

March 14, 1994

1. Transmitted is a revision to Department of Veterans Affairs, Veterans Health Administration Manual M-2, "Clinical Programs," Part VI, "Pathology and Laboratory Medicine Service," Chapter 13, "Inspection, Accreditation, and Enforcement Requirements," formerly "Regionalization of VA Laboratory Service Activities." Brackets have not been used to indicate changes in the text.

2. Principal changes are:

a. Paragraph 13.02: Establishes policy and designates accrediting bodies for VA testing sites.

b. Paragraph 13.03: Defines areas of responsibility of mandated accrediting bodies and the role of VA Central Office services and programs.

c. Paragraph 13.04: Outlines inspection requirements for testing sites.

d. Paragraph 13.05: Outlines enforcement procedures to ensure compliance with inspection and accreditation policies.

3. Filing Instructions

Remove pages

Insert pages

53 through 54

13-i through 13-ii

13-1 through 13-9

13A-1

4. RESCISSIONS: M-2, Part VI, Chapter 13, dated April 3, 1978, and changes 51, 53 and 60.

~~S/3/14/94 by Dennis Smith for~~
John T. Farrar, M.D.
Acting Under Secretary for Health

Distribution: RPC: 1284 is assigned
FD

Printing Date: 3/94

CONTENTS

CHAPTER 13. INSPECTION, ACCREDITATION AND
ENFORCEMENT REQUIREMENTS

PARAGRAPH	PAGE
13.01 Purpose	13-1
13.02 Policy	13-1
13.03 Inspection and Accreditation Bodies	13-1
13.04 Inspection Requirements	13-6
13.05 Enforcement Procedures	13-8
13.06 References	13-9
 APPENDIX	
13A Decentralized Laboratory Testing - JCAHO Requirements	13A-1

March 14, 1994

M-2, Part VI
Chapter 13

M-2, Part VI
Chapter 13

March 14, 1994

RESCISSIONS

The following material is rescinded:

Manual

M-2, Part VI, Chapter 13, dated April 3, 1978, and changes 51, 53 and 60

CHAPTER 13. INSPECTION, ACCREDITATION AND
ENFORCEMENT REQUIREMENTS

13.01 PURPOSE

This chapter defines the scope of inspection, accreditation and enforcement requirements for testing sites that perform laboratory examinations in Department of Veterans Affairs (VA) medical centers and outreach functions that provide tests for patient care.

13.02 POLICY

Each VA medical center testing site that performs tests for the care of patients shall undergo periodic inspections and evaluations. Each testing site, regardless of its location, will comply with the standards of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Testing sites within and contiguous to the medical center will be inspected and accredited by the Commission on Laboratory Accreditation of the College of American Pathologists (CAP) and the American Association of Blood Banks (AABB). All testing sites in the medical center will be under the direction of the Chief, Pathology and Laboratory Medicine Service, for quality management, regardless of their location. Testing sites outside the medical center and those not contiguous, as well as testing sites located in remote sites will be inspected and accredited by the Chief, Pathology and Laboratory Medicine Service, or designee, using the standards, policies, procedures and checklists of CAP and JCAHO.

13.03 INSPECTION AND ACCREDITATION BODIES

a. CAP. CAP is the oldest clinical laboratory Quality Assurance Program utilized by VA Central Office Pathology and Laboratory Medicine Service, and is the keystone of its accreditation program.

(1) CAP's inspection results and accreditation certificate for the main clinical laboratory is accepted by JCAHO in lieu of its own inspection. Every VA testing site that performs laboratory tests for patient care, including decentralized (ancillary) testing sites, must follow JCAHO standards (see Ch. 10). NOTE: JCAHO may choose to inspect outpatient clinic laboratories not inspected by CAP.

(2) Each VA testing site that performs tests for patient care must undergo formal, on-site inspection every 2 years, and must perform a self-examination in the interim year. VA Central Office Pathology and Laboratory Medicine Service provides funding for this, as well as a comprehensive Proficiency Testing Program. The CAP, Interlaboratory Comparison Program, sends a wide variety of samples three times a year to all VA testing sites. The results are returned to CAP, and a report for each VA medical center laboratory's

March 14, 1994

M-2, Part VI
Chapter 13

M-2, Part VI
Chapter 13

March 14, 1994

performance is sent several times a year to VA Central Office Pathology and Laboratory Medicine Service for review, as well as to each VA medical center testing site.

NOTE: If a testing site has too many serious deficiencies on its formal, on-site inspection, VA Central Office Pathology and Laboratory Medicine service contacts the VA Office of Operations, the Regional Director, and the VA Office of Quality Management and when requested by the medical center Director, will visit the deficient laboratory to recommend corrective action.

(3) Pathology and Laboratory Medicine Service, VA Central Office, endorses CAP's policy which requires, as a condition of continuing accreditation, that each accredited laboratory provide and/or be responsible for an inspection team of a size and composition similar to that required for its own inspection, and to perform at least one inspection during its 2-year cycle of accreditation, if requested to do so. This will be more difficult for smaller institutions. In some cases, it may be necessary for the Inspector to form a team from two or three smaller institutions. NOTE: Pathology and Laboratory Medicine Service in VA Central Office, and the Regional VA Inspection Commissioners will assist VA medical center Chiefs of Pathology and Laboratory Medicine Service, and Ancillary Testing Coordinators, in developing these inspection teams.

(4) Areas of Responsibility

(a) CAP

1. Provides inspection and accreditation services for VA testing sites that perform laboratory examinations for patient care within and contiguous to the medical center.

2. Provides mandatory Interlaboratory Comparison Programs to test the proficiency of testing sites in the performance of laboratory tests.

3. Provides each testing site with tables and statistics (participant summary) which will identify testing sites to Survey Programs. This summary will contain the name of the facility, results reported, methods used and mean values as specified by CAP.

4. Furnishes a survey manual to each VA medical center and the Chief, Pathology and Laboratory Medicine Service.

5. Provides a comparison summary to each VA medical center which compares the facility summary with other subscribers who utilize the same instrument/method combination. NOTE: VA Central Office Pathology and Laboratory Medicine Service will receive exception reports from CAP that list testing sites that repeatedly fail in the Interlaboratory Comparison Program. As part of the inspection and accreditation process the VA National Clinical Laboratory Accuracy and Standardization Program (VANCLAS) will have available all official records and documentation of each laboratory's performance in proficiency testing, including remedial training provided to medical centers that fail to meet the performance standards of VANCLAS and CAP.

(b) VA Regional Inspection Commissioners. VA Regional Inspection Commissioners are responsible for providing oversight of CAP, JCAHO, AABB, and Food and Drug Administration (FDA) inspections for all Pathology and Laboratory Medicine Services within their respective regions, this includes:

M-2, Part VI
Chapter 13

March 14, 1994

1. Ensuring that all testing sites are properly prepared for upcoming inspections, and that appropriate action has been taken on previously cited deficiencies.

2. Analyzing CAP, JCAHO, AABB, and FDA inspection results from each VA medical center in their region to record serious deficiencies.

3. Developing programs with CAP to recruit and train existing laboratory personnel to inspect laboratories.

4. Coordinating inspections of outpatient clinics if inspected by JCAHO and that CAP does not inspect.

5. Advising testing sites of new and changed CAP, JCAHO, AABB, and FDA inspection standards.

6. Working with Pathology and Laboratory Medicine Service, VA Central Office's Quality Management Coordinator and Inspection and Accreditation Enforcement Officer to ensure that each testing site is in compliance with inspection and accreditation requirements of CLIA 88.

7. Being responsible for coordinating funding and reimbursement for VA personnel who participate in inspections in the Regional Commissioner's geographic region in accordance with Government regulations; and advises the Quality Management Coordinator in Pathology and Laboratory Medicine Service, VA Central Office, when problems or conflicts occur with funding or reimbursement.

(c) JCAHO. Each VA medical center must have all its testing sites that perform laboratory tests for patient care surveyed by JCAHO in all areas for which JCAHO standards exist.

1. CAP provides the inspection and accreditation services that are reviewed by JCAHO, at the time of the medical center's JCAHO accreditation visit.

2. The Office of Quality Management, VA Central Office, is the liaison with JCAHO, and is responsible for coordinating the annual contract with JCAHO, specifying the medical facilities and the facility programs to be surveyed (tailored surveys).

3. VA Central Office Pathology and Laboratory Medicine Service program officials are responsible for:

a. Analyzing and coordinating CAP and JCAHO survey results from all VA medical centers and outreach laboratory testing sites.

b. Developing policies and guidance to assist field facilities in complying with JCAHO requirements.

c. Advising testing sites of new and changed CAP and JCAHO standards.

d. Ensuring that VA directives, manual chapters, and other VA Central Office published requirements are consistent with established standards.

NOTE: The Office of Quality Management (15), provides VA Central Office clinical services and program offices with copies of proposed changes in JCAHO standards for comments; and apprises VA Central Office clinical services and

March 14, 1994

M-2, Part VI
Chapter 13

M-2, Part VI
Chapter 13

March 14, 1994

other appropriate offices of significant changes in JCAHO standards involving their areas of responsibility.

(d) Regional Directors. Regional Directors are responsible for providing appropriate oversight of facilities within their regions to ensure that testing sites are properly prepared for upcoming JCAHO surveys, and that appropriate corrective actions have been taken on previously cited JCAHO deficiencies.

M-2, Part VI
Chapter 13

March 14, 1994

(e) Medical Center Directors. Medical center Directors are responsible for:

1. Ensuring that testing sites are in sufficient compliance with CAP and JCAHO standards; and

2. Ensuring that appropriate and timely corrective actions are taken on all CAP and JCAHO survey recommendations.

(f) Chief of Staff (COS). The medical center COS is the responsible official for establishing, maintaining, and strengthening standards of quality patient care by ensuring that chiefs of testing sites in all clinical and ancillary services are fulfilling their JCAHO responsibilities.

(g) Service Chiefs. All clinical service chiefs are responsible for:

1. Ensuring that care is delivered, monitored, evaluated and documented in accordance with CAP and JCAHO standards.

2. Utilizing the results of monitoring and evaluation in the reprivileging process as required by JCAHO.

(h) A Joint Commission surveyor will examine the results of the CAP inspection and accreditation of Pathology and Medical Laboratory Services, even though laboratories in VA medical centers are surveyed by CAP. The results of the CAP inspection are scored under the following areas on the Joint Commission grid:

1 . Proficiency Testing,

2. Quality Control,

3. Administrative Procedures,

4. Safety,

5. Professional Staff, and

6. Test appropriateness guidelines (Medical Effectiveness Evaluation).

(i) JCAHO reports the following compliance levels:

1. Score 1 Substantial Compliance,

2. Score 2 Significant Compliance,

3. Score 3 Partial Compliance,

4. Score 4 Minimal Compliance, and

March 14, 1994

M-2, Part VI
Chapter 13

M-2, Part VI
Chapter 13

March 14, 1994

5. Score 5 Non-compliance.

(5) Ancillary Testing Sites (ATS) (see Ch. 10.)

(a) JCAHO implemented Decentralized Ancillary Testing Standards in January 1990, requiring written records and requirements for tests performed outside the main VA medical center laboratory, including identification of personnel performing testing and the responsible laboratory chief (see App. 13A).

M-2, Part VI
Chapter 13

March 14, 1994

(b) JCAHO requires certification of current competency of testing personnel and daily quality control tests. Competency of testing personnel is measured by MP-5, Part I, Chapter 430, Performance Management System.

(c) All ancillary testing laboratories within VA medical centers and their outreach functions are mandated to comply with current CAP Standards for Laboratory Accreditation and the JCAHO Accreditation Manual for Hospitals, regardless of scope and type of testing activity, or volume of tests produced, if they perform laboratory tests for patient care.

(d) All ATS laboratories, regardless of their locations, are required to be fully accredited by JCAHO. The inspection of these sites, located on the main campus of the medical center, will be performed during the same CAP inspection visit for the VA medical center's main clinical laboratory.

NOTE: CAP-inspected ancillary testing sites are not usually required to undergo a second inspection by JCAHO if they have been inspected by CAP; however, JCAHO may choose to perform a second inspection, based on CAP's inspection report. JCAHO may choose to inspect outpatient clinic laboratories not inspected by CAP.

(e) Ancillary testing sites (decentralized laboratories) that perform tests for diagnostic, monitoring, and other patient care purposes must be under the quality management oversight responsibility of the Chief, Pathology and Laboratory Medicine Service. The CAP Commission on Laboratory Accreditation will not perform inspection and/or accreditation unless the VA medical center supports this oversight. If the COS determines that an ancillary testing site should not be under the quality management oversight of the Chief, Pathology and Laboratory Medicine Service, the testing site must apply to JCAHO for inspection and accreditation, and incur additional administrative responsibilities, pre-inspections and costs for the inspections. All ancillary testing sites must follow the policies in Chapter 10, regardless of which inspection body performs its inspection, to comply with VA's congressional mandate (Pub. L. 102-139).

c. Blood Transfusion Quality Assurance Policies and Inspection and/or Accreditation Agencies

(1) AABB. Each medical center that provides blood and transfusion services is required to undergo inspection by AABB which provides an inspection and accreditation program (see Ch. 5).

(2) Food and Drug Administration (FDA) Inspections. Each blood bank and transfusion service will utilize the random inspection services provided by FDA.

(a) FDA provides a randomly assigned inspection program for VA. VA Central Office Pathology and Laboratory Medicine Service is not notified prior to the inspection.

March 14, 1994

M-2, Part VI
Chapter 13

M-2, Part VI
Chapter 13

March 14, 1994

(b) VA Central Office Pathology and Laboratory Medicine Service receives reports from FDA for blood bank inspections on an intermittent basis. These reports provide a cross-check on the accuracy and compliance with AABB and CAP regulations.

(c) FDA inspects VA blood banks using the same criteria and inspection procedures as those used for private sector blood banks. The inspection reports are classified by FDA district offices as:

1. NAI (i.e., No Action Indicated),
 2. VAI-1 to VAI-3 (i.e., Voluntary Action Indicated, 1 to 3 with the sub-categories 1 to 3 indicating severity of problems), and
 3. OAI (i.e., Official Action Indicated).
- d. Nuclear Regulatory Commission (NRC). The requirements for testing sites that perform patient tests utilizing radioactive materials are discussed in 10 Code of Federal Regulations (CFR) Parts 19, 30, 31, and 35.
- e. Occupational Safety and Health Administration (OSHA). NOTE: Refer to Chapter 15, "Environmental and Safety Issues in the Laboratory," for inspection for safety in the laboratory.

13.04 INSPECTION REQUIREMENTS

- a. Each testing site is required as part of each inspection to:
- (1) Permit the inspection team to interview all employees of the testing site concerning the testing site's compliance with the applicable requirements of the medical center's policies and the inspection agencies' accreditation requirements.
 - (2) Test samples, or perform procedures, as required by the accrediting body, or Chief, Pathology and Laboratory Medicine Service, of the parent VA medical center.
 - (3) Allow the inspection team to interview employees of the medical center or outreach site concerning the testing site's compliance with the requirements of CAP, JCAHO, AABB, FDA, and NRC.
 - (4) Permit employees to be observed performing tests, performing data analysis, and reporting activities.
 - (5) Permit inspectors access to all areas of the facility, including:
 - (a) Specimen procurement and processing areas;
 - (b) Storage facilities for specimens reagents, supplies, records, and reports; and
 - (c) Testing and reporting areas.
 - (6) Provide copies of all records and data required under the accrediting agencies' requirements:

(a) The testing site must have all records and data accessible and retrievable within a reasonable time during the inspection.

(b) The testing site must retain:

1. Immunohematology records for a period of not less than 5 years, in accordance with 21 CFR Part 606, subpart I (see Ch. 5 and App. 2B).

2. Anatomic Pathology test reports (such as cytology; surgical pathology) for at least 10 years after the date of reporting (see Ch. 6 and App. 2B).

3. All other testing site records for at least 2 years (see App. 2B).

(c) The testing site must provide, upon request, all information and data needed by the inspector to make a determination of compliance or noncompliance with the applicable requirements of CAP, JCAHO, AABB, FDA, and the NRC.

b. The inspection and/or accreditation application process will be initiated by submission of a completed application containing the necessary information, evidence of enrollment in appropriate proficiency testing programs, and payment of fees. The medical center's Ancillary Testing Coordinator will assist each testing site in the preparation of the required forms and will submit one application form for the medical center which includes all testing sites.

c. Each testing site under the medical center's jurisdiction, must submit to a complete, periodic on-site inspection. For sites within the medical center, CAP will not inspect or accredit a portion of a single cohesive laboratory and/or testing site except under special and/or unusual circumstances; and then only by prior arrangements with, or approval of, the CAP Regional Commissioner. The conduct of inspections and evaluation of results, regardless of the testing site's location, shall be in accordance with the policies and procedures of the CAP Commission on Laboratory Accreditation, JCAHO, AABB, FDA, and NRC. The date of the on-site inspection for all testing sites within the medical center will be on the date that the main clinical laboratory is inspected. Outpatient laboratories located outside the main campus of the medical center will be inspected annually by the VA medical center's Ancillary Testing Coordinator using both CAP and JCAHO standards. NOTE: JCAHO may choose to inspect outpatient clinic laboratories not inspected by CAP.

d. Testing sites undergoing a change in directorship, location, or increase in scope and/or volume, are subject to inspection and evaluation in accordance with applicable policy of CAP and JCAHO.

e. All testing sites are required to perform periodic self-evaluations. When deficiencies are noted, the testing site shall take appropriate corrective action which shall be documented and subject to review by the CAP Commission on Laboratory Accreditation, JCAHO, and AABB and Chief, Pathology and Laboratory Medicine Service. Corrective action responses from the testing site director may be required. The medical center's Ancillary Testing Coordinator will assist testing sites with these requirements (see Ch. 10).

f. Recurrence of the same deficiencies in consecutive inspections is considered a serious problem and is subject to review by the CAP Commission on Laboratory Accreditation, the VA Regional Commissioner, the VA Central Office Enforcement Officer for Pathology and Laboratory Medicine Service, JCAHO, and AABB and the Director, Pathology and Laboratory Medicine Service. Once the deficiencies are satisfactorily corrected and documented, the testing site receives notice of accreditation and a certificate of accreditation. For

March 14, 1994

M-2, Part VI
Chapter 13

M-2, Part VI
Chapter 13

March 14, 1994

testing sites not contiguous to or remotely located from the medical center (primarily outpatient clinics), the certificate of accreditation will be issued by JCAHO as a part of their regular institutional inspection, or after a separate JCAHO inspection.

g. A CAP Accreditation certificate is valid for a 2-year period. Each medical center will be issued one certificate. The certificate may be maintained on a continuous basis

for all testing sites on the medical center's campus, provided the site:

(1) Submits application for reinspection within 2 years of the last on-site inspection. NOTE: Application forms are automatically sent to each testing site 90 days prior to the anniversary date.

(2) Submits a completed self-inspection checklist in the interim year.

(3) Participates annually in CAP's Surveys Program.

(4) Notifies the Chief, Pathology and Laboratory Medicine Service, should there be a change in the testing site's location.

(5) Notifies the Chief, Pathology and Laboratory Medicine Service, should there be a change in the supervisor at the testing site.

13.05 ENFORCEMENT PROCEDURES

a. Remedial Action. Remedial action may be imposed on laboratories that perform clinical diagnostic tests on human specimens when those laboratories are found to be out of compliance with one or more of the inspection and accreditation, proficiency testing, quality control or other quality management criteria. (See Chs. 2, 4, 5, 6, 10, 12 and 14.) Decisions to invoke remedial action are based on:

(1) The overall compliance history of the testing site including, but not limited to any period of non-compliance that occurred between certifications of compliance.

(2) The corrective and long-term compliance outcomes that VA hopes to achieve.

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

(4) The number of failures of the combined group of outcome measurement indicators measuring laboratory outcome that are used by the Director, Pathology and Laboratory Medicine Service, in judging the overall performance of laboratories in patient care.

(5) Whether the deficiencies pose immediate jeopardy to patients.

(6) The nature, incidence, severity, and duration of the deficiencies or non-compliance.

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

March 14, 1994

M-2, Part VI
Chapter 13

M-2, Part VI
Chapter 13

March 14, 1994

b. Lines of Authority for Enforcing Compliance with Policies for Laboratory Inspection, Accreditation, and other Quality Management Functions

(1) The Under Secretary for Health, Veterans Health Administration (VHA), through the Associate Deputy Chief Medical Director for Clinical Programs, has the ultimate responsibility for enforcing compliance with inspection and accreditation policies and compliance with policies for quality improvement in VA laboratories.

(2) The Director, Pathology and Laboratory Medicine Service, VA Central Office, has the responsibility for:

(a) Documentation of compliance with policies and standards. NOTE: This is performed in collaboration with the Regional Directors' Quality Improvement programs, VA Office of Quality Management, the Medical Inspector, and VA Central Office of Operations.

(b) Establishing and updating policies for laboratory inspection, accreditation, and enforcement.

(3) The Pathology and Laboratory Medicine Enforcement Officer coordinates all field inspections, accreditations and quality management activities in conjunction with VA Regional Commissioners, and the Quality Management Coordinator in Pathology and Laboratory Medicine Service.

13.06 REFERENCES

a. Laboratory Requirements, Inspections and Enforcement, 42 C.F.R., Part 493, Subpart Q (1992), (implementing, in part, the requirements of the Clinical Laboratory Improvement Amendments of 1988, Section 353(f) of the Public Health Service Act, 42, U.S.C. (United States Code) section 263 a (f)).

b. Accreditation Manual for Hospitals, Volume I, Pathology and Clinical Laboratory Services, The Joint Commission on Accreditation of Healthcare Organizations, One Renaissance Blvd., Oakbrook Terrace, IL 60181, pp 87-102; 1992.

c. Standards for Accreditation, The College of American Pathologists, 325 Waukegan Road, Northfield, IL, 60093-2750, 1992.

d. Standards for Blood Banks and Transfusion, ed.15, AABB, 1117 North 19th Street, Washington, DC.

DECENTRALIZED LABORATORY TESTING - JCAHO REQUIREMENTS

The requirements of Joint Commission on Accreditation of Healthcare Organizations (JCAHO), taken from "Pathology and Medical Laboratory Services" (PA) in the JCAHO Accreditation Manual for Hospitals 1992, are listed as follows:

1. PA.6.4 Decentralized Laboratory Testing.
2. PA.6.4.1.1 personnel responsible for test performance and those responsible for direction/supervision of the testing activity are identified
3. PA.6.4.1.2 personnel performing tests have adequate, specific training and orientation to perform the test, and demonstrate satisfactory levels of competence
4. PA.6.4.1.3 current written policies and procedures are readily available and address
 - (a) PA.6.4.1.3.1 specimen collection
 - (b) PA.6.4.1.3.2 specimen preservation
 - (c) PA.6.4.1.3.3 instrument calibration
 - (d) PA.6.4.1.3.4 quality control and remedial action
 - (e) PA.6.4.1.3.5 equipment performance evaluation; and
 - (f) PA.6.4.1.3.6 test performance;
5. PA.6.4.1.4 quality control checks are conducted on each procedure each day the procedure is performed, and identified problems are resolved; and
6. PA.6.4.1.5 appropriate quality control and test records are maintained.