MODULE 1

Productivity Management



SLMTA Participant's Manual

TABLE OF CONTENTS

NOTE: Print this document single-sided and in color if possible.

Activity: Process + Structure = Outcome	1
Activity: Improving a Problem Floor Plan	11
Activity: Mapping Out The Floor Plan of Your Laboratory	17
Activity: Redesigning The Floor Plan of Your Laboratory	26
Activity: Making a Cup of Tea	32
Activity: Whisper Down the Alley	33
Activity: What are the Benefits of a Standardized Process?	35
Activity: How Do You Assign Personnel to Tasks?	37
Activity: Creating a Management Calendar	52
Activity: Competency Assessment	62
Activity: Planning and Conducting a Staff Meeting	71
Activity: Creating a Personnel File	76

ACTIVITY SUMMARY SHEET

ACTIVITY Process + Structure = Outcome

Module 1

PURPOSE:

Optimal laboratory design involves two factors:

- physical layout of the allotted space
- workflow path designed around the steps of the process to be performed in that space.

In this activity, participants design a laboratory layout with regard to the workflow using the provided floor plan.

This activity supports the following laboratory management tasks and accreditation preparedness checklist items

Management Tasks



- 1.1 Organize the laboratory and coordinate work space to allow for smooth, efficient service operations
- 1.2 Design workflow for optimal productivity
- 1.12 Develop and implement lab improvement plans based on best practices and feedback from staff, patients, customers, quality indicators, and external assessment
- 1.13 Communicate to upper management regarding personnel, facility, and operational needs
- 2.4 Ensure appropriate physical work environment for testing

Checklist Items



- 2.5 <u>Communications System on Laboratory Operations</u> Does the laboratory communicate with upper management regularly regarding personnel, facility, and operational needs?
- 5.5 <u>Obsolete Equipment Procedures</u> Is non-functioning equipment appropriately labeled and removed from the laboratory & storage areas?
- 12.1 Is the size of the laboratory adequate and the layout of the laboratory, as a whole, organized so that workstations are positioned for optimal workflow?
- 12.2 Are the patient care and testing areas of the laboratory distinctly separate from one another?
- 12.3 Is each individual workstation maintained free of clutter and set up for efficient operation?
- 12.4 Is the physical work environment appropriate for testing?
- 12.8 Is a certified and appropriate Biosafety cabinet (or an acceptable alternative processing procedure) in use for all specimens or organisms considered to be highly contagious by airborne routes? (Biosafety cabinet should be recertified according to national protocol).

KEY MESSAGES

- Optimal laboratory design involves two factors:
 - physical layout of the allotted space
 - workflow path designed around the steps of the process to be performed in that space.
- Mapping the process and diagramming the floor plan are needed tools for laboratory redesign.
- Regardless of the physical space allotted to the laboratory, laboratorians can still make improvements through process and layout design.

Can you:

- Design a layout with regard to the workflow path?
- Create a spaghetti diagram that traces the movement of staff members or specimens?



SELF-ASSESSMENT

For this activity, you will need:
Handout 1:Specimen Flow (101)
Handout 2: Sample Floor Plan (102)
Handout 3: Diagram with Equipment and Inserted Steps (103)
Handout 4: Observed Steps (104)
Handout 5: Spaghetti Diagram (105)
☐ Worksheet 1: Floor Plan (106)
☐ Worksheet 2: Equipment Cut-Outs (107)
☐ Worksheet 3: Diagram with Equipment (108)

Specimen Flow¹⁰¹

	Step	What happens?		Step	What happens?
	1.Order placed	Clinician determines need	IASE	9.Routine quality checks completed	Prior to testing, determine if proper routine QC, reagent validation, equipment maintenance and calibration completed
	2.Patient presents to laboratory	Laboratorian interacts with patient	CAL PF	10.Specimen analyzed	Run analysis on specimen
	3. Requisition completed & reviewed by laboratory staff	Requisition reviewed for proper information	ANALYTICAL PHASE	11.Test results analyzed	Review test results for accuracy, legibility, & validity; Cross-checking Assure proper quality monitoring
ASE	4.Specimen type determined for collection	Note specific test requested and determine what type of sample is needed			
PRE-ANALYTICAL PHASE	5. Specimen collected	Blood drawn from patient; Sputum, urine, stool, or other specimen is collected			
E-ANAL)	6.Specimen logged	Appropriate information recorded in specimen log		12.Test results recorded	Transfer test results into logbook, Record results accurately
PRE	7.Specimen accepted or rejected	Specimen accepted or rejected based on meeting acceptance criteria	POST-ANALYTICAL PHASE	13.Test results communicated / reported	Notify Clinician of results via written report Verbal reporting if necessary Critical Values reporting Assure that referral specimens are properly tracked
	8. Specimen assigned according to test request/s	Requests reviewed for Testing priority - STAT versus routine If multiple tests to be done, sequential workstations versus aliquoting Centrifugation required Send out versus in-house testing	POST-ANAL)	14.Documents and records maintained, filed & stored	File & store results in a retrievable fashion Transfer files to long term storage Dispose of files at an appropriate time

Sample Floor Plan¹⁰²

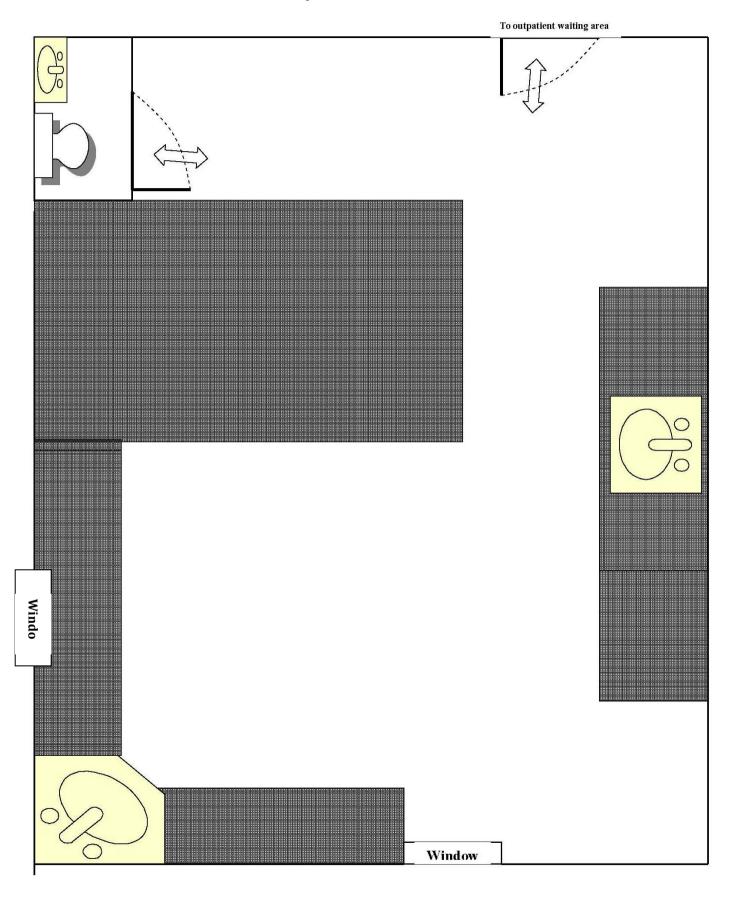
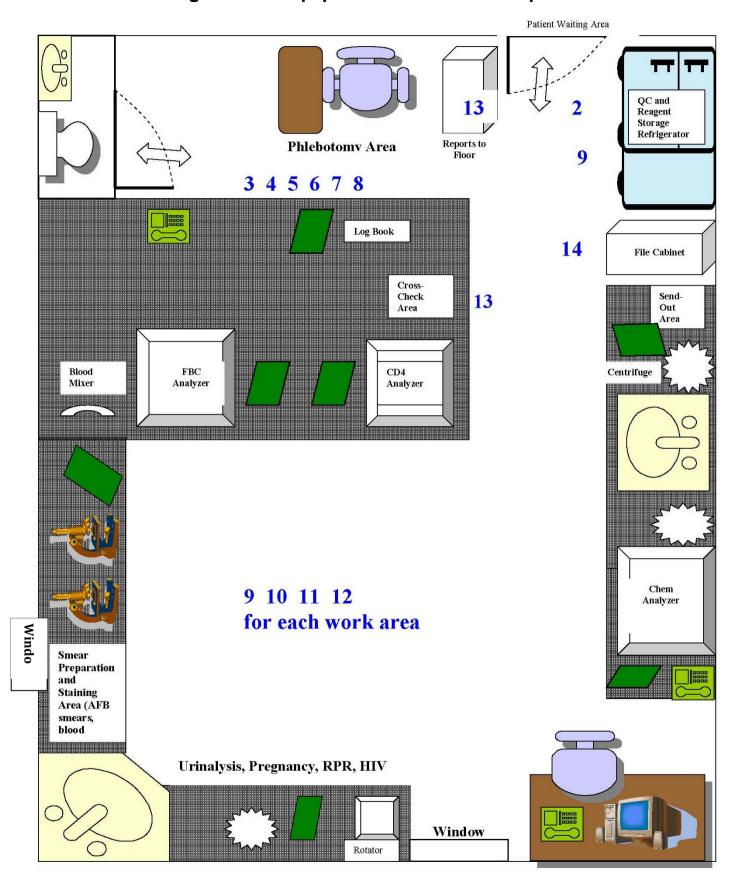


Diagram with Equipment and Inserted Steps 103

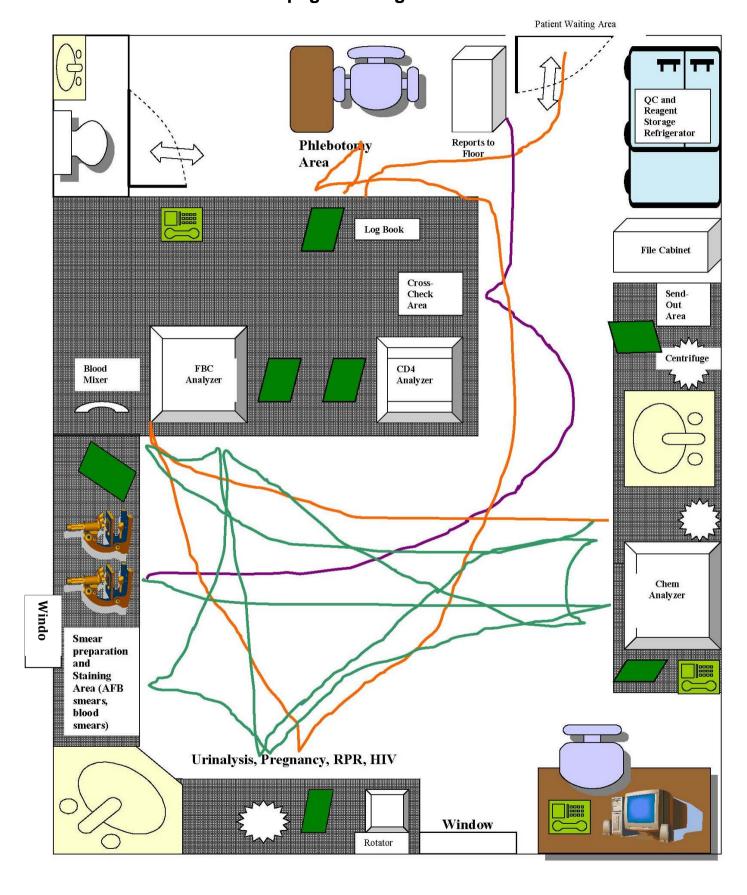


Observed Steps¹⁰⁴

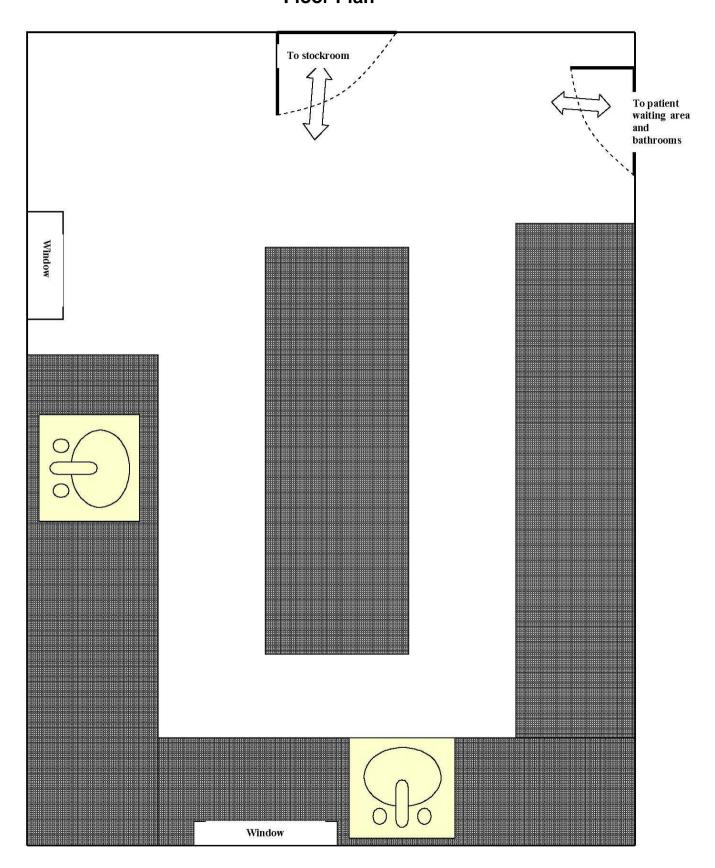
Trace the technologist's observed movement in your floor plan in the sequence listed. Quality control was performed earlier in the day.

- 1. Technologist greets patient
- 2. Requisition completed and reviewed, patient identification is verified
- 3. Specimen type is determined for chemistry profile, FBC, malaria smear, and urinalysis with microscopic
- 4. Urine and blood specimens are collected and labeled
- 5. Specimens are logged
- 6. Specimens are acceptable (urine quantity sufficient for testing, 1 full EDTA, 1 full red top)
- 7. Urine container placed at urinalysis testing area
- 8. EDTA tube is inserted into the mechanical blood mixer
- 9. Red top tube is placed into centrifuge
- 10. EDTA tube is removed from mechanical blood mixer
- 11. Malarial smear is prepared and allowed to air dry
- 12. FBC is analyzed
- 13. FBC results are recorded
- 14. Urinalysis macroscopic is dipped with test strip and analyzed
- 15. Urinalysis macroscopic results are recorded
- 16. Urine aliquot is poured over and placed into a centrifuge
- 17. Red top tube is removed from centrifuge
- 18. Red top tube is placed on chemistry analyzer to begin profile testing
- 19. Malarial smear is stained
- 20. Urine aliquot is decanted and sediment resuspended
- 21. Urinalysis microscopic is performed
- 22. Urinalysis microscopic results are recorded
- 23. Chemistry results are completed and validated
- 24. Chemistry results are recorded
- 25. Malarial smear microscopy is performed
- 26. Malarial smear results are recorded
- 27. Consolidated patient report is cross-checked
- 28. Patient report is released

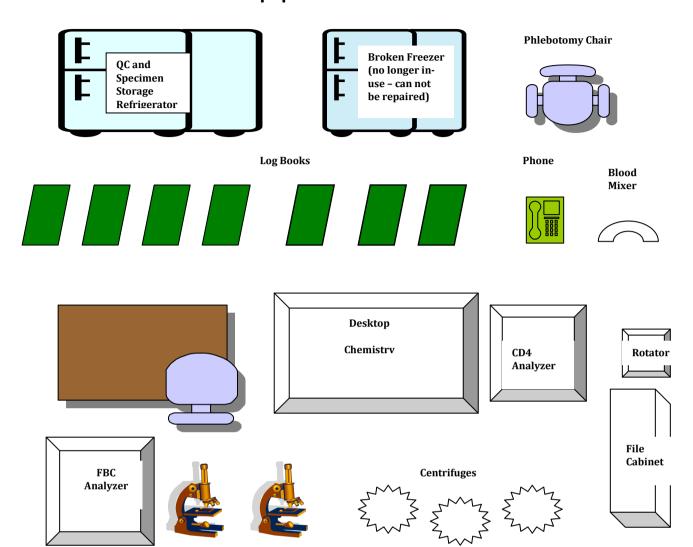
Spaghetti Diagram¹⁰⁵



Floor Plan¹⁰⁶



Equipment Cut-outs¹⁰⁷



INSTRUCTIONS

Cut-out each object and place them into the floor plan. Do not modify shape or size. You may use no more than 7 logbooks and no more than 3 centrifuges for your workflow.

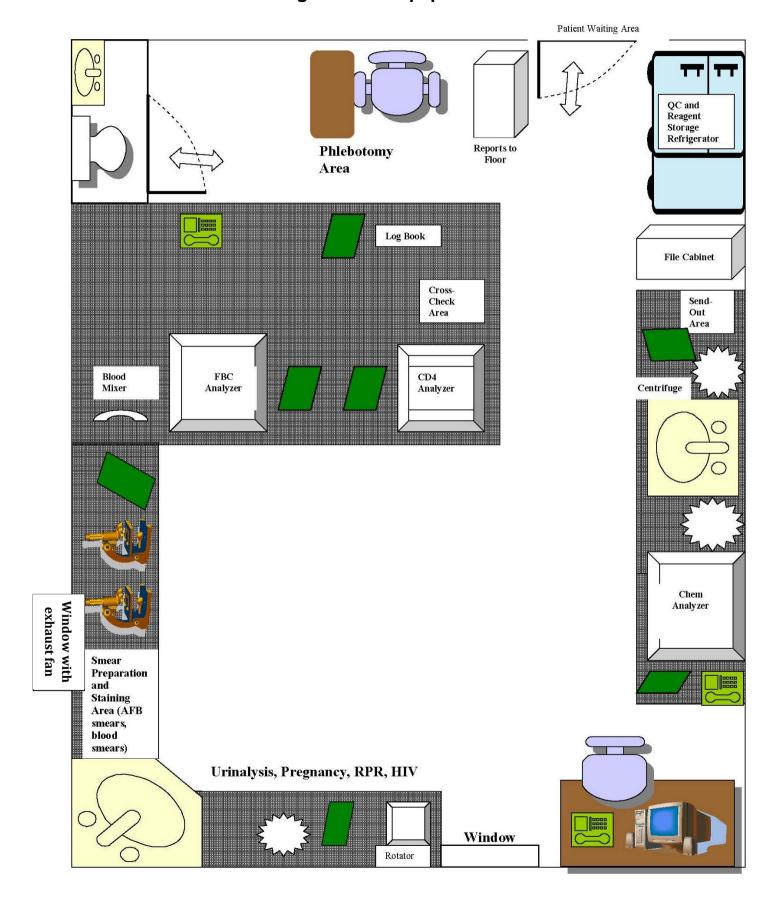
Designate the placement for the following in your floor plan:

- Phlebotomy area
- Send-out area
- Cross-Check area
- Documents and Records area
- Testing area for FBC, Differential, Malarial Smear, CD4, Chemistry Profile, Urinalysis with microscopic, Urine Pregnancy, RPR, Rapid HIV, AFB Smear.

Glue all objects to the floor plan.

Write the designated areas in the floor plan.

Diagram with Equipment 108



ACTIVITY SUMMARY SHEET

ACTIVITY Improving a Problem Floor Plan

Module 1

PURPOSE:

Optimal laboratory design requires that the physical work environment is safe and appropriate for testing.

In this activity, participants will identify hazardous elements in the work environment of the provided laboratory floor plan. Using the floor plan, participants will redesign the layout so that the problems are addressed.

This activity supports the following laboratory management tasks and accreditation preparedness checklist items

Management Tasks



- 1.1 Organize the laboratory and coordinate work space to allow for smooth, efficient service operations
- 1.2 Design workflow for optimal productivity
- 1.13 Communicate to upper management regarding personnel, facility, and operational needs
- 2.4 Ensure appropriate physical work environment for testing

Checklist Items



- 1.4 Laboratory Policies and Standard Operating Procedures Are policies and standard operating procedures (SOPs) for laboratory functions current, available and approved by authorized personnel? (Accommodation and Environmental Conditions, Laboratory Safety or Safety Manual)
- 2.5 Communications System on Laboratory Operations Does the laboratory communicate with upper management regularly regarding personnel, facility, and operational needs?
- 12.1 Is the size of the laboratory adequate and the layout of the laboratory, as a whole, organized so that workstations are positioned for optimal workflow?
- 12.3 Is each individual workstation maintained free of clutter and set up for efficient operation?
- 12.4 Is the physical work environment appropriate for testing?

KEY MESSAGES

- Safety is an integral component in laboratory design.
- Hazardous work environments must never be ignored by creating inappropriate work-arounds. Small changes in layout design can address immediate concerns. For larger issues, the laboratory must communicate facility and safety needs with upper management.
- An inspection of the work environment should be performed periodically to identify problems and unsafe work conditions.

Can you:

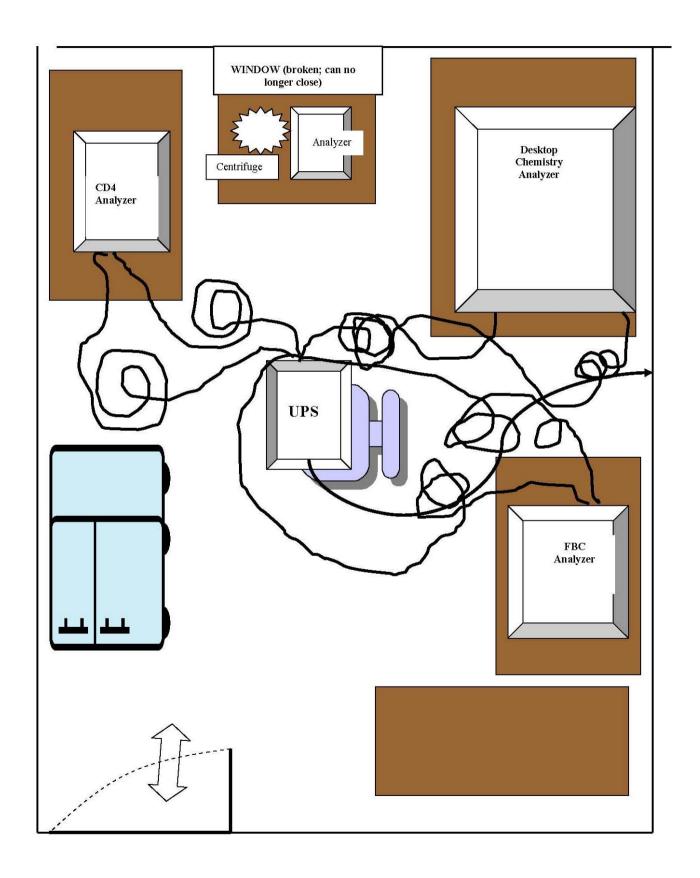
- Identify issues with poor design and unsafe work conditions?
- Redesign a laboratory layout to address unsafe work conditions?



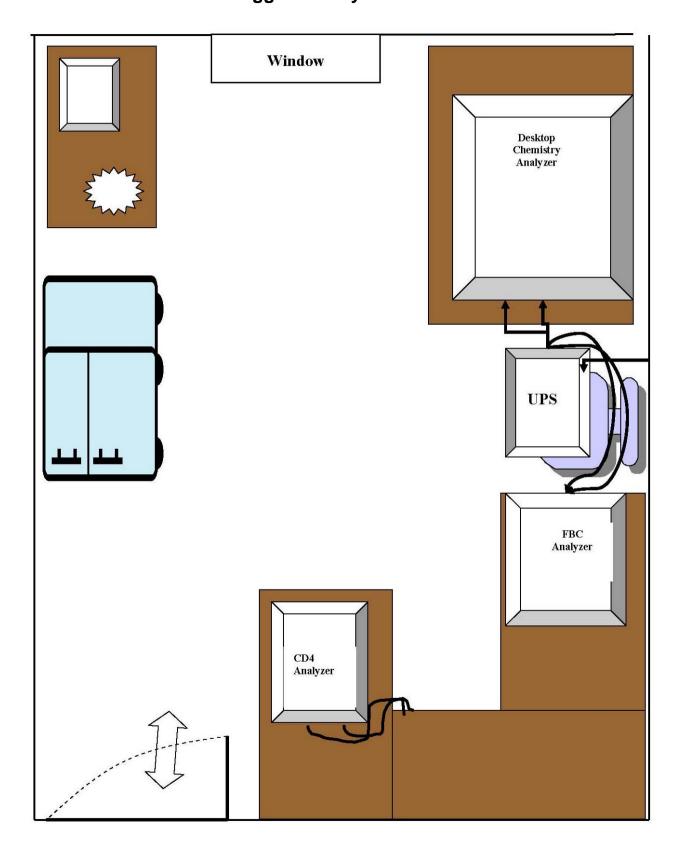
✓ SELF-ASSESSMENT

For this activity, you will need:
☐ Handout 1:Problem Floor Plan (109)
☐ Handout 2: Suggested Layout (110)
☐ Worksheet 1: Floor Plan (111)
☐ Worksheet 2: Equipment Cut-Outs (112)

Problem Floor Plan¹⁰⁹



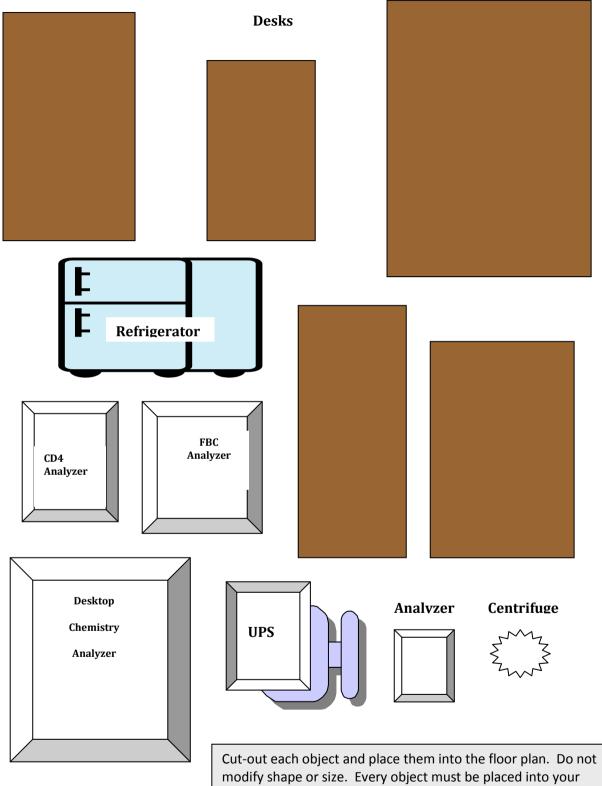
Suggested Layout¹¹⁰



Floor Plan¹¹¹

	Window	
J.	T	

Equipment Cut-outs¹¹²



floor plan.

Arrange the pieces so that the electrical wires no longer pose a safety hazard. Arrange the equipment so that the broken window does not present a water hazard.

Glue all pieces to the floor plan.

ACTIVITY SUMMARY SHEET

ACTIVITY Mapping Out The Floor Plan of Your Laboratory

Module 1

PURPOSE:

A good laboratory floor plan eliminates or significantly reduces waste by removing excess movement, time and effort. To effectively redesign a laboratory, the current floor plan and workflow path must be evaluated. In this activity, participants learn how to create a floor plan of their own laboratories. A follow-up activity will allow them to improve the workflow by redesigning the floor plan of their laboratories.

This activity supports the following laboratory management tasks and accreditation preparedness checklist items

Management Tasks



- 1.1 Organize the laboratory and coordinate work space to allow for smooth, efficient service operations
- 1.2 Design workflow for optimal productivity

Checklist Items



- 12.1 Is the size of the laboratory adequate and the layout of the laboratory, as a whole, organized so that workstations are positioned for optimal workflow?
- 12.3 Is each individual workstation maintained free of clutter and set up for efficient operation?
- 12.4 Is the physical work environment appropriate for testing?

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KEY MESSAGES

- To effectively redesign a laboratory, the current floor plan and workflow path must be evaluated.
- Repositioning movable items alters the workflow path.
- Tracing the workflow path in the floor plan can easily highlight inefficiencies and waste.

Can you:

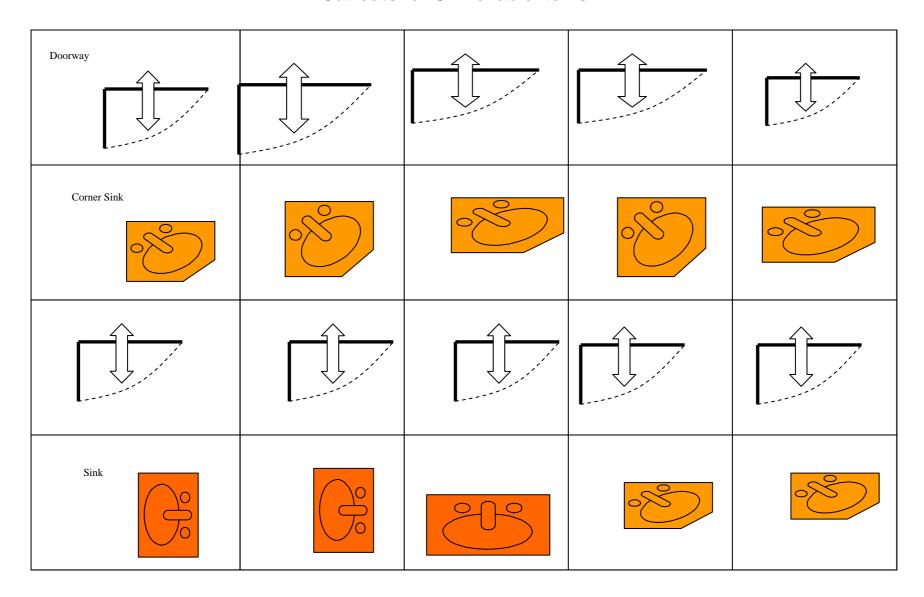
- Create a floor plan?
- Trace the workflow path in a floor plan?
- Recognize that movable items can be repositioned within the limitations of the permanent structures?
- Recognize that changing the placement of movable items alters the workflow path?

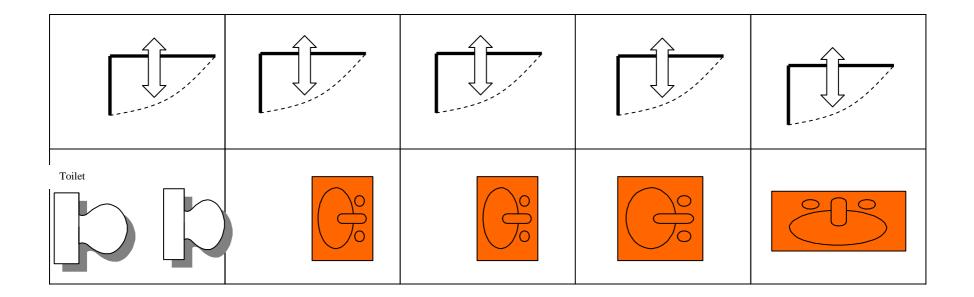


SELF-ASSESSMENT

For this activity, you will need:
☐ Worksheet 1: Cut-outs for Unmovable Items (113)
☐ Worksheet 2: Cut-outs for Workbench (114)
☐ Worksheet 3: Cut-outs for Movable Items (115)

Cut-outs for Unmovable Items¹¹³





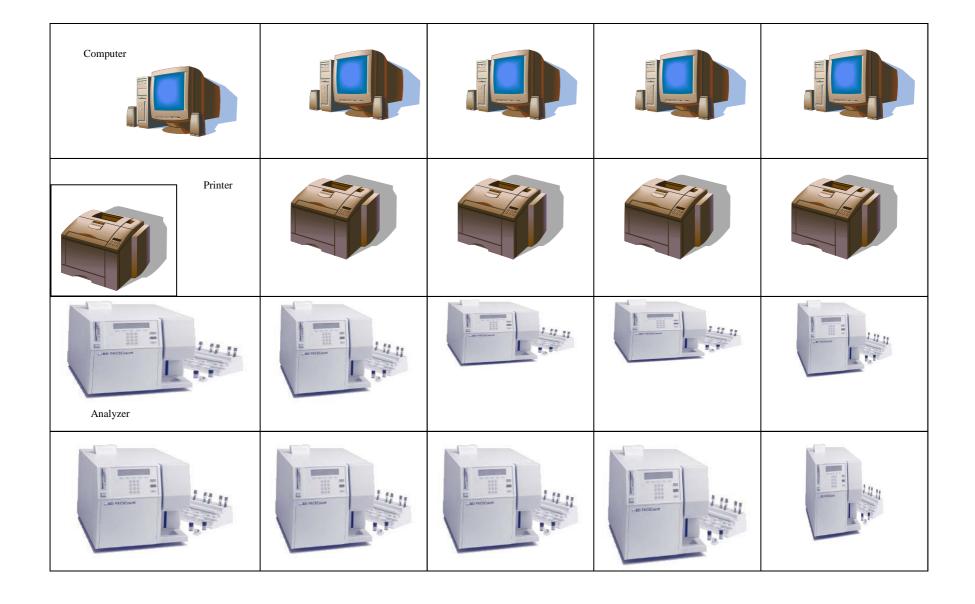
Cut-outs for Workbench¹¹⁴

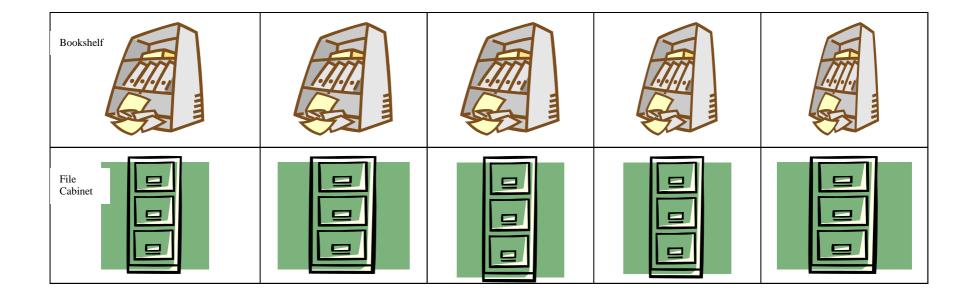
WORK BENCH			WORK BENCH
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WORK BENCH WORK BENCH	WORK BENCH	WORK BENCH
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Cut-outs for Movable Items¹¹⁵

Telephone				
Refrigerator or Freezer	<u>t</u>	‡ ‡	t	ţ ţ
Microscope				
Centrifuge				CHUTTO COLUMN TO THE COLUMN TO





ACTIVITY SUMMARY SHEET

ACTIVITY Redesigning The Floor Plan of Your Laboratory

Module 1

PURPOSE:

A good laboratory floor plan eliminates waste by removing excess movement, time and effort. In this activity participants redesign their laboratory layout to improve the workflow by repositioning movable items in their floor plan.

This activity supports the following laboratory management tasks and accreditation preparedness checklist items

Management Tasks



- 1.1 Organize the laboratory and coordinate work space to allow for smooth, efficient service operations
- 1.2 Design workflow for optimal productivity

Checklist Items



- 5.1 <u>Adherence to Proper Equipment Protocol</u> Is equipment installed and placed as specified in the operator's manuals and uniquely labeled or marked?
- 7.12 <u>Inventory Organization and Wastage Minimization</u> Is First-Expiration-First-Out (FEFO) practiced?
- 11.2 Are quality indicators (TAT, rejected specimens, stock outs, etc.) selected, tracked, and reviewed regularly to monitor laboratory performance and identify potential quality improvement activities?
- 11.3 Are the outcomes of internal and external audits, PT, customer feedback and all other information derived from the tracking of quality indicators used to improve lab performance?
- 12.1 Is the size of the laboratory adequate and the layout of the laboratory, as a whole, organized so that workstations are positioned for optimal workflow?
- 12.2 Are the patient care and testing areas of the laboratory distinctly separate from one another?
- 12.3 Is each individual workstation maintained free of clutter and set up for efficient operation?
- 12.4 Is the physical work environment appropriate for testing?
- 12.6 Is laboratory-dedicated cold and room temperature storage free of staff food items, and are patient samples stored separately from reagents and blood products in the laboratory refrigerators and freezers?
- 12.8 Is a certified and appropriate Biosafety cabinet (or an acceptable alternative processing procedure) in use for all specimens or organisms considered to be highly contagious by airborne routes? (Biosafety cabinet should be recertified according to national protocol).



KEY MESSAGES

- Managers can use the floor plan to explore possible redesign layouts and initially asses the effect on the workflow path by tracing the movement.
- With the simple rearrangement of a few key laboratory movable items, the laboratory's efficiency of work flow can be greatly improved.
- Redesigning a more efficient laboratory begins with thinking, "I could make this easier by doing this."

Can you:

- Recognize the qualities that contribute to a good workflow versus a bad workflow?
- Propose a change by repositioning a movable item in their floor plan?
- Trace the new workflow path resulting from the repositioned item?



SELF-ASSESSMENT

For this activity, you will need:
☐ Floor plans created in the last activity
☐ Moveable items from the last activity
☐ Job Aid 1: Guiding Principles for Laboratory Layout (116)
☐ Job Aid 2: Redesigning Your Laboratory Action Plan (117)

Guiding Principles for Laboratory Floor Plan Design

Laboratory space should be:

- Adequate in size for testing needs
- Organized into distinct work areas
 - sample reception
 - sample preparation
 - testing
 - results production
 - results validation and release
 - reagent and consumable storage
 - data / filing / records (non-testing areas)
- Be clean & uncluttered
 - Expired and unused supplies and reagents should be discarded
 - All non-functioning / out-dated equipment should be removed from the laboratory and store room
- Neat and well-lit

Electrical requirements:

- Extension chords should positioned safely out of the walkways
- All analyzers should have surge protectors
- All analyzers should have UPS (Uninterruptible Power Supply)

Water:

 Lab personnel should know the water type and usage requirements for the equipment in their labs

Equipment should:

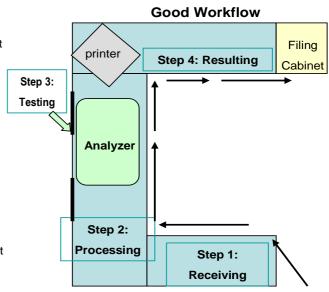
- be placed to facilitate smooth and efficient workflow
- have sufficient operational area
- be safely positioned
- avoid placement in high traffic area
- avoid placement that requires frequent moving for cleaning and maintenance
- avoid direct placement under airconditioners
- avoid nearness to sinks and wet benches
- avoid direct proximity to heat source (instrument or sunlight)
- allow adequate space between instrument back and wall

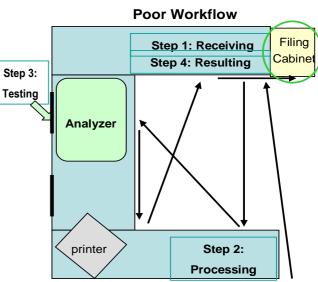
Supplies and reagents should:

- Have dedicated cabinet or shelf space for storage (at each workstation, if possible)
- Be arranged to facilitate compliance with the First-Expiry-First-Out rule

Refrigerators should:

- be positioned to avoid disturbance and overheating
- be well organized and not over-stocked
- only hold items in use or planned for use
- not have close mixing of samples and reagents
- not hold food or drink





Guiding Principles for Workstation Set-up

Required equipment and supplies

- Personal protective equipment gloves, masks, sharps containers, etc.,
- Waste Disposal Containers
- Office supplies pencils, paper, stapler, scissors, etc.
- Materials, consumables, and reagents required to perform maintenance
- Materials, consumables, diluents, and reagents required to perform testing
- Ancillary equipment required for testing (such as pipettes, pipette tips, timer, mixer, vortex, rotator)
- Specimen racks to organize workload
- Equipment Operator's Toolkit

All documentation readily available

- Equipment Owner's Manual
- Equipment Manufacturer's Data (serial number, contact information)
- Logs reagent, QC, equipment maintenance & service, environmental (temperature, humidity, etc.) and corrective action
- Standard Operating Procedures (SOPs)
- Critical Values
- Population Reference ranges (if available)
- Clinician contact information

Optimal workstation Layout

- Follow the sequence of the process
- Place all main instruments together arranged in a semi-circle (or Ushaped) work cell (versus individual workstations spread in various rooms). This arrangement allows a single operator to keep all analyzers running.
- Place highest-volume chemistry and hematology analyzers closest to laboratory entrance to minimize walking.
- Place back-up equipment, if available, behind main analyzers.
- If more than one centrifuge is available, decentralize and place adjacent to the analyzer's workstation. Be aware of possible interference to the analyzer caused by vibrations from operating the centrifuge.
- Specify a permanent location for each item (equipment, tools, and supplies). Mark the outline of each item (i.e., the shape of scissors, stapler) with colored tape so a missing item will be noted & easily replaced

Optimal Work Process

- Define the standard work / operating procedures (SOP) and specify the sequence of steps as well as the key actions an operator must take to ensure high quality
- Utilize constant workflow or small batches to decrease turn around time (TAT) and operator waiting time
- Analyzing specimens using a one-piece flow process (first in/first out) allows earlier detection of quality problems

Redesigning Your Laboratory: Action Plan 117

- 1. Select an area of the laboratory to redesign.
- 2. Create an accurate floor plan of the selected area that diagrams the existing conditions. Include the placement of any utilities such as electrical outlets, data outlets (telephone and computer), and floor drains.
- 3. Generate an equipment list. Collect information about the equipment in the selected area. An excellent resource is the instrument operator's manual.

Manufacturer Name & Model Number	Dimensions (width, depth, height, clearance requirements)	Electrical (volts, amps, emergency power, UPS)	Data (computer connections)	HVAC (heat generated in BTU's, venting requirements, air exchange requirements)	Plumbing (type of water, drain, vacuum)

- 4. Map the processes that contribute to the workflow path in the selected area through direct observation.
 - a. Several observations are required to accurately map the process
 - b. Staff should be encouraged to contribute ideas and sharing information on how they do their work.
 - c. During the direct observation:
 - i. Understand that staff will be uncomfortable while being observed.
 - ii. Explain to the staff that you want to learn from them.
 - iii. Do not interfere with or modify their work.
 - iv. Limit questions.
 - v. Record all actions.
 - vi. Thank them after finishing the observation.
 - d. Compile the information from the observations and create a process map.

Step	Action taken	Person Responsible for Action

- 5. Trace the current workflow path onto the current floor map.
 - a. Look for areas of waste.
 - i. Excess movement because the work stations do not follow the sequence of the mapped process.
 - ii. Excess waiting, processing or transportation time because workstation layout does not support the workflow or the action taken does not add value to the testing process.

6. Redesign the selected area

- a. Collect a baseline measurement using a quality indicator (QI) such as turnaround time to measure outcome (the effectiveness of the change). The baseline data is based upon the current conditions (layout and process).
- b. Review the floor plan layout and processes and suggest changes.
 - i. Consider the removal of all unnecessary equipment and supplies (broken or no longer in use).
 - ii. Review Job Aid 1, "Guiding Principles for Laboratory Floor Plan Design" and Guiding Principles for Laboratory Setup and Workflow."
- c. Trace the workflow path using the revised layout and process map.
- d. Propose suggested changes to both upper management and laboratory staff. Solicit feedback by actively engaging staff.
- 7. Institute changes in layout or workflow.
 - a. Collect data using the same QI to measure the effectiveness of the changes.
 - b. Reassess and look for additional areas to improve. If additional changes are implemented, recollect QI data.
- 8. Report findings to upper management and staff members (i.e. staff meeting).
- 9. Include revised process map and layout into the laboratory's quality manual.
- 10. Consider improving another area through redesign.

ACTIVITY SUMMARY SHEET

ACTIVITY Making a Cup of Tea

Module 1

PURPOSE:

Simple, daily tasks can easily become laborious when the needed supplies and materials are not readily available. This activity demonstrates that organization is the key to performing any daily activity, including making a cup of tea.

This activity supports the following laboratory management tasks and accreditation preparedness checklist items

Management Tasks



- 1.1 Organize the laboratory and coordinate work space to allow for smooth, efficient service operations
- 1.2 Design workflow for optimal productivity
- 2.4 Ensure appropriate physical work environment for testing

Checklist Items



- 12.3 Is each individual workstation maintained free of clutter and set up for efficient operation?
- 12.4 Is the physical work environment appropriate for testing?

KEY MESSAGES

- Organization is essential for completing tasks in an efficient and productive manner. Organization removes waste, i.e. wasted time, effort and movement.
- A disorganized workstation affects the efficiency and quality (outcome) of that workstation.
- A disorganized workstation may affect other workstations by interrupting staff members from their assigned tasks or delaying the workflow process.

Can you:

 Recognize and discuss the affects a disorganized workstation has on productivity and efficiency?



✓ SELF-ASSESSMENT

ACTIVITY SUMMARY SHEET

ACTIVITY Whisper Down the Alley

Module 1

PURPOSE:

This activity demonstrates the need for written step-by-step procedures so that staff members perform tasks in a standardized manner. It highlights the difference between how verbal directions can easily be mis-communicated and how written instructions consistently convey the information accurately.

This activity supports the following laboratory management tasks and accreditation preparedness checklist items

Management Tasks



- 2.6 Ensure Safety Manual with safety procedures for laboratory functions and possible emergencies is accessible to and reviewed by all staff
- 6.1 Ensure that the Quality Manual with quality assurance policies and procedures is accessible to and reviewed by all staff
- 6.11 Ensure that SOP are read and understood by staff
- 10.1 Maintain a library of documents (policies, guidelines, SOPs, references, etc.); review and update annually

Checklist Items



- 1.1 <u>Laboratory Quality Manual</u> Is there a current laboratory quality manual, composed of the quality management system's policies and procedures, and has the manual content been communicated to and understood and implemented by all staff?
- 1.2 <u>Document and Information Control System</u> Does the laboratory have a system in place to control all documents and information (internal and external sources)?
- 1.4 <u>Laboratory Policies and Standard Operating Procedures</u> Are policies and standard operating procedures (SOPs) for laboratory functions current, available and approved by authorized personnel?
- 1.5 Policy and SOPs Accessibility Are policies and SOPs easily accessible/ available to all staff and written in a language commonly understood by respective staff?
- 4.2 <u>Laboratory Handbook for Clients</u> Is there a laboratory handbook for laboratory users that includes information on services offered, quality assurance, laboratory operations, sample collection, transport and agreed turnaround times?
- 4.3 <u>Communication Policy on Delays in Service</u> Is timely, documented notification provided to customers when the laboratory experiences delays or interruptions in testing (due to equipment failure, stock outs, staff levels, etc.) or finds it necessary to change examination procedures?
- 5.7 <u>Equipment Preventive Maintenance</u> Is routine preventive maintenance performed on all equipment and recorded according to SOPs/log sheet?
- 5.13 <u>Manufacturer's Operator Manual</u> Are the equipment manufacturer's operator manuals readily available to testing staff, and where possible, available in the language understood by staff?
- 8.1 Are guidelines for patient identification, specimen collection (including client safety), labeling, and transport readily available to persons responsible for primary sample collection?
- 8.2 Are adequate sample receiving procedures in place?
- 8.6 Is complete procedure manual available at the workstation or in the work area?

- 8.12 Have acceptable ranges been defined for all temperature- dependent equipment with procedures and documentation of action taken in response to out of range temperatures?
- 9.8 <u>Test Result Report</u> Is the laboratory result report(s) in a standard form determined to be acceptable by its customers?

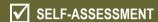
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KEY MESSAGES

- When communicating important information, do not rely on verbal communication; use written instructions.
- Laboratory documents provide the staff with complete, accurate, and consistent information.

Can you:

 Convey important laboratory information in a manner that is accurate, error-free, and understandable to the recipient?



ACTIVITY SUMMARY SHEET

ACTIVITY What are the Benefits of a Standardized Process? Module 1

PURPOSE:

Well-defined processes assure the work is performed the same way each time. The benefits of standardizing the process are:

- It makes errors more difficult to commit
- It makes errors more visible if committed
- It absorbs errors that are committed.

In this activity, a demonstration is used to illustrate these benefits and how they relate to the quality of patient care.

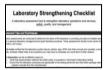
This activity supports the following laboratory management tasks and accreditation preparedness checklist items

Management Tasks



- 1.2 Design workflow for optimal productivity
- 6.10 Customize site-specific SOPs as needed

Checklist Items



- 1.1 <u>Laboratory Quality Manual</u> Is there a current laboratory quality manual, composed of the quality management system's policies and procedures, and has the manual content been communicated to and understood and implemented by all staff?
- 1.4 <u>Laboratory Policies and Standard Operating Procedures</u> Are policies and standard operating procedures (SOPs) for laboratory functions current, available and approved by authorized personnel?
- 1.5 <u>Policy and SOPs Accessibility</u> Are policies and SOPs easily accessible/ available to all staff and written in a language commonly understood by respective staff?
- 8.1 Are guidelines for patient identification, specimen collection (including client safety), labeling, and transport readily available to persons responsible for primary sample collection?
- 8.2 Are adequate sample receiving procedures in place?
- 8.12 Have acceptable ranges been defined for all temperature- dependent equipment with procedures and documentation of action taken in response to out of range temperatures?
- 9.6 <u>Archived Data Labeling and Storage</u> Are archived results (paper or datastorage media) properly labeled and stored in a secure location accessible only to authorized personnel?
- 9.8 <u>Test Result Report</u> Is the laboratory result report(s) in a standard form determined to be acceptable by its customers?



KEY MESSAGES

- The benefits of standardizing the process are:
 - It makes errors more difficult to commit
 - It makes errors more visible if committed
 - It absorbs errors that are committed.
- A well-designed and standardized process improves the quality of patient care by preventing or immediately addressing errors.

Can you:

- Identify the benefits of a welldesigned and standardized process?
- Recognize that preventing or immediately addressing errors improves the quality of patient care provided by the laboratory?



SELF-ASSESSMENT

ACTIVITY SUMMARY SHEET

ACTIVITY How Do You Assign Personnel to Tasks?

Module 1

PURPOSE:

A duty roster helps a manager coordinate tasks among laboratory staff to better serve customers. It assigns personnel to workstations with welldefined tasks and responsibilities. In this activity, participants learn to create a duty roster based on a testing menu, workload, personnel available, and operational hours.

This activity supports the following laboratory management tasks and accreditation preparedness checklist

Management Tasks



- 1.2 Design workflow for optimal productivity
- 1.3 Prioritize and assign work according to personnel skill level, workloads, and completion timeframe
- 1.11 Implement measures to motivate staff to improve quality of work and productivity (e.g., training, job rotation, employee of the month, thank-you letter, etc.)

Checklist Items



- 3.1 Workload, Schedule and Coverage Do work schedules show task assignments & coordination of work for adequate lab staff coverage?
- 3.2 <u>Duty Roster And Daily Routine</u> Are daily routine work tasks established, assigned (duty roster and workstation assignments/tasks), monitored and supervised by qualified professional staff, and which indicates that only authorized personnel perform specific tasks?
- 3.3 Organizational Chart and External/Internal Reporting Systems Are lines of authority and responsibility clearly defined for all lab staff, including the designation of a supervisor and deputies for all key functions?

KEY MESSAGES

- An organized, detailed, and well thought-out duty roster will increase productivity, efficiency, and morale.
- Four factors influence the duty roster: testing menu, workload, personnel available (number of staff, skill level, and hours worked), and operational hours.
- A duty roster provides visual access to accommodate changes affecting operations.

Can you:

- Assign personnel to tasks by assessing workload, staff availability, and hours of operation?
- Reschedule changes to address encountered problems or requests?



✓ SELF-ASSESSMENT

For this activity, you will need:
☐ Handout 1: Duty Scheduling Scenario (118)
☐ Handout 2: Workload Statistics (119)
Handout 3: Workstation Assignments (120)
☐ Worksheet: Duty Roster Schedule (121)
Job Aid: Implementing a Duty Roster (122)

Duty Scheduling Scenario 118

- The laboratory and clinic hours are 8:00 to 4:00 pm.
- The HIV Clinic is open to 6:00pm on Tuesdays and Thursdays. During this extended time only 5 patients are seen. The primary request is for a HIV Rapid test; however, on occasion other tests may also be requested.
- Wednesday is the busiest day because of the demands from the prenatal and ART clinics.
- o 80% of the workload is collected and received by 11 am.
- Work shift times for staff members may be staggered to accommodate clinic hours (i.e. 8-4 shift, 9-5 shift, 10-6 shift).
- o More than one workstation can be assigned to a staff member.
- The clinic employs one Lead Tech, 3 Technologists, 1 Laboratory Aide, and 1 Phlebotomist. You, the manager, and the 3 Technologists are competent in all workstation areas.

Use the following abbreviations to indicate assigned workstations:

H = Hematology and CD₄ SP = Specimen Processing

C = Chemistry P = Phlebotomy

UA = Serology and Urinalysis **SR** = Store Room

BB = Blood Bank X = Cross-Checking and Filing

M = Microbiology

Workload Statistics¹¹⁹

40

Typical workload for this laboratory each week	Mon	Tue	Wed	Thu	Fri	Tests/ Week	Monthly Statistics from Previous Month
Hematology & CD4							
Full Blood Count (FBC) – Automated	12	15	30	15	11	83	334
Differential - electronic	7	8	14	6	3	38	150
Differential - manual (peripheral smear)	1	2	9	1		13	50
CD4 counts – Automated	4	5	29	5	8	51	205
Malarial Smears	8	6	3	9	4	30	120
Chemistry – Automated						0	
Liver Function Tests (LFT)	11	9	20	14	6	60	240
Serum Electrolytes	10	7	15	8	9	49	200
Renal Function Tests	8	6	18	6	7	45	182
Serum Amylase	3	2	7	2	2	16	65
Serum Glucose	11	8	11	8	10	48	190
CSF Chemistries	1	1		3		5	19
Serology & Urinalysis						0	
HIV Rapid	10	15	12	15	9	61	230
Rapid Syphilis	2	2	5	2	2	13	50
RPR	10	8	15	9	8	50	205
Hepatitis B	4	3		3	2	12	49
Urine Pregnancy	3	2	10	2	1	18	78
Urinalysis with Microscopy	13	10	5	10	8	46	187
Microbiology						0	
AFB Smear Microscopy	9	7	5	10	8	39	155
India Ink				2		2	7
CSF Cell Counts	1	1		3		5	21
Gram Stain	5	2		1	3	11	45
Wet Mounts Direct Microscopy (NaCl & KOH)	3	0	2	2	2	9	37
Blood Bank						0	
Type and Crossmatch	1	2			2	5	17
Specimen Processing						0	
Referral Tests	3	10	8	3	9	33	135
Phlebotomy						0	
Venipunctures Performed	32	29	49	29	27	166	649
Dried Blood Spots (DBS)	5	1	1	2		9	37
Glucose by Glucometer (Point-of-care Device)	4	2			1	7	29
Whole Blood Lactate (Point-of-care Device)	1		3			4	14

Hematology & CD4							
Daily Tasks W	Weekly, Monthly, or As-Needed Tasks						
 Inspect work area Adhere to safety practices; ensure all needed safety equipment is available Organize work area for the day's workload Perform all daily maintenance on analyzer and document in log Perform daily analyzer system checks; verify acceptability and document Perform daily QC; verify acceptability and document Perform assigned testing, validation, and interpretation Aliquot specimens properly as needed Troubleshoot and document corrective action on all invalid or discordant results Notify and document all panic values Record results in the log book Store specimens in proper place and temperature; discard specimens that exceed retention time Document and record QA indicators and occurrences Ensure proper disposal of waste Clean and disinfect work area Perform daily and as-needed microscope maintenance and document Restock work area with all needed supplies for the next day 	Perform analyzer weekly, monthly, and as-needed maintenance Perform, verify, and document calibration as needed Analyze and report EQA testing Change stain as needed and verify its performance Perform basic troubleshooting activities and document Contact customer service, document call, and monitor until resolved Issue repair orders and monitor until service is completed Monitor performance of new lots Review supplies and reagents needed at the workstation; update stockroom as needed Ensure sufficient workstation logs are available for the next month; provide blank logs at the end of month Ensure analyzer's toolkit is up-to-date Observe other members and provide feedback and cross-train as needed Review and sign-off on all SOPs for the workstation and overall laboratory policies						

Serology & Urinalysis							
	Daily Tasks	Weekly, Monthly, or As-Needed Tasks					
	Adhere to safety practices; ensure all needed safety equipment is available Organize work area for the day's workload Verify rotator speed and document Perform internal and external QC; verify acceptability and document Perform assigned testing, validation, and interpretation Aliquot specimens properly as needed Troubleshoot and document corrective action on all invalid or discordant results Notify and document all panic values Record results in the log book Store specimens in proper place and temperature; discard specimens that exceed retention time Document and record QA indicators and occurrences Ensure proper disposal of waste Clean and disinfect work area Perform daily and as-needed microscope maintenance and document Restock work area with all needed supplies for the next day	 Track discordant rates Analyze and report EQA testing Issue repair orders and monitor until service is completed Monitor performance of new lots Review supplies and reagents needed at workstation; update stockroom as needed Ensure sufficient workstation logs are available for next month; provide blank logs at end of month Observe other members and provide feedback and cross-train as needed Review and sign-off on all SOPs for the workstation and overall laboratory policies 					

Use this handout to help you assign workstations and duties to your staff. When making the assignments, consider the workload and tasks involved.

	Blood Bank							
	Daily Tasks	Weekly, Monthly, or As-Needed Tasks						
•	Inspect work area	 Analyze and report EQA testing 						
•	Adhere to safety practices; ensure all needed safety equipment is available	 Issue repair orders and monitor until service is completed 						
•	Organize work area for the day's workload	Monitor performance of new lotsReview supplies and reagents						
•	Perform temperature for all areas	needed at the workstation; update						
•	Perform, document all blood monitoring activities	stockroom as needed Ensure sufficient workstation logs						
•	Perform daily QC; verify acceptability and document	are available for the next month; provide blank logs at the end of month						
•	Perform assigned testing, validation, and interpretation	 Observe other members and provide feedback and cross-train as needed 						
•	Aliquot specimens properly as needed	 Review and sign-off on all SOPs for the workstation and overall 						
•	Troubleshoot and document corrective action on all invalid or discordant results	laboratory policies						
•	Notify and document all panic values							
•	Record results in the log book							
•	Store specimens in proper place and temperature; discard specimens that exceed retention time							
•	Document and record QA indicators and occurrences							
•	Ensure proper disposal of waste							
•	Clean and disinfect work area							
•	Notify and document availability of blood units							
•	Restock work area with all needed supplies for the next day							

EQA = External Quality Assessment

Use this handout to help you assign workstations and duties to your staff. When making the assignments, consider the workload and tasks involved.

	lookly Monthly or As Nooded Tasks
Daily Tasks W	eekly, Monthly, or As-Needed Tasks
 Inspect work area Adhere to safety practices; ensure all needed safety equipment is available Organize work area for the day's workload Collect specimens properly Provide instructions for proper specimen collection to patients (AFB, UA) Label and log specimens Perform daily QC on glucometer and lactate POC devices; ensure acceptability and document Record results of glucose and lactate testing Document and record QA indicators and occurrences Ensure proper disposal of waste Clean and disinfect work area Restock work area with all needed supplies for the next day 	Analyze and report EQA testing for POC testing Observe other members and provide feedback and cross-train as needed Review and sign-off on all SOPs for the workstation and overall laboratory policies

EQA = External Quality Assessment

POC = Point of Care

Use this handout to help you assign workstations and duties to your staff. When making the assignments, consider the workload and tasks involved.

Store room							
Daily Tasks	Weekly, Monthly, or As-Needed Tasks						
 Inspect storage area Document and record QA indicators and occurrences Ensure proper disposal of waste 	 Perform stock-count Maintain inventory records Ensure proper storage and rotation of stock Check quality of stored stock periodically Place orders properly Track orders placed Inspect and unpack incoming order Reconcile received stock, reagents, and supplies with order requests and vendor's invoice Follow-up on order discrepancies Ensure sufficient spare parts for microscope (bulb, fuse, etc) and centrifuge (brushes) for all workstations, batteries for POC testing devices Ensure reagents and chemicals are stored properly Ensure sufficient workstation logs are available for the next month; provide blank logs at the end of month Maintain an organized stockroom Remove all clutter, personal items, and old, non-functioning equipment Review and sign-off on all SOPs for the workstation and overall laboratory policies 						

POC = Point of Care

Use this handout to help you assign workstations and duties to your staff. When making the assignments, consider the workload and tasks involved.

Cross-check						
Daily Tasks	Weekly, Monthly, or As-Needed Tasks					
Check accuracy of results						
 Ensure all critical results have been called and documented by workstations 						
Confirm all tests are completed						
 Validate & interpret glucose and lactate POC testing 						
 Ensure results have been reported properly 						
Ensure confidentiality of results						
 Place results in proper location for distribution outside of the laboratory 						
 Perform filing of results for storage and retrieval 						
 Document and record QA indicators and occurrences 						
Clean and disinfect work area						

POC = Point of Care

Duty Roster Schedule 121

Week 1

	Monday	Tuesday	Wednesday	Thursday	Friday
Lead Tech					
Technologist A					
Technologist B					
Technologist C					
Laboratory Aide					
Phlebotomist					

Week 2

	Monday	Tuesday	Wednesday	Thursday	Friday
Lead Tech					
Technologist					
A					
Technologist					
В					
Technologist					
С					
Laboratory					
Aide					
Phlebotomist					

Implementing a Duty Roster¹²²

Use this job aide to help introduce a duty roster to your staff.

- 1. **EXPLAIN** the importance of using a duty roster and the benefits regarding workload, moralee, and productivity in creating a working team environment.
- 2. **DISCUSS** the need to define expectations regarding work assignments.
- 3. **INVITE** input from your staff in developing these expectations.
- 4. **DOCUMENT and POST** the agreed upon expectations in the lab.
- 5. **ENFORCE** the duty roster.
- 6. **ROTATE** workstation assignments on a regular basis.

Suggested list of expectations to discuss with your staff

- Duties to be completed at each assigned workstation.
 For example:
 - Daily- tasks that must be completed at the start of the day before patients are received:
 - Inspect work area
 - Organize work area for testing
 - Perform, analyze, record system checks, environmental checks, and QC
 - Weekly coordination of tasks when roster assignment involves several staff members during the week
 - Monthly/As-Needed coordination of tasks when roster assignment involves several staff members during the month
- Responsibility for the roster each month
- Process for request of days off while roster is under development
- Process for resolution of conflicting requests, such as seniority
- Decision of where the roster will be posted
- Decision of when the next month's roster will be posted.
- Procedure for change requests after the roster is posted (define who is responsible to find a replacement)
- Notification process for work absences (to whom, by when)
- Process for unmet expectations which are predefined
- Responsible person to monitor, follow up, and resolve noncompliance issues

ACTIVITY SUMMARY SHEET

ACTIVITY Creating a Management Calendar

Module 1

PURPOSE:

A calendar is an essential management tool for planning and organizing lab tasks. In this activity, participants learn to create and use a calendar to schedule, coordinate, balance, and prioritize lab activities.

This activity supports the following laboratory management tasks and accreditation preparedness checklist items Management Tasks Cross-cutting Checklist Items Cross-cutting Laboratory Strengthening Checklist

KEY MESSAGES

- A calendar serves as a visual reminder of all important duties/tasks and their timelines. It is also a planning tool with which to distribute critical lab tasks evenly across coming weeks, months, quarters, etc. in a timely manner.
- For the calendar to be an effective tool, it must be kept up-to-date.
- If a task is important and must be completed, then the task must be assigned and scheduled onto the calendar.

Can you:

- Populate the calendar appropriately?
- Use the calendar to schedule, coordinate, balance, and prioritize lab activities?

✓ SELF-ASSESSMENT

For this activity, you will need:

- Handout 1: Tasks To Be Scheduled (123)
- ☐ Handout 2: Sample Calendar (124)
- **☐** Worksheet: Calendar (125)
- Job Aid: Creating An Effective Calendar (126)

Tasks to	be Scheduled into Management Calendar ¹²³						
	M=monthly, Q=quarterly, SM=semi-annual, Y= yearly, AN=as needed)						
Module	Tasks						
1 Productivity Management	Staff meeting (W) Prepare and post duty roster for next month (M) Attend monthly ancillary service management meeting (M) Compile / review previous month's statistics and reports. (M) Send statistics & reports to director (M) Begin review of self-assessment checklist (Q) Follow-up update of self-assessment (Q) Quarterly meeting with director (Q) Quarterly meeting with District Medical Officer (Q)						
2 Work Area Management	Review Environmental Check logs (W) Inspect storage area & confirm all is in order (M) Review occurrence log (M) Annual lab safety training (Y) Annual Safety Assessment (Y)						
3 Inventory	Ensure stock count has been performed (M)						
4 Procurement 5 Equipment	Forecast upcoming needs (Q) Track orders - Quarterly supply order delivery - (Q) Review maintenance log (W) Receive monthly tally from workstations (M) Send pipettes for semi-annual calibration (SM): Dec/June Frequency						
6 Quality Assurance	Review QC, Levy-Jennings & Reagent Logs (W) Review occurrence log, discordant rates and QA indicators (M) Begin performing staff competency reviews (M and Y) Receive Microbiology EQA Sample - (Q): 04/04 Shipment Date Submit Microbiology EQA Results - (Q): 25/04 Reporting Date Review Microbiology EQA results and provide follow-up - (Q): 23/05 Evaluations Mailed Date Report EQA results with staff and director - (Q) Assure staff review and sign all SOPs (Y) Review & sign Heme SOPs Review & sign Chem SOPs Review & sign Serology SOPs						
7 Specimens	Review Specimen transfer log (W) Audit specimen rejection data (M) Audit specimen collection (Q)						
8 Lab Testing	Audit requisitions (M) Audit specimen log (M) Audit Result Reports (M)						
9 Departing	Review customer complaint box (M)						
Reporting 10 Documents & records	Report to staff findings from customer survey (M) Record rotation and new logs in place for next month (M) Review/submit Balanced Scorecard to Management (M) Annual review / update of documents library (M and Y)						
Improvement Project	Plan new improvement projects (TAT of Malaria Smears)and schedule (AN)						

Sample Management Calendar¹²⁴

(W=weekly, M=monthly, Q=quarterly, SM=semi-annual, Y= yearly, AN=as needed)

Month 1: April

Monday	Monday Tuesday		Thursday	Friday	Sat/Sun	
	1 Receive monthly tally from workstations	2 Compile previous month's statistics and reports Send copy to director Attend monthly ancillary service management meeting	3 Staff meeting Report to staff findings from customer survey Review data/progress on improvement project	4 Review maintenance, environmental check, QC, reagent, L-J, and specimen transfer logs	5/6	
7 Begin performing competency assessment reviews	8 Receive Microbiology EQA Sample	9	10 Staff Meeting Assure staff review and sign all SOPs	11 Review maintenance, environmental check, QC, reagent, L-J, and specimen transfer logs	12/13	
Review serology EQA and provide follow-up Begin review of self-assessment checklist	Inspect storage area & confirm all is in order Ensure stock count has been performed	16	17 Staff meeting	18 Review maintenance, environmental check, QC, reagent, L-J, and specimen transfer logs	19/20	
21	22	23 Submit micro EQA results			26/27	
28 Send pipettes for semi- annual calibration Prepare duty roster for next month	Review occurrence log, discordant rates and QA indicators (TAT, requisitions, specimen log, result reports, etc) Review customer complaint box	30 Record rotation and new logs in place for next month				

Sample Management Calendar (W=weekly, M=monthly, Q=quarterly, SM=semi-annual, Y= yearly, AN=as needed)

Month 2: May

Monday	Tuesday	Wednesday	Thursday	Friday	Sat/Sun
			1 Staff meeting	2 Review maintenance, environmental check, QC, reagent, L-J, and specimen transfer logs	3/4
5 Receive monthly tally from workstations	6 Compile previous month's statistics and reports. Send copy to director	7 Attend monthly ancillary service management meeting	8 Staff meeting Review data/progress on improvement project	9 Review maintenance, environmental check, QC, reagent, L-J, and specimen transfer logs	10/11
12	13 Annual Safety Assessment	14	15 Staff meeting Review & sign Heme SOPs	16 Review maintenance, environmental check, QC, reagent, L-J, and specimen transfer logs Ensure stock count has been performed	17/18
19 BSC HEPA filters changed by Biomed and routine maintenance	20 Audit specimen collection	21 Receive Heme EQA Survey	22 Staff meeting	23 Review maintenance, environmental check, QC, reagent, L-J, and specimen transfer logs	24/25
26 Prepare duty roster for next month	27	Review occurrence log, discordant rates and QA indicators (TAT, requisitions, specimen log, result reports, etc) Review customer complaint box	29 Staff meeting	Review maintenance, environmental check, QC, reagent, L-J, and specimen transfer logs Record rotation & new logs in place for next month	31/1

Sample Management Calendar (W=weekly, M=monthly, Q=quarterly, SM=semi-annual, Y= yearly, AN=as needed)

Month 3: June

Monday	Tuesday	Wednesday	Thursday	Friday	Sat/Sun
2 Receive monthly tally from workstations	3 Compile previous month's statistics and reports. Send copy to director Review microbiology EQA and provide follow-up	4 Attend monthly ancillary service management meeting	5 Staff meeting Review data/progress on improvement project Submit Heme EQA Results	6 Review maintenance, environmental check, QC, reagent, L-J, and specimen transfer logs	7/8
9 Follow-up update on self-assessment Contact district to schedule inspection	10 Quarterly supply order delivery due - track orders	11	12 Staff meeting Review & sign Chem SOPs	13 Review maintenance, environmental check, QC, reagent, L-J, and specimen transfer logs	14/15
Ensure stock count has been performed Annual review of documents library	17	18	19 Staff meeting and Annual lab safety training	Review maintenance, environmental check, QC, reagent, L-J, and specimen transfer logs	21/22
23 Quarterly meeting with director Prepare duty roster next month	24 Forecast upcoming needs	Review occurrence log, discordant rates and QA indicators (TAT, requisitions, specimen log, result reports, etc) Review customer complaint box	26 Staff meeting Review maintenance, environmental check, QC, reagent, L-J, and specimen transfer logs		28/29
Quarterly meeting with District Medical Officer Record rotation and new logs in place for next month					

Calendar Worksheets¹²⁵

(W=weekly, M=monthly, Q=quarterly, SM=semi-annual, Y= yearly, AN=as needed)

Month 1: April

Monday	Tuesday	Wednesday	Thursday	Friday	Sat/Sun	
	1	2	3	4	5/6	
7	8	9	10	11	12/13	
14	15	16	17	18	19/20	
21	22	23	24	25	26/27	
28	29	30				

Calendar Worksheets

(W=weekly, M=monthly, Q=quarterly, SM=semi-annual, Y= yearly, AN=as needed)

Month 2: May

Monday	Tuesday	Wednesday	Thursday	Friday	Sat/Sun
			1	2	3/4
5	6	7	8	9	10/11
12	13	14	15	16	17/18
19	20	21	22	23	24/25
26	27	28	29	30	31/1

Calendar Worksheets

(W=weekly, M=monthly, Q=quarterly, SM=semi-annual, Y= yearly, AN=as needed)

Month 3: June

Monday	Tuesday	Wednesday	Thursday	Friday	Sat/Sun	
2	3	4	5	6	7/8	
9	10 11		12	13	14/15	
16	17	18 19		20	21/22	
23	24	25	26	27	28/29	
30						

Steps for Creating and Managing Your Calendar 126

- 1. Populate your calendar with known commitment dates such as meetings or training workshops. Typically these dates offer less flexibility with scheduling.
- 2. Integrate additional calendar schedules into your calendar to create one overall management calendar. Some examples to consider are:
 - In-country holidays that may alter operational hours or available staff
 - External quality assurance proficiency testing schedule
 - Equipment scheduled maintenance performed by vendors
- 3. Populate your calendar with weekly, monthly, yearly, as-needed managerial tasks. Try to minimize scheduling managerial tasks on your heaviest testing volume days. Remember, your first priority as a manager is to ensure the timely reporting of quality patient results.
 - a. If several steps are required for the completion of a task, then first plan and organize the task. Schedule each step of the task into your calendar. Use this plan/organize/schedule approach to address larger projects such as improvement projects, clinician handbook, and quality assurance and safety manuals.
 - b. Use notations and abbreviations to speed entries and keep the calendar organized and legible. For example, 'ST Meet' or "SM" could be used to indicate a staff meeting. "RR" could indicate when the regular review of all logs must be performed and documented.
 - c. WEEKLY TASKS: Even though these tasks are performed each week, note them into your calendar to ensure these essential functions are not overlooked. These notations will serve as a reminder and assist you with coordinating and scheduling new entries or entries requiring rescheduling.
 - d. MONTHLY TASKS: Many monthly tasks must be scheduled towards the end of the month (preparation for the upcoming months) and the beginning of the month (review/statistical compilation/reporting of the previous month). Use the calendar to assist you with balancing and coordinating all your monthly tasks. For example, choose to prepare and post your duty roster during the second or third week instead at the beginning or end of the month.
 - e. ANNUAL TASKS: Tasks performed on a yearly basis can easily pile up as the fiscal or calendar year draws to a close. By staggering these tasks throughout the year, such as March-to-March or October-to-October time periods, they can be accomplished more reliably and less hurriedly.
 - f. AS-NEEDED TASKS: As needs arise within the laboratory, they must also be planned and scheduled. Remember an effective calendar ensures that no task, large or small, is overlooked. If a task is performed sometime during the month and not on a specific date, write the entry in the top margin of the calendar to serve as a reminder. As large tasks are broken down into smaller steps, the deadlines for each step can be noted on the specific date.

- 4. Keep the calendar current and effective by immediately updating your calendar with new entries, additional information, or changes. Some suggestions to accommodate schedule changes/updates/ongoing activities quickly and easily are:
 - a. Circle the entry and draw an arrow to the rescheduled date. For example, the District Medical Officer called to reschedule the meeting. Circle the entry and draw a line pointing to the rescheduled date. Remember to include a notation if the routine meeting time has changed. Another example is mailing the hematology (Heme) survey a day early to accommodate decrease in available personnel due to training or vacations.
 - b. Strike through an entry and add a notation if needed, to indicate a change or update. For example, the laboratory did not receive the AFB Survey as expected. Slash the entry and add the notation "Call" to remind you to follow-through.
 - c. Note agenda topics to be discussed for an upcoming meeting under the meeting's calendar entry. This reminder ensures the topic will be included in the agenda. For example, upon weekly review the manager discovered incomplete documentation on the Acid Fast Bacilli (AFB) Stain QC Log. The manager adds the notation, "AFB Stain QC" under the upcoming staff meeting entry. Staff can also add topics for discussion. For example, the person assigned to the store room workstation wants a discussion regarding the disorganized storeroom.
- 5. Consult the previous year's calendar. Last year's calendar can serve as a reminder and organizer when planning for the upcoming year.

Suggestions to use the calendar effectively

- 1. Visit the calendar daily for current commitments.
- 2. Scan the upcoming days, weeks, and months routinely so you are always aware of upcoming tasks. This will enable you to think ahead as well as to better accommodate and coordinate last-minute changes or additions.
- 3. Use the calendar to organize and communicate staff responsibilities. When assigning tasks to specific personnel, write the task and the staff name on the calendar. The date of the entry provides the deadline for the task and a reminder for you to follow up. Additionally, if a staff member is on vacation, the person assigned to take over his responsibilities can review the calendar and know what activities must be performed.
- 4. Invite the staff to help manage the calendar to facilitate a smooth and productive laboratory. Frequently, staff members will mention ideas, suggestions, or needs in passing that should be entered on the calendar. Having staff directly update the calendar reduces your load, while simultaneously encourages staff to participate and contribute with overall duties from a managerial perspective.

ACTIVITY SUMMARY SHEET

ACTIVITY Competency Assessment

Module 1

PURPOSE:

Competency assessment is important in assuring the quality of the laboratory output. This activity provides suggested policy and guidelines for implementing competency assessment for personnel performing diagnostic clinical testing in the laboratory.

This activity supports the following laboratory management tasks and accreditation preparedness checklist items

Management Tasks



- 1.4 Assess personnel competency against standards and determine corrective action and training needs
- 1.6 Meet with staff individually to communicate expectations, provide feedback, coaching, or on-the-job training to ensure competency and productivity
- 1.8 Maintain and update personnel records (training, certification, competency assessment)
- 6.13 Periodically observe/assess accuracy of staff performance and take corrective action
- 8.1 Monitor testing to ensure SOPs are followed and tests are performed and reported properly and promptly

Checklist Items



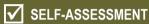
- 1.4 <u>Laboratory Policies and Standard Operating Procedures</u> Are policies and standard operating procedures (SOPs) for laboratory functions current, available and approved by authorized personnel? (Conflict of Interest, Personnel Records/Files, Personnel Training, Competency Assessment)
- 3.5 Personnel Filing System Are Personnel Files present?
- 3.6 <u>Staff Competency Assessment and Training</u> Is there a system for competency assessment of personnel (both new hires and existing staff) and does it include planning and documentation of retraining and reassessment, when indicated?
- 3.7 <u>Laboratory Staff Training</u> Does the laboratory have adequate training policies, procedures, and/or training plans, including cross-training within the laboratory team, one-on-one mentoring, and/or off-site external training?

KEY MESSAGES

- Assuring the quality of the testing process relies on all the inputs. As a key input into this process, laboratory staff must be assessed for their competency to ensure a quality output – accurate & reliable testing information.
- Laboratory managers must assure staff competency prior to authorizing the staff to perform testing.
 Competency must be validated routinely and documented in the personnel file.
- Reviewing competency includes reviewing safety practices in all aspects of testing.

Can you:

- Assess the competency of individual staff as they are observed performing a procedure?
- Develop & implement a competency assessment program when they return to their laboratory?
- Assess the competency of their staff as an improvement project?



Competency Evaluation Policy¹²⁷

Purpose:

The CLIA'88 legislation [United States (U.S.) regulation] requires a mechanism to evaluate and demonstrate competency in test performance for each person who performs a clinical diagnostic test. This means that the laboratory director, site supervisor, or other designated person must critically observe the individual being checked to determine that procedural methods and protocols are followed correctly, technique is adequate and safety guidelines are followed.

In contrast, "internal proficiency testing" is a process evaluating a remote location's ability to correctly generate a result from an unknown test sample; the process is operated by the central regional laboratory. "External proficiency testing" is similar to internal proficiency testing, except that the process is operated and evaluated by an independent agency and the reports are sent to the U.S. CMS or other central authority. In all cases, actual test performance must be validated by the site supervisor.

Personnel:

These guidelines apply to personnel who perform clinical tests on human specimens. Persons performing clinical tests are required to exercise good judgment in protecting themselves, their patients and co-workers.

It is the site supervisor's responsibility to monitor compliance and assure that competency evaluations are performed according to the schedule outlined below.

Interval:

Competency evaluation must be performed according to the following schedules:

New personnel must demonstrate competency in performing each test procedure prior to reporting patient results.

New personnel must demonstrate competency in performing each test procedure twice during the first year in which they begin to perform the procedure.

After the first year of testing, each person must demonstrate test proficiency on an annual basis. If a new test method is added, or existing procedures substantially changed, all testing personnel must demonstrate competency (prior to the testing of clinical samples, 6 months later, and annually thereafter) in performing the new (or altered) test procedure.

Specimen:

Competency evaluation will be performed using clinical specimens or training materials. Serum, whole blood, urine or other clinical specimens or quality control material appropriate for the procedure in question may be used. Refer to the specific written procedure in the laboratory manual.

SAFETY NOTICE: Reagents developed from human blood or body fluids may be infectious. Standard (Universal) precautions are required when working with reagents of human origin.

Materials:

Instruments:

All instruments must be in working order and of the same type as used for routine clinical determinations.

Supplies, Reagents and Standards:

All reagents and Q.C. materials must be in date and of the same type as used for routine clinical determinations.

Evaluation:

The evaluator, usually the site supervisor, will directly observe the entire testing procedure with special emphasis on the following:

Specimen accession, handling and processing.

Test performance according to written protocols.

Appropriate QA checks must be performed and recorded.

Monitoring and recording of results according to written protocols.

Instrument maintenance and function checks are properly performed.

Assessment of problem solving skills.

Adherence to appropriate safety guidelines.

All samples are to be tested in the same manner as routine clinical materials.

Results:

Individual Competency Evaluation Worksheet

Make as many copies of the Individual Competency Worksheet as needed so that each person has their own evaluation form.

Record the name of the individual and site location on each form.

Indicate the approved test complexity level for the individual.

The evaluator, site supervisor or designee, will observe the person performing each clinical procedure.

For each test evaluated, each of the criteria, listed in Evaluation (VI, A.) above, will be scored as pass or fail. Acceptable test performance requires a "pass" score in all of the seven criteria.

The evaluator will note the date, individual criteria and overall pass or fail. If an individual fails any portion of the assessment, any corrective action or retraining initiated must be documented.

The evaluator must initial the box opposite the test evaluated.

The site supervisor will review each person's individual Competency Evaluation form, sign and date the form.

The Laboratory Director must also sign the Individual Competency Evaluation on a yearly basis. .

The Individual Competency Evaluation form will be maintained by the site supervisor.

Annual Site Competency Record; (a summary of all individuals and the procedures that they may perform)

Make as many copies of the "Annual Site Competency Record" as needed.

Record all of the indicated information as appropriate.

It is the site supervisor's responsibility to maintain up to date copies of both the Individual Competency Evaluation and Annual Site Competency Record forms on site.

The Annual Site Competency Record will be sent to the Laboratory Director for review and signature on a scheduled basis once a year. Alternatively, the Laboratory Director may sign the form(s) during a site visit.

File the Annual Site Competency Record with the quality control records.

Corrective Action:

The following remedial actions will be taken whenever an individual fails to generate acceptable results against sample unknowns. "Acceptable Results" are defined as at least 80% correct test performance (100% correct test performance for ABO/RH testing) as evidenced by test results when five or more unknown (blind) samples are tested. If fewer than five samples tested, "Acceptable Results" will be defined as 100% correct test performance.

The site supervisor will review the competency test results with the individual.

An individual that fails any portion of the competency assessment should review the written test procedure and quality control guidelines with the site supervisor.

The site supervisor will observe the individual while they repeat the test procedure.

Consult with the Laboratory Director as the need warrants, especially if there seems to be a problem with the competency sample itself.

If competency assessment issues cannot be resolved on-site by the site supervisor, the Laboratory Director will arrange for remedial training and/ or additional testing materials as appropriate.

The individual will not perform the test for any clinical purposes until they have satisfactorily passed their competency evaluation.

A corrective action report will be completed and attached to or included on the annual competency evaluation form.

Records:

File all records for two years on site. All records must be signed by the site supervisor and reviewed by the Laboratory Director on an annual basis.

Individual annual competency evaluation forms should be kept at the testing site.

References:

Federal Register, 42 CFR Part 74, Wednesday March 14, 1990: Revision of Laboratory Regulations, (Clinical Laboratory Improvement Amendments of 1988).

Section 493.1451 (b) (8) and Section 493.1501 (h) (1 & 2).

XI. Authors:

William S Sottile, Ph.D., D(ABMM), Laboratory Director, Northern Michigan Regional Laboratory, Houghton, MI.

Ken Terpstra, Laboratory Manager, Kent County Department of Public Health, Grand Rapids, MI.

Procedure Review:

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revised 2: August 4, 2005

printed: December 18, 2014

	Date									
	Initials									
Date installed or replaced/ Date removed/										
Supervisor:					Direc	Director:				

Reference: www.michigan.gov/documents/mdch/RQA.16 178848 7.doc

Individual Competency Evaluation

Employee:	ee: Year										
Emp. ID# or SSN: Evaluator:											
Health Dept:,									_		
Approved T	est Complexity	/ Leve	el: () v	waive	d, ()	mode	rately	comp	olex () highl	y complex
Tank D			Criteria (<u>P</u> ass/ <u>F</u> ail)								Reviewer
lest P	rocedure	Α	В	С	D	Е	F	G	G H Date		Initials
Overall Rating	(Pass / Fail)										
Criteria: A = Specimen handling and processing B = Test procedure C = Quality Control testing and recording D = Results recording and interpretation E = Instrument maintenance and function checks F = Assessment of problem solving skills G = Safety guidelines H = Problem solving skills											
		(Corre	ctive A	Action	(if an	y):				
Date											
Review:											
	-					dical	Direc	tor: _			
Date:					_						

Annual Site Competency Record

Healt	th Dept:					,							
	Name: last, first	Employe or SS		Α	В	С	D	Е	F	G	Н	I	J
P = pa	assed, $F = failed$, $N/A = T$	est not perfo	rmed by	l / em	 ploye	ee							
Key	Test		Manu	fact	urer								
Α	Urine Pregnancy Test (h	nCG)											
В	Urine Dipstick												
С	Hemoglobin (mcx)												
D	Hemoglobin (w)												
Е	Cholesterol, HDL Chole Triglycerides & Glucose												
F	Cholesterol, HDL Chole Triglycerides & Glucose	sterol,											
G	Whole Blood Glucose (v												
Н	Wet Mounts (mcx)												
I													
J													
Revi	ew:												
Supervisor:				ab D	irect	or:							
Date:	:												

Competency Evaluation Quiz¹²⁸

Based on Competency Evaluation Policy

1.	What is the recommended frequency of routine competency assessments?
2.	T or F The evaluator must directly observe the procedure.
3.	If a person fails any part of the evaluation, what must he or she do?
4.	If a person fails any part of the evaluation, what must the supervisor do?
5.	Where are the competency assessment results kept?
6.	What type of specimens will be used to evaluate performance?
7.	T or F When new personnel are hired, they can begin testing right away and complete the competency assessment within the first 6 months after hiring.
8.	List seven (7) criteria that must be assessed during a competency evaluation
9.	What qualifications must the QC materials that are used in competency assessment meet?
10.	How long are competency evaluations kept?

ACTIVITY SUMMARY SHEET

ACTIVITY Planning and Conducting a Staff Meeting

Module 1

PURPOSE:

Effective staff meetings yield a cohesive and informed staff working together toward shared institutional goals. As the curriculum unfolds, this activity encourages participants to complete their own list of appropriate items for a staff meeting agenda.

This activity supports the following laboratory management tasks and accreditation preparedness checklist items

Management Tasks



- 1.5 Conduct weekly staff meetings to coordinate activities, review lab operations, reward success, celebrate accomplishments, and resolve issues
- 1.11 Implement measures to motivate staff to improve quality of work and productivity (e.g., training, job rotation, employee of the month, thank-you letter, etc.)

Checklist Items



- 1.4 <u>Laboratory Policies and Standard Operating Procedures</u> Are policies and standard operating procedures (SOPs) for laboratory functions current, available and approved by authorized personnel? (Communication, Advisory Services, Resolution of Complaints and Feedback)
- 2.2 <u>Review of Quality and Technical Records</u> Does the laboratory supervisor routinely perform a documented review of all quality and technical records?
- 3.8 Staff Meetings Are staff meetings held regularly?

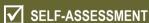
^

KEY MESSAGES

- Staff meetings provide an opportunity for communication regarding laboratory operations.
- These meetings also promote team building and shared decision-making capacity among the staff.
- Conducting a meeting requires planning before the meeting, leadership during the meeting, and follow-up after the meeting.

Can you:

- Conduct an effective, productive, successful, staff meeting that is as short as possible?
- Populate an agenda with appropriate items for a staff meeting?



For this activity, you will need:
☐ Job Aid 1: Tips for Planning and Conducting a Staff Meeting (129)
☐ Job Aid 2: Staff Meeting Agenda Template (130)
☐ Worksheet: Topics for Staff Meeting Agenda (131)

Tips for Planning and Conducting a Staff Meeting 129

The Goal: To conduct a meeting that is effective, productive, predictable, successful, and as short as possible.

Before The Meeting

- 1. Define the purpose of the meeting
- 2. Develop an agenda in cooperation with the staff.
- 3. Distribute or provide the agenda and circulate background material, documents or articles prior to the meeting.
- 4. Choose an appropriate meeting time. Set a time limit and stick to it. To keep meetings short, consider having members stand during the meeting.
- 5. Choose a location suitable to your group's size, and if possible, arrange the room so that members face each other, i.e., a circle or semi-circle.
- 6. Use visual aids for interest (e.g., posters, diagrams, etc.). Post a large agenda up front to which members can refer.
- 7. Be sure everyone knows where and when the next meeting will be held.

During The Meeting

- 1. Greet members and make them feel welcome.
- 2. Start on time. End on time.
- 3. Review the agenda and set priorities for the meeting.
- 4. Stick to the agenda.
- 5. Encourage group discussion to get all points of view and ideas.
- 6. Encourage feedback. Ideas, activities and commitment to the organization improve when members see their impact on the decision making process.
- 7. Keep conversation focused on the topic. Feel free to ask for only constructive and non-repetitive comments.
- 8. Keep minutes of the meeting for future reference in case a question or problem arises.
- 9. As a leader, be a role model by listening, showing interest, appreciation and confidence in members. Admit mistakes.
- 10. Summarize agreements reached and end the meeting on a unifying or positive note. Summarize action items, indicating who is responsible, and when the activities are due.
- 11. Set a date, time and place for the next meeting.

After The Meeting

- 1. Write up and distribute minutes within 3 or 4 days.
- 2. Discuss any problems during the meeting with other staff; come up with ways improvements can be made.
- 3. Follow-up on delegation decisions. See that all members understand and carry-out their responsibilities.
- 4. Give recognition and appreciation to excellent and timely progress.
- 5. Put unfinished business on the agenda for the next meeting.
- 6. Conduct a periodic evaluation of the meetings. Note any areas that can be analyzed and improved for more productive meetings.

And remember, effective meetings will keep them coming back!

Excerpts from: Effective Meetings (2008). Retrieved May 26, 2009, from Meeting Wizard Web site: http://www.meetingwizard.org/meetings/running-effective-meetings.cfm

Staff Meeting Agenda Template 130

Date/Time:	Location:						
Meeting Goal:							
Attendees:							
Leader:							
Note-taker:							
	· '						
TOPIC		TOPIC LEAD	TIME				
Plan Next Action(s)							
Plan Aim/Goal and Agenda for next meeting	g						
Evaluate/Process Check (How can we improve this meeting?)							

Topics for Staff Meeting Agenda 131

List possible topics, covered in the various activities, which would be appropriate for communication at a staff meeting.

ACTIVITY SUMMARY SHEET

ACTIVITY Creating a Personnel File

Module 1

PURPOSE:

Managing human resources requires documentation and organization of employee information, education, work history, training, and performance data. This fast-paced activity allows participants to give a rationale for including items in a personnel file and to indicate which items are inappropriate for personnel files.

This activity supports the following laboratory management tasks and accreditation preparedness checklist items

Management Tasks



- 1.6 Meet with staff individually to communicate expectations, provide feedback, coaching, or on-the-job training to ensure competency and productivity
- 1.7 Provide/coordinate new-hire orientation and training to staff
- 1.8 Maintain and update personnel records (training, certification, competency assessment
- 1.11 Implement measures to motivate staff to improve quality of work and productivity (e.g., training, job rotation, employee of the month, thank-you letter, etc.)

Checklist Items



- 1.1 <u>Laboratory Quality Manual</u> Is there a current laboratory quality manual, composed of the quality management system's policies and procedures, and has the manual content been communicated to and understood and implemented by all staff?
- 1.4 <u>Laboratory Policies and Standard Operating Procedures</u> Are policies and standard operating procedures (SOPs) for laboratory functions current, available and approved by authorized personnel? (Conflict of Interest, Personnel Records/Files, Personnel Training, Competency Assessment)
- 3.3 <u>Organizational Chart and External/Internal Reporting Systems</u> Are lines of authority and responsibility clearly defined for all lab staff, including the designation of a supervisor and deputies for all key functions?
- 3.4 Quality Management System Oversight Is there a quality officer/manager with delegated responsibility to oversee compliance with the quality management system?
- 3.5 Personnel Filing System Are Personnel Files present?
- 12.17 Are laboratory personnel offered appropriate vaccination//preventive measures?
- 12.21 Is a trained safety officer designated to implement and monitor the safety program in the laboratory, including the training of other staff?

KEY MESSAGES

- Personnel files provide an organized record of workrelated information.
- Documentation in the laboratory extends to human resource issues including performance, competency, education, training, etc.
- These human resource files are confidential and require secure storage.
- An employee's medical records are confidential and should be stored separately from other 'business' records.

Can you:

- Provide reasons for creating a personnel file?
- Identify items that belong in a personnel file?
- Provide reasons for including or excluding an item in the personnel file?



✓ SELF-ASSESSMENT

For this activity, you will need:

Job Aid: General Guidelines for Personnel Files (133)

General Guidelines for Personnel File 133

Material to Include in a Personnel File

- Education / Training
 - Documentation of all education & training including:
 - a. Preservice
 - b. In-service
 - c. Continuing Education
- Employment History
 - Recruiting / Job Application / Interview report
 - Summary of experience
 - Screening / Verification
 - Contract including dates of employment
 - Orientation / Receipt of Handbook
 - Job Description
- Certification & Licensure (if required)
- Performance Management
 - Performance review New employees within first 6 months
 - Performance review Annual for all employees
 - Commendations
 - Thank-you letter
 - Comments regarding staff on customer satisfaction surveys
 - Work-related incident and/or accident
 - Discipline
- Competency Assessment
 - Assessed on his/her assigned duties
- Wage, Salary, and Benefit Information
- Human Resource Information
 - Curriculum Vitae or Resume
 - Diplomas / Certificates
 - Contact Data
 - Demographic information
 - Employee Health Services
 - Shifts & Staffing Patterns

Material to **Omit** from a Personnel File

- Medical Records (Always consult specific country policy; however, in general, it is best to keep medical records separate from the personnel file.)
- Unsupported opinions