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Deciphering Document Control

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- **A organized and secure process to effectively manage the large quantities of data created in a laboratory.**

- **Laboratory Compliance**
- **Quality Management System**





REGULATIONS: ISO17025(2017)

- **7.5 – Technical records**
- **8.2 – Management system documentation**
- **8.3 – Control of management system documents**
- **8.4 – Control of records**





REGULATIONS: TNI(2016)

Volume 1, Module 2, Section 4 – Quality System Requirements

- 4.2.8.4.f: Quality Manual
- 4.3.1 : General
- 4.3.2: Approval and Issuance
- 4.3.3: Document changes





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REGULATIONS: EPA(2005)

- **8.1: Legal defensibility**
- **8.2: Maintenance of records**
- **8.3: Sampling records**
- **8.4: Analytical records**
- **8.5: Reconstruction of data**
- **8.6: Computer programs**





REGULATIONS: CLIA(1988)

- **493.1105: Record Retention**
- **493.1251: Procedure Manual**
- **493.1283: Test Records**

**** All records must be accessible and retrievable****





TOP DEFICIENCIES

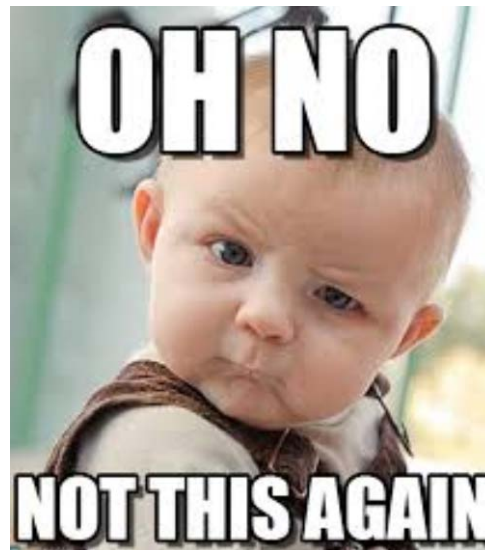
- **CLIA:**
 - Procedure manual deficiencies (various)
 - Maintenance records (various)
 - Lack of PT review by Director
 - Test reports lack required content
 - Method validations lack Director approval
- **TNI**
 - Lack of clear document control process
 - Failure to properly store records
 - Insecure spreadsheets and not validated
 - Failure to have a master list of current forms
- **ISO**
 - Lack of a process to effectively control records
 - Revision and edits to records and forms not approved prior to use
 - Failure to maintain original worksheets
 - Master list not up to date
 - Using obsolete procedures or forms
 - Forms lacked unique identification





PROBLEM/CONSEQUENCE

- **Problem**: Employees did not use the most current version of a work form.
- **Consequence**: Auditor identified the lapse and lab was cited.





PROBLEM/CONSEQUENCE

- **Problem**: Spreadsheet formulas were not locked or verified.
- **Consequence**: Root cause analysis and corrective action to prevent the occurrence in the future was done. Sample results were assessed and amended reports were issued, as needed.





PROBLEM/CONSEQUENCE

- **Problem**: Competency assessment paperwork was not readily available to an assessor.
- **Consequence**: Unable to prove compliance with training regulation and citation issued.





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PROBLEM/CONSEQUENCE

- **Problem**: SOPs were not edited, reviewed and approved by the Director before the review date.
- **Consequence**: Lack of compliance with the quality management system. All affected groups were required to complete a corrective action and monitor SOPs for the next year to minimize this occurrence.





PROBLEM/CONSEQUENCE

- **Problem**: Employee was trained on an obsolete version of an SOP.
- **Consequence**: The procedure was performed incorrectly affecting multiple patient results. Time was spent correcting the error.





PROBLEM/CONSEQUENCE

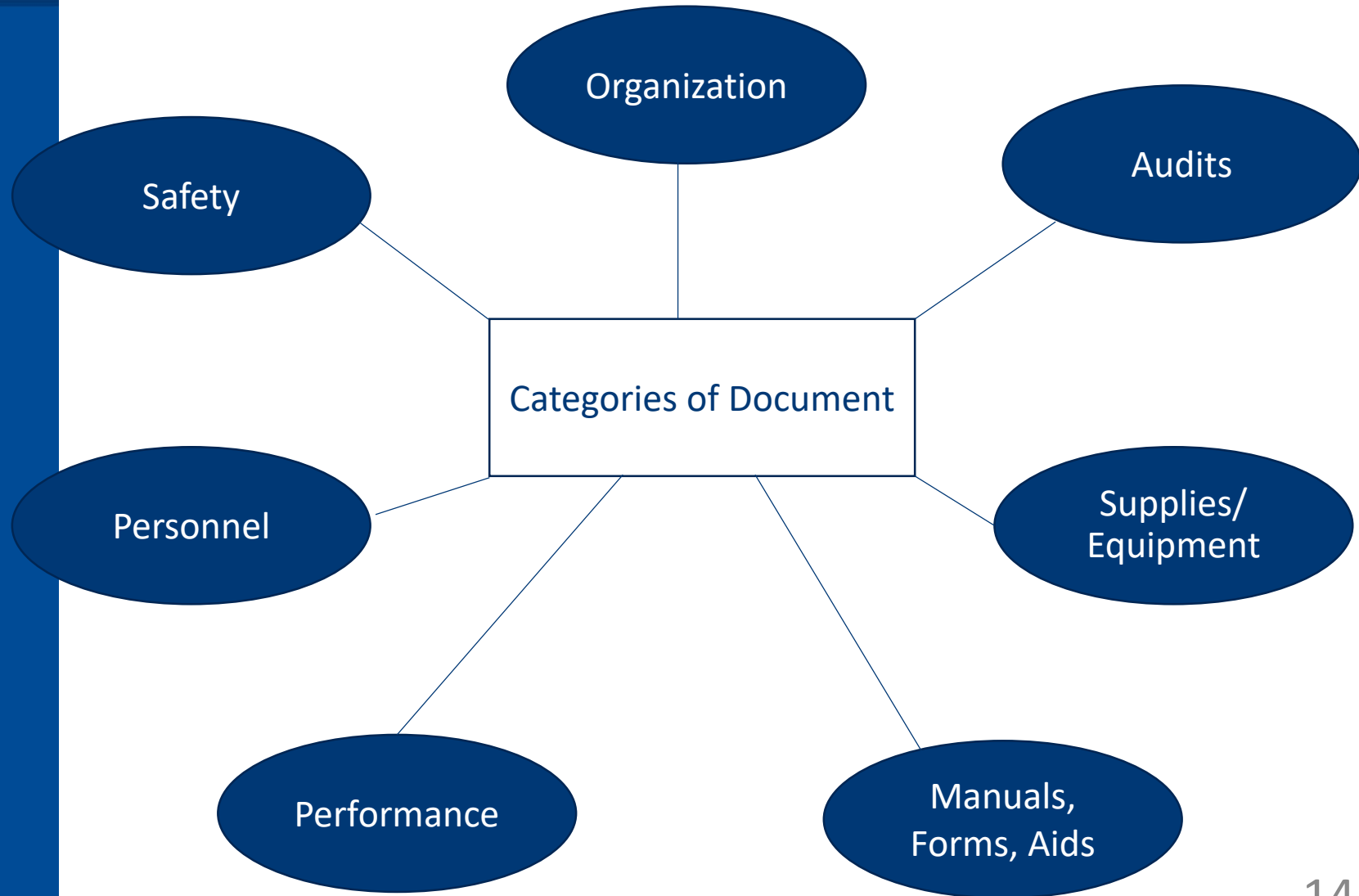
- **Problem:** Approved forms were altered.
- **Consequence:** Not all employees were collecting the same information during testing. Additionally, it resulted in a non-conformance during an audit.





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DOCUMENT CATEGORIES





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PERSONNEL



- Training
- Competency
- Qualifications
- Job/position descriptions

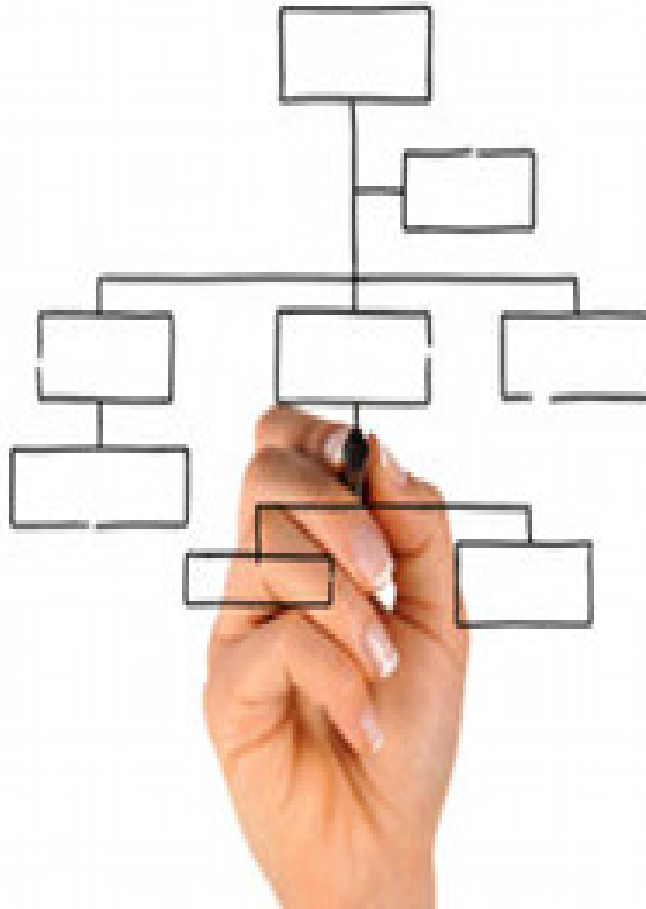




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ORGANIZATION



- **Organizational Charts**
- **Inspection/ accreditation records**
- **Quality plan**
- **Provision of service plan**



SAFETY

- Accident reports
- Chemical hygiene plans
- Biohazardous waste disposal plan
- Shipping/handling of biological substances
- Infection control plan





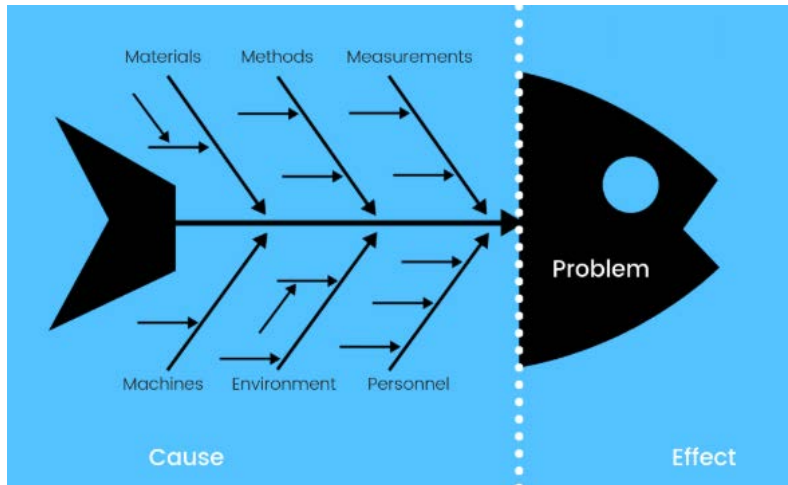
AUDITS

- Internal audits



- External audits

PERFORMANCE DOCUMENTS



- QA records
- Performance improvement records
- Reporting errors/accidents
- Root cause analysis
- Corrective action plans



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SUPPLIES AND EQUIPMENT DOCUMENTS



- Identification
- Inventory lists
- Validation records
- Maintenance checks
- Quality control records



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MANUALS, FORMS, AIDS



- Policies
- Processes
- Procedures
- Job Aids
- Records



ISO AND TNI DOCUMENT TYPES

- **Technical records:**
 - Results
 - Reports
- **Documents include:**
 - Policy statements
 - Procedures
 - Specifications
 - Manufacturer's instructions
 - Calibration tables
 - Charts
 - Text books
 - Posters
 - Notices
 - Memoranda
 - Drawings
 - Plans





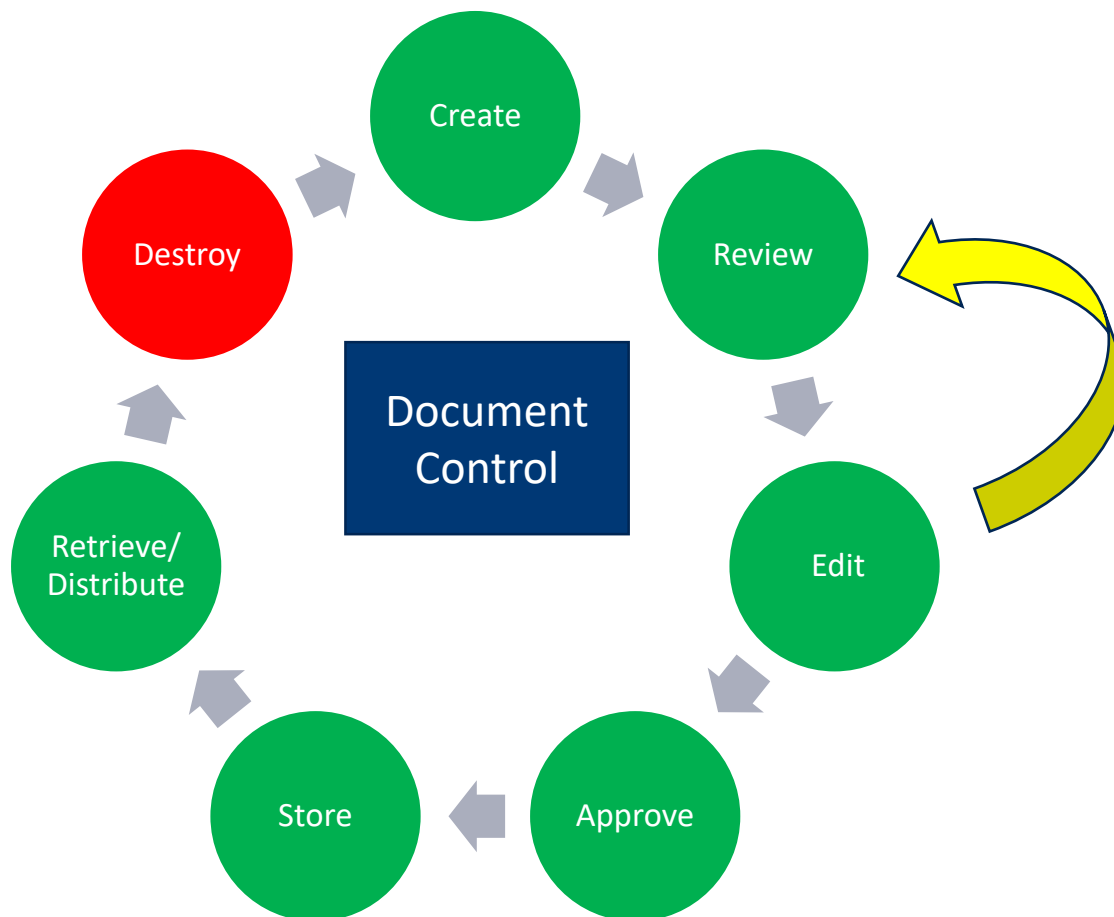
DOCUMENT CONTROL METHODS

- **Manual**
- **Electronic**
- **Manual and Electronic**





PHASES OF DOCUMENT CONTROL





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ADVANTAGES



- **Ensure procedures and processes are approved by the Director**
- **Maintain compliance with accreditation agencies**
- **Strengthen work process and reduce lab errors**
- **Minimize unauthorized changes to documents**
- **Provide data traceability and bolster data integrity**
- **Link documents to specific procedures and processes**
- **Automation of tasks using templates**
- **Encourage innovation**



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CHALLENGES

- **Training**
- **Difficult to ensure compliance with the document management process**
- **Loss of the master copy**
- **Altering approved forms**
- **Can be time consuming**





PERSONAL SUCCESSES

- **Standardized workflows and consistent processes**
- **Electronic reminders**
- **Monitor metrics**



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