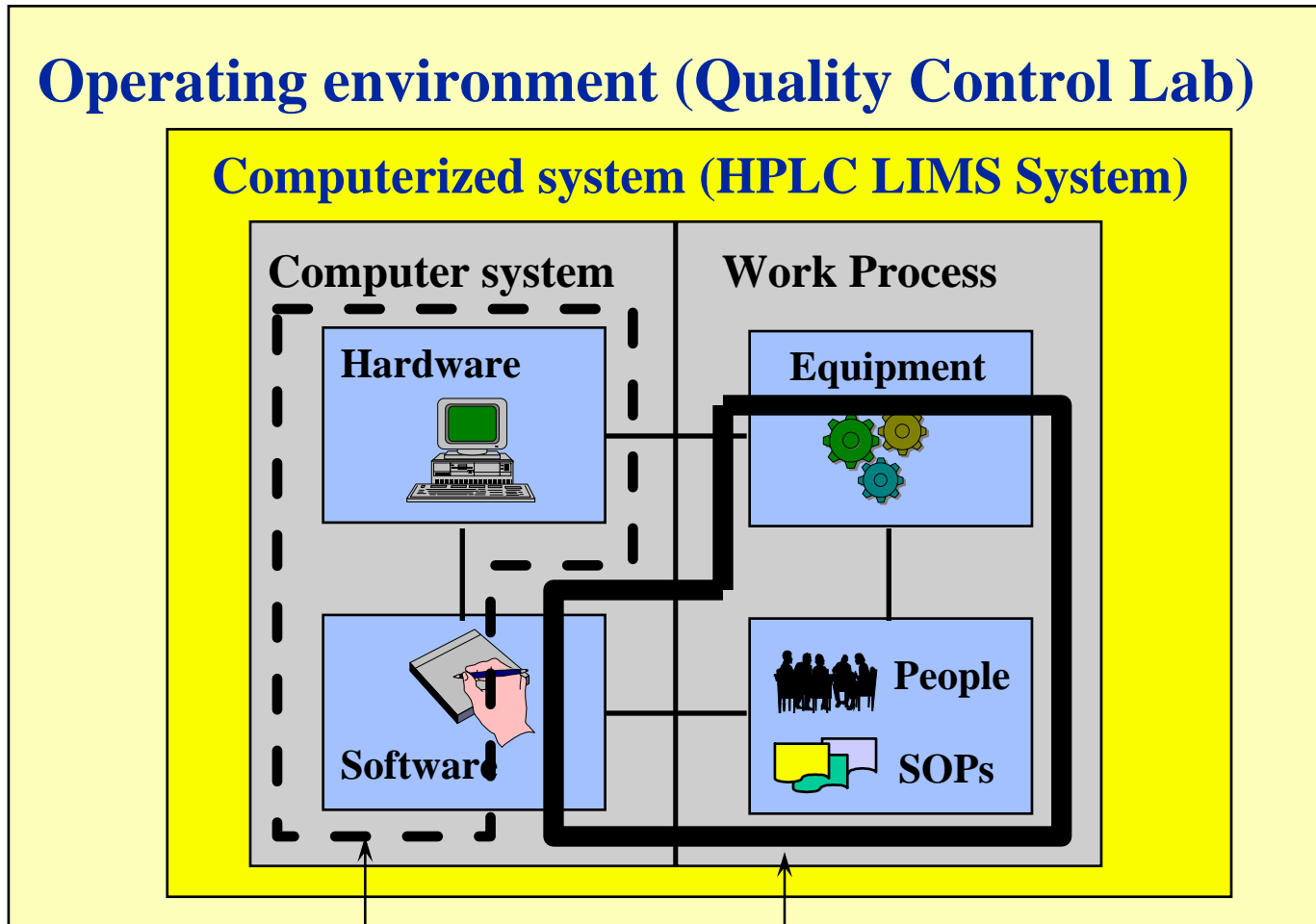# *ASQ FD&C GMP Quality Conference*

End User Testing for Performance Qualification of GXP/ Part 11 Systems – Off The Shelf (OTS)
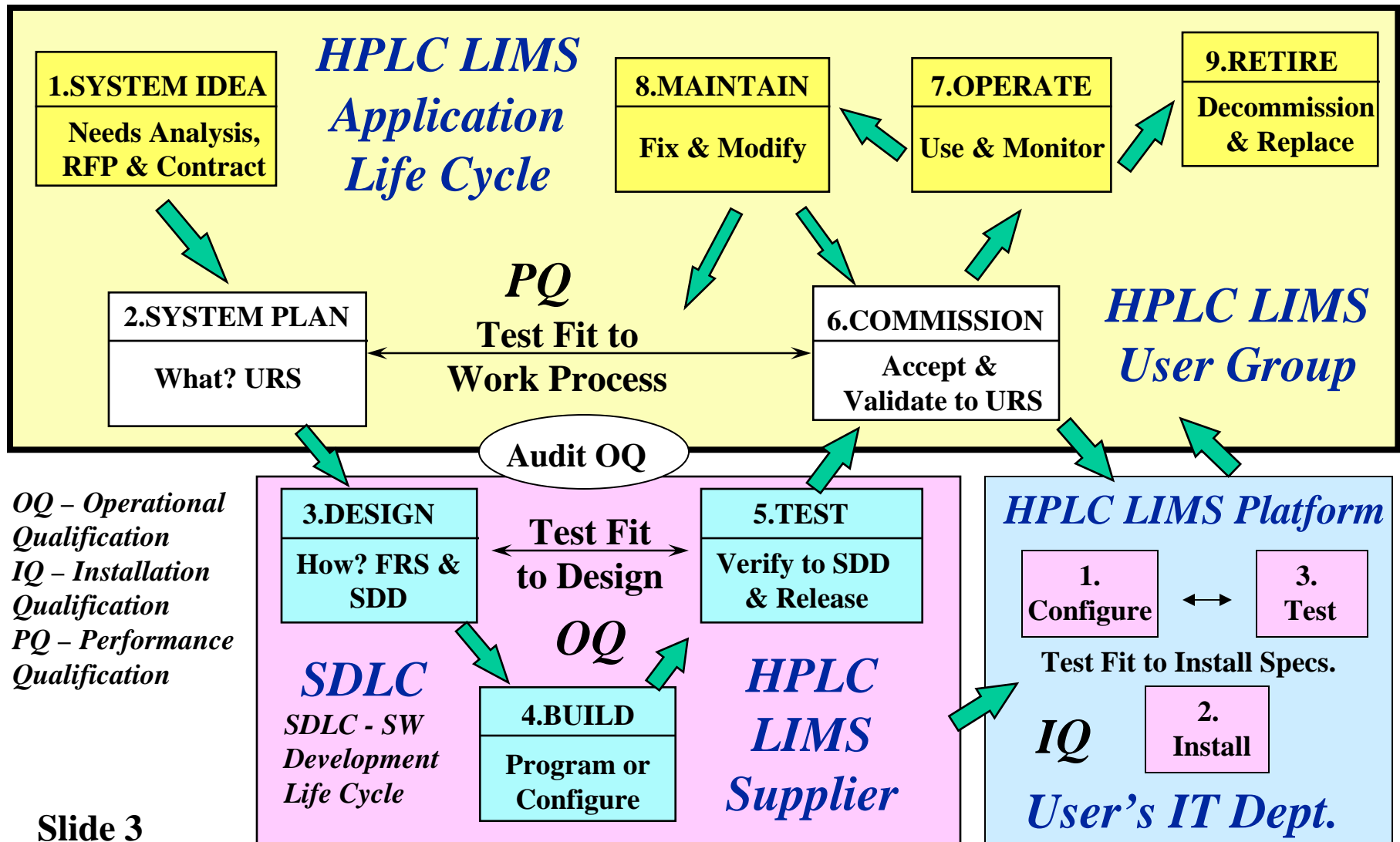
Dr. Teri Stokes, <u>GXP</u> International,
Concord, MA – USA

www. GXPInternational.com
Email: GXPINTL@RCN.com

Context for Computer Validation Testing

Operating environment (Quality Control Lab)

Computerized system (HPLC LIMS System)

Computer system

Work Process

Hardware

Equipment

Software

People

SOPs

Infrastructure Platform (IT/IQ)   **Software Application (User/PQ)**

User Acceptance at System Go-Live

HPLC LIMS Application Life Cycle

1.SYSTEM IDEA
Needs Analysis, RFP & Contract

2.SYSTEM PLAN
What? URS

8.MAINTAIN
Fix & Modify

7.OPERATE
Use & Monitor

9.RETIRE
Decommission & Replace

HPLC LIMS User Group

PQ
Test Fit to Work Process

6.COMMISSION
Accept & Validate to URS

Audit OQ

OQ – Operational Qualification
IQ – Installation Qualification
PQ – Performance Qualification

3.DESIGN
How? FRS & SDD

Test Fit to Design

5.TEST
Verify to SDD & Release

HPLC LIMS Platform

1. Configure ↔ **3. Test**

Test Fit to Install Specs.

SDLC
SDLC - SW Development Life Cycle

4.BUILD
Program or Configure

OQ

HPLC LIMS Supplier

2. Install

IQ
User's IT Dept.

Slide 3

Change Control and Ongoing Testing

Application Life Cycle

1.SYSTEM IDEA
Needs Analysis, RFP & Contract

2.SYSTEM PLAN
What? URS

Test Fit to Work Process

8.MAINTAIN
Fix & Modify

7.OPERATE
Use & Monitor

9.RETIRE
Decommission & Replace

6.COMMISSION
Accept & Validate to URS

System User

SDLC
SDLC - Software Development Life Cycle

3.DESIGN
How? SDD

Test Fit to Design

5.TEST
Verify to SDD & Release

4.BUILD
Program or Configure

Software Supplier

1.
Change

3.
Test

Test Fit to Design & Work

2.
Install

Platform Systems

Change Symbol

Application User's PQ* Package

Prepared and maintained by User Department(s) Team

Standard user's CSV package

QMS

Validation Plan

Applic. Admin. SOPs & Applic. Config. Mgt. Logs

Test Plan(s) Startup & Ongoing

Needs Analysis, RFP, Contract, URS, SLAs

Test Cases, Scripts, Data & Result Logs

Trace

Change Control Log, QA Audit Log, Supplier Reports & BDG Minutes

Test Summary Report(s)

User Manuals, CVs, Trng Records, Dept. SOPs, WIs, Help Logs

System Control

Testing Control

Human Control

Users' PQ Package Summary Report

*PQ = Performance Qualification: Application meets URS workflows

CSV Package Team Model

Package Sponsor

Funds and Approves Validation Work

Team Leader
(Project Mgr.)

Quality Assurance

Package Manager
(QC of Pkge. Docs.)

Trains Team and Audits CSV Pkg.

CSV Package Team

Ad hoc Members
(Tester, Witness…)

Team to Develop and Maintain a CSV Pkg.

Test Coordinator
(Test Plan, Scripts…)

Requirements are required for testing.

All formal testing requires a metric or benchmark (e.g. requirement) to test against. If you don't know your "expected results" then testing is meaningless and validation is not possible.

α ω
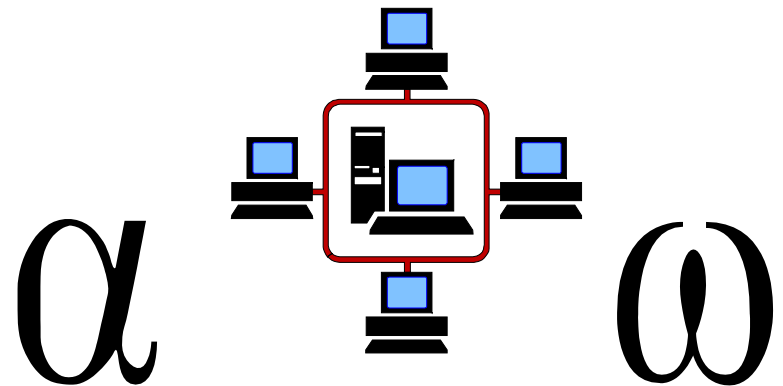
What do you need in a system?

IQURS

Identify infrastructure needs

PQ URS

Identify work process needs

Requirements

Do You Have a Requirement or a Wish?

Can it be tested?

Yes = Requirement

NO = Wish
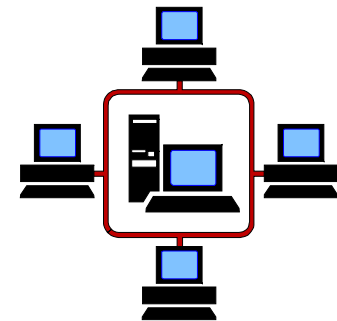
Step #1 Develop User Requirements

Req. ID	User's Work Step	System Role – User Req.	User Accept. Test
UR01	Secure data entry	Control user access and log off intruders	Use pos. and neg. IDs Log off after 3 failed tries
UR02	Track data edits	Audit data changes – Part 11	Change items. Check screen. Run Report.

IQURS PQ URS

What Does the User's Process Need? (URS)

Production Planner:

UR ID	Work Process Steps	User PQ Tests	Challenges
UR016	Picking list to production orders	Check signals for creating a picking list	What happens if material is physically non-existent
		Check principals for picking a batch	
		Check principals for picking a material	
		Check rest or shelf life	
		Check authorized status	
		Check special dosage	

PQ URS

What Does the User's Process Need? (URS)

Production Operator -1:

UR ID	Work Process Steps	User PQ Tests	Challenges
UR017	Material is picked and taken to working station for weighing of components	Check printing of labels (if weighing station)	Check correct storage bin
		Check feedback rest material to warehouse	Handling of wreckage
		Check reg. of loss (waste)	
		Check special dosage	
		(Finance Checker: Check product costing)	
UR018	Feedback per workstation - time and materials	Check function in system	Check rules for yield
		(Finance Checker: Check signals to cost price)	Creation of extra batches
		(Finance Checker: Check product costing)	

PQ URS

Slide 12

Data Capture – Lab URS View for PQ

Lab Methods

Instruments

Devices

Capture & Analysis Systems (PCs)

Analysts & Supervisors

Reagents

SOPs & Work Instructions

Sample Handling

Laboratory Workflow(s)

Defined Raw Data

Calculations

Results

Verification

Analytical Report
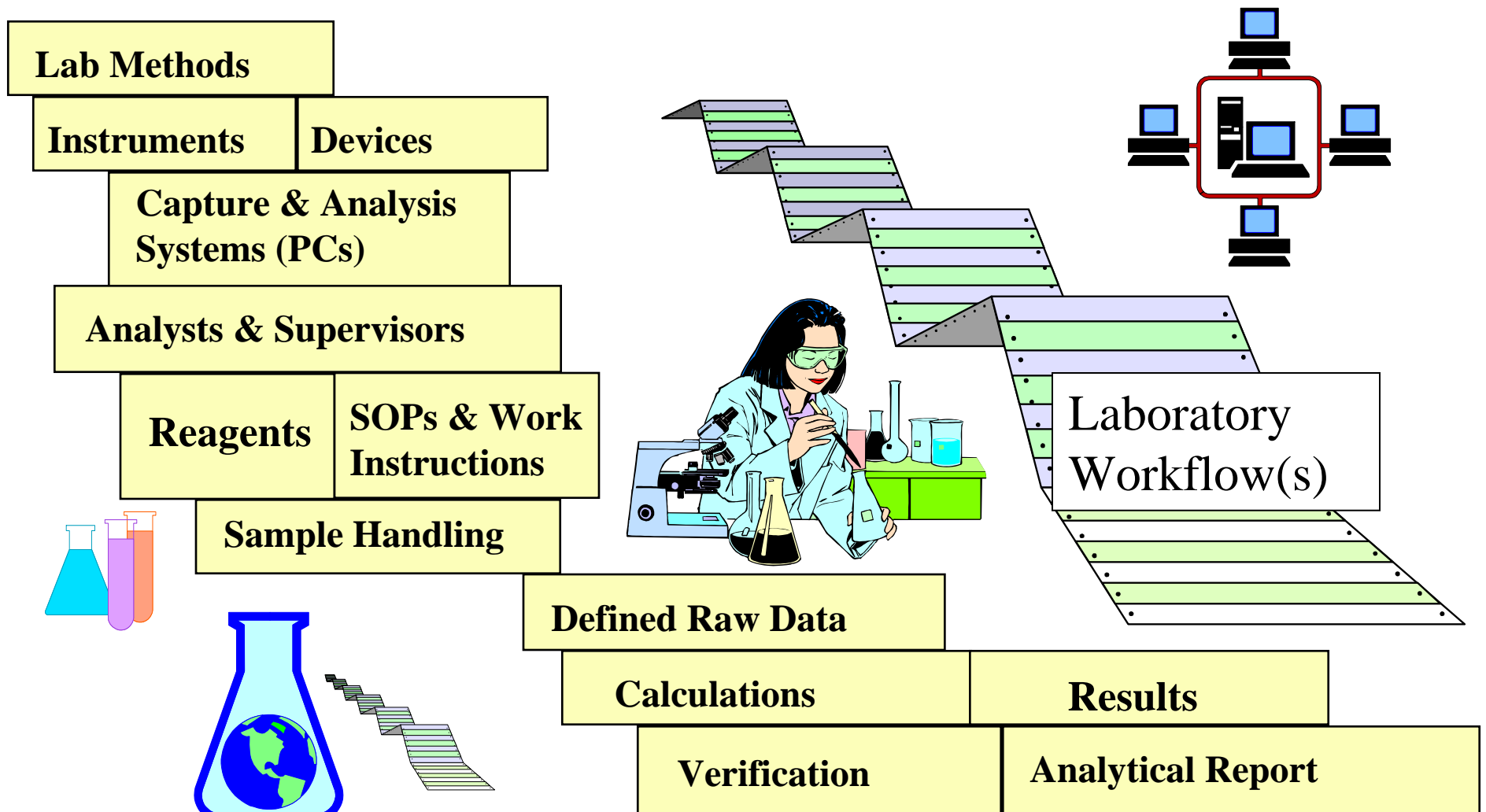
OECD GLP – Acceptance Testing

- "…there should be evidence that the system was adequately tested for conformance with acceptance criteria … prior to being put into routine use."

- "Formal acceptance testing requires the conduct of tests following a pre-defined plan and retention of all testing procedures, test data, test results, a formal summary of testing, and a record of formal acceptance."
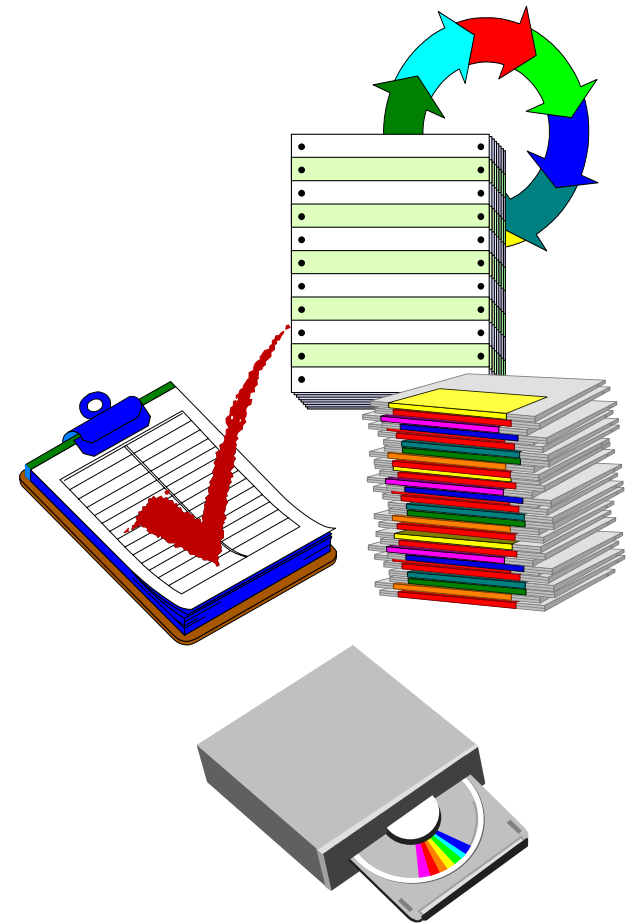
Step #2 – Map System to Work Process

1. **Team agrees a common workflow for use of system in the work process (URS).**

   Workflow Acts (URS)

2. **Workflow steps interacting with the system are identified.**

3. **Critical workflow steps are described in an SOP or Work Instruction.**
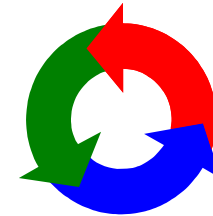
   Critical steps criteria

Step #2 – Map System to Work Process

4. **Each workflow step has positive and negative challenges identified in testing step procedures.**

5. **Test scripts are organized by logical groups of workflow activities into Test Cases.**

6. **Test Scripts and related documents are managed with large envelopes.**

Workflow Needs (URS)
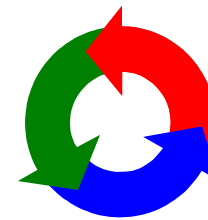
Critical work steps
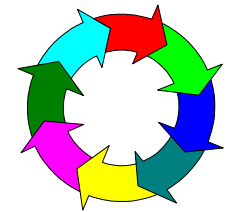
Test step procedures

Test script

Test scripts

Print-outs
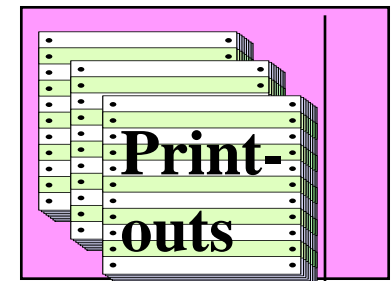
Test envelopes

Step #3 – Make Logical Groups of Test Scripts

Don't get tangled up in lots of Test Scripts! Organize them into Test Cases based on work process flow and requirements.

Step #3 – Make Logical Groups – Test Cases

Outline adapted from - IEEE Std. 829-1983

1. Test Case Identifier – unique & related to Test Plan ID
2. Test items - scope of features being tested & URS items addressed with table of Test Scripts to be used
3. Input requirements - user roles, system privileges, input data types ...
4. Output requirements - reports, listings, screen printouts
5. Environmental needs - user materials, training, physical setup
6. Special procedure requirements - anomaly handling
7. Inter-case dependencies - cases to be run prior to this

User Test Case Descriptions (PQ)

To include normal, problem, and stress conditions in user's work process environment.

TC01. Work Area Preparedness – SOP, WI, Manual

TC02. System Setup/Admin – User Profiles, DB schema

TC03. Work Process – Activity A (*vanilla run*)

TC04. Work Process – Activity B (*chocolate issues*)

TC05. Work Process – Activity C (*strawberry stresses*)

TC06. Special Challenges – Multi-user, Problem work

Server Test Case Descriptions (IQ)

To include normal, problem, and stress conditions in IT/IS environment.

TC01. Hardware Operations

TC02. Operating System (O/S) & Software Tools

TC03. Database Engine (DB) & Query Tools

TC04. Network Operations – LAN/WAN

TC05. Platform Routine Backup & Recovery

TC06. Platform Disaster Recovery – System & Data

Test Step # 4 Develop a Test Plan

Prepared and maintained by User Department(s) Team

Standard user's CSV package

Test Plan(s)
Startup & Ongoing

URS

Trace

Test Cases, Scripts, Data & Result Logs

System Control

Test Summary Report

Human Control
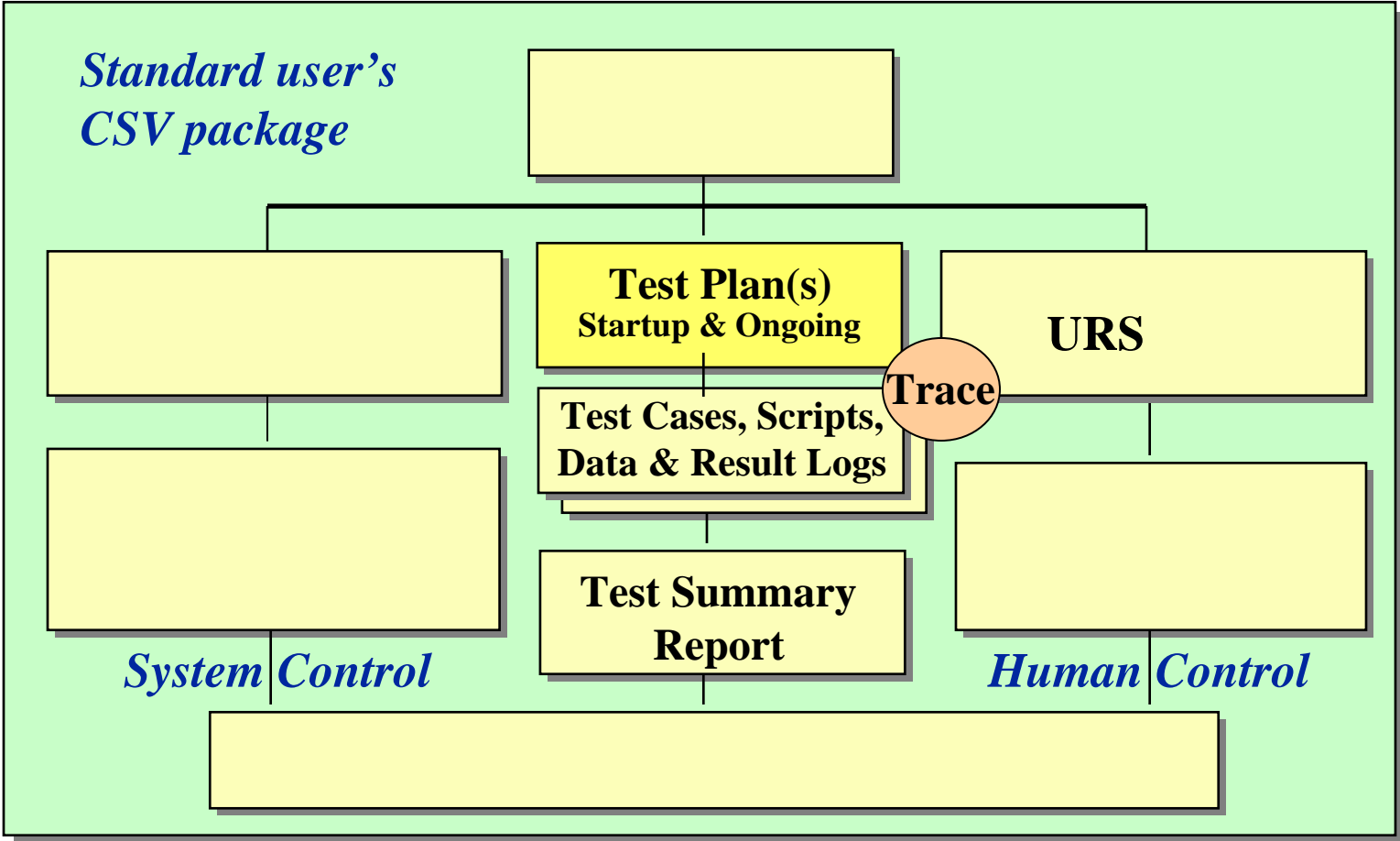
Test Step # 4a Develop a Trace Matrix

No testing project is too big or too small for a trace matrix. Always trace Test Scripts to Requirements to ensure that all requirements have been sufficiently tested.

IEEE Format for a Software Test Plan

Software Test Plan Outline - IEEE Std. 829-1983

1. Test plan identifier
2. Introduction
3. Test items
4. Features to be tested
5. Features not to be tested
6. Approach
7. Item pass/fail criteria
8. Suspension criteria & resumption requirements

IEEE Format for a Software Test Plan

Software Test Plan Outline - IEEE Std. 829-1983

9. Test deliverables

10. Testing tasks

11. Environmental needs

12. Responsibilities

13. Staffing and training needs

14. Schedule

15. Risks and contingencies

16. Approvals   (IEEE Tel: 800-678-4333)

Who Is Who in Testing?

Test Coordinator – writes test plan, test cases, and prepares testing materials. Trains testers & witnesses, manages testing process, and tracks results and anomalies. Writes conclusion per case. Writes test summary report. Organizes test records in a test records binder.

Roles & Responsibilities

Who Is Who in Testing?

Script author - can never be tester or approver of same script, but can witness testing of same script

Script approver – independent reviewer of script for content and strategy

Tester- performs test, records system response, and signs script for accurate recording of system response

Witness - verifies that tester is prepared and ready to perform test, checks presence of final test records, and signs script for compliance to testing practices SOP

Roles & Responsibilities

Test Script Author Guidelines – High 5

1. **Keep Tester Alert** – author scripts that can be executed within 30-50 minutes.

2. **Rule of Three** – test key functions 3 times using a variety of challenges – normal, problem a, and issue b

3. **Trace to Requirements** – identify requirements being addressed by each script.

4. **System Output** – have at least one screen print or report per test script. Identify label info needed for output.

5. **More than Pass/Fail** – have tester write out an observed system response.
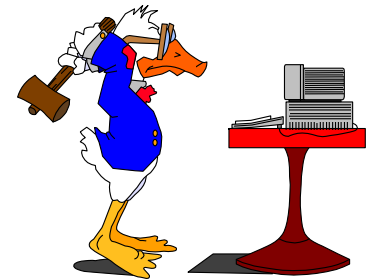
Part 11 Guidance*: GXP Testing Principles

5.1 System requirements Specifications: Established,
documented end user requirements are essential. (GXP,
Part 11, work process – scanning, scalability, operating
environment requirements)

5.2 Documentation of Validation Activity:
Management approved plan(s), procedures and
report(s).

5.3 Equipment Installation: Qualify installation prior to
testing.

* Retracted Draft Guidance

Part 11 Guidance*: GXP Testing Principles

5.4 Dynamic Testing: 5.4.1 - Test conditions, simulation tests, and live, user-site tests. 5.4.2 - Software testing to include structural, functional, and program build testing. 5.4.3 – Quantifiable tests recorded in quantified, not pass/fail terms.

5.5 Static Verification Techniques: Document and code inspections, walk-throughs, and technical reviews.

5.6 Extent of Validation: System risk to product safety, efficacy, and quality. System risk to data integrity, authenticity, and confidentiality. System complexity.

* Retracted Draft Guidance

Part 11 Guidance*: GXP Testing Principles

5.7 Independence of Review: CSV to be performed by persons other than system developers.

5.8 Change Control (Configuration Management): Systems to control changes and evaluate extent of revalidation needed. Regression testing is a key tool.

5.6 Extent of Validation: Based on
- *System risk to product safety, efficacy, and quality*
- *System risk to data integrity, authenticity, and confidentiality*
- *System complexity.*

* Retracted Draft Guidance

Step #5 - Prepare Test Script Materials

Prepared by Test Coordinator & Package Team

Standard Test Script Envelope

Test Data Form, SOP, Work Instr.

Incident Form (Red Note) & WI

Test Script

URS Trace & Script Pass/Fail T/W Signatures

Step Procedures

Result Logs & System Issues

Witness Checklist

Support Materials, Result Printouts...

Large Mailing Envelope
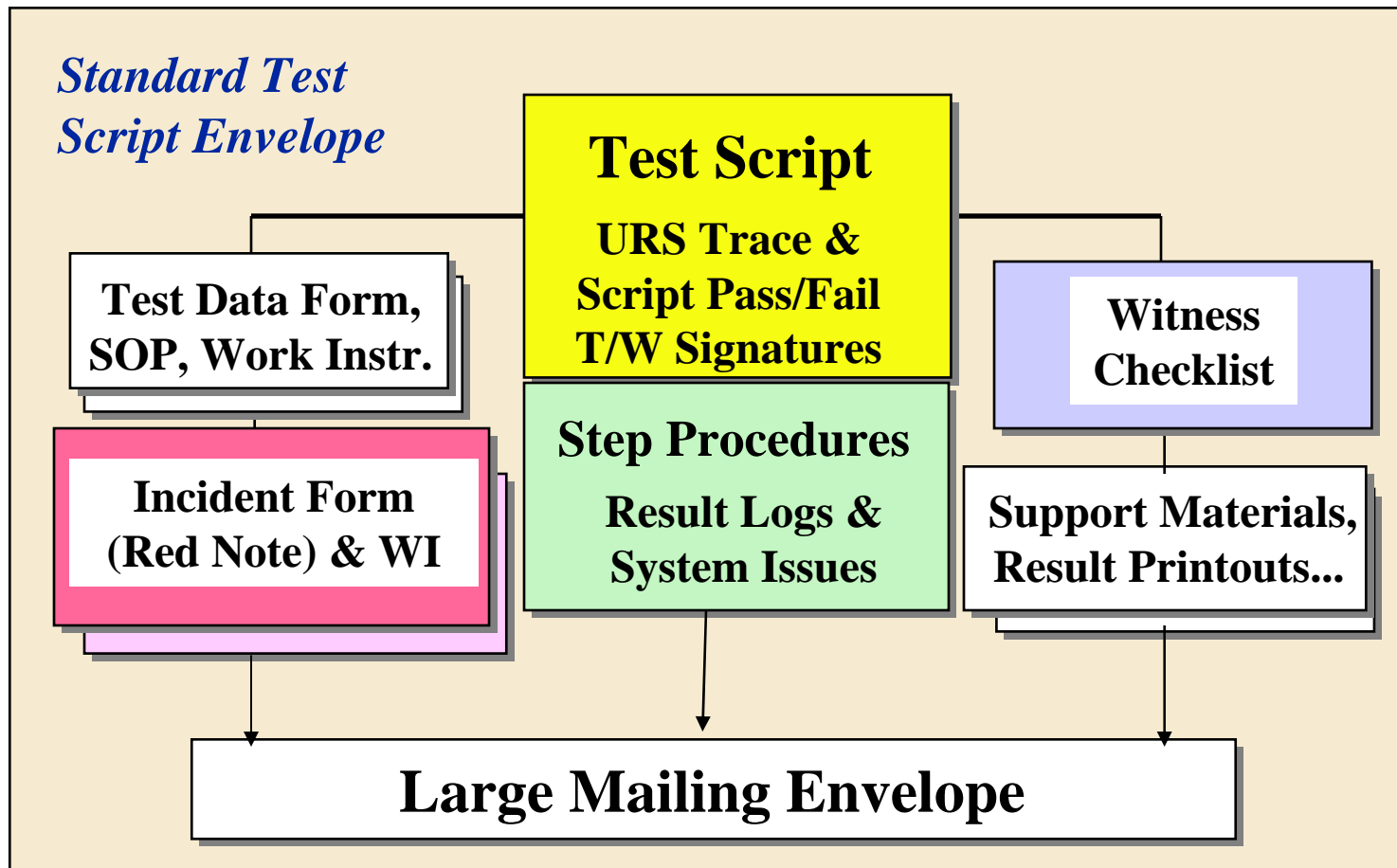
Step #6 - To Do's in Formal Testing

T.S. Envelope

Print-outs
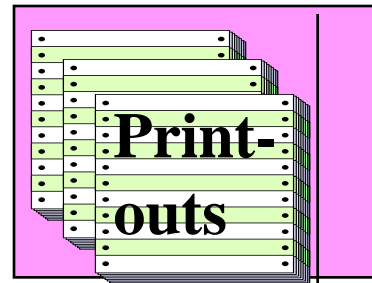
System Setup
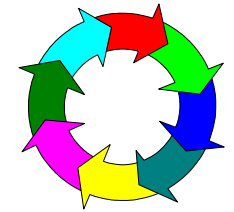
System Testing

1. Check script, logs, data, & testing area.
2. Record all system responses as they occur.
3. Use only indelible ink to record results.
4. Correct with single line through record & new result next to it. Initial, date & explain.
5. Draw single line through unused log spaces.
6. Label, sign & date all printouts or CD/diskettes.

Step #6 - The Don'ts in Formal Testing
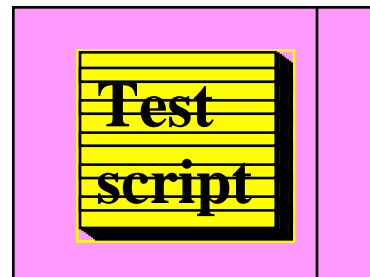
T.S. Envelope

Print-outs
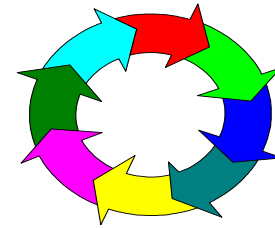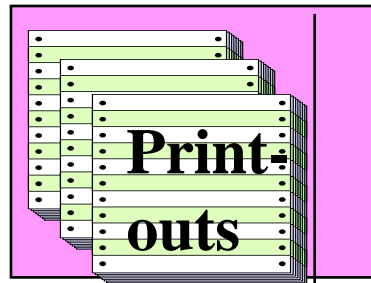
System Testing

1. Don't use pencil or other erasable media.
2. Don't correct by using white-out or scribble over to obliterate prior result.
3. Don't use check marks, dittos, Y/N or other abbreviations. Write results & comments in full.
4. Don't leave large blank spaces in result logs. Line through.
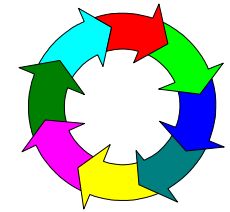5. Don't forget to sign & date all output documents & logs.

Witness Participation in Testing

T.S. Envelope

Test script

System Setup

System Testing

1. Checks contents of T.S. Envelope with Tester for completeness and understanding.

2. Checks System Setup with Tester for logon access. Watches start of first testing step.

3. After testing, T.S. Envelope is re-examined. Checks Test Script and printouts for completeness, signatures, dates and labels.

Print-outs
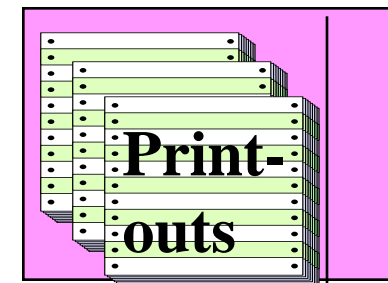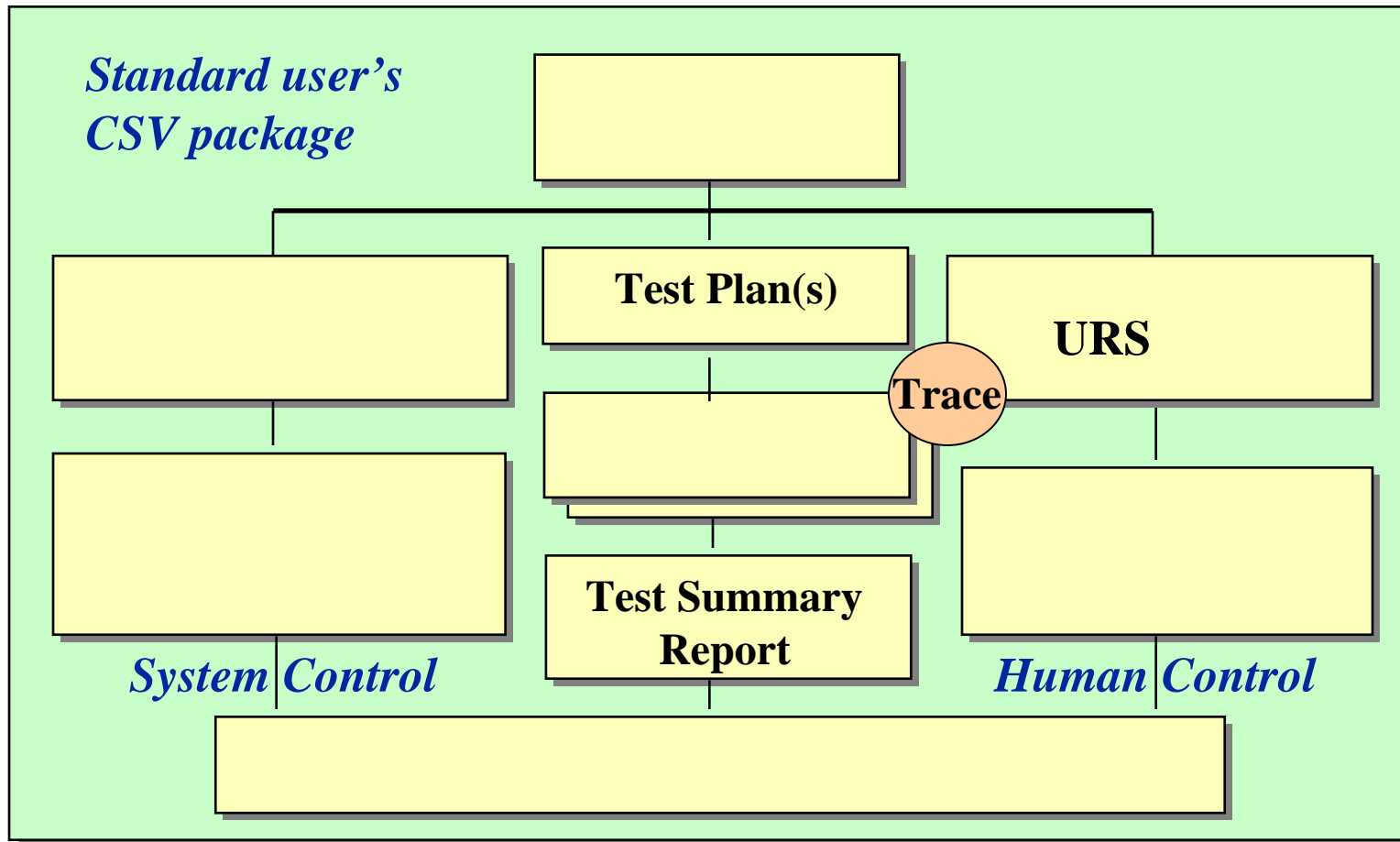
T.S. Envelope

Step #7 – Prepare a Test Summary Report
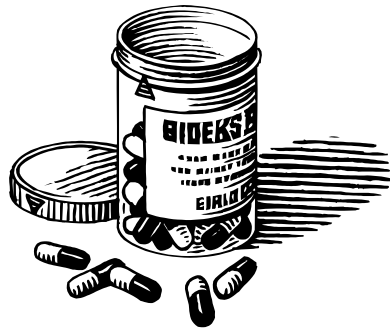
Testing is finished at last!!

Reporting on Test Results

Prepared and maintained by Site User Team

*Standard user's
CSV package*

Test Plan(s)

URS

Trace

Test Summary
Report

System Control

Human Control

Test Plan Summary Report

IEEE Std. 829-1983 Adapted

1. Test Summary Report Identifier - Unique ID traceable to associated Test Plan.

2. Summary - Describes items tested (application version), test environment (platform system), and test documentation used (Test Cases, Test Scripts, T.S. Envelope contents).

3. Variances - States any deviations from Test Plan or Test Scripts and reason why.

4. Comprehensive Assessment - Discusses assumptions and limits to scope of testing. Were scope of testing and results obtained sufficient to assess system reliability? Discuss reasons for limits chosen.
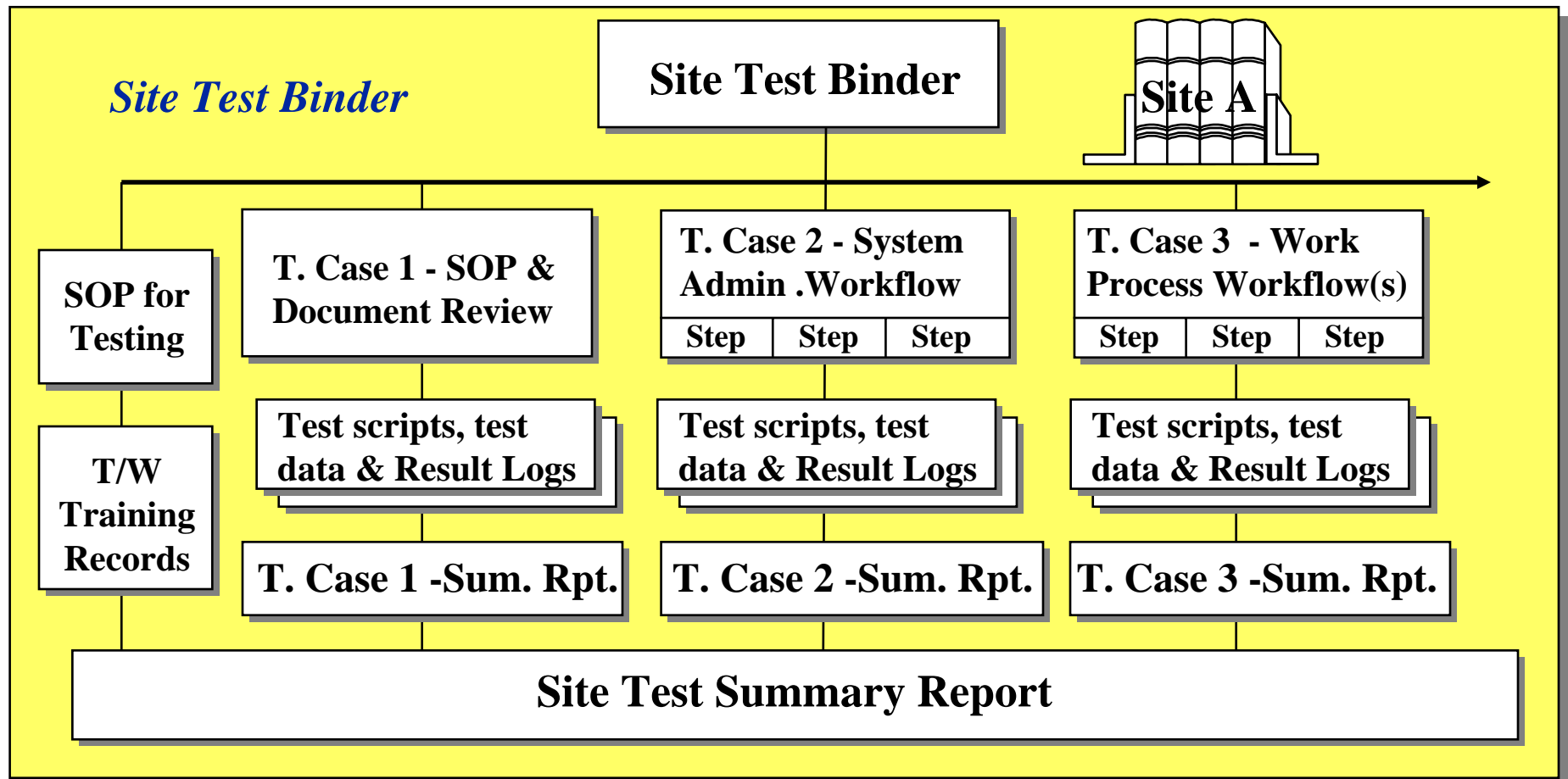
Test Plan Summary Report
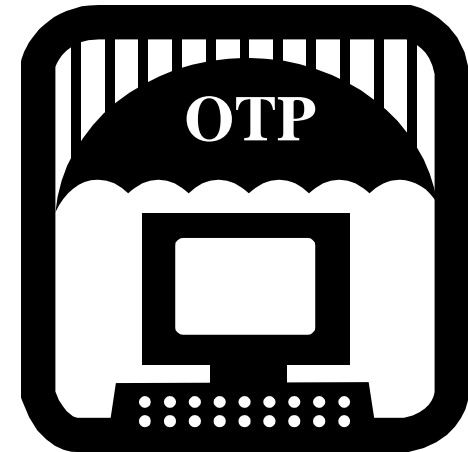
IEEE Std. 829-1983 Adapted

5. Summary of Results - Gives table of testing results per Test Case. Table of anomalies and their resolutions. List of outstanding issues and risks (unresolved anomalies).

6. Evaluation - Pass/Fail conclusion based on test results and criteria in the Test Plan.

7. Summary of Activities - Tester/Witness staffing, task list from Test Plan with updated status.

8. Approvals - Names, titles, signatures, dates and meaning of signatures.

9. Appendix - Table of Contents list for test documentation

Step #7 - Store Test Results for Audit

Prepared by Test Coordinator at Site

Site Test Binder

Site Test Binder

Site A

SOP for Testing	T. Case 1 - SOP & Document Review	T. Case 2 - System Admin .Workflow			T. Case 3 - Work Process Workflow(s)		
		Step	Step	Step	Step	Step	Step

T/W Training Records

Test scripts, test data & Result Logs — **Test scripts, test data & Result Logs** — **Test scripts, test data & Result Logs**

T. Case 1 -Sum. Rpt. — **T. Case 2 -Sum. Rpt.** — **T. Case 3 -Sum. Rpt.**

Site Test Summary Report

Step #8 – Write an Ongoing Test Plan
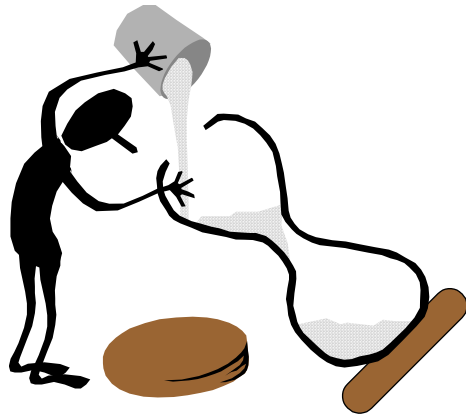
Over time systems change. An Ongoing Test Plan sets up the process for maintaining a validated status as change occurs. It identifies major, moderate, and minor types of system change and corresponding degree of formal testing to be performed any validation tasks to be updated.

Slide 40

Audit Points for Test Documentation

- Test Plan was approved with or after Validation Plan approval date and before Test Script approval dates.

- Test Plan describes system to be tested, gives specific strategy for testing, and identifies tasks and roles responsible.

- All issues arising are recorded, tracked, and resolved.

- Repeat testing is performed using a new copy of a script and the run number is identified.

- Test Script author is not tester or approver for same script.

Audit Points for Test Documentation

- All printouts are labelled with tester ID, date, and script ID.

- All log entries are made in indelible blue or black ink.

- No abbreviations (P/F, Y/N), ditto or check marks were used.

- Signature page identifies names, initials, signatures, and Tester/Witness roles.

- Test Script identifies Requirements being tested, Testing Site, Test Run, Author, Approver, Tester, Witness and overall conclusion.

Slide 42

Audit Points for Test Documentation

- Test Summary Report clearly describes what happened, how problems were handled, who was responsible, and how the Test Plan was followed or what deviations were made and why.

- Test Summary Report should show that test execution was consistent with Test Plan strategy.

- PQ testing uses GXP work process SOPs and work instructions to test their suitability for working with the system.

- IQ testing uses IT Dept. SOPs and work instructions to test their suitability.

Formal Testing Major Themes

MANAGEMENT CONTROL

- Formal Testing Practices SOP
- Approved Test Plans, Test Scripts, & Test Summary Reports
- Anomaly Tracking Process
- User & Support Documents

SYSTEM RELIABILITY

- Requirements & Specifications
- Trace Matrix – Tests to Requirements
- Defined Acceptance Criteria in Test Procedure
- Limits, Logic & Problem Testing

DATA INTEGRITY & PRIVACY

- Tester & Witness Signatures
- Result Logs in Indelible Ink
- IQ for Automated Testing Tools
- Security & Disaster Recovery Tests
- Audit Trail Tests

AUDITABLE QUALITY

- Approved Plans & Reports
- Traceable test coverage for all Requirements & Specifications
- Documented Anomaly Resolution
- Independence of Testing Process

Slide 44

ASQ FD&C GMP Quality Conference

Thank You!

Merci

Tak, Tack, Takk

Gracias

Obrigado

Spasibo

Nandri

Cobjai

It's the little things that can bite you in an audit of test records!

Common Sense Computer Validation

How would you answer these questions?

The software supplier has tested this software a lot and other people have bought it and are using it, so why do we have to validate it with our own testing?

Why test off the shelf systems that everyone else is using in their businesses?

Why must end users be involved in the PQ testing?

Can't IT or outside testing folks do the job for us?

Our job is our work process, how should we know what to do for testing a computer system?

Any Questions or Comments?