Department of Defense

INSTRUCTION

NUMBER 6440.2

April 20, 1994

ASD(HA)

SUBJECT: Clinical Laboratory Improvement Program (CLIP)

References: (a) Assistant Secretary of Defense (Health Affairs) Memorandum, "Policy Statement Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA'88) within the Department of Defense (DoD)," October 8, 1993 (hereby canceled)

(b) Public Law 100-578, "Clinical Laboratory Improvement Amendments of 1988," October 31, 1988

(c) Memorandum of Agreement (MOA) between the Department of Defense and Department of Health and Human Services, "Implementation of the Clinical Laboratory Improvement Amendments of 1988 (CLIA'88) within DoD," January 16, 1993

1. PURPOSE

This Instruction:

1.1. Supersedes reference (a).

1.2. Implements references (b) and (c) by establishing policy, assigning responsibilities, and prescribing procedures to implement and administer the CLIP within the Department of Defense.

1.3. Establishes the CLIP office at the Armed Forces Institute of Pathology (AFIP).

2. APPLICABILITY

This Instruction applies to the Office of the Secretary of Defense; the Military

Departments; and the Uniformed Services University of the Health Sciences (hereafter referred to collectively as "the DoD Components").

3. DEFINITIONS

Terms used in this Instruction are defined in enclosure 1.

4. POLICY

It is DoD policy that:

4.1. The DoD Components will ensure the quality and reliability of all medical tests performed by clinical laboratories under their purview.

4.2. DoD standards to improve the quality of clinical laboratory testing in DoD facilities conducting testing on human specimens for health assessment or for the prevention, diagnosis, or treatment of disease will be comparable, but not necessarily identical, to those issued by the Department of Health and Human Services (HHS) under Pub. L. No. 100-578 (1988) (reference (b)).

4.3. Under the MOA (reference (c)), Clinical Laboratory Improvement Amendments (CLIA) comparable regulations governing the operation of clinical laboratories will incorporate to the maximum extent possible the regulations issued by HHS under reference (b), modified only as may be required to meet unique aspects of DoD missions, training, and preparations during peace, contingency, and war time operations which preclude compliance with Clinical Laboratory Improvement Amendments (CLIA).

5. RESPONSIBILITIES

5.1. The Assistant Secretary of Defense for Health Affairs shall have responsibility for program oversight and policy review on the implementation of CLIA comparable regulations.

5.2. The Secretaries of the Military Departments shall:

5.2.1. Enact the DoD CLIP policy and CLIA comparable regulations within their respective Service's Active and Reserve Components to include oversight, inspections, proficiency testing, personnel standards, and training in clinical

laboratories.

5.2.2. Establish procedures to take corrective action on clinical laboratory facilities whose proficiency testing or performance criteria fall outside the standards of the Tri-Service CLIP regulations.

5.2.3. Establish the standards and regulations governing the operation, management, and oversight of clinical laboratory assets assigned to operational forces. Except where operational constraints preclude compliance, these standards governing clinical laboratory assets assigned to operational forces will incorporate the Tri-Service CLIP regulations to the maximum extent possible without impeding operational requirements.

5.3. The Secretary of the Army (Executive Agent for AFIP), shall conduct a periodic review of the CLIP Office to ensure the quality of program execution and reporting.

6. PROCEDURES

6.1. The CLIP office shall be established by the Director, AFIP and shall be staffed by an officer and an enlisted representative from each of the Military Departments. The officer assigned to the CLIP office by each of the Military Departments may interact directly with the respective Service Surgeon General or his or her designee on matters relating to this comprehensive clinical laboratory quality improvement program.

6.2. The CLIP office shall:

6.2.1. Serve as the DoD CLIA program manager.

6.2.2. Develop and issue, with the approval of the Assistant Secretary of Defense for Health Affairs (ASD(HA)), the Tri-Service CLIP regulations to establish the minimum standards for clinical laboratory operations and testing sites within the Department of Defense. Such Tri-Service CLIP regulations do not preclude additional clinical laboratory quality standards as may be required by the Secretaries of the Military Departments.

6.2.3. Identify, register, and certify all appropriate clinical laboratory testing sites within the Department of Defense.

6.2.4. Provide information on clinical laboratory proficiency testing performance or deficiencies to the appropriate Service Surgeon General for resolution.

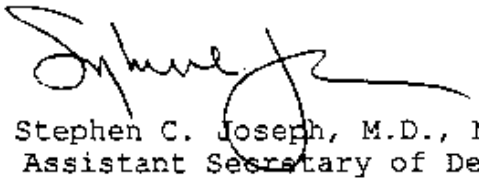
6.2.5. Provide to the Deputy Assistant Secretary of Defense for Health Affairs (Professional Affairs and Quality Assurance) (DASD(HA) (PA&QA)), a listing of clinical laboratories of the DoD Components to which suspension, limitation, or revocation of CLIP certificates have been imposed.

6.2.6. Respond to all requests from Federal, State, or civilian health agencies for access to information contained within the CLIP office data base. All requests for information and/or access, with subsequent written approval or disapproval of said requests, shall be retained by the CLIP office at the AFIP for administrative documentation and audit review.

6.3. Requests from Federal, State, or civilian health agencies for access to information contained within the CLIP office data base shall be submitted in writing to the Armed Forces Institute of Pathology, Clinical Laboratory Improvement Program Office, Washington, DC, 20306-6000.

7. EFFECTIVE DATE AND IMPLEMENTATION

This Instruction is effective immediately. The Military Departments shall forward two copies of implementing documents to the Assistant Secretary of Defense for Health Affairs within 120 days.



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Enclosures - 1

1. Definitions

E1. ENCLOSURE 1

DEFINITIONS

E1.1.1. Clinical 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 prevention, diagnosis, 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 clinical laboratories.

E1.1.2. Clinical Laboratory Improvement Amendments (CLIA) Comparable Regulations. Regulations and instructions by 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 war time operations which preclude compliance with CLIA.

E1.1.3. Clinical Laboratory Improvement Program (CLIP) Certificate. Any of the following types of certificates, as defined in the Tri-Service CLIP regulations, issued by the Secretaries of the Military Departments or their designees:

E1.1.3.1. certificate of Waiver.

E1.1.3.2. certificate for Physician-Performed Microscopy.

E1.1.3.3. certificate of Registration.

E1.1.3.4. certificate of Accreditation - Moderate Complexity.

E1.1.3.5. certificate of Accreditation - High Complexity.

E1.1.4. Clinical Laboratory Improvement Program (CLIP) Office. The office located in the Office of Clinical Laboratory Affairs at AFIP.

E1.1.5. Tri-Service Clinical Laboratory Improvement Program (CLIP) Regulations. That body of rules and regulations, establishing the minimum standards

for clinical laboratory operations within the Department of Defense, developed by the CLIP Office, with the approval of the ASD(HA), and implemented by Tri-Service regulations.