calibration verification instructions.

(b) Using the criteria verified or established by the laboratory under this section:

1. Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification.

2. 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.

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

1. 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.

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

3. 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.

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

g. Standard: Control Procedures

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

(2) 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 this section.

(3) The control procedures must:

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

(b) 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.

(4) Unless CMS approves a procedure, specified in Reference (h), that provides equivalent quality testing, the laboratory must:

(a) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements in this section.

(b) 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 this section.

(c) Each day patient specimens are assayed or examined perform the following for:

1. Each quantitative procedure, include two control materials of different concentrations.

2. Each qualitative procedure, include negative and positive control material.

3. Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively.

4. Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process.

5. 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.

(d) For thin layer chromatography:

1. 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.

2. 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.

(e) For each electrophoresis procedure include, concurrent with patient specimens, at least one control material containing the substances being identified or measured.

(f) Perform control material testing as specified in this section 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.

(g) Over time, rotate control material testing among all operators who perform the test.

(h) Test control materials in the same manner as patient specimens.

(i) 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.

(j) Establish or verify the criteria for acceptability of all control materials.

1. 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.

2. 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.

3. 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.

(5) For reagent, media, and supply checks, the laboratory must:

(a) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, susceptibility disks, bacteria stains, antisera, (except those specifically referenced in this section 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.

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

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

(d) Before, or concurrent with the initial use:

1. Check each batch of media for sterility if sterility is required for testing.

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

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

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

(6) 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.

(7) The laboratory must document all control procedures performed.

(8) 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.

h. Standards: Quality Control. The laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process for each of the following subspecialty in accordance with sections 492.1262 – 493.1278 of Reference (e): Bacteriology, Mycobacteriology, Mycology, Parasitology, Virology, Routine Chemistry, Hematology, Immunohematology, Histopathology, Cytology, Clinical Cytogenetics, Histocompatibility.

i. Standard: Comparison of Test Results

(1) 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.

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

- (a) Patient age.
- (b) Sex.
- (c) Diagnosis or pertinent clinical data.
- (d) Distribution of patient test results.
- (e) Relationship with other test parameters.

(3) The laboratory must document all test result comparison activities.

j. Standard: Corrective Actions. 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. The laboratory must document all corrective actions taken, including action taken when:

(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in this section, 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.
- (c) When the laboratory determines that the reference intervals 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 this section, are not met.

k. Standard: Test Records

- (1) The laboratory must maintain an information or record system that includes:
  - (a) The positive identification of the specimen.
  - (b) The date and time of specimen receipt into the laboratory.
  - (c) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability.
  - (d) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).
- (2) Records of patient testing including, if applicable, instrument printouts, must be retained.

l. Standard: Analytic Systems Quality Assessment

- (1) 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 this section.
- (2) 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.
- (3) The laboratory must document all analytic systems quality assessment activities.

15. QUALITY SYSTEM FOR NON-WAIVED TESTING - POSTANALYTIC SYSTEMS

a. Condition: Postanalytic Systems. Each laboratory that performs non-waived testing must meet the applicable postanalytic systems requirements in section 14 of this enclosure unless HHS approves a procedure, specified in section 493.1290 of Reference (e) 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 this section for each specialty and subspecialty of testing performed.

b. Standard: Test Report

(1) 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:



- (a) Results reported from calculated data.
  - (b) Results and patient-specific data electronically reported to network or interfaced systems.
  - (c) 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.
- (2) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to the CCLM upon request.
- (3) The test report must indicate:
- (a) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number.
  - (b) The name and address of the laboratory location where the test was performed.
  - (c) The test report date.
  - (d) The test performed.
  - (e) Specimen source, when appropriate.
  - (f) The test result and, if applicable, the units of measurement or interpretation, or both.
  - (g) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.
- (4) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person (i.e., physician or doctor, physician's assistant, nurse practitioner) who ordered the tests and, if applicable, the individual responsible for using the test results.
- (5) 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 section 14 of this enclosure. 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.
- (6) 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.

(7) 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 critical or alert values.

(8) 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.

(9) If a laboratory refers patient specimens for testing:

(a) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory.

(b) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person (i.e., physician or doctor, physician's assistant, nurse practitioner) who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report.

(c) The authorized person (i.e., physician or doctor, physician's assistant, nurse practitioner) 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.

(10) 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.

(11) When errors in the reported patient test results are detected, the laboratory must:

(a) Promptly notify the authorized person (i.e., physician or doctor, physician's assistant, nurse practitioner) ordering the test and, if applicable, the individual using the test results of reporting errors.

(b) Issue corrected reports promptly to the authorized person (i.e., physician or doctor, physician's assistant, nurse practitioner) ordering the test and, if applicable, the individual using the test results.

(c) Maintain duplicates of the original report, as well as the corrected report.

c. Standard: Postanalytic Systems Quality Assessment

(1) 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 section 14 of this enclosure.

(2) 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.

(3) The laboratory must document all postanalytic systems quality assessment activities.

16. PERSONNEL FOR NON-WAIVED TESTING - GENERAL. Sections 17, 18, and 19 of this enclosure consist of the personnel requirements that must be met by laboratories performing non-waived testing. As feasible, medical laboratories located outside of the United States will meet these personnel rules to ensure quality laboratory services, but ASD(HA) or the Service's Surgeon General may waive specific personnel requirements if necessary for national defense.

17. PERSONNEL FOR NON-WAIVED TESTING – LABORATORIES PERFORMING PPM PROCEDURES. In accordance with section 493.19 of Reference (d), 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 sections 493.1355 through 493.1365 of Reference (e).

18. PERSONNEL FOR NON-WAIVED TESTING - LABORATORIES PERFORMING MODERATE COMPLEXITY TESTING

a. Moderate Complexity Laboratory Director Qualifications and Responsibilities. The laboratory must have a director who meets the qualification requirements of section 493.1405 of Reference (e) and provides overall management and direction in accordance with section 493.1407 of Reference (e).

b. Moderate Complexity Technical Consultant Qualifications and Responsibilities. The laboratory must have a technical consultant who meets the qualification requirements of section 493.1411 of Reference (e) and provides technical oversight in accordance with section 493.1413 of Reference (e).

c. Moderate Complexity Clinical Consultant Qualifications and Responsibilities. The laboratory must have a clinical consultant who meets the qualification requirements of section 493.1417 of Reference (e) and provides clinical consultation in accordance with section 493.1419 of Reference (e).

d. Moderate Complexity Testing Personnel Qualifications and Responsibilities. The laboratory must have a sufficient number of individuals who meet the qualification requirements of section 493.1423 of Reference (e), to perform the functions specified in section 493.1425 of Reference (e) for the volume and complexity of tests performed.

**19. PERSONNEL FOR NON-WAIVED TESTING - LABORATORIES PERFORMING HIGH COMPLEXITY TESTING**

a. **High Complexity Laboratory Director Qualifications and Responsibilities.** The laboratory must have a director who meets the qualification requirements of section 493.1443 of Reference (e) and provides overall management and direction in accordance with section 493.1445 of Reference (e).

b. **High Complexity Technical Supervisor Qualifications and Responsibilities.** 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 section. 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 personnel on an as needed basis to provide supervision. The Technical Supervisor provides technical supervision in accordance with section 493.1451 of Reference (e). The laboratory technical supervisor must:

(1) Meet the qualification requirements of section 493.1449 of Reference (e) and be certified by the American Society of Clinical Pathologists (ASCP), American Medical Technologists (AMT) or other board of registry deemed comparable by CCLM as a medical technologist (MT) or medical laboratory scientist (MLS); or

(2) Be a commissioned laboratory officer in the Military Services, and have earned a bachelor's degree from an accredited institution; and have at least 3 years of laboratory experience in high complexity testing and be certified by the ASCP, AMT, or other board of registry deemed comparable by CCLM as an MT or MLS.

(3) Technical supervisors in the subspecialty of immunohematology must have completed a Committee on Allied Health Education and Accreditation accredited school's program for specialist in blood banking, have at least 3 years of laboratory experience in high complexity testing within the specialty of immunohematology; and be certified by the ASCP, AMT, or other board of registry deemed comparable by CCLM as a specialist in blood banking.

c. **High Complexity Clinical Consultant Qualifications and Responsibilities.** The laboratory must have a clinical consultant who meets the requirements of section 493.1455 of Reference (e) and provides clinical consultation in accordance with section 493.1457 of Reference (e).

d. **High Complexity General Supervisor Qualifications and Responsibilities.** The laboratory must have one or more general supervisors who meets the requirements of section 493.1461 of Reference (e) or who qualifies as testing personnel in accordance with paragraph 19g of this section and have at least 2 years of laboratory training or experience, or both, in high complexity testing. The general supervisor provides general supervision in accordance with section 493.1463 of Reference (e).

e. High Complexity Cytology General Supervisor Qualifications and Responsibilities. For the subspecialty of cytology, the laboratory must have a general supervisor who meets the qualification requirements of section 493.1469 of Reference (e), and provides supervision in accordance with section 493.1471 of Reference (e).

f. High Complexity Cytotechnologist Qualifications and Responsibilities. For the subspecialty of cytology, the laboratory must have a sufficient number of cytotechnologists who meet the qualifications specified in section 493.1483 of Reference (e) to perform the functions specified in section 493.1485 of Reference (e).

g. High Complexity Testing Personnel Qualifications and Responsibilities. The laboratory has a sufficient number of individuals who meet the qualification requirements of section 493.1489 of Reference (e) to perform the functions specified in section 493.1495 of Reference (e) for the volume and complexity of testing performed.

(1) Each individual performing high complexity testing must meet the qualification requirements of section 493.1489 of Reference (e); and have earned an associate degree or higher in a laboratory science, or medical laboratory technology from an accredited institution and be certified by the ASCP, AMT or other board or registry deemed comparable by OASD(HA) or their designee (CCLM) as a MLT or MT/MLS; or

(2) Have successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and currently hold the military enlisted occupational specialty of medical laboratory specialist (laboratory technician).

## 20. INSPECTIONS

a. Condition: Inspection Requirements Applicable to All CLIP-Certified Laboratories. Each laboratory issued a CLIP certificate must meet the requirements in this section and the specific requirements for its certificate type.

b. Standard: Basic Inspection Requirements for All Laboratories Issued a CLIP Certificate

(1) Laboratory. A laboratory issued a certificate must permit the CCLM to conduct an inspection to assess the laboratory's compliance with CLIP. A laboratory that requests, or is issued a certificate of accreditation, must permit the CCLM to conduct validation and complaint inspections. Reports of complaint inspections are governed by section 1102 of Reference (f).

(2) General Requirements. As part of the inspection process, the CCLM may require the laboratory to:

(a) Test samples, including PT samples, or perform procedures.

(b) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of the CLIP.

(c) Permit laboratory personnel to be observed performing all phases of the total testing process (preanalytic, analytic, and postanalytic).

(d) Permit the CCLM access to all areas encompassed under the certificate including, but not limited to: specimen procurement and processing areas; storage facilities for specimens, reagents, supplies, records, and reports; testing and reporting areas.

(e) Provide the CCLM with copies or exact duplicates of all records and data it requires.

(3) A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection.

(4) A laboratory must provide, upon request, all information and data needed by the CCLM to make a determination of the laboratory's compliance with the applicable requirements of CLIP.

(5) The CCLM may re-inspect a laboratory at any time to evaluate the ability of the laboratory to provide accurate and reliable test results.

(6) The CCLM may conduct an inspection when there are complaints alleging noncompliance with any of the requirements of the CLIP. Reports of complaint inspections are governed by section 1102 of Reference (f).

(7) Failure to permit the CCLM 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 section 21 of this enclosure.

c. Standard: Inspection of Laboratories Issued a Certificate of Waiver or a Certificate for PPM Procedures

(1) A laboratory that has been issued a certificate of waiver, certificate for PPM procedures is NOT subject to biennial inspections. However, when an MTF is accredited by TJC, waived and PPM testing sites within that facility must be either surveyed by TJC in conjunction with the facility's TJC accreditation survey or be separately inspected or accredited by an accreditation agency granted deeming authority by TJC.

(2) If necessary, the CCLM may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for PPM procedures at any time during the laboratory's hours of operation to:

(a) 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.

(b) Evaluate a complaint from health care providers, beneficiaries, commanders, or other users of the laboratory. Reports of complaint inspections are governed by section 1102 of Reference (f).

(c) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory.

(3) The laboratory must comply with the basic inspection requirements of this section.

d. Standard: Inspection of Laboratories That Have Requested or Have Been Issued a Certificate of Compliance

(1) Initial Inspection

(a) A laboratory issued a registration certificate must permit an initial inspection to assess the laboratory's compliance with the requirements of CLIP before the CCLM issues a certificate of compliance.

(b) The inspection may occur at any time during the laboratory's hours of operation.

(2) Subsequent Inspections

(a) The CCLM may conduct subsequent inspections on a biennial basis or with such other frequency as the CCLM determines to be necessary to ensure compliance with the requirements of CLIP.

(b) The CCLM bases the nature of subsequent inspections on the laboratory's compliance history.

(3) The inspection sample for review may include testing in the subcategory of PPM procedures.

(4) The laboratory must comply with the basic inspection requirements of this section and section 493.1773 of Reference (e).

e. Standard: Inspection of Laboratories Requesting or Issued a Certificate of Accreditation

(1) The CCLM may conduct a validation inspection of any accredited laboratory at any time during its hours of operation.

(2) The CCLM 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. Reports of complaint inspections are governed by section 1102 of Reference (f).

(3) 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 the CCLM, in accordance with section 5 of this enclosure.

(4) Laboratories requesting or issued a certificate of accreditation must comply with the basic inspection requirements in this section.

## 21. ENFORCEMENT PROCEDURES

### a. Basis and Scope will follow section 493.1800 of Reference (e)

(1) In accordance with section 1072 of Reference (f), DoD is given jurisdictional responsibility under law for the operation of its facilities.

(2) This section sets forth the policies and procedures that the CCLM will follow to enforce the requirements applicable to laboratories under the CLIP and the appeal rights of laboratories on which sanctions are imposed.

### b. General Considerations will follow section 493.1804 of Reference (e)

(1) Enforcement mechanisms are taken to improve the quality of laboratory services available to beneficiaries. As such, all investigation and complaint reports are governed by section 1102 of Reference (f). Enforcement mechanisms must:

(a) Provide accurate and reliable test results.

(b) Protect all individuals served by DoD laboratories against substandard testing of specimens.

(c) Safeguard DoD laboratory staff, health care providers and other MTF staff, and health care beneficiaries against health and safety hazards that might result from substandard laboratory activities.

(2) A decision to impose sanctions is based on the deficiencies found by the CCLM 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), or unsuccessful participation in PT. The CCLM imposes one or more of the alternative or principle sanctions specified in this section when the CCLM finds that a laboratory has condition level deficiencies.

(3) Imposition of alternative sanctions.

(a) The CCLM 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.



(b) The CCLM may impose alternative sanctions after the laboratory has had an opportunity to respond through command channels.

(4) The CCLM 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 the CCLM:

(a) Whether the deficiencies pose immediate jeopardy.

(b) The nature, incidence, severity, and duration of the deficiencies or noncompliance.

(c) Whether the same condition level deficiencies have been identified repeatedly.

(d) The accuracy and extent of laboratory records (e.g. of remedial action) in regard to the noncompliance and their availability to the CCLM.

(e) The relationship of one deficiency or group of deficiencies to other deficiencies.

(f) The overall compliance history of the laboratory including, but not limited to, any period of noncompliance that occurred between certifications of compliance.

(g) The corrective and long-term compliance outcomes that the CCLM hopes to achieve through application of the sanction.

(h) Whether the laboratory has made any progress toward improvement following a reasonable opportunity to correct deficiencies.

(i) Any recommendations within the chain of command as to which sanctions would be appropriate.

(5) The CCLM 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.

(6) The appeal process for laboratories is set forth in this section.

c. Available Sanctions

(1) The CCLM may impose one or more of the sanctions specified in paragraphs 21c(1) through 21c(3) of this section on a laboratory that is out of compliance with one or more CLIP conditions.

(2) The CCLM may impose any of the three principal sanctions, which are suspension, limitation, or revocation of any type of CLIP certificate.

(3) The CCLM may impose one or more of the following alternative sanctions in lieu of, or in addition to, imposing a principal sanction.

- (a) Directed plan of correction, as set forth in this section.
- (b) Directed on-site monitoring as set forth in this section.

d. Imposition and Lifting of Alternative Sanctions

(1) If the CCLM identifies condition level noncompliance in a laboratory, the CCLM gives the laboratory, through command channels, written notice of:

- (a) The condition level noncompliance that it has identified.
- (b) The sanction or sanctions that the CCLM proposes to impose against the laboratory.
- (c) The rationale for the proposed sanction or sanctions.
- (d) The projected effective date and duration of the proposed sanction or sanctions.
- (e) The authority for the proposed sanction or sanctions.
- (f) The time allowed for the laboratory to respond to the notice.

(2) During the period specified in section 20 of this enclosure, the laboratory may submit for review, through command channels to the CCLM, written evidence or other information against the imposition of the proposed sanction or sanctions.

(3) After evaluation of data submitted in accordance with section 20 of this enclosure, 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:

- (a) The sanction(s) to be imposed against the laboratory.
- (b) The authority and rationale for imposing the sanction(s).
- (c) The effective date and duration of the sanction(s).

(4) Sanctions become effective according to the following criteria:

(a) The CCLM determines that the deficiencies pose immediate jeopardy, and the CCLM provides a notice of at least 5 days before the effective date of the sanction.

(b) The CCLM determines that the deficiencies do not pose immediate jeopardy, and the CCLM provides a notice of at least 15 days before the effective date of the sanction.

(5) An alternative sanction continues until:

(a) The laboratory corrects all condition level deficiencies; or

(b) CCLM's suspension, limitation, or revocation of the laboratory's CLIP certificate becomes effective.

(6) Alternative sanction(s).

(a) General rule. Alternative sanctions are not lifted until a laboratory's compliance with all condition level requirements is verified.

(b) Credible allegation of compliance. When a sanctioned laboratory submits a credible allegation of compliance, the CCLM determines whether:

1. It can certify compliance on the basis of the evidence presented by the laboratory in its allegation.

2. It must revisit to verify whether the laboratory has, in fact, achieved compliance.

e. Action When Deficiencies Pose Immediate Jeopardy. If a laboratory's deficiencies pose immediate jeopardy:

(1) The CCLM 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.

(2) If the findings of a revisit indicate that a laboratory has not eliminated the jeopardy, the CCLM suspends or limits the laboratory's CLIP certificate no earlier than 5 days after the date of notice of suspension or limitation. CCLM may later revoke the certificate.

(3) In addition, if the CCLM 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, the CCLM may direct that the activity be immediately discontinued, regardless of the type of CLIP certificate the laboratory had been previously issued.

f. Actions When Deficiencies Are at the Condition Level But Do Not Pose Immediate Jeopardy. If a laboratory has condition level deficiencies that do not pose immediate jeopardy:

(1) Initial action:

(a) CCLM may suspend, limit, or revoke the laboratory's CLIP certificate.

(b) If the CCLM does not impose a principal sanction under section 1 of this enclosure, the CCLM may impose one or more alternative sanctions. In the case of unsuccessful participation in PT, the CCLM may impose the training and technical assistance requirement set forth in this section in lieu of, or in addition to, one or more alternative sanctions.

(2) If the CCLM 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, the CCLM:

(a) Following a revisit that indicates that the laboratory has not corrected its condition level deficiencies, the CCLM notifies the laboratory through command channels that it proposes to suspend, limit, or revoke the CLIP certificate, as specified in this section and the laboratory's right to respond in writing through command channels within 30 days to the CCLM; and

(b) May impose (or continue if already imposed) any alternative sanctions.

(3) If a final decision upholds a proposed suspension, limitation, or revocation of a laboratory's CLIP certificate, the CCLM discontinues any alternative sanctions as of the day the suspension, limitation, or revocation becomes effective.

g. Action When Deficiencies Are Not at the Condition Level. If a laboratory has deficiencies that are not at the condition level:

(1) The laboratory must submit, through command channels to the CCLM, a plan of correction that is acceptable to the CCLM in content and time frames.

(2) If, on a revisit, it is found that the laboratory has not corrected the deficiencies within 12 months after the last day of inspection, the CCLM notifies the laboratory through command channels of its intent to suspend, limit, or revoke the laboratory's CLIP certificate and of the laboratory's right to respond in writing through command channels to the CCLM within 30 days.

h. Ensuring Timely Correction of Deficiencies

(1) The CCLM 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.

(2) If during a visit it is found that a laboratory has not corrected its deficiencies, the CCLM may propose to suspend, limit, or revoke the laboratory's CLIP certificate.

(3) 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, the CCLM 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.

(4) If at the end of the period covered by the plan of correction the laboratory still has deficiencies, the rules of paragraph 21f and 21g of this section apply.

i. Directed Plan of Correction and Directed Portion of a Plan of Correction

(1) The CCLM 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.

(2) Procedures for imposing either course of action are:

(a) When imposing a directed plan of correction, the CCLM:

1. Gives the laboratory prior notice of the sanction and opportunity to respond in accordance with paragraph 21d of this section.

2. Directs the laboratory to take specific corrective action within specific time frames to achieve compliance.

3. May direct the laboratory to submit the names of laboratory clients for notification purposes, as specified in paragraph 21i(2)(b) of this section.

(b) When imposing a directed portion of a plan of correction, the CCLM 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, the CCLM:

1. Directs the laboratory to submit to the CCLM, 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 the CCLM. This list will include any civilian health care providers that have been furnished with laboratory test results under the TRICARE program, 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.

2. Within 30 calendar days of receipt of the information, the CCLM 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.

3. Sends to each laboratory client notice of the rescission of an adverse action within 30 days of the rescission.

(c) If the CCLM imposes a principal sanction following the imposition of an alternative sanction for which the CCLM has already obtained a list of laboratory clients, the CCLM may use that list to notify the clients of the imposition of the principal sanction.

(3) If the CCLM 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.

(a) CCLM notifies the laboratory, through command channels, of its intent to suspend, limit, or revoke the laboratory's CLIP certificate.

(b) The directed plan of correction continues in effect until the day suspension, limitation, or revocation of the laboratory's CLIP certificate becomes effective.

j. Directed On-Site Monitoring

(1) The CCLM 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, 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.

(2) Before imposing this sanction, the CCLM, through the MTF's chain of command, provides a notice of sanction and an opportunity to respond in accordance with paragraph 21d of this section.

(3) If the CCLM imposes on-site monitoring, the sanction continues until:

(a) The CCLM determines that the laboratory has the capability to ensure compliance with all condition level requirements.

(b) If the laboratory does not correct all deficiencies within 12 months, and a revisit indicates that deficiencies remain, the CCLM 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 waived testing.

k. Training and Technical Assistance for Unsuccessful Participation in PT

(1) If a laboratory's participation in PT is unsuccessful, the CCLM 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 PT program. This requirement is separate from the principal and alternative sanctions set forth in this section.

(2) Upon failure to successfully participate in PT, as defined in section 6, 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

PT. The remedial action will be documented and sent to the CCLM within 30 days of receipt of the proficiency results for review and approval.

1. Suspension, Limitation, or Revocation of Any Type of CLIP Certificate

(1) CCLM may initiate adverse action to suspend, limit, or revoke any CLIP certificate if the CCLM finds that a laboratory's commander, director, or one of its staff members has:

(a) Been guilty of misrepresentation in obtaining a CLIP certificate.

(b) 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 CLIP certificate.

(c) Failed to comply with the certificate requirements and performance standards.

(d) Failed to comply with reasonable requests by the CCLM for any information or work on materials that the CCLM concludes is necessary to determine the laboratory's continued eligibility for its CLIP certificate or continued compliance with performance standards set by the CLIP.

(e) Refused a reasonable request by the CCLM for permission to inspect the laboratory and its operation and pertinent records during the hours the laboratory is in operation.

(f) Violated or aided and abetted in the violation of any provisions of CLIP.

(g) Failed to comply with an alternative sanction imposed under this section.

(h) Within the preceding 2-year period, directed a laboratory that had its CLIP certificate revoked. This provision applies only to the director of the laboratory.

(2) If the CCLM determines that a laboratory has intentionally referred its PT samples to another laboratory for analysis, the CCLM will, through the Service's Surgeon General, revoke the laboratory's CLIP certificate. The period of revocation of the CLIP certificate (established with due consideration of DoD health care mission requirements, especially in remote or outside of the continental United States (OCONUS) locations) and the corrective alternative sanctions imposed will be of sufficient duration and extent to ensure appropriate policies or procedures are in place to prevent the reoccurrence of intentional referral of PT. Individuals found to be responsible for such referral(s) will be held accountable for their actions subject to the provisions of Chapter 47 of Reference (f) (commonly known and referred to as the Uniform Code of Military Justice) or applicable judicial and administrative civilian regulations.

(3) Procedures for suspension or limitation of a CLIP certificate:

(a) The CCLM will not suspend or limit a CLIP certificate until after personnel responsible for the laboratory have responded to the CCLM in writing through command channels.

(b) Exceptions: The CCLM may suspend or limit a CLIP certificate before the written response through command channels under the following circumstances:

1. The laboratory's deficiencies pose immediate jeopardy.
2. The laboratory has refused a reasonable request for information or for work on materials.
3. The laboratory has refused permission for the CCLM to inspect the laboratory or its operation.
4. The laboratory has failed to respond to the CCLM in writing through command channels within 30 days.

(4) CCLM may revoke a CLIP certificate even if it had not previously suspended or limited that certificate.

(5) CCLM must notify the Service's Surgeon General of any CLIP certificate suspended, limited, or revoked under this section within 30 days of the action.

m. Final Decision Appeal Procedures

(1) The following actions are initial determinations and therefore are subject to appeal in accordance with this section:

(a) The suspension, limitation, or revocation of the laboratory's CLIP certificate by the CCLM because of noncompliance with CLIP requirements.

(b) The denial of a CLIP certificate.

(c) The imposition of alternative sanctions under this section (but not the determination as to which alternative sanction or sanctions to impose).

(2) Actions that are not listed in this section are not initial determinations and therefore are not subject to appeal under this section. They include, but are not necessarily limited to:

(a) The finding that a laboratory accredited by a CMS-approved accreditation organization is no longer deemed to meet the conditions set forth in section 6 and sections 10 through 20 of this enclosure. However, the suspension, limitation, or revocation of a certificate of accreditation is an initial determination and is appealable.



(b) 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.

(c) The determination not to reinstate a suspended CLIP certificate because the reason for the suspension has not been removed or there is insufficient assurance that the reason will not recur.

(d) The determination as to which alternative sanction or sanctions to impose.

(e) The determination that a laboratory's deficiencies pose immediate jeopardy.

(3) Effect of requested appeals of action are:

(a) The effective date of an alternative sanction is not delayed because the laboratory has appealed and the appeal decision is pending.

(b) The effect on suspension, limitation, or revocation of a laboratory's CLIP certificate are:

1. Suspension, limitation, or revocation of a CLIP. Suspension, limitation, or revocation of a CLIP certificate is not effective until after an appeal decision by the CCLM is issued.

2. Exceptions. If the CCLM determines that conditions at a laboratory pose immediate jeopardy, the effective date of the suspension or limitation of a CLIP certificate is not delayed because the laboratory has appealed the final decision through command channels. CCLM may also suspend or limit a laboratory's 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 the CCLM to inspect the laboratory or its operation.

(4) Any laboratory or prospective laboratory dissatisfied with a suspension, limitation, revocation, or denial of its CLIP certificate, or with the imposition of an alternative sanction under section 21, is entitled to an appeal of the action to the CCLM. Such appeal must be in writing and sent through command channels to reach the CCLM within 30 days of the receipt of the final decision notice. When more than one of the actions specified in this section are carried out concurrently, the laboratory has a right to only one appeal on all matters at issue.

(5) Notice of adverse action:

(a) If the CCLM suspends, limits, or revokes a laboratory's CLIP certificate, the CCLM gives notice to the laboratory, and may give notice to physicians, providers, suppliers, and other laboratory clients, according to the procedures set forth in this section. In addition, the CCLM may notify DoD health care beneficiaries each time one of the principal sanctions is imposed.

(b) The notice to the laboratory:

1. Sets forth the reasons for the adverse action, the effective date and effect of that action, and the response or appeal process, if any.

2. When the certificate is limited, specifies the specialties or subspecialties of tests that the laboratory is no longer authorized to perform.

(c) The notice to other entities includes the same information except the information about the laboratory's response or appeal process.

(6) Effective date of adverse action:

(a) 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.

(b) 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.

n. Laboratory Registry

(1) Upon request, the CCLM will make available to the Services Surgeons General, specific information that is useful in evaluating the performance of their laboratories, including:

(a) A list of laboratories that have had their CLIP certificates suspended, limited, or revoked, and the reason for the adverse actions.

(b) A list of laboratories on which alternative sanctions have been imposed, showing:

1. The effective date of the sanctions.

2. The reasons for imposing the sanctions.

3. Any corrective action taken by the laboratory.

4. If the laboratory has achieved compliance, the verified date of compliance.

(c) A list of laboratories whose accreditation has been withdrawn or revoked and the reasons for the withdrawal or revocation.

(2) The laboratory registry is compiled for the calendar year proceeding 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.

## 22. NON-FIXED MTF LABORATORIES

a. Applicability. This section is applicable to non-fixed MTF laboratories 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 in the Glossary of this manual.

### b. Concept

(1) Non-fixed MTFs performing laboratory testing while in garrison during peacetime are required to meet the CLIP requirements stated in this section. Laboratories in these units must obtain CLIP certificates of registration and if applicable, certificates of compliance.

(2) Deployment of non-fixed MTFs 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, except for exemption from PT, as described in this section unless the requirements are temporarily modified in writing by CCLM. 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.

(3) CCLM or their designee will provide technical assistance as described in this section to non-fixed MTFs and deployable medical units to assure CLIP requirements are met.

### c. Responsibilities

(1) Unit. At a minimum, units will:

(a) Maintain a certification of compliance as defined in section 3 of this enclosure if performing moderate or high complexity testing.

(b) Comply with all provisions of this manual except where exemption is specified herein (e.g., non-fixed MTF Laboratories are exempt from mandatory external PT).

(c) Participate in continuing education when available.

(d) Notify CCLM within 6 months when there is a change to the testing menu.

(2) CCLM Support. Minimal support consists of:

(a) Providing technical consultation.

(b) Conducting or directing bi-annual assist visits to each unit performing moderate or high complexity testing to determine compliance with the CLIP.

(c) Providing training on good laboratory practices, as necessary.

23. LABORATORY JOINT WORK GROUP (LJWG)

a. The LJWG provides unified leadership to guide and influence ASD(HA) policy and decision making on DoD clinical and anatomic laboratory operations; leads standardization and consolidation efforts across the DoD and when or where appropriate, with the Department of Veterans Affairs (VA) to improve utilization, quality, and customer support while focusing on cost effective business practices. Meetings will be held at least semi-annually at a location and in a forum determined by the co-chairpersons.

b. The LJWG will be co-chaired by one pathologist and one laboratory officer, appointed by the Director, DHA. The Army, Navy, and Air Force Pathology and Laboratory consultants or specialty leaders to their respective Service's Surgeon General will alternate co-chairmanship biennially. The co-chairpersons will be from different Services.

c. Members:

(1) Voting

- (a) Pathology Consultant, Army Surgeon General
- (b) Pathology Specialty Leader, Navy Surgeon General
- (c) Pathology Consultant, Air Force Surgeon General
- (d) Clinical Laboratory Consultant, Army Surgeon General
- (e) Medical Technology Specialty Leader, Navy Surgeon General
- (f) Clinical Laboratory Consultant, Air Force Surgeon General
- (g) Chief Medical Officer Representative Defense Health Agency (DHA)
- (h) DHA Member Benefits & Reimbursement Office Representative
- (i) Director, Joint Pathology Center

(2) Non-Voting

- (a) Pathology Consultant, Veterans Affairs
- (b) Clinical Laboratory Consultant, Veterans Affairs
- (c) Deputy Director, Office of Laboratory Management/Secretary-Recorder

- (d) CCLM Office Representative
  - (e) Director, Armed Services Blood Program Office
  - (f) Clinical Laboratory Consultant, Coast Guard
  - (g) DHA Ancillary Services Chief Information Manager
  - (h) Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA))  
Patient Safety Center Representative
  - (i) DoD Laboratory Response Network (LRN) Gatekeeper, OASD(HA)/Force Health  
Protection & Readiness
  - (j) Joint Staff Surgeon Representative
- (3) Ad Hoc Members: Subject matter experts may be invited as required.
- d. The LJWG's core objectives and goals include but are not limited to:
- (1) Establish inter- and intra-Service regional networks to coordinate, research, and recommend standardized or consolidated military laboratory service or initiatives.
  - (2) Develop processes and structures guiding laboratory medicine related decisions and policies.
  - (3) Develop and deploy DoD laboratory medicine costing, funding, and manning mechanisms.
  - (4) Research and exploit clinical and anatomic laboratory information management systems; recommend advances to state-of-the-art technology and implement same; establish full system interoperability for laboratory and data transfer.
  - (5) Provide DoD Referral Laboratory Services in the most cost-effective manner to promote and support inter- or intra-Service consolidation and recapture.
  - (6) Work in coordination with the Executive Secretary of the DoD Laboratory Network (DLN), and within the governance rules of the DLN, will: Establish, support, and expand, as appropriate for bio-defense, the continental United States and OCONUS LRN in conjunction with the Centers for Disease Control and Prevention, FDA, VA, and other federal agencies.
  - (7) Establish, support, and expand test systems and processes, as appropriate, for readiness and force health protection both in-garrison and deployed.
  - (8) Evaluate and recommend to the ASD(HA) laboratory standards and practices for laboratory operations within DoD just as the HHS Clinical Laboratory Improvement Advisory

Committee (CLIAC) does for the civilian community throughout the United States. Advise and make recommendations on technical and scientific aspects of the provisions of the CLIP. Review and adopt, with or without modifications, the recommendations of the HHS CLIAC concerning:

- (a) Personnel standards.
- (b) Facility administration and quality systems standards.
- (c) PT standards.
- (d) Applicability to the standards of new technology.
- (e) Other issues relevant to the CLIP, if requested by OSAD(HA), or any Service's Surgeon General.
- (f) OSAD(HA) or appropriate designee will be responsible for providing the data and information, as necessary, to the members of the LJWG.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

AMT	American Medical Technologists
ASCP	American Society of Clinical Pathologists
ASD(HA)	Assistant Secretary of Defense for Health Affairs
CAP	College of American Pathologists
CCLM	Center for Clinical Laboratory Medicine
CLIA	Clinical Laboratory Improvement Amendments of 1988
CLIAC	Clinical Laboratory Improvement Advisory Committee
CLIP	Clinical Laboratory Improvement Program
CMS	Centers for Medicare & Medicaid Services
DHA	Defense Health Agency
DLN	DoD Laboratory Network
DoDI	DoD instruction
FDA	Food and Drug Administration
GED	General Education Development
HHS	Department of Health and Human Services
LJWG	Laboratory Joint Working Group
LRN	Laboratory Response Network
MLS	medical laboratory scientist
MT	medical technologist
MTF	military treatment facility
NLCP	National Laboratory Certification Program
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
OCONUS	outside of the continental United States
PPM	provider performed microscopy
PT	proficiency testing
TJC	The Joint Commission
VA	Department of Veterans Affairs

## PART II. DEFINITIONS

Unless otherwise noted, these terms and their definitions are for the purposes of this manual.

accredited institution. A school or program that:

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 General Education Development (GED) examination.

Is legally authorized within a State to provide a program of education beyond secondary education;

Provides an educational program for which it awards a bachelor's degree or provides not less than a 2-year program that is acceptable toward such a degree, or provides an educational program for which it awards a master's or doctoral degree.

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 the ASD(HA) or 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.

analytic phase. Includes the actual steps in the test analysis.

approved accreditation organization. A private, nonprofit accreditation organization that has formally applied for and received CMS's approval based on the organizations compliance with Reference (e).

authorized person. An individual authorized under military regulations to order tests or receive test results, or both.

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.

challenge. For quantitative tests, an assessment of the amount of substance or analyte present or measured in a sample. For qualitative tests, a challenge means the determination of the presence or the absence of an analyte, organism, or substance in a sample.

CLIA. See Reference (d).

CLIA comparable regulations. Regulations and instructions for the DoD Components based on the CLIA regulations issued by the HHS. CLIA comparable regulations are similar to, but not necessarily identical to HHS CLIA regulations, modified only as may be required to meet unique aspects of DoD missions, training and preparations during peace, contingency, and wartime operations which preclude compliance with CLIA.

CLIAC. Established by HHS to advise and make recommendations on technical and scientific aspects of the provisions of Reference (d).

CLIP procedures states the minimal conditions that all laboratories must meet to be certified to perform testing on human specimens.

CLIP certificate. Any of the following types of certificates issued by the ASD(HA) or designee:

certificate of compliance. A certificate issued to a laboratory after an inspection that finds the laboratory to be in compliance with all applicable condition level requirements.

certificate for PPM procedures. A certificate issued to a laboratory in which a physician, midlevel practitioner or dentist performs no tests other than PPM procedures and, if desired, waived tests.

certificate of accreditation. A certificate 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).

certificate of registration or registration certificate. A 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.

certificate of waiver. A certificate issued to a laboratory to perform only waived tests.

condition level deficiencies. Non-compliance with one or more condition level requirements.

condition level requirements. Any of the requirements identified as "conditions" in section 7 and sections 10 - 20 of Enclosure 3 of this manual.

credentials. The documents that constitute evidence of qualifying education, training, licensure, certification, experience, and expertise of healthcare providers. It includes professional qualifications such as a professional degree, post-graduate training and education, board certification, and licensure, etc.

credible allegation of compliance. A statement or documentation that 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; 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 indicates that the problem has been resolved.

decentralized laboratories. Decentralized laboratories include all places in the facility where medical laboratory tests are performed. Examples of common decentralized laboratories in MTF's include the following: medical laboratory tests performed in the intensive care unit, critical care unit, emergency department, or other medical clinics, such as the physical examination clinic, or the occupational health clinic, in vitro laboratory test performed by respiratory therapy or nuclear medicine; laboratory tests performed by nursing or other non-laboratory staff on patients wards; and laboratory tests performed by preventive medicine personnel as part of medical screening programs or health fairs.

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 MTF.

electrophoresis. The motion of dispersed particles relative to a fluid under the influence of a spatially uniform electric field.

GED. Tests taken to certify that the taker has American or Canadian high school-level academic skills. The GED is also referred to as a General Education Diploma, General Equivalency Diploma, or Graduate Equivalency Degree.

gynecologic cytology. A field of pathology concerned with the investigation of disorders of the female genital tract.

FDA-cleared or approved test system. A test system cleared or approved by the FDA through the premarket notification or premarket approval process for in vitro diagnostic use. Unless otherwise stated, this includes test systems exempt from FDA premarket clearance or approval.

fixed MTF. An established land-based medical center, hospital, clinic, or other facility that provides medical, surgical, or dental care and that does not fall within the definition of non-fixed MTF.

hospital ship. A mobile, flexible, rapidly responsive afloat MTF. It provides acute medical and surgical care in support of forward deployed troops in areas of hostility.

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 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 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.

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 MTF.

non-fixed MTF. Medical facilities for field services, such as aid stations, clearing stations, and division, field and force combat support and evacuation hospitals; medical facilities afloat, such as hospital ships and sick bays aboard ships; and tactical casualty staging facilities and medical advance base components contained within mobile-type units.

non-waived test. Any test system, assay, or examination that has not been found to meet the statutory criteria for waived (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).

performance specification. A value or range of values for a performance characteristic established or verified by the laboratory that 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 MTF.

post-analytical phase. Steps taken after the analytical phase of testing, to including test interpretation and reporting.

pre-analytical phase. Refers to all the steps taken prior to the actual testing of a specimen (e.g. specimen collection, transport, accessioning).

PT. PT determines the performance of individual laboratories for specific tests or measurements and is used to monitor laboratories' continuing performance.

prospective laboratory. A laboratory that is operating under a registration certificate or is seeking any of the three other types of CLIP certificates.

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 PT performance for all testing events for at least 1 year for a specific test, analyte, subspecialty, or specialty and has been designated by an HHS approved PT program as a referee laboratory for analyzing PT 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 PT is required by Reference (d). The list and minimal performance in PT events is stated in section 9 of Enclosure 3 of this manual.

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 PT). The material that is to be tested by the participants in the PT 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.

susceptibility disks. Antibiotic-impregnated disks used to test whether particular bacteria are susceptible to specific antibiotic.

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 by the Clinical and Laboratory Standards Institute; previously known as the National Committee for Clinical Laboratory Standards. 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.

titer. The process, operation, or method of determining the concentration of a substance in solution.

test system. The instructions and all of the instrumentation, equipment, reagents, and supplies needed to perform an assay or examination and generate test results.

thin layer chromatography. A chromatography technique used to separate non-volatile mixtures.

unsatisfactory PT performance. Failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event.

unsuccessful participation in PT

Unsuccessful performance for the same analyte in two consecutive or two out of three testing events.

Repeated unsuccessful overall testing event scores for two consecutive or two out of three testing events for the same specialty or subspecialty.

An unsuccessful testing event score for those subspecialties not graded by analyte (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. Per paragraph 7b(3) of Enclosure 3 of this manual, CLIP requires individual assessment of PT performance for each analyte rather than following CLIA's practice of combining procedures into subspecialty groups.

Failure of a laboratory performing gynecologic cytology to meet the standard in paragraph 7h of Enclosure 3 of this manual.

unsuccessful PT 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. A test system, assay, or examination that HHS has determined meets the CLIA statutory criteria for waiver.