



VETERANS ADMINISTRATION MARYLAND HEALTH CARE SYSTEM
BALTIMORE DIVISION
10 NORTH GREENE STREET
BALTIMORE, MD 21201

GEN00001.2

PATHOLOGY & LABORATORY MEDICINE SERVICE

Document Control Policy version 2 General Procedure # GEN00001

PURPOSE:

To establish the means by which laboratory policies and procedures will be published and revised and maintained (change control).

POLICY:


Policies and procedures using ONLY Microsoft Word files or HTML for Anatomic Pathology will be established according to the program needs and accreditation requirements by the consensus of the senior laboratory staff. Policies and procedures will be approved before implementation by the Chief, P&LM Service. Policy revisions are published on the VAMHCS intranet as needed.

RESPONSIBILITIES:

To ensure that the collection of technical protocols is complete, current and that technical approaches are scientifically valid and clinically relevant, the Chief of P&LMS has designated knowledgeable, technical professional staff to assist in this critical task.

1. These staff members are listed below:
 - Supervisory Health System Specialist: General lab
 - Director: Microbiology/ Serology
 - Section Chief: Hematology/Blood Bank/Urinalysis
 - Section Chief: Chemistry
 - Section Chief: Anatomic Pathology
 - Ancillary Testing Coordinator: Point of Care
 - Supervisor: Chemistry
 - Supervisor: Hematology/Urinalysis
 - Supervisor: Blood Bank
 - Supervisor: Microbiology/Serology
 - Supervisor: Histology/Cytology
 - Supervisor: Stat Lab
 - Quality Management Technologist

The supervisor is responsible for disseminating information to the laboratory staff and documenting that the information was received.

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PROCEDURE:

A. FORMAT

1. The individual will prepare the policy in a collaborative manner to meet the needs of the program. The content of the policy will provide general guidelines for all VAMHCS laboratories and specific instructions as necessary to fit laboratory needs and regulatory requirements. Drafts should be made available on Outlook for peer critique and suggestions. Final approval will be made by Chief, P&LM Service.
2. A new policy will be given a unique ID consisting of three alphabetic characters and five numbers without any spaces. The three alphabetic prefixes are:
 - a. BBB blood Bank
 - b. BMI Microbiology
 - c. BSP Anatomic Pathology
 - d. CHE Chemistry
 - e. GEN General
 - f. HEM Hematology
 - g. BAT Ancillary Testing
 - h. MOL Molecular Diagnostics

This number will be included in the heading on all pages of the Word document or under the revision history section for subsequent reviews.

Example:

Procedure 1-1 would be: BBB00001.1

Procedure 2-1 would be: BBB00002.1

Procedure 7-3 would be: BBB00007.3

3. The main font will be Arial 11 point with a few exceptions such as 14 point for short policy titles.
4. Document control format will include the following pages as demonstrated by the last page of this policy.
 - i. Title Sheet, at the end of each SOP with the assigned number, policy title, author, date adopted, review date for each document version, reviewer signature(s) and date retired.
 - ii. Revision History Section will include changes, author, date, review signature(s) and staff notification. Policy revisions will have the reason for revision and a summary of the changes. The name and title of the initiating person will be recorded there.
5. Supervisors will ensure that employees read, sign and date that they have read and understand the policy and/or revision on the employee review form. This form will be stored in a separate folder/binder.



6. The document footer will show on all pages the filename on the left the abbreviated policy title capitalized and also the page number at the right (Page 1 of 4) etc.
7. To standardize the review of manuals within P&LMS all procedures/policies will be reviewed biennially. At no time will more than 24 months pass between reviews.
8. The master policies will be stored in the Administrative office with a copy of the Word file on electronic media. Coordination of the policies is performed by, but not limited to the Health System Specialist.
9. Retired policies will be kept on file by the supervisor of each section for at least two years.
10. The supervisor will prepare the procedure to meet the National Committee on Clinical Laboratory Standards (NCCLS) "Clinical Laboratory Procedure Manuals" requirements. The area supervisor is responsible to ensure that the procedure reflects the practices of the work area and follows manufacturer instructions. Manufacturer instructions may be included, but not used in place of the written procedure. Final approval will be made by Chief, P&LM Service.
11. The procedure will be stored in each section/site area available to laboratory workers.

B. QUALITY ASSURANCE DOCUMENTS

1. Documents with patient information will be safeguarded respecting patient confidentiality as required by the Privacy Act of 1974.
2. Quality assurance documents will be made available to regulatory and legal entities but are not to be published without consent of the Chief, P&LM Service.

C. REFERRAL DOCUMENTS:

The regulatory or legal reference should be specifically listed such as CAP Checklist date and year. Also any other reference used to prepare the policy guidelines would be helpful.

D. VAMHCS POLICIES:

A. FORMAT (Intranet)

1. General VAMHCS policies are to receive final approval by the Hospital Director.
2. The policy memorandum will be assigned a sequential number using the following format:
 - a. 512-113/PL-XXX (XXX=sequential numbers; i.e. 001,002, etc.)

3. The policy will include the following sections:

- a. Purpose- Reason for writing document
- b. Policy Statement- Sets parameters of the issue. Statement relating VAMHCS policy, philosophy to Mission, Vision, Values and Strategic Plan.



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- c. Definitions- Description of terms used to document
- d. Responsibility- Lists titles (no names), services, clinical centers of those who provide oversight and direction for contents and implementation of document.
- e. Actions- Describes procedures and instructions involved in implementing process
- f. Reference- Citation of sources pertaining to subject
- g. Responsible Office- Sponsor of document
- h. Rescission- List any documents being deleted/replaced by this update
- i. Recertification- The month/year in which the document expires. VAMHCS requires policies/SOPs to be reviewed for revising, updating, deleting every three (3) years.

4. Publication Process:

- a. Routing for Concurrence- Generate an MS Outlook Message (Outlook Message #12)
- b. Activate Message Options- Voting button (approve/reject) option, request "read receipt" to create a tracking log.
- c. Collect Collate and Review Concurrences to determine whether the suggestions will be accepted/ rejected.
- d. After concurrences are received (within 2 weeks of original message) and content of document finalized, assemble a "Policy Package File Folder", insert supporting documentation, routing slip and VAF 3222b. Use only paper clips, do not use staples or hole punch.
- e. Submit to Publications Control Office (POC) via hand-delivery or interoffice mail- BT/11/PC.

REFERENCES:

1. CAP Laboratory General Checklist, August 2016
2. VHA Handbook 1106.1 (2016)
3. NCCLS "Clinical Laboratory Procedure Manuals" GP2
4. VAMHCS Policies & SOP's, Quick Review. Performance Improvement & Accreditation 2014



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DATE ADOPTED	Author of Procedure/Policy	Chief of Service
1/25/2010	Paul D. Gruver, MT	Signature: Dong H. Lee M.D.

Policy/Procedure(s) Retired:	1. Document Control (Change) policy dated 7/3/07 2. Annual procedure Manual Review dated 4/9/07	Date retired: 1/25/2010
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Review Date	Version Number	Signature of reviewer
11/13/12		
8/27/13		
5/25/16	1.2	
10/12/17		

REVISION HISTORY

Date revised	Revision #	Changes made	Signature
11/12/13	1.1	pg 3, #7 Review of procedures/policies changed from annual to bi-annually	
3/25/14	1.2	pg 4 - D-added VAMHCS policy format instructions	