**University of California, Davis**
**Health System, Sacramento**
**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) or in the hospital's approved document control system (OnBase). Master paper copies of Lab Administrative policies and procedures (with the Director's "wet" signature) are maintained in the Pavilion Lab (CAO's office); file paper copies of Lab Administrative policies and procedures are maintained in the Specialty Testing Center (STC) library. Backup copies of technical section policies and procedures are maintained in the technical sections; paper copies are marked as "File Copy".

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.

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

- 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.
- Do not use ditto marks, "down arrows", scribbled over entries, or white out.
- 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 UCDHS Department. A Policy must be reviewed biennially (every two years) by the Department Chair and a copy provided to UCDHS Medical Staff Office. Policies are 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 UCDHS Departments. Administrative procedures are reviewed biennially by the the section Medical Director or Laboratory Director. Administrative Procedures are written using the format outlined in Attachment 2.

3. A Technical Procedure is a written procedure establishing a standardized testing procedure. These procedures must be reviewed biennially by technical staff and faculty responsible for the testing. 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 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). Forms will be listed in a Forms Table of Contents. The Forms Table of Contents must 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 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 as drafts.

   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.

   d. The Laboratory Director refers 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. Each departmental policy must be reviewed every two years (biennial or every 24 calendar months).

   f. A file copy of final policy is maintained by administrative staff on the departmental WAN at S:/ PoliciesandProcedures /*.* or within document control site.

   g. Policies will be listed in a Table of Contents. The Table of Contents must be updated with month and year (mm/yy) of review/revisions.

2. Administrative Procedures:

   a. Each Administrative Procedure will have a designated issuing authority or "owner". The "owner" is responsible for biennial 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". Reviewers may document their review using Procedure Review Tracking Form (Attachment 4).

d. Any procedure with no changes or minor re-formatting may be listed as "Biennial Review".

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

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

g. 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 Chief Administrative Officer or designee).

h. The final paper copy of the signed Administrative Procedure will be maintained in the Clinical Pathology CAO's office in Administrative P&P Binders. Backup P&P manuals contain electronically signed copies will be maintained in the STC for use if electronic access is limited.

i. The final electronic copy of the signed Administrative Procedure will be posted to the department document site (e.g. S:/PoliciesandProcedures/ *.*, OnBase).

j. Procedures will be listed in a Table of Contents. The Table of Contents must be updated with the month and year (mm/yy) of review/revision.

k. Each Administrative Procedure must be reviewed every two years (biennial or every 24 calendar months).

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

c. 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.

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

B. The Department of Pathology Administrative Policy and Procedure Manual is maintained in Laboratory Administration by the Clinical Pathology CAO. A backup copy is maintained in STC. No other hard copies are kept in the lab sections. Management of Pathology Administrative Policy and Procedure Manual (electronic and paper copies) is the responsibility of the Quality Management Section.

C. Technical Section Procedures are not included in the Administrative Policy and Procedure Manual. The Administrative Policy and Procedure Manual's Table of Contents also lists the Section Technical Procedure numbers, but not the procedure titles.

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 or backup paper copies 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 after the date of revision or discontinuation. Electronic versions are also archived based on the date of revision or discontinuation.

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

**REFERENCES:**

Clinical and Laboratory Standards Institute. Laboratory Documents, Development and Control – Approved Guideline Fifth Edition. CLSI document GP2-A5 (ISBN 1-56238-600-X). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne Pennsylvania 19087-1898 USA, 2006

ISO International Standard 15189: Medical laboratories – Particular requirements for quality and competence. Geneva; International Organization for Standardization, 2003.

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, 2013.

**Attachment 1: Example of Policy Format**

University of California, Davis
Health System, Sacramento
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 |
|---|---|---|---|---|
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**Attachment 2: Example of Administrative Procedure Format**

University of California, Davis
Health System, Sacramento
Department of Medical Pathology & Laboratory Medicine

*Procedure Name* Administrative Procedure ####.A

PURPOSE:

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POLICY:

PROCEDURE:

Step wise procedure

REFERENCES:

**PROCEDURE HISTORY**

| Date | Written / Revised by | Review / Revision | Approved Date | Approved by |
|---|---|---|---|---|
| | | | | |
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**Attachment 3: Example of Technical Procedure Format**

University of California, Davis
Health System, Sacramento
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 |
|---|---|---|---|---|
| | | | | |
| | | | | |

**Attachment 4: Policy and Procedure Review Tracking**

University of California, Davis
UC Davis Health System, Sacramento
Department of Pathology & Laboratory Medicine
Policies & Procedures Review Cover Sheet

To: _____ *(Reviewer )*

From: _____ **(***Owner )*

Title of Policy/Procedure to be reviewed: _____ *Procedure ####.(A)*

**Please indicate that you have completed the following:**

☐ Correct setting has been identified;

☐ References are included, and updated;

☐ Changes have been made in Word, via track changes

☐ Review and update other related attachments, policies, procedures as applicable;

☐ Banned abbreviations do not exist in the policy (For example: U, IU, QD, QOD, MS, MSO4, MgSO4…).

**Select One:**

☐ Approve policy as is;

☐ Approve this policy with changes;

☐ Disapprove. Why?

Please **print** your name, title and extension:

**Additional Comments, if any**:

**RETURN by email to _[name]_____@ucdmc.ucdavis.edu by mm/dd /yy .**

## 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 |
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