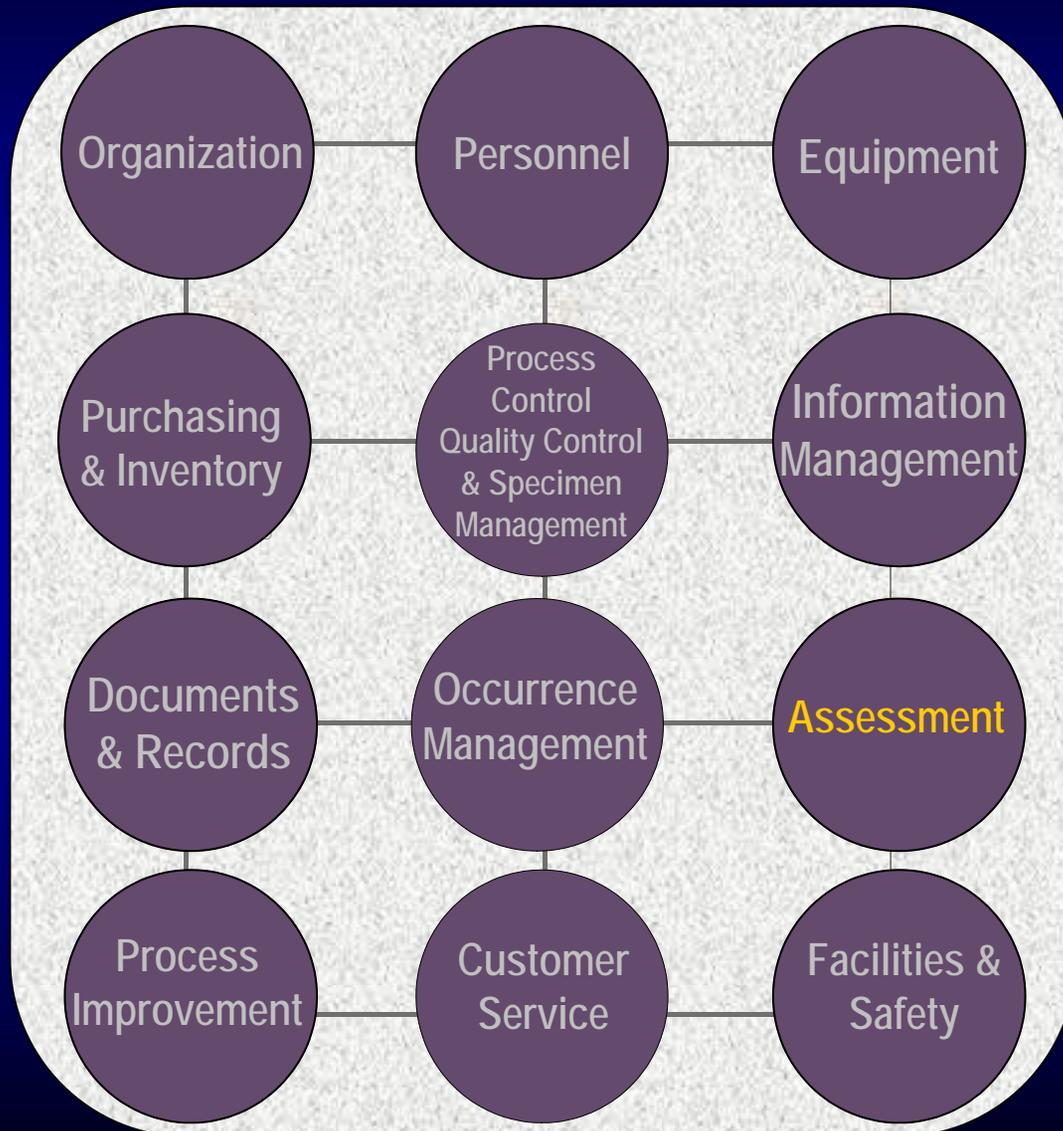


# Module 13: External Quality Assessment (EQA)

## On-site Evaluation and Re-Testing



# The Quality System



Supervisors or Managers



Testers

# Learning Objectives

At the end of this module, you will be able to:

- Assess operations at test site to determine if quality requirements are met
- Take corrective actions following External Quality Assessment (EQA)
- Keep appropriate records related to EQA
- Avoid common problems associated with EQA specimen management



# Content Overview

- What is EQA and why is it important?
- EQA Responsibilities
- EQA Methods
  - Proficiency Testing
  - On-Site Evaluation
  - Re-testing
- How to implement EQA



# External Quality Assessment (EQA): Definition

Objective assessment of a test site's operations and performance by an external agency or personnel

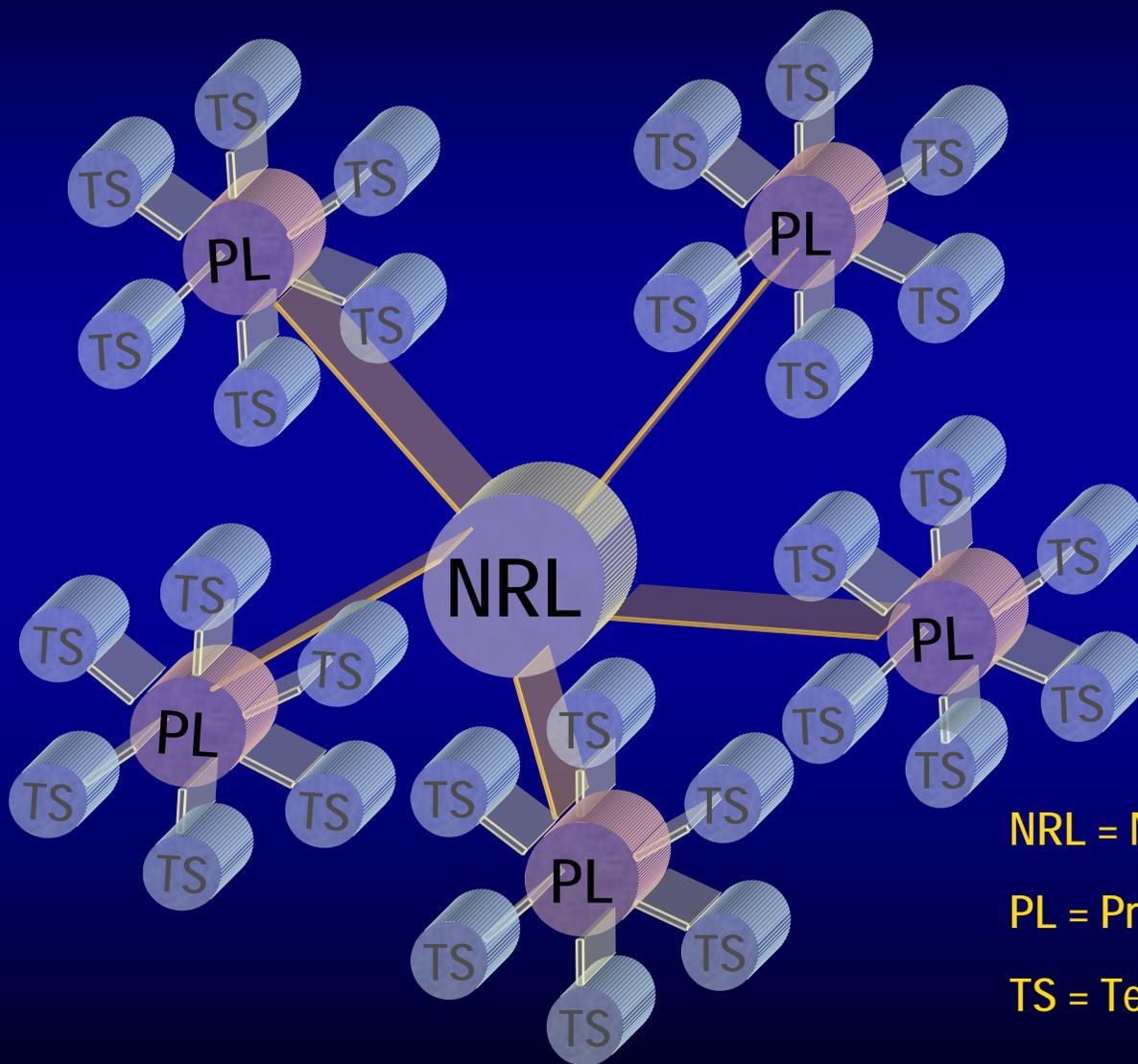
# Why EQA?

- Allows comparison of performance and results among different test sites
- Provides early warning for systematic problems associated with kits or operations
- Provides objective evidence of testing quality
- Indicates areas that need improvement
- Identifies training needs





# EQA: Conducted at All Levels of Testing



NRL = National Reference Lab

PL = Provincial or Intermediate Lab

TS = Test Site (Point of Service)



Supervisors or Managers



Testers



# Management Responsibilities: Overview

- Determines policies for EQA (WHO, WHAT, WHEN, HOW)
- Assigns responsibility
- Establishes and maintains a system for assessment visits
  - Schedules visits
  - Conducts evaluations
- Receives EQA results and supports corrective action measures
- Monitors and maintains records
- Investigates deficiencies
- Manages corrective action efforts
- Communicates outcomes





# Testing Personnel's Responsibilities: Overview

- Participate in the EQA program
- Take corrective actions
- Maintain EQA records
- Communicate outcomes to supervisors

# EQA Methods

Proficiency  
Testing

On-site  
Evaluation

Re-checking/  
Re-testing



# What is Proficiency Testing?

Proficiency  
Testing

On-site  
Evaluation

Re-checking/  
Re-testing

- Panels of specimens are sent to multiple test sites by reference laboratory
- Test sites perform tests and report results
- Results indicate quality of personnel performance and test site operations
- Results are often compared across several testing sites



# What is On-site Evaluation?

Periodic site visits to systematic assessment of lab practices

- Focuses on how the lab monitors its operations and ensures testing quality
- Provides information for internal process improvement

Proficiency  
Testing

On-site  
Evaluation

Re-checking/  
Re-testing



# What is On-site Evaluation? – Cont'd

Proficiency  
Testing

On-site  
Evaluation

Re-checking/  
Re-testing

- Also referred to as audits, assessments, or supervisory visits
- Learn “where we are”
- Part of every lab quality system
- Measures gaps or deficiency
- Collect information for:
  - Planning & implementation
  - Monitoring
  - Continuous improvement



# What is Re-testing?

Proficiency  
Testing

On-site  
Evaluation

Re-checking/  
Re-testing

- The process by which a random selection of specimens are collected from the routine workload at the test site and sent to the reference laboratory for validation
- Used to detect errors



# EQA Should Lead to Corrective Actions



## ***“Corrective Action”***

An action taken to correct a problem or deficiency

### Examples:

- Production of an incorrect result
- Not following procedures



# Problems May Occur Throughout the Testing Process

## Pre-Testing

Specimen compromised during preparation, transport, or after receipt by improper storage or handling

## Testing

Reagents, test methods, QC  
Competency of staff

## Post-Testing

Report format  
Interpretation



# Take Corrective Actions

- Use problem-solving team:
  - Investigate root causes
  - Develop appropriate corrective actions
- Implement corrective actions
- Examine effectiveness
- Record all actions and findings



# Sample of Corrective Action Form

**CORRECTIVE ACTION FORM**

**This Corrective Action is a result of:**

_____ Occurrence	Date _____	Time: _____
_____ Internal Assessment	Date _____	Time: _____
_____ External Assessment:	Date _____	Time: _____

**Description of Problem or Finding:** *(What happened and Why)*

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

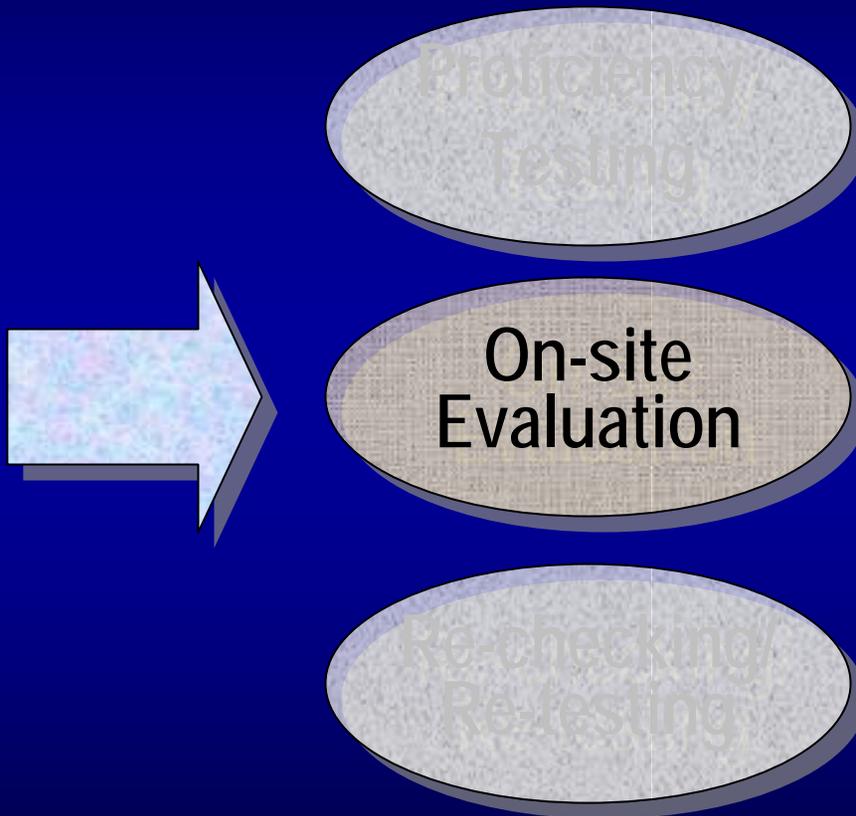
Reported by: (Staff Name) \_\_\_\_\_

**Corrective Action Taken:** *(What was done to prevent re-occurrence?)*

\_\_\_\_\_

\_\_\_\_\_

# How To Implement EQA

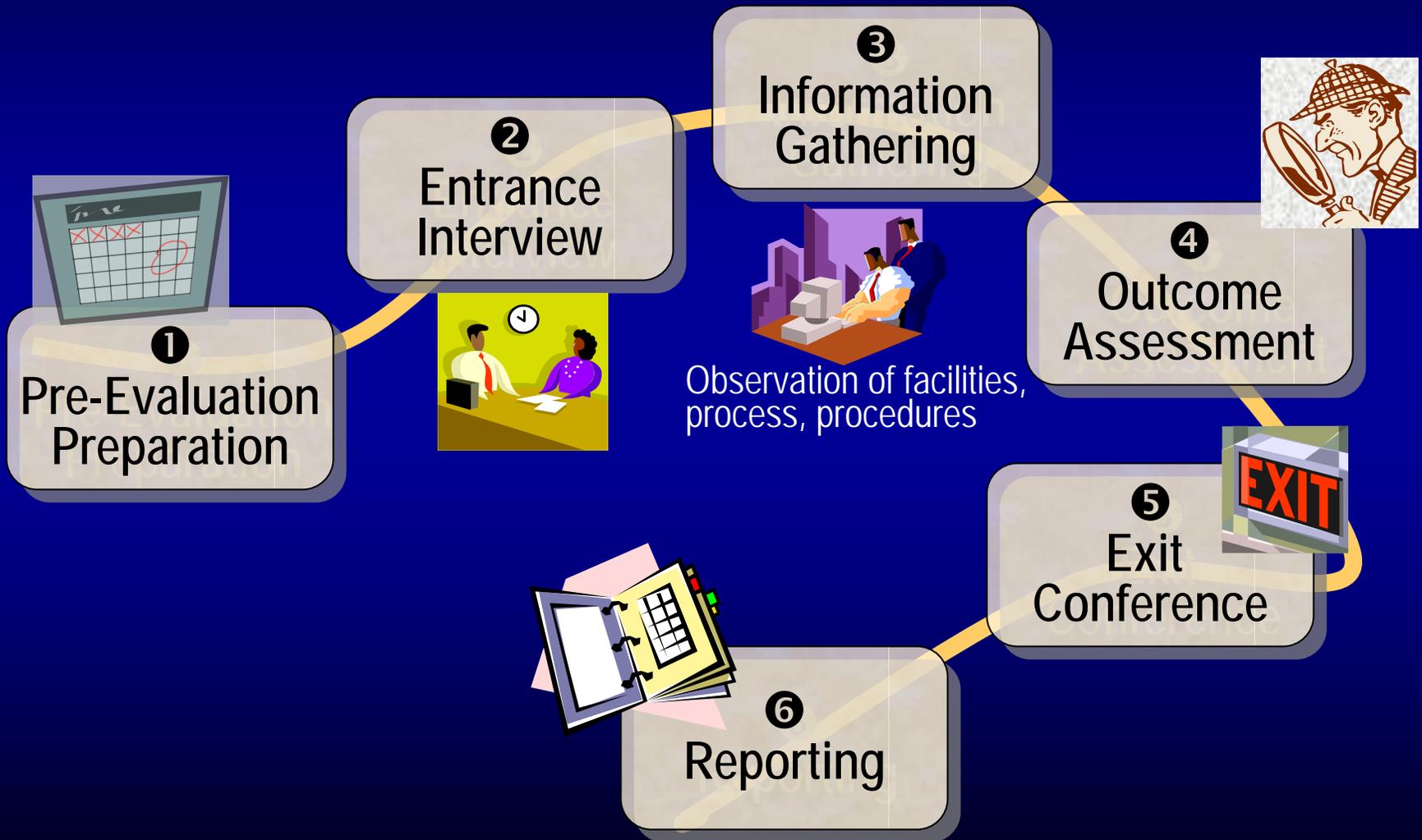


Supervisors or Managers



Testers

# On-Site Evaluation Process



Supervisors or Managers



Testers



# On-Site Evaluation Checklist



Site Visit Checklist – Assessment of Quality System

Quality System Essential		Yes	No	Assessor's comments
<b>Organization</b>	<ul style="list-style-type: none"> <li>▪ Is there a quality policy manual present and accessible?                             <ul style="list-style-type: none"> <li>○ Does the policy manual address all elements of the quality system?</li> </ul> </li> </ul>			
	<ul style="list-style-type: none"> <li>▪ Does the site have a designated quality officer?</li> </ul>			
	<ul style="list-style-type: none"> <li>▪ Is the site manager aware of all quality system efforts?</li> </ul>			
<b>Personnel</b>	<ul style="list-style-type: none"> <li>▪ Do testing staff members possess certificate indicating successful participation in HIV rapid test training?</li> </ul>			
	<ul style="list-style-type: none"> <li>▪ Has the staff been oriented to the patient/client flow at the test site?</li> </ul>			
	<ul style="list-style-type: none"> <li>▪ Does staff demonstrate professionalism?</li> </ul>			
	<ul style="list-style-type: none"> <li>▪ Is number of staff adequate for the site workload?                             <ul style="list-style-type: none"> <li>○ Approximately how many tests does each staff member perform per month?</li> </ul> </li> </ul>			
<b>Documents and Records</b>	<ul style="list-style-type: none"> <li>▪ Are standard operating procedures for all aspects of the testing process written, up-to-date, and accessible to staff?</li> </ul>			
	<ul style="list-style-type: none"> <li>▪ Is the handwriting legible?</li> </ul>			
	<ul style="list-style-type: none"> <li>▪ Do worksheets include appropriate information?</li> </ul>			
	<ul style="list-style-type: none"> <li>▪ Are external quality control records up-to-date, easily reviewed?</li> </ul>			
	<ul style="list-style-type: none"> <li>▪ Are corrective actions recorded?</li> </ul>			
<b>Purchasing and Inventory</b>	<ul style="list-style-type: none"> <li>▪ Are results interpreted and recorded according to the SOP and VCT:PMCT protocol?</li> </ul>			
	<ul style="list-style-type: none"> <li>▪ Are kits and reagents stored properly?</li> </ul>			
	<ul style="list-style-type: none"> <li>▪ Is staff following "first expired, first out" method when managing inventory stock?</li> </ul>			
	<ul style="list-style-type: none"> <li>▪ Is there a policy for re-ordering kits and supplies?</li> </ul>			





# Tester Responsibilities: Ensuring a Productive Site Visit

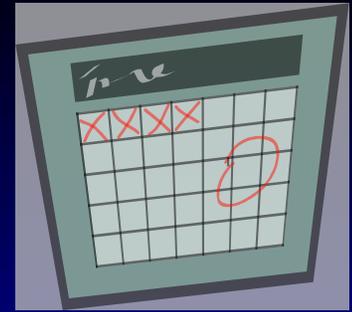
- Before Visit:
  - Record keeping is essential. Get organized
  - Confirm date of visit
  - Review written policies and procedures
  - Conduct internal assessment in preparation of site visit
- During Visit
  - Participate in visits – cooperate
  - Ask questions of site assessors
- After Visit
  - Take corrective actions, where necessary

**Remember – visits are instructive, not punitive**



# On-site Evaluation:

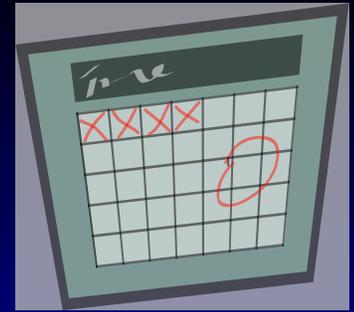
## ① Pre-Evaluation Preparation



- Assign Responsibility
  - Laboratory management
  - Quality Manager
- Use Integrated team approach
- Determine who will conduct on-site evaluations
  - Select auditors with necessary skills:
    - Attention to detail
    - Ability to communicate effectively
    - Diplomacy
  - Provide appropriate training
- Schedule site visits

# On-site Evaluation:

## ① Pre-Evaluation Preparation



- Determine site visit frequency:
  - Established sites - At least twice per year
  - New Sites - Quarterly
- For efficiency, cluster evaluations geographically
- Schedule in advance
  - Announced or unannounced visits

# On-site Evaluation:

## ② Entrance Interview



**The entrance interview sets the tone for the entire visit**

- Be prepared, positive and courteous
- Introduce evaluation team - show identification
- Provide overview of process in terms of what will be done
  - Review of facility
  - Record review
  - Observation
  - Interview with testing staff
  - Use of proficiency panel
  - Exit interview

# On-site Evaluation:

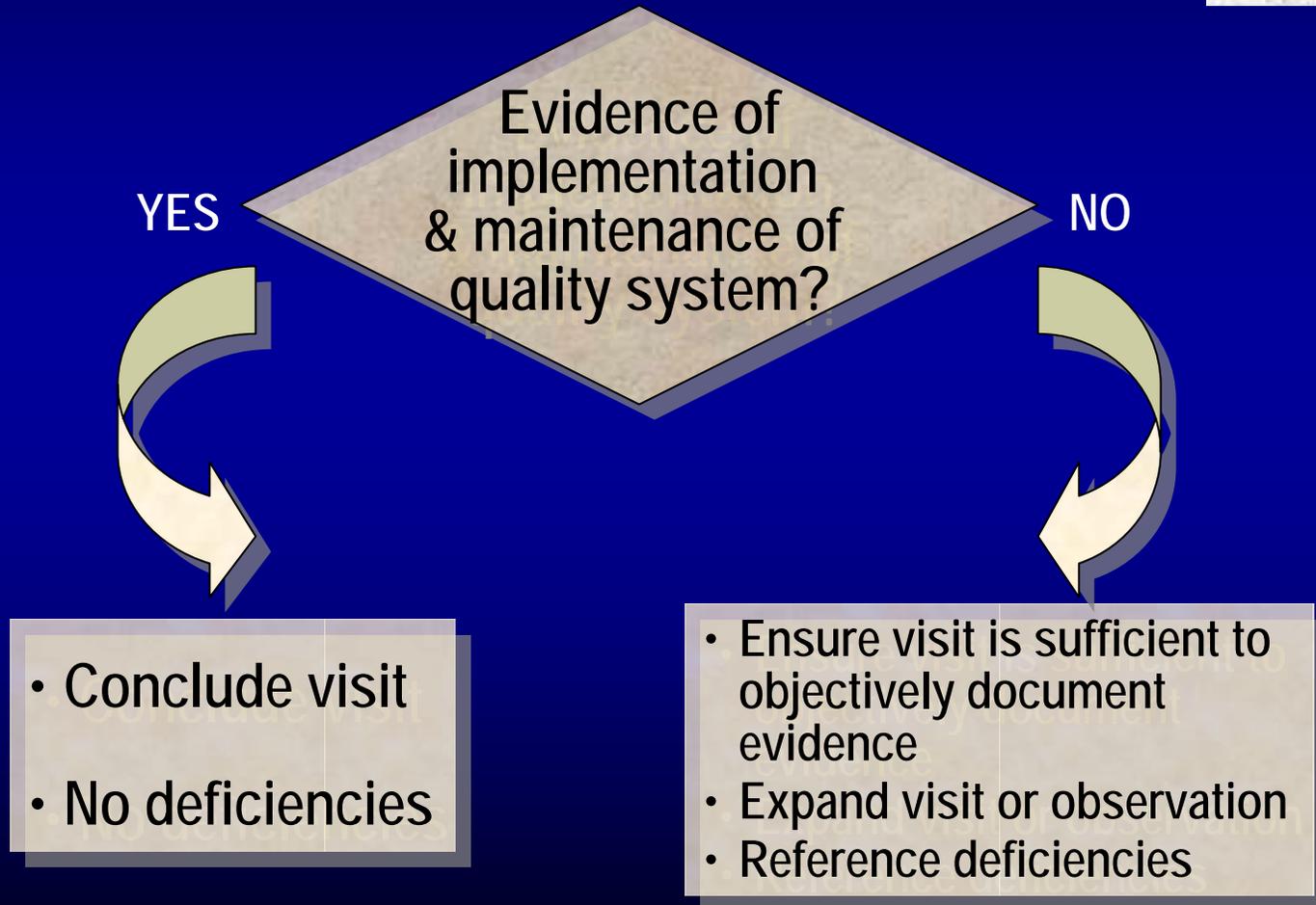
## ③ Information Gathering



- Observe physical layout of the site
- Evaluate testing operations
  - Specimen collection
  - Observation of test performance
  - Quality control
  - Inventory of kits
  - Record-keeping
- Use quality systems checklist
- Conduct in an instructional, not punitive, manner.

# On-site Evaluation:

## ④ Outcome Assessment



# On-Site Evaluation:

## ⑤ Exit Conference

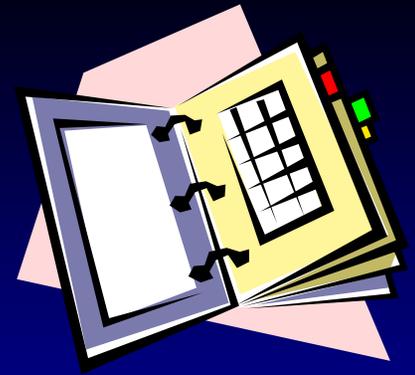


Review findings with supervisory and testing staff

- Make positive statements first – acknowledge staff cooperation and support
- Address negative findings – allow test site to discuss findings and provide additional information
- Provide instructions and timeframe for submitting plan for correcting problems

# On-site Evaluation:

## ⑥ Reporting



- Include information:
  - Site Name & Location
  - Date of Visit
  - Assessment Team Members
  - Major Findings
  - Recommendations for corrective actions
- Submit completed checklist and report to relevant authorities



# Example: Assessment Report

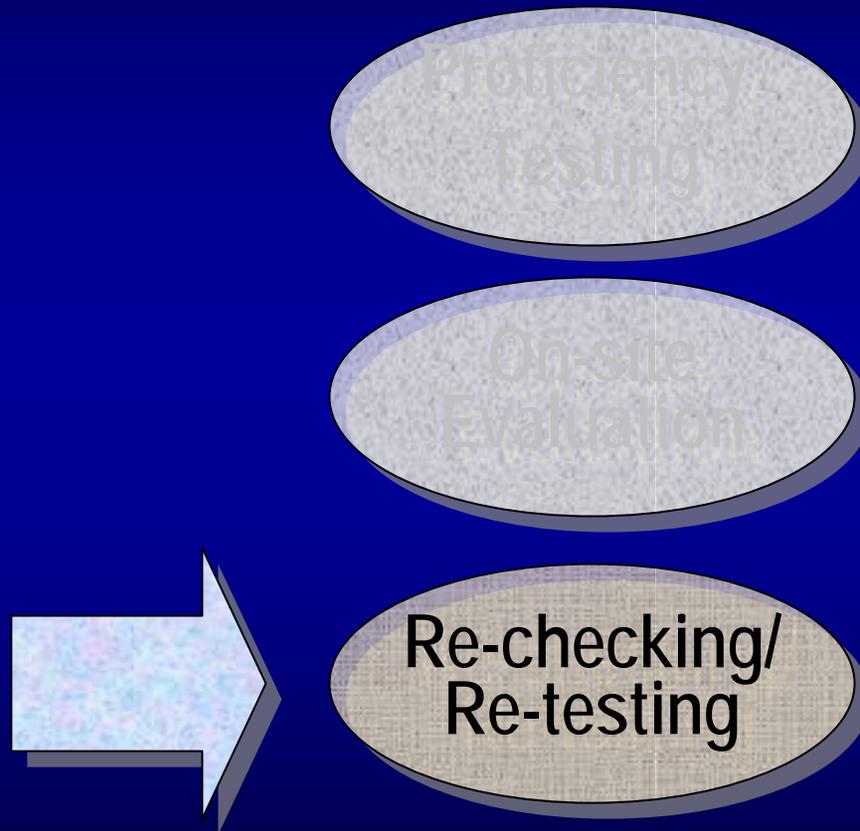


# Role Play: On-site Evaluation Visit

- Objective: To experience situations which may compromise test results that an evaluator may observe
- Volunteers to play the following roles:
  - Patient/Client
  - Quality Manager
  - Laboratory Manager
  - Person performing tests
- Rest of the group will observe
- Role play time: 20 minutes



# How To Implement EQA



Supervisors or Managers



Testers

# Issues to Consider Prior to Implementing a Re-testing Program

- What is the purpose of re-testing?
- Is re-testing feasible?
- Does technical capacity exist at reference lab?
- Can turnaround of re-testing be accomplished in a timely manner allowing for immediate corrective actions?
- What type of specimen should be collected for re-testing?
- How should EQA specimens be labeled and recorded?
- When should specimens be shipped/transported to reference laboratory?
- Which laboratory should re-test specimens submitted by test sites?

# Statistical Basis for Re-testing: Error Detection

Volume (Per Site)	1%* error	5%* error	Retesting Feasibility
<b>Very low</b> 50 spec	<b>Re-test 48</b> (96%)	<b>Re-test 31</b> (62%)	No
<b>Low</b> 500 spec	<b>Re-test 225</b> (45%)	<b>Re-test 56</b> (11%)	Possible
<b>High</b> 5000 spec	<b>Re-test 290</b> (5.8%)	<b>Re-test 59</b> (1.2%)	Yes

**\*95% Confidence**

# Re-testing: Example Sampling Plan

Volume (Per Site)	1%* error	5%* error	Retesting Feasibility
<b>Low</b> 500 spec	<b>Re-test 225</b> (45%)	<b>Re-test 56</b> (11%)	Possible

For monthly re-testing:

- Determine the number of specimens required to detect desired error detection rate
- For 1% error detection = 225 specimens/month
- Divide 225 by 4 = ~56 specimens/week = ~11 specimens/day
- Select number of specimens per day randomly – e.g., every 3<sup>rd</sup> specimen

**\*95% Confidence**

# Re-testing Process

- ① Determine specimen type
- ② Determine sampling plan and time interval
- ③ Collect specimens
- ④ Store specimens until transport
- ⑤ Package and transport specimens along with paperwork to designated laboratory
- ⑥ Compare re-test results with site results
- ⑦ Take Corrective actions, if needed

# Tester Responsibilities: Re-testing

- Follow written policies and procedures
- Collect appropriate specimen
- Record keeping is essential
- Take necessary precautions to avoid transcription errors
- Package and transport EQA specimens to designated reference laboratory
- Take necessary corrective actions



# Specimen Requirements

- Dried Blood Spots (DBS)
  - 100  $\mu$ l collected on labeled filter paper
  - Store refrigerated in appropriately packaged re-sealable plastic bag
- Serum or Plasma
  - 0.5 ml aliquot in labeled cryovial
  - Store at 2-8°C for up to 1 week
  - Store at -20°C or below if longer than 1 week



# Specimen Management : Common Problems

- Transcription errors
  - Mislabeling cryovial or DBS card
  - From Lab register to specimen transfer log
  - From reference lab to testing site
- Inadequate specimens



# Summary

- Describe your responsibilities in EQA.
- What is proficiency testing? On-site evaluation? Re-testing?
- Explain the process for on-site evaluation.
- What are some issues to consider prior to implementing a re-testing program?
- Explain the process for re-testing.
- What are some common problems associated with specimen management?

