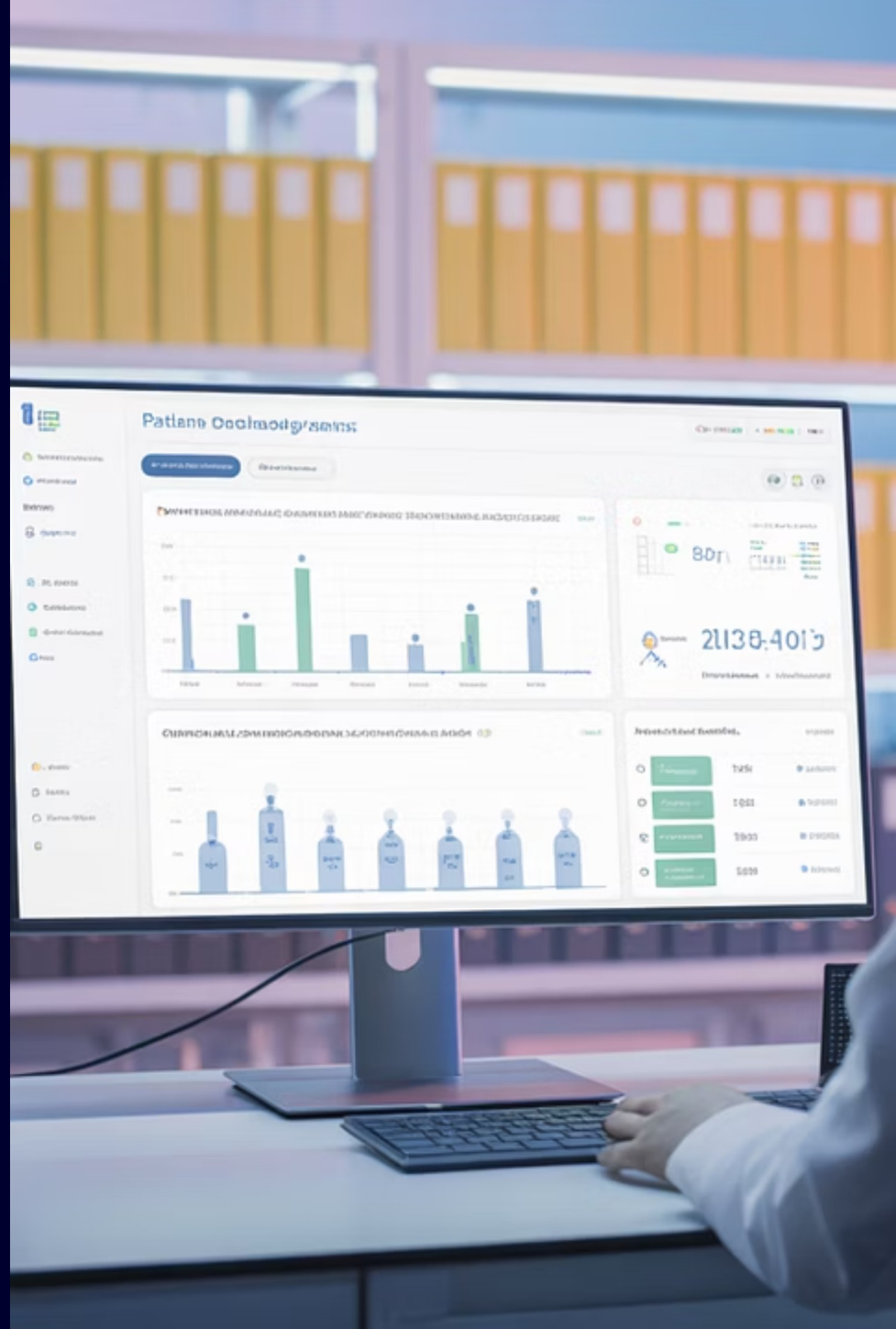
Fertility Guidance Technologies

Laboratory Document Control: Managing Policies for Compliance & Quality

This comprehensive guide provides laboratory managers and staff with essential strategies and requirements for effective document control. From systematic review processes to best practices for policy management, you'll learn how to maintain regulatory compliance while optimizing your laboratory's quality management system.



Document Control: Purpose and Scope

Why Document Control Matters

Document control is the cornerstone of quality management in clinical laboratories. It ensures that all policies, procedures, protocols, and forms are:

- Regularly reviewed and updated
- Compliant with current regulatory standards
- Approved by authorized personnel
- Accessible to staff at the point of need
- Tracked through a systematic version control process

Effective document control promotes accuracy, reduces errors, and provides evidence of compliance during inspections and audits.

Regulatory Requirements

Clinical laboratories must maintain document control to meet standards from:

- College of American Pathologists (CAP)
- Clinical Laboratory Improvement Amendments (CLIA)
- Food and Drug Administration (FDA)
- Occupational Safety and Health Administration (OSHA)
- World Health Organization (WHO)

Specifically, CAP GEN.20375 requires laboratories to maintain a document control system that ensures all policies and procedures are current, reviewed periodically, and properly approved.

Key Roles and Responsibilities

Document Owner

Initiates the review process at least biennially

Collaborates with subject matter experts to update and revise documents

Maintains accurate records of document review activities

Obtains necessary approvals and signatures

Reviewers

Verify accuracy, clarity, and compliance with applicable standards

Provide feedback and suggestions for improvement

Identify potential issues or inconsistencies

Collaborate to resolve identified issues

Approver (Lab Director)

Reviews revised documents for regulatory alignment

Confirms all concerns have been addressed

Provides necessary signature or authorization

Ensures proper implementation of approved documents

Clear definition of roles prevents document control bottlenecks and ensures accountability throughout the review process. While multiple staff members may contribute to document development, final approval authority rests with the laboratory director per CAP COM.10200.

The Document Control Procedure

Document Identification

Maintain a centralized document control system to track laboratory documents

Identify documents subject to biennial review based on regulatory requirements

Ensure derivative documents (card files, quick references) are included in the control system

Label each document with revision type, author, version number, and effective date

Document Review

Document owner initiates the review process (at least biennially)

Distribute to designated reviewers with clear instructions and deadlines

Reviewers examine for accuracy, relevance, compliance, and clarity

Consolidate feedback and collaborate with subject matter experts

Revise document to incorporate necessary changes and improvements

Document Approval

Submit finalized document to the designated approver (laboratory director)

Approver conducts final review for accuracy and compliance

Approver provides signature or electronic authorization

Communicate approved document to relevant personnel

Sign-Off and Record Keeping

Maintain records of the review process (dates, revisions, personnel)

Document is signed by owner, approver, and other required signatories

Store in centralized document management system

Maintain version history and review dates for audit purposes

When Should Laboratory Policies Be Updated?

Scheduled Reviews

- According to a predetermined schedule (typically biennial)
- Using a 1/24 monthly rotation (review 1/24 of policies each month)
- Before accreditation inspections
- As part of annual laboratory quality assessment

Event-Driven Reviews

- When a gap or issue is identified in current procedures
- Following critical or serious incidents
- When regulations or accrediting requirements change
- After equipment, process, or staff role changes

Proactive policy management requires both scheduled and responsive reviews. The most effective laboratories develop a review calendar that assigns policy updates throughout the year, preventing last-minute rushes before inspections. This systematic approach ensures continuous compliance while distributing the workload evenly across time periods.

Elements of Effective Policies and Procedures

Title and ID

Clear, descriptive name and unique identifier

Version number and document type

Dates and Approval

Signature and date of last review

Effective date clearly shown

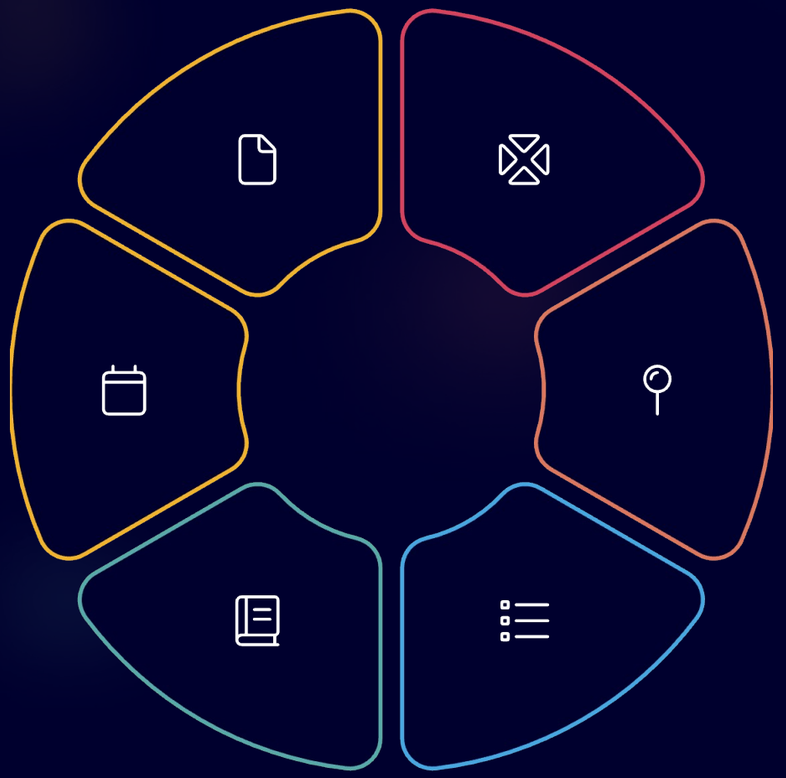
Next review date indicated

References

CAP/CLIA standards cited

Manufacturer instructions

Scientific literature when applicable



Purpose

Clearly states why the policy exists

Explains the objective and intended outcome

Scope

Defines where and to whom it applies

Identifies limitations or exceptions

Procedure

Step-by-step instructions

Clear actions and decision points

Written at appropriate technical level

Well-crafted policies are specific, clear, and written for the staff who will implement them. They avoid ambiguity and provide sufficient detail to ensure consistent performance of laboratory activities. Technical policies should be written at an appropriate level for the intended users, with consideration for training needs.

Laboratory Director's Role in Document Approval

CAP COM.10200 Requirements

The College of American Pathologists establishes specific requirements for laboratory directors regarding document control. According to CAP COM.10200, the laboratory director must:

- Review and approve all new technical policies and procedures before implementation
- Review and approve substantial changes to existing documents prior to use
- Provide a paper or secure electronic signature as evidence of approval
- Ensure policies are consistent with the laboratory's quality management system
- Verify that procedures meet regulatory and accreditation requirements

While the laboratory director may delegate some review responsibilities to qualified personnel, the final approval authority cannot be delegated.

Documentation of Approval

Evidence of the laboratory director's approval must be clearly documented. This can be accomplished through:

- Handwritten signature with date on paper documents

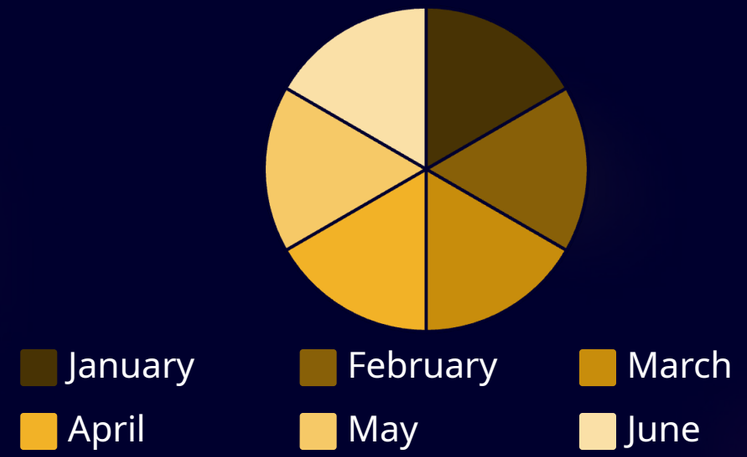
Best Practices for Policy Review Scheduling

The 1/24 Monthly Review Method

One of the most effective approaches to document control is the 1/24 monthly review method, where approximately 1/24 of all technical policies are reviewed each month. This approach offers several advantages:

- Avoids large review backlogs before inspections or deadlines
- Distributes the workload evenly throughout the year
- Ensures continuous attention to document currency
- Makes the review process more manageable for the laboratory director
- Provides ongoing opportunities to improve documentation
- Creates a regular rhythm for quality management activities

With this method, the entire policy library is reviewed over a two-year period, meeting biennial review requirements while maintaining a consistent workflow.



Sample distribution of policy reviews across first half of the year (assuming 288 total policies)

Required Documentation Elements

Reviewer Identification

Each policy or procedure must clearly show who reviewed it. This includes the name and title of all individuals who participated in the review process. For technical procedures, this must include the laboratory director or designee with appropriate qualifications.

Review Date

The date when the review was completed must be documented. This establishes the timeline for the next required review and provides evidence of compliance with biennial review requirements. The review date should be distinct from the implementation date.

Approval Signature

Documentation of approval through signature or electronic authentication is required. This can be a handwritten signature, electronic signature, or secure digital approval, but must be unique to the approver and include the date of approval.

Document Control Metadata

Each document must include metadata such as version number, revision history, effective date, and document identifier. This information ensures proper tracking and establishes which version is currently authorized for use in the laboratory.

A single signature on a cover page or table of contents is not sufficient per CAP requirements. Each policy or procedure must have individual documentation of review and approval. This ensures that each document receives appropriate scrutiny and prevents overlooking specific procedures during the review process.

Sufficient Evidence of Review

Requirement	What Qualifies	What Doesn't Qualify
Director sign-off	Paper signature or secure e-signature for each individual document	Single signature on an index or table of contents; initials without full signature; undated signatures
Version control	Document includes effective date, revision date, version number, and change history	Documents without version numbers; inconsistent version formats; undated revisions
Archiving	Discontinued documents saved for 2+ years with initial use and retirement dates recorded	Discarding old versions; archiving without dates; insufficient retention period
Availability	Current policies accessible at workbench in paper, electronic, or web-based form	Outdated versions at workstation; policies only accessible in management offices
Audit trail	Maintained log of who reviewed, approved, and edited the policy with dates	Missing review history; incomplete audit information; gaps in documentation

The laboratory must be able to produce evidence of document control during inspections. Inspectors will often request to see the complete history of a document, including past versions, review dates, and approval signatures. Electronic document management systems can significantly simplify this process by automatically maintaining audit trails and version histories.

Handling Document Changes

1 Identify Change Type

Determine whether the change is major or minor. Major changes affect the procedure's intent, scope, or scientific principles. Minor changes include formatting, clarification, or corrections that don't alter the procedure's core methodology.

Major changes require full review and approval before implementation, while minor changes may follow a simplified review process.

2 Document Revision Details

Create a clear record of what was changed, why it was changed, and who authorized the change. This information should be included in a revision history or change log within the document.

Examples of documentation include:

- Change summary in document header or footer
- Detailed change log as an appendix
- Track changes or highlighting for visibility

3 Obtain Appropriate Approvals

Secure the necessary signatures based on the type of change. The laboratory director must approve all major changes to technical procedures before implementation.

Document the approval with signatures, dates, and verification that the change has been reviewed for potential impacts on quality and patient safety.

4 Update Version Control Information

Increment the document version number according to your laboratory's convention (e.g., from v1.0 to v1.1 for minor changes or v1.0 to v2.0 for major revisions).

Update the effective date and next review date. Ensure all metadata is consistent throughout the document.

5 Communicate and Implement Changes

Notify all affected staff of the changes and provide training if necessary. Document this communication and any resulting training.

Remove previous versions from all workstations and replace with the new version. Archive the outdated version according to retention policies.

Document Archiving Requirements

Retention Periods

Laboratories must maintain archives of discontinued or superseded documents for specified periods:

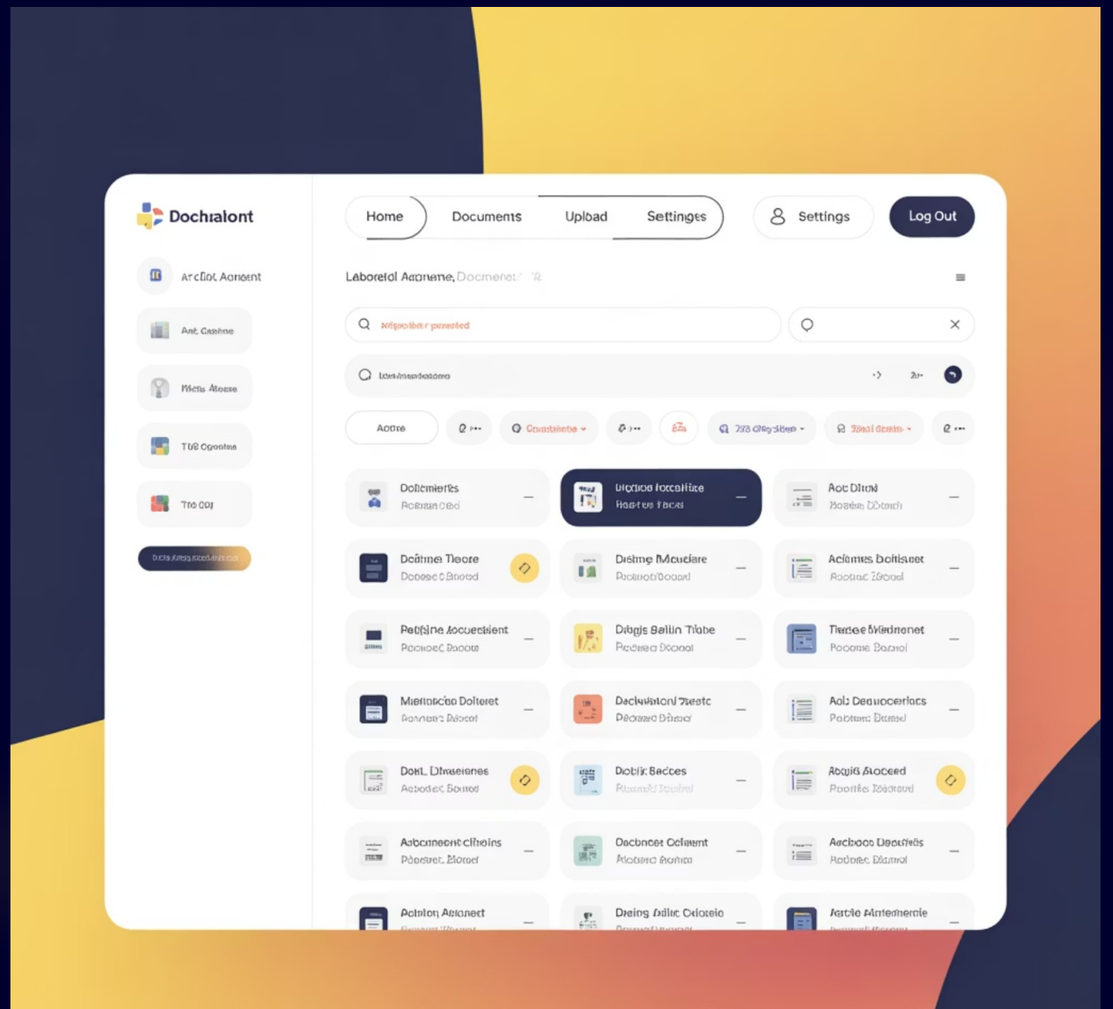
- **Minimum 2 years:** Standard requirement for most laboratory documents per CAP and CLIA
- **Test records:** Minimum 2 years, but varies by test type (some require longer retention)
- **Quality control records:** 2 years minimum
- **Proficiency testing records:** 2 years minimum
- **Equipment maintenance logs:** Life of the instrument plus 2 years
- **Personnel records:** Duration of employment plus 2 years

Some state regulations may require longer retention periods. Always follow the most stringent requirement applicable to your laboratory.

Archive Documentation Requirements

When archiving discontinued documents, you must record:

- Initial date of use (when the document was first implemented)
- Retirement date (when the document was discontinued)
- Reason for retirement (e.g., superseded by new version, procedure discontinued)
- Authorization for retirement (who approved taking it out of use)



Workbench Accessibility Requirements

Paper-Based Systems

Traditional binders or manuals containing printed procedures must be:

- Located within the immediate work area
- Organized logically by department or procedure type
- Protected from damage (water-resistant covers)
- Updated promptly when procedures change
- Regularly audited to verify current versions

Electronic Systems

Digital procedure access through computers or tablets must provide:

- Quick access without excessive login steps
- Workstations positioned within view of testing areas
- Reliable system with backup if network issues occur
- Clear indication of current approved version
- Ability to print if needed for reference

Innovative Access Methods

Modern laboratories are implementing:

- QR codes on instruments linking to relevant procedures
- Card files with condensed critical information
- Mobile device access to procedure libraries
- Digital displays embedded in work areas
- Voice-activated procedure lookups

Regardless of the access method, the key requirement is that current procedures must be immediately available to staff performing the work. Inspectors will often ask staff to demonstrate how they access procedures during routine and emergency situations.

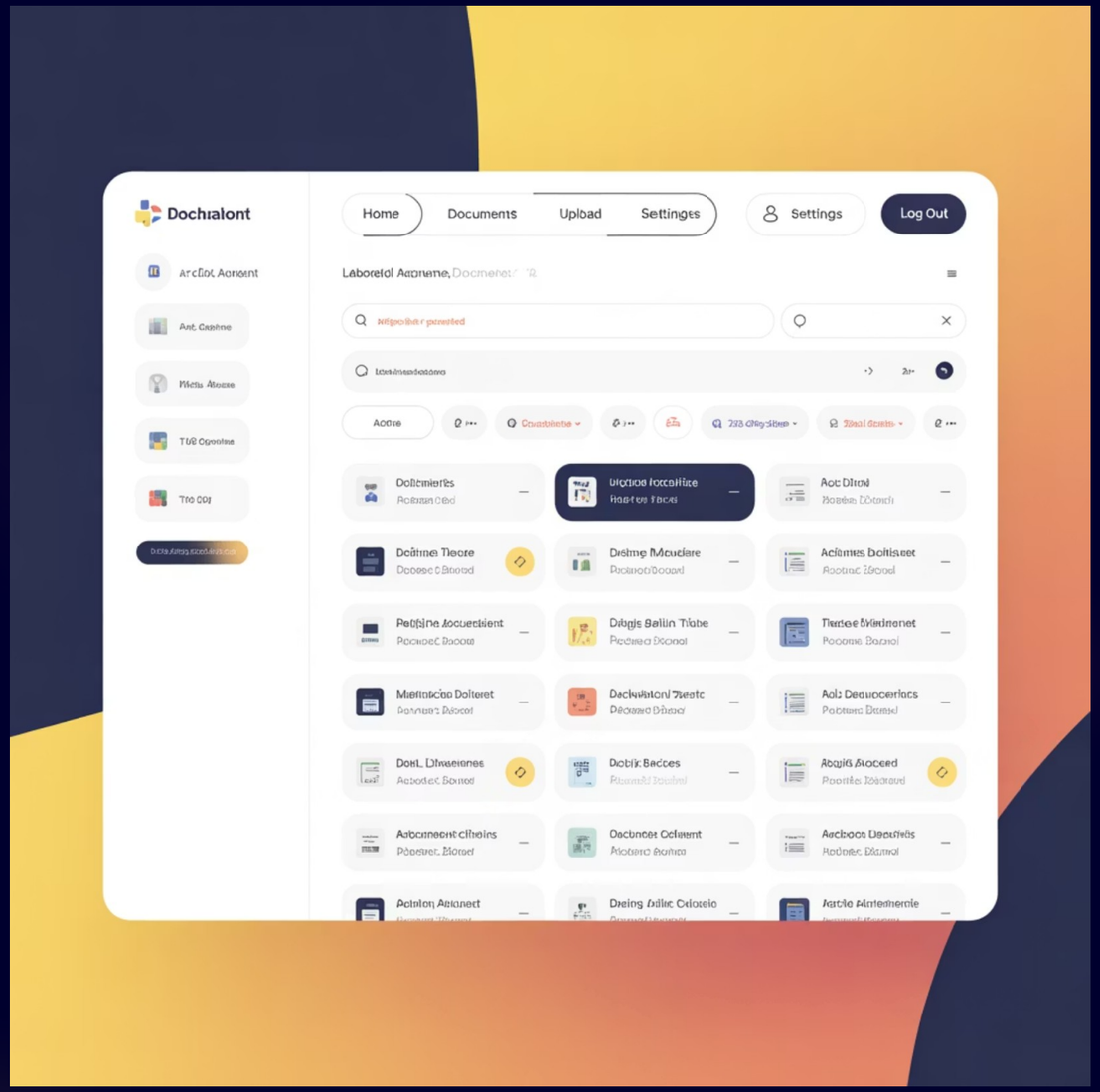
Using ART Compass for Document Control

Key Features for Compliance

ART Compass provides specialized functionality for laboratory document control:

- **Document creation:** Templates ensure consistent formatting and required elements
- **Version control:** Automatic tracking of document history and changes
- **Electronic approvals:** Secure e-signatures that meet regulatory requirements
- **Review deadline tracking:** Automated notifications for upcoming reviews
- **Document archiving:** Compliant storage of retired documents with metadata
- **Staff attestations:** "Read and understand" tracking for critical policies
- **Audit trails:** Complete history of document activity

These capabilities ensure your document control process meets CAP GEN.20375 requirements while streamlining workflow.



Implementation Best Practices

When using ART Compass for document control:

1. Establish standardized document templates for consistency

Biennial Review Process

1 Preparation (Month 22)

Two months before the biennial review deadline:

- Generate a list of documents due for review
- Assign responsible reviewers for each document
- Schedule review meetings with subject matter experts
- Gather relevant regulatory updates or changes

2 Initial Review (Month 23)

One month before the deadline:

- Reviewers assess documents for technical accuracy
- Compare procedures to current practice
- Identify gaps or opportunities for improvement
- Draft necessary updates and revisions

3 Technical Verification (Month 24)

During the final month:

- Subject matter experts validate technical content
- Quality manager reviews for compliance elements
- Finalize document revisions
- Prepare change summary for approval

4 Director Approval (End of Month 24)

By the biennial deadline:

- Laboratory director reviews final documents
- Director provides signature or electronic approval
- Document control system updated with new versions
- Staff notified of approved changes

5 Implementation (Month 1 of new cycle)

Following approval:

- Update all access points with new versions
- Archive previous versions
- Conduct training on significant changes
- Document completion of the review cycle

The biennial review process should be continuous rather than compressed into the final months. Using the 1/24 monthly review approach distributes this work throughout the two-year period, preventing last-minute rushes and ensuring thorough review of each document.

Training and Competency Requirements

Staff Training on Document Control

All laboratory personnel involved in document processes must receive appropriate training on:

- The laboratory's document control system and procedures
- How to access current procedures at the workbench
- Process for suggesting changes or improvements
- Reporting discrepancies between procedures and practice
- Responsibilities regarding document review
- Completing read-and-understand attestations

This training should be provided during initial onboarding and reinforced annually through refresher training. Any significant changes to the document control system should trigger additional training.

Competency Assessment

Document control competency should be evaluated as part of overall staff assessment. Sample competency checklist items include:

Task	Completed	Verified By
Reviewed 1/24 of technical policies this month	☐	☐
Submitted updated version with change log	☐	☐
Lab Director provided e-signature in ART Compass	☐	☐
Staff notified of policy changes	☐	☐
Archived retired version with dates	☐	☐

Documentation of completed competency assessments should be maintained in personnel records and be available during inspections.

Common Document Control Findings During Inspections

Missing Director Approval

Technical procedures lacking evidence of laboratory director review and approval is one of the most common deficiencies. This occurs when:

- Only a supervisor has signed off on technical procedures
- Group approval is used instead of individual document approval
- Electronic approvals lack proper authentication
- Approval is present but undated

Outdated Procedures

Procedures that have not been reviewed within the required timeframe (typically two years) are frequently cited. Problems include:

- No documented review date
- Review dates that exceed the biennial requirement
- Inconsistent review dates across related documents
- Procedures that don't reflect current practice

Inadequate Archiving

Failures in the archiving of discontinued documents create compliance gaps:

- Inability to produce retired versions when requested
- Missing dates of initial use or retirement
- Insufficient retention period (less than 2 years)
- Incomplete archives without all required metadata

Inspectors will often select several procedures at random and ask to see the complete history of review, approval, and revisions. They may also request to see archived versions of discontinued procedures. Laboratories should conduct mock inspections of their document control system to identify and address potential findings before official inspections.

Pro Tips for Document Control Excellence

Create a Monthly Policy Review Tracker

Develop a spreadsheet or use ART Compass to schedule and track policy reviews throughout the year. Assign specific policies to each month and set automatic reminders 30 days before reviews are due. This prevents end-of-year backlogs and distributes the workload evenly.

Example columns: Policy ID, Title, Last Review Date, Next Review Date, Assigned Reviewer, Status, Notes

Schedule Email Alerts for Review Deadlines

Configure automated email notifications to alert document owners and reviewers about upcoming deadlines. Set a series of escalating reminders at 90, 60, and 30 days before the review deadline, with final urgent alerts at 14 and 7 days. Include direct links to the documents requiring review.

Hold Quarterly Compliance Huddles

Schedule brief quarterly meetings focused specifically on document control and compliance needs. Review upcoming CAP documentation requirements, discuss any challenges with the document control process, and share best practices. This creates regular touchpoints for quality management system maintenance.

Assign a QMS Champion

Designate a Quality Management System Champion who takes primary responsibility for monitoring policy review status, audit trails, and overall document control compliance. This individual serves as the point person for questions about the document control process and helps maintain consistency across departments.

Staff Knowledge Assessment

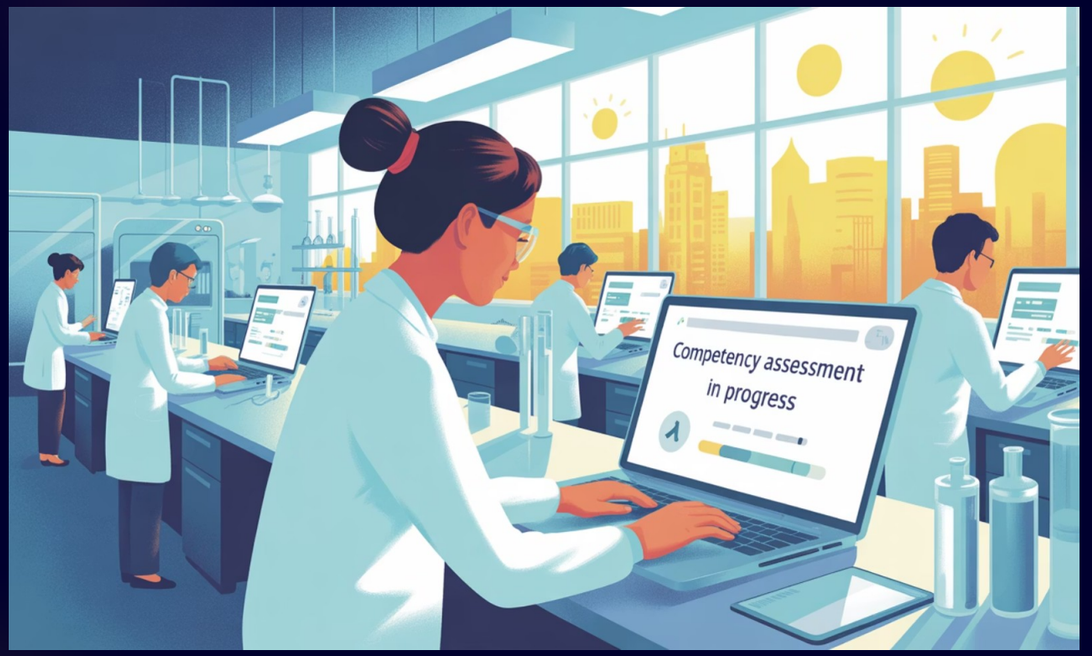
Key Review Questions

1. **When must a lab policy or procedure be reviewed?**At least biennially (every two years), and additionally when regulations change, after critical incidents, when gaps are identified, or when there are changes to equipment, processes, or staff roles.
2. **Who is responsible for reviewing and approving technical procedures?**The laboratory director must review and approve all technical policies and procedures, as well as substantial changes to existing documents, before implementation.
3. **What makes a policy "effective"?**An effective policy includes a clear title, purpose, scope, step-by-step procedure, references, review/approval signatures, and effective/review dates. It should be specific, clear, and written for the staff who will implement it.
4. **How long must you retain discontinued procedures?**Discontinued or superseded documents must be retained for a minimum of 2 years, with documentation of initial use and retirement dates.
5. **Why is a single signature on the index page not acceptable?**CAP requires evidence of review and approval for each individual document to ensure proper scrutiny of each procedure. A single signature does not demonstrate that each document received appropriate review.

Competency Demonstration

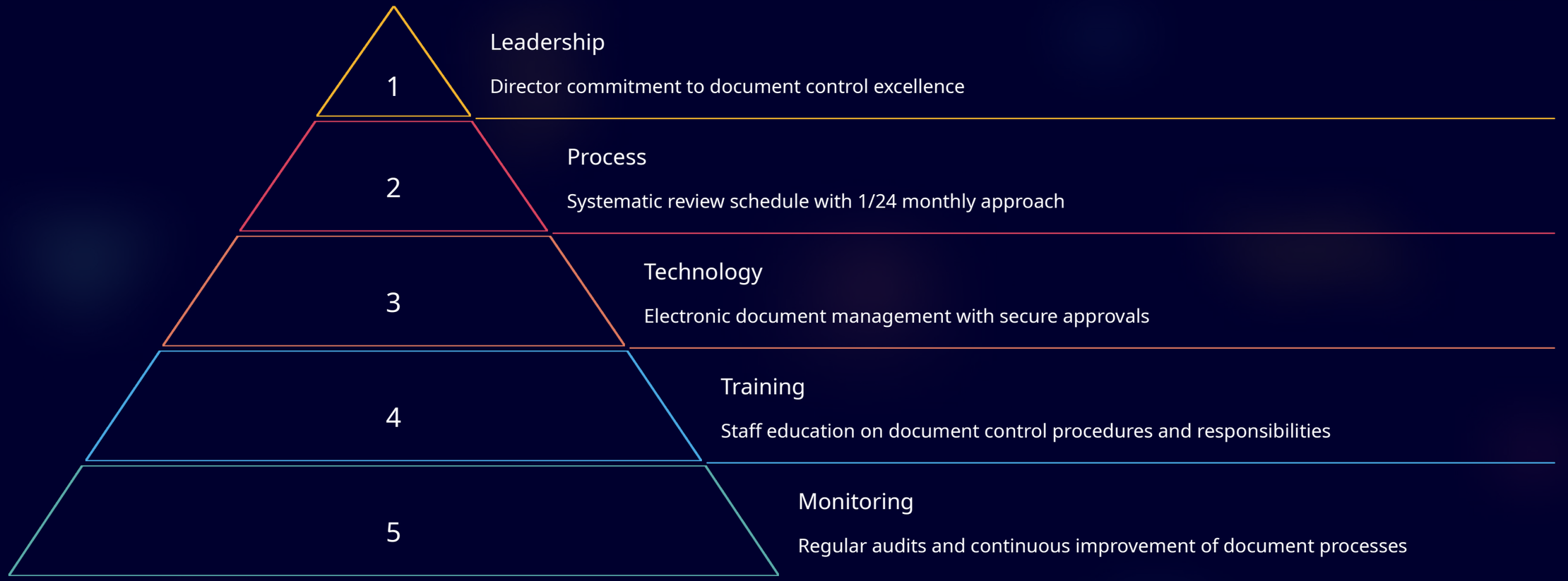
In addition to answering review questions, staff should be able to demonstrate:

- How to access current procedures at their workstation
- The process for suggesting changes to a procedure
- Where to find the effective date and version number on a document
- How to complete read-and-understand attestations
- The proper handling of outdated procedure copies



Document control knowledge should be assessed during initial training and annually thereafter. Documentation of this assessment should be maintained in personnel records as evidence of ongoing competency.

Summary: Keys to Document Control Success



Effective laboratory document control is not just about regulatory compliance—it's about ensuring patient safety, maintaining quality, and supporting efficient operations. By establishing robust processes for document creation, review, approval, and archiving, your laboratory builds a foundation for excellence in all aspects of testing and service delivery.

Document control should be viewed as an ongoing process rather than a periodic task. With proper leadership commitment, staff training, and technological support, your laboratory can transform document management from a compliance burden into a strategic advantage.

Remember that the ultimate goal is to ensure that laboratory staff always have access to current, accurate procedures that reflect best practices and regulatory requirements. When this goal is achieved, compliance naturally follows.