



DEPARTMENT OF THE ARMY
HEADQUARTERS, UNITED STATES ARMY MEDICAL COMMAND
2050 WORTH ROAD
FORT SAM HOUSTON, TX 78234-6000

REPLY TO
ATTENTION OF

OTSG/MEDCOM Policy Memo 09-075

MCHO-CL-R

Expires 3 September 2011

03 SEP 2009

MEMORANDUM FOR COMMANDERS, MEDCOM REGIONAL MEDICAL COMMANDS

SUBJECT: Plan of Action Policy for Failed Clinical Laboratory Proficiency Testing

1. References:

a. Armed Forces Institute for Pathology (AFIP) Pamphlet 40-24, Technical Instructions for the Department of Defense (DoD) CLIP, 1 Sep 07.

b. Public Law 100-578, Clinical Laboratory Improvement Amendments of 1988 (CLIA 88), 31 Oct 88 (Section 353), Public Health Service Act, 42 USC 263c.

c. Department of Defense Instruction (DoDI) 6440.2, Clinical Laboratory Improvement Program (CLIP), 20 Apr 94.

d. Army Regulation 40-3, Medical, Dental and Veterinary Care, 18 Oct 07.

e. 42 Code of Federal Regulations (CFR) Part 493, Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications, 3639-3714, 24 Jan 03.

f. Joint Commission (JC), Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing (CAMLA), last updated 7 Aug 08.

g. Memorandum of Agreement (MOA) between the DoD and the Department of Health and Human Services (HHS) on the Clinical Laboratory Improvement Amendment of 1988, MOU-03-12, 16 Jan 03.

h. College of American Pathologists (CAP) Commission on Laboratory Accreditation, Laboratory Accreditation Program, 2008.

2. Proponent: The proponent for this policy is the Assistant Chief of Staff for Health Policy and Services Directorate, Ancillary Services Division.

3. Background:

a. Public Law with the oversight of Centers for Medicare and Medicaid Services (CMS) requires all laboratories that provide testing on human specimens for health assessment,

MCHO-CL-R

SUBJECT: Plan of Action Policy for Failed Clinical Laboratory Proficiency Testing

diagnosis, prevention or treatment of disease be certified and meet published quality assurance requirements. HHS recognized the unique mission of the military and authorized the certification and quality assurance oversight of DoD laboratories be vested with the Assistant Secretary of Defense (Health Affairs) (ASD(HA)). The CLIP was established by ASD(HA) to provide the guidance and oversight of DoD laboratories required pursuant to public law. The Office of the Center for Clinical Laboratory Medicine (CCLM) published CLIP technical guidelines in order to meet the elements of certification and quality assurance oversight. Regulatory elements include the oversight of personnel standards, employee training, inspections, certification, accreditation, patient test management, and proficiency testing (PT).

b. Regulated PT is a quality assurance tool that is government mandated and required for the JC and CAP accreditation. Regulated PT is a quality indicator with potentially grave sanctions for laboratories with unsuccessful performance. Laboratories are subject to regulatory sanctions after failing two of three PT events. PT requires the expenditure of significant effort in order to meet regulatory PT requirements and maintain certification and accreditation standards. This MEDCOM policy establishes the procedure to take when PT results fall outside acceptable standards.

4. Definitions:

a. Analyte - A substance or constituent for which the laboratory is registered, licensed, or certified to conduct testing.

b. PT Program - A program, external to the laboratory, where private, nonprofit organizations, or federal or state agencies, approved by HHS provide samples with test constituents whose results are unknown to the personnel at the laboratory being tested. After testing, the organization providing the PT sends the laboratory's scores to the laboratory and the applicable certifying agencies.

(1) PT Event - Each set of unknown samples, commonly called a survey, constitutes a testing event. For regulated analytes, three surveys, each with a minimum of five challenges for each analyte, are required annually. Therefore, for each regulated analyte, three testing events are required per year.

(2) Regulated Analytes - Analytes listed in 42 CFR Part 493 Subpart I for which external laboratory PT must be performed and reported to the HHS, its designee, or deemed agencies to meet the requirement of the law.

(3) Specialty - Major subdivisions of the medical laboratory as defined by CLIA. Defined specialties include Microbiology, Diagnostic Immunology, Chemistry, Hematology, Pathology, Immunohematology, Radiobioassay, Histocompatibility, and Clinical Cytogenetics. For condition-level deficiencies, principal or alternative sanctions may be imposed upon the entire laboratory, a specialty, a subspecialty, or against the performance of specific laboratory tests.

MCHO-CL-R

SUBJECT: Plan of Action Policy for Failed Clinical Laboratory Proficiency Testing

(4) Subspecialty - Subdivisions of major laboratory specialties as defined by CLIA. Examples of subspecialties include Bacteriology, Parasitology, Mycology, Mycobacteriology, and Virology — subspecialties of Microbiology; and Routine Chemistry, Toxicology, and Endocrinology — subspecialties of Chemistry. For condition-level deficiencies, limited or alternative sanctions may be imposed upon a specialty, a subspecialty, or against the performance of specific laboratory tests.

(5) Unregulated Analytes - Analytes that are not listed in 42 CFR Part 493 Subpart I for which external laboratory PT may or may not be available for performance and reporting to accrediting bodies. PT for these analytes is required, if commercially available, by accrediting organizations but is not subject to regulatory sanctions. However, a laboratory must verify the accuracy of any analyte or subspecialty without analytes specified in Subpart I that is not evaluated or scored by a CMS-approved proficiency testing program (at least twice annually, a laboratory must verify the accuracy of any test or procedure that is not included in Subpart I, or any test or procedure listed in Subpart I for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program).

(6) Unsatisfactory PT Performance - Failure to attain the minimum satisfactory scores for an analyte, test subspecialty, or specialty for a testing event. Failure could be a result of an error or errors associated with the pre-analytic, analytic, post-analytic operations and/or associated with the administrative functions of complying with the PT program.

(7) 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. Failure could be a result of an error or errors associated with the pre-analytic, analytic, post-analytic operations and/or associated with the administrative functions of complying with the PT program.

5. Regional Medical Command (RMC) Responsibilities:

a. The Quality Assurance/Performance Improvement Office at each RMC will ensure compliance with this policy throughout its area of responsibility.

b. Directors of pathology and laboratory managers at RMCs will also serve as regional pathology and laboratory consultants, respectively. The pathology and laboratory consultants are responsible for providing technical assistance and oversight for all US Army medical laboratories located in their respective regions. This responsibility includes review of PT results and provision of technical assistance and advice in improving laboratory service and quality throughout the region.

MCHO-CL-R

SUBJECT: Plan of Action Policy for Failed Clinical Laboratory Proficiency Testing

6. PT Requirements:

a. General.

(1) Each CLIP registered laboratory must enroll and successfully participate in a PT program that is approved by CMS. The CLIP laboratory must authorize the PT program used to release all data to CCLM and CMS with regard to demonstrating compliance with PT requirements and maintaining the accuracy of the offered testing procedures.

(2) Each CLIP registered laboratory is responsible for subscribing to survey programs appropriate to the testing being performed, both specialties and subspecialties. PT is required for only the test system, assay, or examination used as the primary method for patient testing. If the 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. For laboratories using the CAP as their PT program source, subscription orders and modifications are to be coordinated through the Office of the Center for Clinical Laboratory Medicine, Armed Forces Institute of Pathology. For those tests performed by the laboratory that are not included in a PT program, the laboratory must establish and maintain a system for verifying the accuracy of its test results at least twice a year.

(3) Each CLIP registered laboratory must integrate the PT samples into the routine laboratory workload. The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the PT program in the same manner as it tests patient specimens. The PT sample must be analyzed by personnel who routinely test patient samples, must be tested using the same primary method as patient samples, and are to undergo replicate testing only if patient specimens are routinely analyzed in the same manner. 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.

(4) Inter-laboratory communication (including across sites/locations in laboratories with multiple testing sites or separate locations) regarding the results of PT prior to reporting of results to the PT provider or sending the PT samples to another laboratory for analysis is strictly forbidden. Improper PT referral, such as reporting and sending in another laboratory's PT results as your own, is strictly forbidden.

(5) The Quality Control Plan of each CLIP registered laboratory must specifically address the handling of the PT program within the laboratory. The laboratory must document the pre-analytic, analytic, and post-analytic steps in testing and reporting the results of PT samples. The laboratory must maintain a copy of all records, including a copy of the PT report forms and the attestation statement signed by the analyst and the laboratory director for at least 2 years (5 years for Immunohematology).

MCHO-CL-R

SUBJECT: Plan of Action Policy for Failed Clinical Laboratory Proficiency Testing

(6) Upon receipt of the PT report from the approved PT program source, the laboratory director or designated technical supervisor of each laboratory specialty will, as a minimum, review the PT results and document the action. Additional steps are required if PT results indicate unsatisfactory or unsuccessful performance.

b. Minimum required actions for unsatisfactory test performance (failure during a single testing event; actions are applicable to both regulated and unregulated analyte PT performance).

(1) The laboratory must perform an investigation to determine the cause of failure, undertake remedial actions to correct the problem, and document all actions taken.

(2) The laboratory must undertake the appropriate training and/or employ the technical assistance necessary to correct the problems associated with the PT failure. Remediation pursued must be validated and documented. Obtain assistance as required from the supporting medical treatment facility (MTF), RMC, HQ MEDCOM, or CCLM office.

(3) The laboratory must provide satisfactory evidence, through comprehensive documentation, that a thorough investigation was conducted and that appropriate steps were taken that will ensure successful testing accuracy. The laboratory will maintain this documentation of remedial action for a minimum of 2 years (5 years for Immunohematology) from the date of the PT event.

c. Minimum required actions for unsuccessful test performance (failure in two consecutive or two of three consecutive testing events; actions are applicable to both regulated and unregulated analyte PT performance).

(1) The laboratory must suspend patient testing for the failed analyte and/or test.

(2) The laboratory must perform an investigation, determine cause of failure, undertake remedial actions to correct the problem, and document all actions taken.

(3) The laboratory must undertake the appropriate training and/or employ the technical assistance necessary to correct the problems associated with the PT failure. Remediation pursued must be validated and documented by regional pathology or laboratory consultant. The laboratory will obtain assistance as required from the supporting MTF, RMC, HQ MEDCOM, or CCLM office.

(4) The laboratory must ensure the validity of patient results by verifying on two consecutive occasions that the corrective action taken has resolved the problem. This may be done by reanalysis and/or retesting of frozen or additional PT material, purchase of supplemental PT material, or blind, split-sample testing of patient material with another certified laboratory.

MCHO-CL-R

SUBJECT: Plan of Action Policy for Failed Clinical Laboratory Proficiency Testing

(5) The laboratory will document corrective action taken. The laboratory will maintain documentation of remedial action for at least 2 years (5 years for Immunohematology) from the date of the event.

(6) The laboratory director will review the effectiveness of the corrective action(s) and, if satisfied, will document his/her recommendation whether to resume testing.

(7) A copy of the supporting documentation and laboratory director's request to resume testing will be sent to the regional pathology or laboratory consultant for subsequent review. In those cases where the affected laboratory is the medical center, the regional consultant, who may be either the department chief or laboratory manager, will provide the required review.

(8) The regional consultant will return a decision to the originating laboratory (i.e., the laboratory that failed the PT challenge) within 24 hours. Patient testing will remain suspended until documented approval to resume testing is received by the originating laboratory.

(9) Within 72 hours of the receipt of documentation from the regional consultant, the originating laboratory (i.e., the laboratory that failed the PT challenge) will send a copy of all corrective action documentation, including the higher level review and approval to restart testing, to the supporting RMC Quality Assurance office and the service director at the CCLM office.

(10) JC accredited laboratories must also notify the Manager, Laboratory Accreditation Services, at the JC, of an unsuccessful testing event.

d. Minimum required actions for repeat unsuccessful testing performance (failure in three consecutive or three of four consecutive testing events; actions are applicable to both regulated and unregulated analyte PT performance).

(1) The laboratory will suspend testing for the failed analyte and/or test.

(2) The laboratory will notify next higher level MTF of the situation and request assistance.

(3) The laboratory will follow the procedures in paragraphs 5c(2) through 5c(6), above.

(4) The laboratory will send a copy of the supporting documentation and originating laboratory director's recommendation to the regional pathology or laboratory consultant and the Service Director at the CCLM office for subsequent review.

(5) The Service Director at the CCLM office in coordination with the MEDCOM Laboratory Program Manager will make the decision to resume patient testing for the failed analyte and/or test.

MCHO-CL-R

SUBJECT: Plan of Action Policy for Failed Clinical Laboratory Proficiency Testing

7. Each certified laboratory will initiate the Plan of Action for Failed PT in a timely fashion. Documentation of corrective action for unsuccessful performance should reach the office of CCLM within 72 hours following resumption of testing.

8. Address problems with implementation of this policy to the Service Director, CCLM, DSN 662-2514, commercial (202) 782-2514, commercial (202) 782-6022, or FAX DSN 662-6022.

FOR THE COMMANDER:


HERBERT A. COLEY
Chief of Staff