UC Davis Health
Sacramento, CA
Department of Pathology and Laboratory Medicine

DOCUMENT CONTROL PROCEDURES **Administrative Procedure 810.A**

PURPOSE:

To establish standards and procedures for the development, maintenance, review and management of Department of Pathology and Laboratory Medicine policies, procedures and critical documents (quality management, forms and records). Departmental policies and procedures must follow Hospital policies when available and applicable.

POLICY:

Documents (policies, procedures and forms) are maintained electronically on the department's shared drive (S drive) and/or in the hospital's approved document control system. Backup copies of technical section policies and procedures are maintained in the technical sections; if paper copies are used as back up, they are marked as "File Copy". Policies that are not maintained in document control system are reviewed and approved on paper and are accessible to staff on S Drive.

Copies of approved policies and procedures (P&P) may be printed for use within a certain time period or for a special use as long as copies are marked as "uncontrolled" to indicate that the copy will not be accounted for when making revisions or retiring the document. Printing copies of procedures should be done with approval of supervisor or manager. Copies of procedures should be marked as "*Uncontrolled: printed dd/mm/yy*".

Policies and procedures are tracked for review, revision, archive and discontinuation by the individual laboratory sections. Only the current versions of department policies are to be used.

Laboratory records such as patient reports, worksheets, quality control records, that are converted onto another medium for storage and retention are to be verified for accuracy, legibility, and completeness before the original record is destroyed if applicable.

Documents must be retained according to regulations (see Lab Administrative procedure 145.A Record Retention).

Job aids and forms are considered documents and are subject to document management system processes and procedures.

DOCUMENTATION: Laboratory records and changes to such records must be legible and indelible.

- Use dark colored, permanent ink that can be photocopied and that does not smear (blue/black or red).
- When correcting erroneous entries, line through with a single line, date and initial the entry. (Erasures, white and correction fluid are Unacceptable)
- Do not use ditto marks, "down arrows" or scribbled over entries.
- Do not use banned abbreviations.

- Documentation of record review must include reviewer identification (name/initials) and date of review.

DOCUMENTS

A. The Department of Pathology subdivides policies and procedures as follows.

1. A Policy is a written departmental, divisional or sectional philosophy and/or procedure that may affect another UCDH Department. A Policy must be reviewed by the Department Chair and a copy provided to UCDH Medical Staff Office. Policies are recommended to be written using the format outlined in Attachment 1.

2. An Administrative Procedure is a written departmental, divisional or sectional procedure used to rationalize, establish or standardize an internal process. Administrative Procedures do not affect other UCDH Departments. Administrative procedures are reviewed by the section Medical Director or Laboratory Director. Administrative Procedures are recommended to be written using the format outlined in Attachment 2.

3. A Technical Procedure is a written procedure establishing a standardized testing procedure. Technical procedures are reviewed biennially by the section Medical Director or Laboratory Director. Paper/electronic signature review must be at the level of each procedure, or as multiple signatures on a listing of named procedures. The Director should sign with at least the first initial and last name and record the review date on every named procedure. Technical Procedures are recommended to be written using the format outlined in Attachment 3.

4. A Job Aid is information excerpted from an approved procedure that is presented in a more readily viewable format. Job Aids are controlled (referenced procedure, version date and date printed).

5. A Form is an electronic or paper document on which the results from the performance of a procedure or information from other activities are captured. A completed form becomes a record. Examples of quality forms are validation documents, method comparison documents, training and competency assessment documents. Examples of operational forms include temperature log sheets and equipment maintenance log sheets. Forms are to be marked and controlled (numbered, version, revision/review date). Each section will maintain a list of forms and if Forms Table of Contents is used, it can be updated with month and year (mm/yy) of review/revisions.

B. Departmental policies and procedures will be organized and numbered as follows. Policy will end with a **.P** suffix. Administrative Procedures will end with a **.A** suffix. Technical procedures will end with a **.T** suffix.

Section	Assigned Number Sequence

Faculty	001 through 099
Operations	100 through 799
General Operations	100 through 199
Health, Safety and Security	200 through 399
Education	400 through 499
SARC	500 through 599
Client Services	600 through 699
Quality Management	700 through 799
Business and Administration	800 through 899
Administration	800 through 824
Finance	825 through 849
Personnel	850 through 875
Information Services	900 through 999
Clinical Pathology	1000 through 7999
Hematology/Coagulation	1000 through 1999
Transfusion Services	2000 through 2999
Chemistry	3000 through 3999
Immunology	4000 through 4999
Toxicology	5000 through 5999
Microbiology	6000 through 6999
Core Lab	7000 through 7999
Anatomic Pathology	10000 through 14999
Surgical Pathology	10000 through 10999
Histology	11000 through 11999
Immunopathology	12000 through 12999
Autopsy	13000 through 13999
Cytology	15000 through 15999
Pathology Office	16000 through 16999
Clinical Reference and Development	17000 through 19999
Outreach Services	17000 through 17999
Molecular Pathology	18000 through 18999
Lab Development	19000 through 19999

PROCEDURE:

A. New policies and administrative procedures or changes to current policies and administrative procedures can be recommended by any Department of Pathology faculty or staff member. Procedures may also arise from outside the department, such as from regulatory agencies.

1. Policies

a. The Laboratory Director may assign a department Faculty or staff member to write, review or rewrite departmental policies.

1) The responsibility for review of new and/or substantially revised policies and procedures will be restricted to the Laboratory Director whose name appears on the CLIA certificate. Per CLIA requirements these responsibilities cannot be delegated.

b. All new policies are submitted to the Laboratory Director for review.

c. Recommended changes to current policies are submitted to the Laboratory Director in the following written format:

1) Changes from the original policy and are indicated by using "track changes".
2) Procedure history page documents revision date and person making the revision. History page is not required in electronic document control system as it captures the pathway of policy review and history.

d. The Laboratory Director may refer draft or revised policies to the appropriate department Faculty and/or staff for review and comment. The Laboratory Director has final editorial discretion and approval over all policies.

e. A file copy of final policy is maintained on the departmental WAN such as S:/ PoliciesandProcedures /*.* or within document control site.

2. Administrative Procedures:

a. Each Administrative Procedure will have a designated issuing authority or "owner". The "owner" is responsible for ongoing as needed review, edits, updating references and ensuring all applicable procedures that may be affected by revisions are accounted for. All staff are encouraged to suggest changes to the procedure "owner".

b. Drafts of new or revised Administrative Procedures are circulated to

applicable section supervisors and Managers for review and input.

c. Recommended changes to new or existing Administrative Procedures are submitted back to the "owner".

d. Any procedure with significant revisions must be listed as "revised" and should include a brief description of the major revisions.

e. The final of each Administrative Procedure will be reviewed by the issuing authority before submitting to the Medical or Laboratory Director.

f. The appropriate level director has final editing and approval authority for all new and revised Administrative Procedures (Laboratory Director for Department level, AP or CP Director for Divisional level and Section Medical Director for Sectional level as well as Director or designee).

g. The final electronic copy of the signed Administrative Procedure will be posted to the department document site (e.g. S:/PoliciesandProcedures/ *.* and/or Document Control System).

3. Technical Procedures:

a. Drafts of new or revised Technical Procedures are developed by technical staff and issued by a technical director. (Administrative Procedure 715.A Writing Technical Section Procedures)

b. All new technical procedures as well as substantial changes to existing documents must be reviewed and approved by CLIA Laboratory Director.

c. An electronic file copy of final Technical Procedures is maintained by the Technical Section on the departmental document site(e.g. S:/PoliciesandProcedures /*.*, Document Control System).

d. Copies of the procedures may be printed and kept in binders in the Technical Sections as backup procedures for system downtime. The Technical Section will ensure printed copies are current and match the on-line version.

e. Each technical procedure must be reviewed every two years (biennial or every 24 calendar months).

D. Managers and Supervisors are responsible for ensuring that staff have read procedures relevant to related job activities and that staff know how to access electronic procedures when needed.

E. Policies, procedures and forms that are revised or no longer in use are archived in a separate file for a minimum of 2 years (5 years for Transfusion Medicine) after the date of revision or discontinuation. Electronic versions are also archived based on the date of revision or discontinuation.

F. All policies, procedures, forms and records are maintained under this document control procedure.

G. Department of Pathology documents (Polices, Procedures, Method Validations) are for staff use/reference and available for review by the inspecting team for accreditation purposes. Any request received to share these documents externally should be escalated to section supervisor/manager for their approval.

- Pathology will not share original method validation data with other entities (except as required by regulatory agencies standards and/or as required by law); as this is proprietary information and should be treated as confidential.
- All method performance specification summaries are available to clients and inspection team upon request for current test methods. It should be treated as confidential, not used for their own test development and not shared with any other party except as required by law.
- Specimen collection/handling procedures are electronically available to all clients.

REFERENCES:

- ISO International Standard 15189: Medical laboratories – Particular requirements for quality and competence. Geneva; International Organization for Standardization, 2012.

- CLSI. *Quality Management System: Development and Management of Laboratory Documents; Approved Guideline—Sixth Edition*. CLSI document QMS02-A6. Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2018.

- College of American Pathologists (CAP) Laboratory General Checklist, 2020 Edition

Attachment 1: Example of Policy Format

UC Davis Health
Sacramento, CA
Department of Medical Pathology & Laboratory Medicine

Policy Name **Administrative Policy ####.P**

PURPOSE:

POLICY:

POLICY HISTORY

Date	Written/ Revised by	Review / Revision	Approved Date	Approved by

Attachment 2: Example of Administrative Procedure Format

UC Davis Health
Sacramento, CA
Department of Medical Pathology & Laboratory Medicine

Procedure Name Administrative Procedure ####.A

PURPOSE:

.

POLICY:

PROCEDURE:

Step wise procedure

REFERENCES:

PROCEDURE HISTORY

Date	Written / Revised by	Review / Revision	Approved Date	Approved by

Attachment 3: Example of Technical Procedure Format

UC Davis Health
Sacramento, CA
Department of Pathology, Anatomic Pathology
Immunopathology

IMMUNPEROXIDASE STAINING
(PARAFFIN SECTIONS) General IP Stains Procedure ####.T

I. PURPOSE:

II. POLICY:

Statement (numbered if needed)

III. PROCEDURE:

IV. SOLUTIONS:

Detailed technical procedure (numbered as needed).

V. TECHNICAL CONSIDERATIONS (if needed):

A. Incubations:
B. Dilutions:
C. Controls:
D. Reagents:
E. Instrumentation:

V. NOTES (if needed**)**

VI. REFERENCES:

PROCEDURE HISTORY

Date	Written/Revised by	Review / Revision	Approved Date	Approved By

PROCEDURE HISTORY

Date	Written/ Revised By	Review/Revision	Approved Date	Approved By
4/90	D. O'Sullivan	New	4/90	R.D. Cardiff
9/93	D. O'Sullivan	Annual Review	9/93	R.D. Cardiff
10/94	D. O'Sullivan	Annual Review	10/94	R.D. Cardiff
5/96	D. O'Sullivan	Annual Review	5/96	R.D. Cardiff
11/96	D. O'Sullivan	Annual Review	11/96	R. Green
12/97	D. O'Sullivan	Annual Review	12/97	R. Green
7/99	D. O'Sullivan	Annual Review	7/99	R. Green
6/00	D. O'Sullivan	Annual Review	6/00	R. Green
7/01	D. O'Sullivan	Annual Review	7/01	R. Green
8/02	D. O'Sullivan	Annual Review	8/02	R. Green
10/03	D. O'Sullivan	Revised	10/03	R. Green
11/04	D. O'Sullivan	Revised	11/04	R. Green
10/05	D. O'Sullivan	Annual Review	10/05	R. Green
9/06	D. O'Sullivan	Annual Review	9/06	R. Green
10/07	D. O'Sullivan	Annual Review	10/07	R. Green
4/08	D. Wright	Revised	4/08	R. Green
5/09	D. Wright	Revised	5/09	L. Howell
8/10	D. Wright	Annual Review	8/10	L. Howell
12/10	T. Cook	Updated Signature of Procedures	12/10	L. Howell
5/11	D. Wright	P&P Review	5/11	L. Howell
10/12	T. Cox	Revised: biennial review; two P&P binders; attachment 4	10/12	L. Howell
09/14	T. Cox	Revised: removed EM&Cytogenetics	09/14	L. Howell

PROCEDURE HISTORY

Date	Written/ Revised By	Review/Revision	Approved Date	Approved By
12/14	T. Cox	Revised: added printing, forms, aids	12/14	L. Howell
12/16	S. Okimura	Biennial Review	12/16	L. Howell
09/18	N. Kaur	Revised: Updated Biennial review & removed attachment 4	09/18	L. Howell Via OnBase
09/20	N. Kaur, E. Karanja	Revised: Location of Administrative policies, document sharing process.	09/20	L. Howell Via OnBase
07/21	E. Karanja	Revised: Added requirements for records converted onto another medium	08/21	L.Howell Via Onbase