QUALITY POLICY: DOCUMENTS AND RECORDS

☒ St. Joseph Medical Center Tacoma, WA ☒ St. Clare Hospital Lakewood, WA ☒ St. Elizabeth Hospital Enumclaw, WA
☒ St. Francis Hospital Federal Way, WA ☒ St. Anthony Hospital Gig Harbor, WA ☒ PSC

PURPOSE

This policy provides guidance for the processes and procedures to be used in controlling the Franciscan Health System (FHS) Laboratory Service documents and records.

RELATED DOCUMENTS

R-F-AD-0604	Documents – Change Control Form
R-PR-AD-0615	Documents – Development and Revision Process
R-PR-AD-0605	Documents – Implementation Process
R-PO-AD-0610	Documents – Retention Policy
R-W-AD-0606	Documents – Policy Creation or Revision
R-W-AD-0607	Documents – Process Creation or Revision
R-W-AD-0608	Documents – Work Instruction Creation or Revision
R-W-AD-0609	Documents – Form Creation or Revision
R-W-AD-0611	Documents – Master List
R-W-AD-0612	Documents – Discontinuation
R-PR-AD-0620	Document Control Process

POLICY

The management of the FHS Laboratory Service, with the oversight of the Laboratory Quality Manager, will ensure that its documents and records are managed from creation or receipt to archive or destruction according to established processes that reflect the organization's commitment to quality, as well as meet legal and regulatory requirements. This includes all points listed below.

1. All copies of documents in use will be the approved current version.
   - Obsolete documents will be promptly removed from the workplace.
   - Documents which have been superseded by a new revision will be stored in the appropriate history file.
   - Discontinued documents will be quarantined in a separate file for a minimum of 2 years after the date of discontinuation (5 years for Transfusion Medicine).
2. Staff will have immediate access to the documents they need to perform their work.
   - Personnel will read and review all policies/procedures, etc, relevant to their job activities.
3. Document classification and hierarchy are defined as

Document Level	Type of Document	Purpose of Document
I	Policy	What will be done and why
II	Process	Who does what and when to meet policy intent
III	Work Instruction	How to do it
IV	Forms, Worksheets, Labels, etc.	Documentation and recordkeeping

   Note: Any tool that is used at the workbench as an aid to remember items or tasks, will be included as an appendix to the relevant work instruction and be subject to document control.
4. All documents will be subject to change and process control.

5. All documents will adhere to standardized FHS document format to ensure consistent and effective representation of all requirements.

6. Document title and its filepath name must be identical.

7. Documents must be able to be searched for in the online manual with appropriate keywords entered into the document Properties screen.

8. The first word of the title must be the main topic of the document which will allow documents on the same subject being alphabetically grouped together in the online manual. Example:

   Crossmatch – Gel Method
   Crossmatch – Immediate Spin
   Crossmatch – LISS Method

9. The following documents will require committee approval prior to implementation (see related documents):
   - All new documents
   - All revised documents that are regional in nature or apply to more than one facility.

10. All documents will be reviewed, authorized, and signed by the laboratory director prior to implementation.

11. Policies and procedures will be reviewed at least biennially by the laboratory medical director, or designee.

12. A master list of all current documents and the locations of copies (including derivative documents such as card files and summary charts) will be maintained.

13. Documents will be maintained, stored, retrievable, and retained for periods specified in the approved retention schedule. At the end of the retention period, the documents will be destroyed.

14. Work Instructions and Process documents will undergo verification/validation prior to implementation.

15. Documents will be stored on the shared drive in the *lab/lab/document control* folder.

16. Electronic manuals will have a backup available on CD or flash drive.

DOCUMENT FORMAT

Writing documents in a consistent format across the laboratory provides improved readability and comprehension, as well as a higher assurance of correct process output. All four levels of FHS Laboratory documents must meet the following criteria:

- Use the FHS Laboratory Header and Footer Template
- Margins will be 1/2". And Ariel font 11 used for the body of the document.
- Tables will be written in font 8, 9, or 10. Font 10 is preferred, but smaller fonts may be used to accommodate information in a single table on a single page. Column headings will be bolded, in Title case. Gray scale 15% shading in heading row or column. Table centered on the page. Spacing justification and table size condensed to fit content.
- Section headings will be font 11, bolded, all caps, with two spaces above the heading
- Subsection headings will be font 11, bolded, Title case, with 1 space above heading
- Steps will be numerical in order
- Bullets will be used for sub-steps
- References will be in Ariel font 10. Spacing between references will be formatted to 6 pts.
- File path, effective date, and page numbers in footer will be written in Ariel font 8 (built into template).
- Properties section of the document will be completed with key words
- A Document Approval table will be placed at the end of the document which includes:
  --reason(s) for current revision
  --committee approval date, if required
  --Medical Director signature and date

FHS Laboratory Header and Footer Format

Header and footer formats are the same for each level of document.

Header Row (R)	Header Section Name	Header Section Information
R1 & R2	FHS Logo	Do not change – located at left margin
R1	Document Level	Located at right margin (Font = Arial 14, bolded): • Policy (red violet) • Process (green) • Work Instruction (blue) • Form (black)
R2	Document #	**Use the following document ID# format** ***(example: R-W-TS-0506-04)*** **A-BC-DEF-1234-56** (font = Arial 12, bolded) **A = Facility to which document applies** • R = regional to include all sites • M = More than one site, but not regional in scope • A = SAH only • C = SCH only • E = SEH only • F = SFH only • J = SJMC only • ENUM = Enumclaw Clinic • GIGL = Gig Harbor Clinic • PSC = PSC – applies to <u>all</u> PSCs **B-(C) = Type of document** • PO = policy • PR = process • W = work instruction • F = form **D-E-(F) = Lab Section** • AD = Administration & Quality • AP = Anatomic Path • CG = Coagulation • CH = Chemistry • CLT = Client Services • EQ = Equipment • HEM = Hematology • IS = Information Systems • LOG = Logistics • MB = Microbiology • OPP= Outpatient Processing • POC = Point of Care • PSC= Patient Service Center • SER = Serology • SPC = Specimen Center • TS = Transfusion Services • UA = Urinalysis **1-2-3-4 = Document number 0001- 9999** **5-6 = Revision number 00- 99**
R3	Title of Document	All Caps with document type included in the title for all types except work instructions and forms Font = Arial 14, bolded
R4 & 5	<u>Facilities List</u>. A checkmark in the box will indicate at which facilities the document will be used.	☐ St. Anthony Hospital ☐ St. Clare Hospital ☐ St. Elizabeth Hospital ☐ St. Francis Hospital ☐ St. Joseph Medical Center ☐ PSC = Patient Service Center
Footer Row	**Section Name**	**Information**
R1	Left box	File Name and path Font = Arial 8
R1	Middle box	Effective date – changes with each revision Font = Arial 8
R1	Right box	Page number and total number of pages in entire document Font = Arial 8
R2	Declaration	Do not edit

	of Propriety	Font = Arial 9, red, italicized

The following elements must be included when applicable to the policy, process, or test procedure. Additional headings may be used to assist with reading clarity and comprehension as necessary.

Document Level	Document Type	Headers
I	Policy	Purpose Background (Optional) Related Documents Policy statement(s) Reference
II	Process	Flowchart format • Related Documents (on second page above the table which includes the medical director signature) Table format • Purpose • Related Documents • Process (in table format) • Reference
III	Work Instruction	***FHS required*** Purpose Background (Optional) Related Documents ***Below are CAP required elements (when applicable to procedure)*** Principle & Clinical Significance Patient Preparation Specimen Requirements • Specimen collection, labeling, storage, preservation, transportation, processing and referral, and criteria for specimen acceptability and rejection Equipment/Supplies Calibration Preparation (of reagents, controls, calibrators, etc) Quality Control Steps (of the procedure) Microscopic Examination Interpretation Normal Ranges Critical Ranges Analytic Measuring Range (AMR) Cerner Ordering and Resulting Limitations Test System Failure Actions (reference to specific related document) Reference
IV	Forms	Related Documents (on page 2 of the document above the approval section that contains the medical director's signature.)

REFERENCE

Clinical and Laboratory Standards Institute. *A Quality Management System Model for Health Care: Approved Guideline – Second Edition.* CLSI (formerly NCCLS) document HS1-A2. CLSI, Wayne, Pennsylvania, 2004

Clinical and Laboratory Standards Institute. *Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition.* CLSI document GP2-A5. CLSI, Wayne, Pennsylvania, 2006

CAP Checklists

DOCUMENT APPROVAL Purpose of Document / Reason for Change:			
• Added OPP as a section for specific documents post RPI. Other minor revisions: • Added that the document *type* (policy, process, flow chart) will be included in the title of the document except for work instructions and forms. • Added that keywords will be entered in properties for the document to enable searching on portal to match our practice			
Committee Approval Date	☒ Date: 12/13/12 ☐ NA – revision of department-specific document which is used at only one facility	**Medical Director Approval** *(Electronic Signature)*	Linda D. Burkhardt, MD 12/17/12