LABORATORY QUALITY SYSTEM FILE STRUCTURE

Getting on top of your quality records from the start will stand you in good stead for a successful assessment. While it seems like a simple thing, many laboratories make it too complicated and some even end up having difficulties with NATA because of lost records.

Setting up a system that the people who follow after you can understand and continue will save time and money in the future!
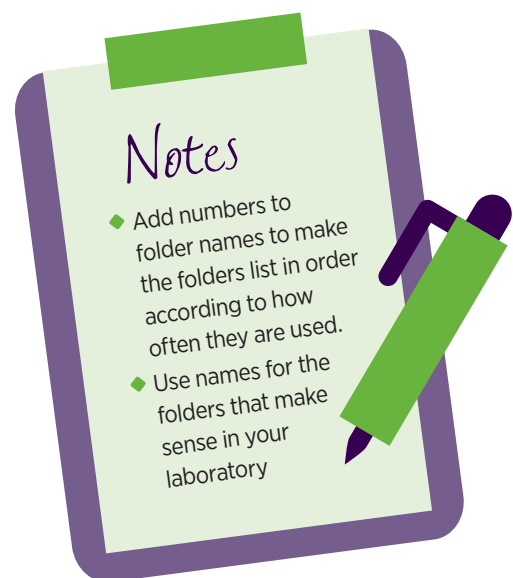
TOP LEVEL

- ▾ Laboratory Management System
  - › 1 Forms
  - › 2 Procedures_Quality Manual
  - 3 Standards External Documents
  - › 4 Equipment Records
  - 5 Proficiency Testing QAA
  - › 6 Quality Improvement Program (QIP, NCA, CAPA)
  - › 7 Lab Meeting Minutes
  - 8 MSDS
  - 9 Preferred Suppliers
  - 10 Staff Training Records
  - › 11 Internal Audits
  - 12 Customer Survey Results
  - 13 Management Reviews
  - › 14 NATA Correspondence
  - 15 Projects and Planning
  - 16 Site Laboratory QA Records

GENERAL PRINCIPLE

Operational records (i.e. project files and records of testing) are not included in this file structure. Most laboratories have already developed their own job numbering system that dictates where these records are kept.

Notes

- Add numbers to folder names to make the folders list in order according to how often they are used.
- Use names for the folders that make sense in your laboratory

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The filing system explained here is drawn from lean principles, in particular 5S. If you know 5S you know that its real purpose is to identify abnormalities. Having orderly files, with consistent naming, means you will notice straight away if something is missing or out of place. Read more about 5S here*.

CONTROLLED DOCUMENTS

- ⌄ 📁 2 Procedures_Quality Manual
  - › 📁 Drafts
  - › 📁 Superceded & Withdrawn
  - 📄 DOC 001 Document Management V1.0.docx
  - 📄 DOC 002 Management Review V1.0.docx
  - 📄 DOC 003 Management Review Agenda V1.0.docx
  - 📄 DOC 004 Management Review Minutes V1.0.docx
  - 📄 DOC 005 Handling Complaints Incidents V1.0.docx
  - 📄 DOC 006 Internal Audit Blank Checklist V1.0.docx
  - 📄 DOC 008 Annual Competency Assessment V1.0.docx
  - 📄 DOC 009 Training and Competency Assessment V1.0.docx
  - 📄 DOC 010 Orientation Checklist V1.0.docx
  - 📄 DOC 011 Training Checklist V1.0.docx
  - 📄 DOC 012 Internal Audits V1.0.docx
  - 📄 DOC 013 PEC Report V1.0.docx
  - 📊 Document Register.xlsx

EQUIPMENT

- ⌄ 📁 Equipment
  - ⌄ 📁 Equip ID 1
    - 📄 20170310 Equip ID 1 Calibration.docx
    - 📄 20170911 Equip ID 1 check.docx
    - 📄 20180305 Equip ID 1 Calibration.docx
    - 📄 20180915 Equip ID 1 check.docx
    - 📄 20190401 Equip ID 1 Calibration.docx
    - 📄 20190925 Equip ID 1 check.docx
    - 📄 20200315 Equip ID 1 Calibration.docx
    - 📄 20200915 Equip ID 1 check.docx
  - 📁 Equip ID 2
  - 📁 Equip ID 3
  - 📁 Equip ID 4
  - 📁 Equip ID 5
  - 📁 Equip ID 7
  - ⌄ 📁 Out of Service
    - 📁 Equip ID 6

GENERAL PRINCIPLE

By having orderly filing systems and clear naming conventions, you can avoid the need for registers.

STAFF RECORDS

- ⌄ 📁 10 Staff Records
  - 📁 Ann Robins
  - 📁 Bill Smith
  - 📁 Joe Black
  - 📁 Marie Hay
  - 📁 Mary Brown
  - 📁 Peter Green
  - 📁 x Staff (departed staff members)

Contains induction, training and competency assessments. Using the naming convention with yyyymmdd at the beginning of the filename (as shown for the equipment records), these will sort neatly, showing the employment history for the staff member.

GENERAL PRINCIPLE

Avoid having to click into too many sub-folders by naming files with the date at the beginning of the filename, followed by a simple and clear name for the content.

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ACCREDITATION