



Department of Defense **INSTRUCTION**

NUMBER 6440.02
May 29, 2014

USD(P&R)

SUBJECT: Clinical Laboratory Improvement Program (CLIP)

References: See Enclosure 1

1. PURPOSE. This instruction:

a. Reissues DoD Instruction (DoDI) 6440.2 (Reference (a)), in accordance with the authority in DoD Directive 5124.02 (Reference (b)) and pursuant to the Memorandum of Understanding between the Department of Defense and the Department of Health and Human Services (HHS) (Reference (c)), Public Law 100-578 (Reference (d)), and part 493 of Title 42, Code of Federal Regulations (Reference (e)), to establish policy, assign responsibilities, and prescribe standards and procedures to implement and administer the CLIP within the DoD.

b. Establishes the Center for Clinical Laboratory Medicine (CCLM), formerly known as the Clinical Laboratory Improvement Program Office, under the Defense Health Agency (DHA). CCLM has the primary responsibility to develop Clinical Laboratory Improvement Amendments (CLIA) comparable regulations and administer the CLIP in accordance with Reference (c).

2. APPLICABILITY. This instruction applies to 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 Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (referred to collectively in this instruction as the "DoD Components").

3. POLICY

a. In accordance with Reference (c), CLIA comparable regulations will incorporate, to the maximum extent possible, the regulations issued by HHS pursuant to Reference (e). These may be modified only as may be required to meet unique aspects of DoD missions, training, and preparations during peace, contingency, and wartime operations which precludes exact compliance with CLIA.

b. In accordance with this instruction and Reference (c), 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.

4. RESPONSIBILITIES. See Enclosure 2.

5. PROCEDURES. See Enclosure 3.

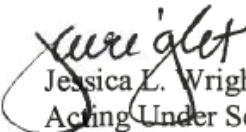
6. RELEASABILITY. **Unlimited**. This instruction is approved for public release and is available on the Internet from the DoD Issuances Website at <http://www.dtic.mil/whs/directives>.

7. EFFECTIVE DATE. This instruction:

a. Is effective May 29, 2014.

b. Must be reissued, cancelled, or certified current within 5 years of its publication to be considered current in accordance with DoDI 5025.01 (Reference (f)).

c. Will expire effective May 29, 2024 and be removed from the DoD Issuances Website if it hasn't been reissued or cancelled in accordance with Reference (f).


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ENCLOSURE 1

REFERENCES

- (a) DoD Instruction 6440.2, "DoD Clinical Laboratory Improvement Program," April 20, 1994 (hereby cancelled)
- (b) DoD Directive 5124.02, "Under Secretary of Defense for Personnel and Readiness (USD(P&R))," June 23, 2008
- (c) Memorandum of Understanding between the Department of Defense and the Department of Health and Human Services on the Clinical Laboratory Improvement Amendments of 1988 (CLIA 1988), January 14, 2009
- (d) Public Law 100-578, "Clinical Laboratory Improvement Amendments of 1988," October 31, 1988
- (e) Part 493 of Title 42, Code of Federal Regulations
- (f) DoD Instruction 5025.01, "DoD Directives Program," September 26, 2012, as amended
- (g) Chapter 55 of Title 10, United States Code
- (h) DoD Manual 6440.02, "Clinical Laboratory Improvement Program (CLIP) Manual," May 29, 2014

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. 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 (g)).

b. Establishes the CCLM in the DHA.

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

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 instruction.

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

2. 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, personnel standards, and training in laboratories performing testing on human specimens as defined under "laboratory" in the Glossary of this instruction.

b. In accordance with DoD Manual 6440.02, (Reference (h)), follow CLIP procedures for corrective action on laboratory facilities whose proficiency testing or performance criteria fall outside the standards of CLIP policy.

c. In accordance with Reference (h), 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 instruction.

ENCLOSURE 3

PROCEDURES

1. DHA. The DHA:

a. Provides administrative and operational management and support to CCLM, including the budget, personnel, information, facilities, and other resources required to support the missions and function of the CCLM. The Director, DHA, at least annually reports CCLM activities to the Assistant Secretary of Defense for Health Affairs (ASD(HA)).

b. The Director, DHA, secures adequate funding for the CCLM. Funding will be within the Defense Health Program (DHP), incorporated with the Military Health System DHP submission during the Budget Estimation Submission, President's Budget, and Program Objective Memorandum.

2. CCLM. The Director, CCLM:

a. Plans, organizes, and leads the technical and management operations of CCLM and applies resources to short-term and long-term goals. Coordinates complex and future administration and business strategy programs with DoD senior leaders and headquarters staff. Interacts with the Joint Staff, other government agencies and laboratory customers of the Military Departments driving programmatic and budgetary initiatives.

b. Coordinates the day-to-day activities of the CCLM, in accordance with the policies established by the OASD(HA), and the plans, programs, standards, and procedures established by the DoD and the Military Departments.

c. Develops and establishes the minimum standards and procedures, and CLIA comparable regulations to be used by the Military Departments to implement References (b), (c), and (d).

d. Serves as the primary laboratory representative with Centers for Medicare & Medicaid Services (CMS), Food and Drug Administration (FDA), and other federal and civilian agencies.

e. Working in coordination with the DoD-Department of Veterans Affairs (VA) Laboratory Joint Working Group (LJWG), provides unified leadership to guide and influence OASD(HA) policy and decision making on DoD clinical and anatomic pathology operations.

f. Leads standardization and consolidation efforts across the DoD, and when or where appropriate, with the VA; to improve utilization, quality, and customer support while focusing on cost effective business practices. These coordinated efforts may include, but are not limited to, the following:

(1) Establish inter-Service networks and referral lab services to coordinate, recapture, and direct implementation of standardized or consolidated military laboratory services or initiatives in the most cost-effective manner.

(2) Identify and make recommendations to the Military Departments concerning duplicative services to ensure cost-effective utilization of laboratory resources in the direct-care and purchased-care sectors.

(3) Develop processes and structures guiding laboratory medicine related decisions and policies as appropriate.

(4) Collaborate with the Military Departments to develop DoD laboratory medicine costing, funding, and manning mechanisms as appropriate.

(5) Research and recommend clinical and anatomic laboratory information management systems, recommend advances to and implement state-of-the-art technology, and establish full system interoperability for laboratory data transfer.

(6) Coordinate inter-Service efforts for equipment standardization and contract management.

(7) Working 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 outside the continental United States Laboratory Response Network in conjunction with the Centers for Disease Control, FDA, VA, and other federal agencies.

(8) Establish, support, and expand test systems and processes, as appropriate, for readiness and force health protection in both in-garrison medical treatment facilities and in deployed military treatment facilities.

3. MILITARY DEPARTMENTS

a. The Surgeons General of the Military Departments:

(1) Appoint laboratory officers in the grade of O-6 to serve as clinical laboratory consultant or specialty leader to their respective Surgeon General and as their Military Department's Director at CCLM. The same individual may serve in both capacities for a Military Department.

(2) Assign three medical laboratory technicians (one from each Department - Air Force, Army, and Navy) in the grade of E-7 or above, serving as CLIP program managers for their respective Military Department. All CCLM members carry out CCLM assignments as their primary duty. These are priority fill positions and require an interview by the respective CCLM Military Department Director.

(3) Assign additional staff to include: one Air Force Biomedical Laboratory Officer, in the grade of O-4 serving as the Deputy Director, CCLM; one Army Clinical Laboratory Officer in the grade 0-3/0-4, possessing an advanced Information Technology degree to serve as the Laboratory Informatics Program Manager; one Navy Advanced Laboratory Technician in the grade of E-5 or above serving as the Assistant Program Manager of CLIP. These are priority fill positions and require an interview by the respective CCLM Military Department Director.

b. Commanders of laboratories performing testing on materials derived from the human body for the purpose of diagnosis or treatment will ensure compliance with CLIA comparable regulations as defined by CCLM and ensure CLIP registration of all medical laboratories within their command as applicable.

c. Laboratory medical directors have primary oversight and responsibility for ensuring compliance with all regulations and guidance described in References (b), (c), and (d) and other applicable accrediting agency requirements and CCLM standards and procedures.

d. The Military Department Directors, CCLM:

(1) Provide executive oversight of the CLIP program for their respective Military Department. Monitor regulatory and statutory changes to public law and recommend appropriate changes to DoD standards. Maintain contact with regulatory organizations or other agencies for the provision of inspection, accreditation, and proficiency testing services required for DoD laboratories.

(2) Monitor proficiency testing and accreditation agency inspection results, and overall CLIP compliance for their respective service laboratories. When deemed necessary, initiate or recommend enforcement procedures. Review and validate corrective action plans. Provide information on performance or deficiencies to the respective Surgeons General when action is required for resolution.

(3) Issue laboratory certification documents, and certify all appropriate clinical laboratory testing sites within the DoD.

(4) As the OASD(HA) designee:

(a) Impose sanctions or other corrective actions deemed appropriate for CLIP certified laboratories with repetitive failures of CMS-approved proficiency failures or other non-compliance with CLIP policy and CLIA comparable regulations as defined by CCLM.

(b) Revoke the CLIP certification of laboratories whose actions significantly endanger patient care.

(c) Reinstate the CLIP certification for laboratories that have successfully completed corrective actions.

(5) Interact with their respective Military Department's Surgeon General on matters relating to References (c), (d), (e), and (f).

(6) Provide to the ASD(HA), Director DHA and Military Department Surgeons General, a listing of clinical laboratories of the DoD Components to which suspension, limitation, or revocation of CLIP certificates have been imposed.

(7) Provide information on clinical laboratory issues and regulatory compliance to registered sites via newsletters, seminars, and workshops as appropriate. Respond to regulatory and accreditation compliance questions from registered sites.

(8) Provide consultation and impact analysis for laboratory policy issues for the ASD(HA), Director DHA and Military Department Surgeons General.

(9) Prepare reports for laboratory consulting activities for the ASD(HA), Director DHA and Military Department Surgeons General.

(10) Respond to complaints relative to laboratory services from federal, State, or DoD beneficiaries and provides consultation or inspection of sites where appropriate.

(11) Assist the Director, CCLM, with the duties outlined in paragraphs 2a through 2f of this enclosure.

e. CLIP Program Managers and Assistant Program Managers:

(1) Serve as primary liaison for their respective Military Department's laboratories on matters pertaining to the CLIP.

(2) In accordance with Reference (d), assist in executive oversight of the CLIP program for their respective Military Department. Maintain contact with regulatory organizations or other agencies for the provision of inspection, accreditation, and proficiency testing services required for DoD laboratories.

(3) Monitor proficiency testing and accreditation agency inspection results and overall CLIP compliance for their respective service laboratories. When necessary, initiate or recommend enforcement procedures. Review and validate corrective action plans. Provide information on performance or deficiencies to the respective Military Department's Director or the CCLM Deputy Director when action is required for resolution.

(4) Prepare laboratory certification documents for all appropriate clinical laboratory testing sites within their Military Department.

(5) Maintain CLIP database and prepare reports of laboratory activities for their respective Military Department's Director, or the CCLM Deputy Director.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

ASD(HA)	Assistant Secretary of Defense for Health Affairs
CCLM	Center for Clinical Laboratory Medicine
CLIA	Clinical Laboratory Improvement Amendments of 1988
CLIP	Clinical Laboratory Improvement Program
CMS	Centers for Medicare & Medicaid Services
DHA	Defense Health Agency
DHP	Defense Health Program
DLN	DoD Laboratory Network
DoDI	DoD Instruction
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
LJWG	Laboratory Joint Working Group
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
VA	Department of Veterans Affairs

PART II. DEFINITIONS

These terms and their definitions are for the purposes of this instruction.

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.

CLIP. Body of rules and regulations establishing the minimum standards for clinical laboratory operations within the DoD, developed by CCLM, with the approval of OASD(HA), and implemented by DoD Components.

laboratory. A facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure,

or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

LJWG. An organization that provides unified leadership to guide and influence OASD(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 VA to improve utilization, quality, and customer support while focusing on cost effective business practices.