



Defense Health Agency

PROCEDURAL INSTRUCTION

NUMBER 6440.01
September 20, 2021

DAD-HCO

SUBJECT: Governance of the Military Health System Clinical Laboratories

References: See Enclosure 1.

1. PURPOSE. This Defense Health Agency-Procedural Instruction (DHA-PI), based on the authority of References (a) and (b), and in accordance with the guidance of References (c) through (i), establishes the Defense Health Agency (DHA) procedures to govern the Military Health System (MHS) clinical laboratories.

2. APPLICABILITY. This DHA-PI applies to:

a. DHA, DHA Markets, and the Military Departments (MILDEPs).

b. DoD Military Medical Treatment Facilities (MTF) and DoD healthcare practitioners who are involved in the delivery of healthcare services to eligible beneficiaries.

3. POLICY IMPLEMENTATION. It is DHA's instruction that:

a. References (d), (e), and (h) prescribe laboratory operations within the DoD relative to Reference (f), and its implementation by Reference (g). Reference (f) was enacted to revise the authority for the regulation of clinical laboratories and improve the oversight, proficiency, quality assurance measures, regulatory standards, and enforcement procedures governing clinical laboratories. By authority of References (h) and (i), and the U.S. Department of Health and Human Services (HHS) Secretary's authority under Subpart 493.3(c) of Reference (g), Reference (e) was modified to address DoD specific readiness, training, and mission requirements during peace, contingency, and wartime operations as Clinical Laboratory Improvement Program (CLIP).

b. The MHS clinical laboratories shall comply with References (d) and (e). This provides a regulatory framework comparable to the Centers for Medicare and Medicaid Services (CMS)-administered Clinical Laboratory Improvement Amendments (CLIA) of 1988 (Reference (f)), as implemented by Reference (g).

c. The Center for Laboratory Medicine Services (CLMS), DHA, has the primary responsibility for overseeing and administering clinical laboratory compliance within the MHS and for developing CLIA comparable regulations in accordance with Reference (d).

d. Clinical laboratories in the MHS must, in accordance with the applicable procedures and requirements as specified in Reference (e), be registered with CLMS, compliant with the listed conditions and standards of performance, and accredited by an accreditation organization which has been granted deeming authority by the CMS, HHS, or be certified as compliant by CLMS.

4. RESPONSIBILITIES. See Enclosure 2.

5. PROCEDURES

a. Clinical laboratories in the MHS must comply with References (d) and (e). Clinical laboratories must follow policy and directives established by CLMS for compliance, accreditation, and administrative management of operations.

b. Changes in References (e) and (g) require interagency notification between CMS, HHS, and the DoD and the assessment of equivalency and the justification for proposed modifications for Reference (g). In addition, Reference (h) establishes a term period for renewal of the CMS-DoD Memorandum of Understanding. CLMS will act as lead agent to initiate coordination of DoD's interagency notifications.

6. PROPONENT AND WAIVERS. The proponent of this publication is the Deputy Assistant Director, Healthcare Operations. When Activities are unable to comply with this publication the activity may request a waiver that must include a justification, to include an analysis of the risk associated with not granting the waiver. The activity director or senior leader will submit the waiver request through their supervisory chain to the Deputy Assistant Director, Healthcare Operations to determine if the waiver may be granted by the Director, DHA or their designee.

7. RELEASABILITY. **Cleared for public release.** This DHA-PI is available on the Internet from the Health.mil site at: <https://health.mil/Reference-Center/Policies> and is also available to authorized users from the DHA SharePoint site at: <https://info.health.mil/cos/admin/pubs/SitePages/Home.aspx>.

8. EFFECTIVE DATE. This DHA-PI:

a. Is effective upon signature.

b. Will expire 10 years from the date of signature if it has not been reissued or cancelled before this date in accordance with Reference (c).

/S/
RONALD J. PLACE
LTG, MC, USA
Director

Enclosures

1. References
2. Responsibilities

Glossary

ENCLOSURE 1

REFERENCES

- (a) DoD Directive 5136.01, “Assistant Secretary of Defense for Health Affairs (ASD(HA)),” September 30, 2013, as amended
- (b) DoD Directive 5136.13, “Defense Health Agency (DHA),” September 30, 2013
- (c) DHA-Procedural Instruction 5025.01, “Publication System,” August 24, 2018
- (d) DoD Instruction 6440.02, “Clinical Laboratory Improvement Program (CLIP),” May 29, 2014 as amended
- (e) DoD Manual 6440.02, “Clinical Laboratory Improvement Program (CLIP) Procedures,” May 29, 2014
- (f) United States Code, Title 42, Section 263a, “Clinical Laboratory Improvement Amendments of 1988”
- (g) Code of Federal Regulations, Title 42, Part 493
- (h) Memorandum of Understanding 15-46 between the Department of Defense and the Department of Health and Human Services on the “Clinical Laboratory Improvements Amendments of 1988 (CLIA 1988),” January 14, 2015¹
- (i) United States Code, Title 42, Section 421

¹This reference can be found at: <https://health.mil/Reference-Center/Policies/2018/12/27/MOU-on-the-CLIA-1988-between-DoD-and-HHS>.

ENCLOSURE 2

RESPONSIBILITIES

1. DIRECTOR, DHA. Under the authority, direction, and control of the Assistant Secretary of Defense for Health Affairs, the Director, DHA executes the responsibilities and functions pertaining to CLMS and CLIP operations as described in Reference (d).

2. SECRETARIES OF THE MILDEPS. The Secretaries of the MILDEPS will ensure compliance with the DHA-PI.

3. DIRECTOR, CLMS. In coordination with the CLMS' MILDEP Directors, the Director, CLMS will:
 - a. Oversee, administer, and ensure appropriate execution of the responsibilities and functions as required within the CLIP in accordance with References (d) and (e).

 - b. Advise, evaluate, and establish policy involving clinical laboratory standards.

 - c. Develop and update, as appropriate, Reference (g)-comparable regulations.

 - d. Enforce clinical laboratory compliance with all applicable federal regulations and other requirements and guidelines, as applicable.

4. MARKET, SMALL MARKET AND STAND-ALONE MEDICAL TREATMENT FACILITY ORGANIZATION, AND DEFENSE HEALTH AGENCY REGION DIRECTORS. Market, Small Market and Stand-Alone Medical Treatment Facility Organization, and Defense Health Agency Region Directors work through Market Laboratory Consultants to ensure regulatory compliance in accordance with Reference (e).

5. MTF DIRECTORS. MTF Directors will ensure laboratories under their oversight will maintain active CLIP registrations and sustain compliance with the CLIP in accordance with References (d) and (e).

6. LABORATORY DIRECTORS. Laboratory Directors will ensure their laboratories:
 - a. Register with CLMS and obtain a CLIP certificate before starting patient testing.

 - b. Renew CLIP registration of laboratories before expiration of the CLIP certificate.

- c. Do not exceed the complexity categorization of testing services (i.e., waived, moderate complexity (including the subcategory of provider performed microscopy), and/or high complexity) that is authorized by the CLIP certificate maintained by the laboratory.
- d. Are inspected/accredited in accordance with Reference (e).
- e. Enroll in a Proficiency Testing program for each of the specialties/subspecialties in which testing is performed.
- f. Make required notifications to CLMS within the defined time frames in accordance with Enclosure 3 of Reference (e).
- g. Establish a Quality Management System and ensure it is integrated into the MTF's program.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

CLIP	Clinical Laboratory Improvement Program
CLMS	Center for Laboratory Medicine Services
CMS	Centers for Medicare and Medicaid Services
DHA	Defense Health Agency
DHA-PI	Defense Health Agency-Procedural Instruction
HHS	U.S. Department of Health and Human Services
MHS	Military Health System
MILDEP	Military Department
MTF	Military Medical Treatment Facilities

PART II. DEFINITION

Clinical laboratory. A facility which performs clinical and/or anatomical pathology examinations 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. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances and organisms in the body. Facilities only collecting, preparing specimens, and/or only serving as a mailing service and not performing testing are not considered laboratories. Laboratories performing research only, and whose results or reports are not used in diagnosis, treatment, or assessment of health, are not subject to CLIP governance or this DHA-PI.