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# Considerations for the Paperless Laboratory

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# Presentation Overview

- 1) Identify The End Goal of being Paperless
- 2) Identifying critical documentation areas within the laboratory
- 3) Classify the document groups/types
- 4) Common Methods for E-Doc storage
- 5) Examining each document class using examples of documents routinely encountered
- 6) Deciding on actual paperless storage method
- 7) Identifying actual storage formats

# Define the Objective

## Paperless Has a Purpose

- Examples of Common Needs
  - Environmentally Friendly
  - Common and Centralized Storage
  - Ability to Data Mine and Retrieve easily
  - Research and Project Organization
  - Regulatory Compliance
  - Ease of Access

# Common Methods

## Common Methods for Electronic Document Storage:

- Scientific Data Management System (SDMS)
- Laboratory Information Management System (LIMS)
- Cloud Based Structural Storage
- Local Area Network structural Storage

# SDMS Method

## Why SDMS?

1. Designed specifically for Scientific Electronic Document Organization
2. Routinely provides ability for collaboration and project based research and organization
3. It is sole focused

## Why Not SDMS?

1. Potentially expensive for a sole task
2. One more system to maintain and interact with

# Cloud Based Method

## Why Cloud?

1. Documents are stored off site (Disaster Recovery)
2. Very Flexible Design
3. Access from anywhere on the web

## Why Not Cloud?

1. Flexible design means you must design your own.
2. Potential Security Issues

# LAN Method

## Why LAN?

1. Documents are stored within Network making them secure
2. Very Flexible Design
3. Access from anywhere in the network while providing permissions controls

## Why Not LAN?

1. Flexible design means you must design your own.
2. Security Controls require management from IT

# LIMS Method

## Why LIMS?

1. Some Modern LIMS Allow for uploading of e-docs
2. Centrally stored and accessible
3. Cloud hosting may be possible
4. Likely already in use for routine operations

## Why Not LIMS?

1. LIMS may not have capacity



# Areas Affected

Once Storage Method has been decided its time to break the laboratory down into structural/functional areas where e-docs would exist

- Field Operations and Sample Collection
- Laboratory Receipt
- Laboratory Testing
- Results Submission and Reporting

# Classify Retained Documents

- 1) Common Laboratory Document Types
  - Sample Collection Information (Chain of Custody)
  - Field Observations and On-Site Testing Results
  - Site Imagery
  - Sample Preparation Logs
  - MSDS and Standard COAs
  - Sample Analysis Logs (Bench Sheets)
  - Instrument Outputs and Summaries
  - Review and Approval Documents
  - Certificates of Analyses and/or Deliverables

# Stored Document Format

Knowing what to store and where to store is key.

Then consider the format for the file?

- Consider ability of document to be edited
  1. .pdf, .tif, or image-like format reduces likelihood of editing.
- Consider who will be using the file in the future
  1. Instrument files requiring specific software to view can be problematic in the future
    - Consider export to common format

# Process Integration

Once the overall method has been defined, documents identified and storage formats finalized:

Its time to consider process integration

- User Roles responsibility at specific points in work cycle
- Checks must exist to verify that critical documents have been preserved
- Document your Document Procedures

## The Time Cost of Technology

- Complexity consumes time
- Creating necessary traceability can be complex
- These considerations provide justification for single system approach

# Disaster Recovery

Depending on the method of storage selected, recovery of electronic files needs to be considered before going live.

- Plan for Disaster Recovery Now
- If storage location is on site – determine backup frequency and off site backup storage
- If offsite (cloud or central IT), verify frequency and recovery is possible.
- Floods and Fire have the same affect on computers as they do on paper.

# Final Considerations

- Evidence vs. Traceable
  - Think about whether the file has to have a signature (Chain of Custody: Relinquish vs. Receipt)
    - Is a Scan of a signature acceptable or is the actual signature on paper required
    - Electronic Signature can be enforced by a system and can be an image of a signature or digital certificate.
      - Will these signature methods meet your regulatory needs?

# Keys to Success

- Prior to Beginning:
  - Identify all document classes
  - Determine file types best suited to need
  - Always consider e-sig requirements
  - Consider impact to current operations
- Once Underway:
  - Document The Process
  - Perform Routine Reviews to ensure adherence



# Questions and Answers

- Q&A