# Quality Assurance Documentation

## Procedures and Records

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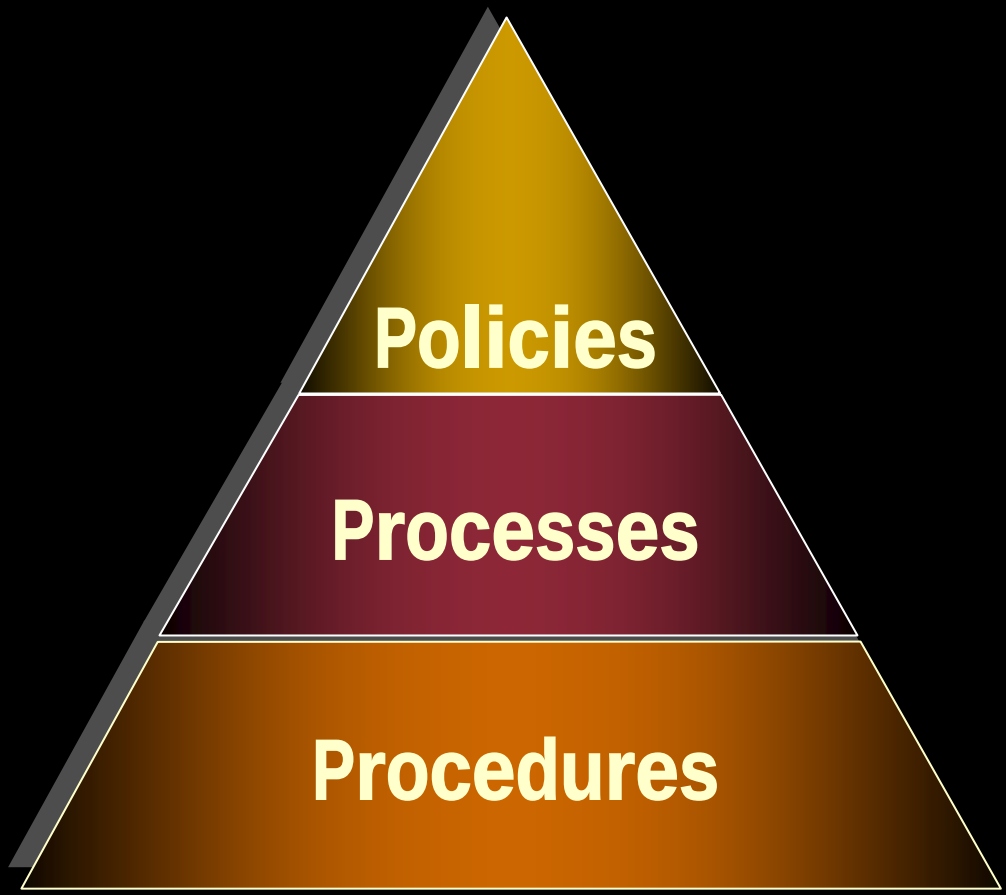
# Quality System Documentation



# Purpose

- Ensure consistency of laboratory operations in the pursuit of quality
- Train new laboratory personnel
- Troubleshoot problem areas

# Procedure Manual

A collection of written policies that establishes acceptable procedures for the laboratory

# A Technical Procedure must include:

- Title
  - Descriptive of test performed
- Principle
  - Clinical Reasons for performing the test
- Specimen requirements
  - Criteria for specimen collection, labeling, rejection, storage, transport
  - Procedures for submission to central labs
  - Procedures for microscopic examinations

# A Technical Procedure must include:

- Reagents or Media, Supplies, Equipment
  - Preparation of reagents, stains, or other materials used in testing
  - Storage Requirements
- Calibration (If applicable)
  - Frequency, step-wise instructions

# A Technical Procedure must include:

- Quality Control
  - Identify control materials to use
  - Preparation, handling, and storage
  - Frequency of testing
  - Expected results
  - Corrective actions
  - Recording and storage of QC data
  - Alternatives (If no QC materials are available)

# A Technical Procedure must include:

- Step-by-step instructions
  - Quantitative Testing
  - Qualitative Testing
  - Interpretation
- Calculations (if applicable)

# A Technical Procedure must include:

- Reporting Results
  - Reference intervals
  - Procedures for reporting abnormal results
  - Reporting format
- Procedure Notes
  - Special precautions
  - Possible sources of error
  - Answers to common problems

# A Technical Procedure must include:

- Limitations of Methods
- A troubleshooting or back-up plan
- References
- Effective Date
- Signature of Laboratory Director

# Procedure Manual: Layout

- No set format
  - Should be determined by the lab's needs and organization
  - Job Aids
    - Loose-leaf binder, Card Index System
    - Flow Diagrams, Poster
- Clearly presented in a language familiar to all
- Should be easily accessible
- Expected to be used

# Resources

- Manufacturer’s product inserts
- NCCLS PG2-A2
- Journals
- Publications
- Textbooks
- Research and validation

# Why Record?

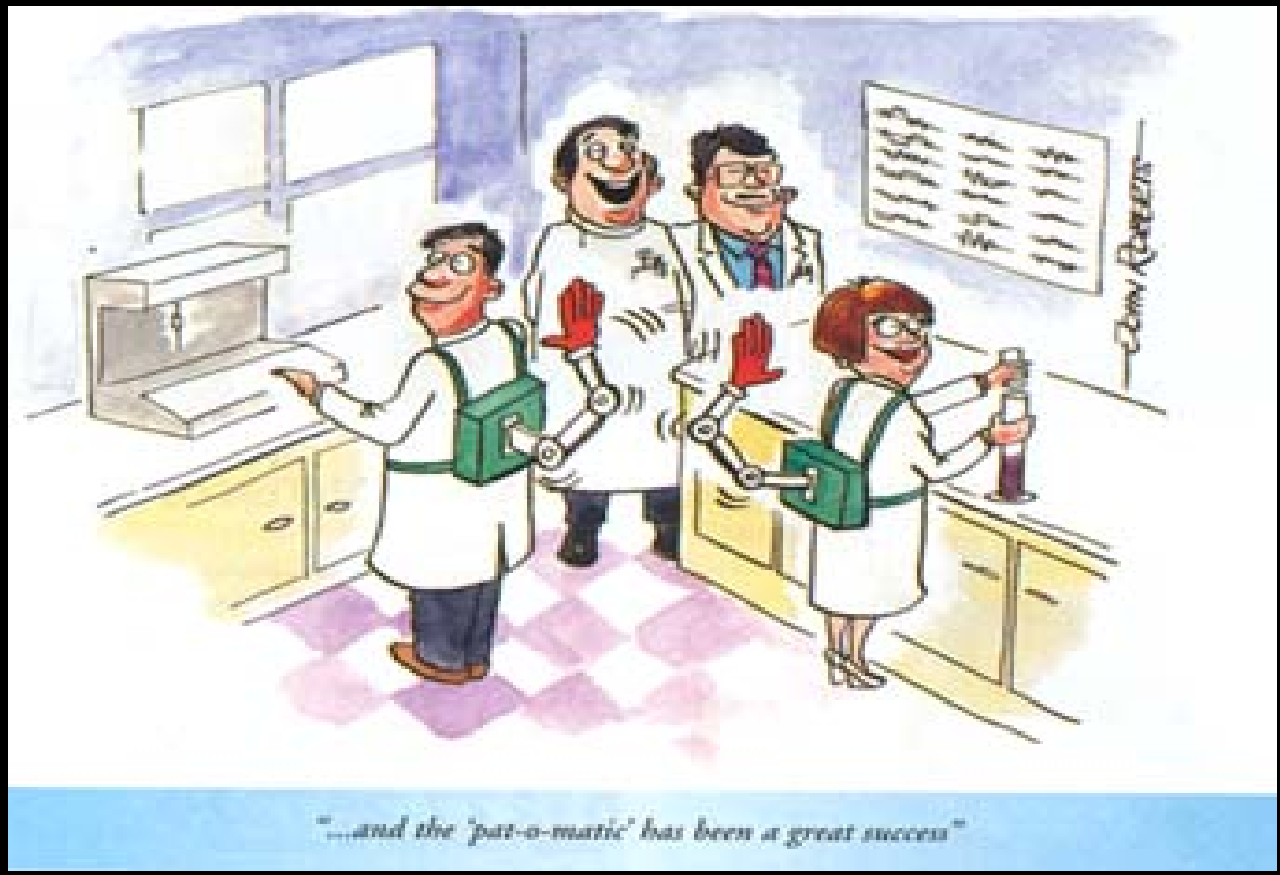
- Minimized chances of error through clarity of instructions – Technical Procedures
- Sharing of information
- Revisit information; reference
- Quality Assurance monitoring
  - continuous action/service
- Management tool
  - Policy and planning

# QA Records

- Technical procedures
- Specimen log book
- Laboratory workbooks/sheets
- Instrument printouts – Maintenance records
- QC / EQA records
- Personnel
- Patient test reports
- Quality improvement records

# Summary: Effective Recording

- Focus on accuracy and detail
- Focus on clarity and legibility
- Check ! Recheck!
- Never assume. Verify and validate
- No short cuts. Follow standardized procedures
- Always focus on testing objective
  - Patient Management
  - Public Health Management


"...and the 'pat-o-matic' has been a great success"