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COLORADO LABORATORY – QUALITY ASSURANCE PROGRAM

LABORATORY DOCUMENT CONTROL POLICY

PURPOSE

This document outlines the process for creating, editing, authorizing, reviewing, archiving and securing documents and procedures within the laboratory. Kaiser Permanente laboratories will use the Laboratory website secure drive to store the documents. Only two individuals have access to editing. One is the Quality Assurance Manager and the second is the webmaster.

DEFINITIONS

Documents covered by the Document Control System will include:

Policies – statements of intent, an organizational mandate

Protocols – plans for a course of action – the course of action is defined in procedures

Process maps – description of who does what, when, how something happens, presents activities in a sequence

Procedures – instructions for how to do an activity within the larger process; includes instrument operating procedures

Forms and logs – the means by which data and documentation is captured

Guidelines – recommendations for performing certain tasks that because of the inherent variability of the task cannot be defined specifically

Flowcharts – visual depictions of the workflows or decision trees that are used to define processes or steps taken

STANDARDS

1. Documents in the laboratory will be strictly controlled to maintain uniform content, approval, and distribution throughout the laboratory system.

2. Each document will be developed using the attached procedure template.

3. The Medical Directors will review and sign all technical policies and procedures before implementation, after significant updates and/or changes, and bi-annually thereafter.

4. For the Medical Office laboratories, the Laboratory Medical Director approves all new procedures and revisions and thereafter, individual Medical Directors or their designee will review and sign bi-annually.

5. Documents will be posted on the Laboratory Website.

6. Notification of the revised document will be communicated to all staff.

7. The QA Manager is responsible for obtaining the Medical Director's signature, distribution, and posting the procedure to the Laboratory Website. Director signature pages will be attached to each document. See process for obtaining Director signatures below.

9. Printing of procedures and storing them in personal binders or drawers is prohibited. If printing of a procedure is required for training or any other activity it is to be discarded when the activity is completed. Storing electronic procedures on P (personal) drives is prohibited.

REVISION REQUIREMENTS

Any laboratory employee who identifies a need for document revision is encouraged to discuss the need with their immediate supervisor or the QA Manager.

1. The process owner will check out the procedure from the QA Manager, revise and review for accuracy, grammatical errors, and technical language and send back to the QA Manager for Director signature and posting to the Laboratory Website.

2. The template for procedures will be available on the Laboratory Website in the Quality Assurance Program.

3. Prior to implementation of a procedure, ascertain that prior versions of the procedure are retired, designated as retired and removed from general staff access. Retired procedures will be housed on a separate drive with limited access.

4. The document file name will be saved as:

The instrument or process name, the specific process or procedure, followed by the date

i.e. iSTAT Maintenance Procedure 06May12

KAISER PERMANENTE®
COLORADO LABORATORY (Arial 12)

PROCEDURE TEMPLATE (Bold Arial all CAPS font size 14)

PRINCIPLE (font size 12, no underlining)
space
Text in Arial 12 – no bolding
space
SCOPE

Text in Arial 12 – no bolding

SPECIMEN REQUIREMENTS

EQUIPMENT AND MATERIALS

REAGENTS

CALIBRATION

QUALITY CONTROL

PROCEDURE

REPORTING RESULTS

REFERENCE RANGES

LIMITATIONS OF THE PROCEDURE

DISTRIBUTION

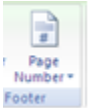
REFERENCES

Text in Arial 10 – no bolding

Document margins will be set at:
Top: 0.6 Bottom: 0.6
Left: 0.8 Right: 0.8

REVISING THE FOOTER/ADDING PAGE NUMBERS

1. Click on “Insert” in the toolbar
2. Click on “Footer”
3. Click on “Edit footer”
4. To add page numbers, click on Page Number



5. Choose bottom of page, scroll to the Page 1 of 1 example and choose this template

6. Make the changes to the left side of the footer if needed. Use the format:

   - name (first initial followed by the full last name) and the month/year of revision. i.e. J. Doe 5/05

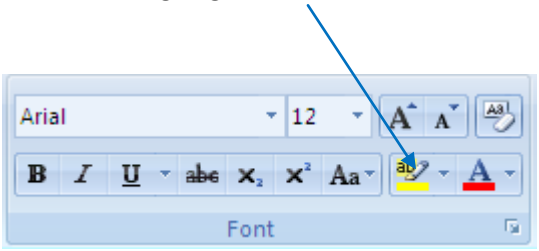
7. Click on the red X in the upper right end of the toolbar to close and save the footer

*Note: depending on the version of MS Word that is being used, the steps above may be slightly different.

IDENTIFICATION OF CHANGES

To aid in the communication of revisions, new or revised text will be highlighted in yellow. These highlights can be uploaded to the Laboratory Website and can be easily identified when personnel access the procedure. To highlight text use the following procedure:

1. Place the mouse cursor at the left side of the text you want to highlight
2. With the left mouse button depressed, drag the cursor through the text.
3. Notice that the text “highlights” as the cursor is dragged across the text.
4. Release the left mouse button
5. In the Font menu at the top of the screen, click on the highlight icon



6. The text will automatically be highlighted in yellow. To remove highlighting, perform steps 1-4 above then click on the drop down arrow on the right side of the icon. From the drop down, choose “no color.”

STORING DOCUMENTS

Documents are stored on a secure computer drive with limited access. Once changes have been made to the documents, they are uploaded to the secure drive and from there pushed to the Laboratory Web Site.

COMMUNICATION OF CHANGES

Changes to procedures are communicated to the affected personnel via the Laboratory Communications Team. The communication will provide details of the changes or revision that were made and a link to the procedure on the Laboratory website will be added.

RECORD MANAGEMENT SYSTEM

Only approved policies and procedures will be in use.

New procedures will be identified in collaboration with new departments, instrumentation, medical office locations, content matter experts and the Medical Office Directors.

Retired procedures will be stored on the secure drive and will be identified as retired by adding the retirement date to the file name. i.e. Urease Procedure 04May08 – retired 09Mar11. Retired procedures will be retained for two years per the Record Retention Policy.

To prevent previous versions or retired procedures from being used at the desktop, printing of paper copies of procedures will be prohibited. An exception will be made during the training of a new employee. Once training has been completed, paper copies of procedures will be disposed of. Discard procedures in paper recycling bins.

During power outages or if the Laboratory Website is down, paper copies may be used to complete testing. Follow procedures established by the Computer Downtime Policy before printing procedures. Once power has been restored, paper copies are destroyed. Discard procedures in paper recycling bins.

A hard copy of every procedure is maintained at the Regional Reference Laboratory as a backup. These same copies are provided to CAP inspectors during the year the lab is being inspected.

To aid in the management of policy and procedure, a spreadsheet has been developed that captures all procedures, the author, the manual they are housed in, the process owner and the dates of revisions and review. This spreadsheet will be used to crosswalk procedures with other instruments, procedures, locations and processes to ensure consistent language and procedure.

DIRECTOR SIGNATURE

Once a policy or procedure has been revised, the QA Manager will send an email notification to the Laboratory Directors with the revised procedure attached. The Directors will respond to the email with a response of “approved.” The date and time of the email will be maintained on a signature page attached to the hard copy of the procedure.