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QSE 8: Documents and Records Management

Policy	The laboratory has a process for documenting the management's instructions to staff about the laboratory's work, what to do, how to do it, and how to maintain the records of what happened when work was done.
Purpose	This policy provides direction for the processes and procedures to effectively manage the laboratory's documents and records.
Responsibility	The Laboratory Director is responsible for reviewing/approving all documents before implementation and on an annual basis. The Quality Manager is responsible for establishing and maintaining the document control system. The Laboratory Supervisor/Lead Technologists are responsible for authoring, modifying, distributing, and retaining documents, forms, and records as needed. Laboratory Staff are responsible for following document control policies and procedures as necessary to complete their work.
Documents	The laboratory has a document control system to ensure that all documents in use are written in the approved format, reflect the current version, and are reviewed and approved by the laboratory director at least annually.
Procedures	All procedures used in the laboratory will be documented, reviewed, and signed by the Laboratory Director or designee prior to implementation and at least annually thereafter.
Records	Records are created, modified, stored, archived, and destroyed in a way that facilitates retrieval, prevents damage and unauthorized use, and maintains patient confidentiality.
Storage	All laboratory records, inclusive of requisitions, patient results, and QC, QA, and maintenance logs, will be retained for at least five years following the date of application to the FDA.
Supporting Documents	The following processes support this policy: • New Document Creation, Review, and Approval • Revision of Approved Existing Documents • Document Control • Records Review, Retention, Storage, Retrieval, and Destruction • Records Modification

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Process for Creating, Reviewing, and Approving New Documents

What Happens	Who's Responsible	Procedures
Need for new document is identified	• Any Staff Member	• Writing Policy, Process, Procedure, and Form Documents
Document Change Request Form is completed and approved	• Any Staff Member • Quality Manager • Laboratory Supervisor • Laboratory Director	• Writing Policy, Process, Procedure, and Form Documents • Document Change Request Form
New document is drafted	• Assigned Author	• Writing Policy, Process, Procedure, and Form Documents
Independent review and verification are performed	• Assigned Staff Reviewer	• Reviewing and Verifying New or Changed Documents
Review and approval signatures are obtained	• Laboratory Director • Laboratory Supervisor • Quality Manager	• Reviewing and Verifying New or Changed Documents
Document is entered into Master List and assigned a unique identifier	• Quality Manager	• Document Control • Document Master List
A Master File is created for the document	• Quality Manager	• Document Control • Master File
Working copies of the document are distributed as needed	• Quality Manager • Laboratory Supervisor	• Document Control
Staff notification is made	• Laboratory Supervisor • Lead Technologist	• Notifying Staff of Document Changes
Staff is trained in use of new document, and document is implemented	• Laboratory Supervisor • Lead Technologist	• Notifying Staff of Document Changes • Staff Training Procedures

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Process for Revising Existing Documents/Forms

What Happens	Who's Responsible	Procedures
Need for change to existing (previously approved) document is identified	• Any Staff Member	• Editing Documents • Document Change Request Form
Document Change Request Form is completed and approved	• Any Staff Member • Laboratory Director	• Editing Documents • Document Change Request Form
Changes needed to related documents are identified and Document Change Request Forms are completed	• Assigned Staff • Quality Manager	• Editing Documents • Document Change Request Form
Current document version is retrieved from master file	• Assigned Author • Quality Manager	• Document Control • Editing Documents
Current document version is edited	• Assigned Author	• Editing Documents
Independent review and verification are performed	• Assigned Staff Reviewer	• Reviewing and Verifying New or Changed Documents
Review and approval signatures obtained	• Laboratory Director • Laboratory Supervisor • Quality Manager	• Reviewing and Verifying New or Changed Documents
The old version of the document is retired and archived in the Master File. The new version is retained in the Master File.	• Quality Manager	• Document Control • Master File • Archiving Retired SOPs
Master List is updated	• Quality Manager	• Document Control • Document Master List
All working copies of old versions are replaced with new versions. Discontinued working copies are destroyed	• Quality Manager • Laboratory Supervisor	• Document Control • Destruction of Documents
Staff notification is made	• Laboratory Supervisor • Lead Technologist	• Notifying Staff of Document Changes
Staff is trained in use of new document, and document is implemented	• Laboratory Supervisor • Lead Technologist	• Notifying Staff of Document Changes • Staff Training Procedures

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Process for Document Control

What Happens	Who's Responsible	Procedures
Each document is uniquely identified to ensure traceability throughout the document life cycle	• Quality Manager	• Document Control
Document is entered on the Document Master List	• Quality Manager	• Document Control • Document Master List
A Master File containing master copies of current and previous document versions is created for each document	• Quality Manager	• Document Control • Master File • Archiving Retired SOPs
Master List is used to identify locations of working copies of documents	• Quality Manager	• Document Control • Document Master List
Working copies of the document are made from the master copy and distributed	• Quality Manager • Laboratory Supervisor	• Document Control
Discontinued working copies are destroyed	• Quality Manager	• Document Control • Document Destruction
Documents are reviewed and signed (at least annually)	• Quality Manager • Laboratory Supervisor • Laboratory Director	• Document Control • Document Review • Document Review Schedule

Process for Reviewing, Retaining, Storing, Retrieving, and Destroying Records

What Happens	Who's Responsible	Procedures
Records are created	• Any Staff Member	• Associated Pre-analytic SOPs • Associated Analytic SOPs • Associated Post-analytic SOPs
Records are listed in a Records Index	• Quality Manager	• Maintaining Laboratory Records
Records are reviewed according to established schedules	• Laboratory Supervisor • Quality Manager • Laboratory Director	• Maintaining Laboratory Records
Records are labeled, stored, and archived	• Laboratory Supervisor • Quality Manager • Any Staff Member	• Storing Laboratory Records • Record Retention
Records are scheduled for destruction. Documentation of destruction is maintained	• Laboratory Supervisor • Quality Manager	• Record Retention • Destruction of Records

Process for Modifying Records

What Happens	Who's Responsible	Procedures
The need for a change to a record is identified	• Any Staff Member	• Associated Pre-analytic SOPs • Associated Analytic SOPs • Associated Post-Analytic SOPs • Modifying Records
Modification of record is made	• Assigned Staff Member • Quality Manager • Laboratory Supervisor	• Modifying Records
Laboratory management and other appropriate individuals are notified of changes to records. Notification is documented	• Assigned Staff Member • Quality Manager • Laboratory Supervisor • Patient Care Providers	• Modifying Records
Copies of the original record, modified record, and notification documentation are maintained	• Assigned Staff Member • Quality Manager	• Modifying Records • Storing Laboratory Records • Record Retention