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I. PRINCIPLE/PURPOSE

The purpose of this policy is to provide guidelines on managing document control within the clinical laboratory.

This policy is designed to ensure that:

- All laboratory procedures/policies and related documents are generated in accordance with the laboratory's quality management system, federal regulations and accreditation requirements.
- New documents and substantial changes to these documents are controlled and handled appropriately.

Document management applies to all policies, procedures, forms, work/job aids and quality management documentation within the path of workflow.

II. RESPONSIBILITIES

It is the responsibility of the CLIA Laboratory Director to review and approve all technical policies and procedures that are new and those that already exist but have undergone substantial changes. All documents must be approved and reviewed before they can be implemented.

It is the responsibility of the laboratory area manager/supervisor to ensure that:

- All copies of policies and procedures are current and accessible
- All personnel have read the documents relevant to their job activities and ensure evidence of said review
- All new technical policies/procedures have been authorized and signed by the CLIA Laboratory Director before implementation
- All policies and procedures are reviewed at least every 2 years by the laboratory director or designee. More frequent reviews may be determined / defined by the laboratory section.
- Any changes to a document are made by authorized personnel who are listed on a delegation document.
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