



Laboratory Management of a Quality System

Module 4: Equipment and
Supply Chain Management





ACKNOWLEDGEMENT

- Ministry of Health and Social Welfare - Tanzania
- Muhimbili University of Health and Allied Science
- World Bank
- ECSA- HC
- EAC





Learning Objectives

- Describe the importance of a good instrument management program
- Identify the important steps to follow when instrument is installed in the laboratory
- Manage the calibration, operation, troubleshooting and maintenance of laboratory instruments





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- Describe the importance of a good instrument management program
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Learning Objectives (Continued)

- Describe an effective preventive maintenance program
- Describe the elements of a well organized storeroom
- Implement a good inventory control program
- Calculate and define reorder levels for laboratory supplies





Today's Agenda

- The Quality System
- Equipment Management Process
 - Instrument Selection
 - Selection Criteria & Costs
 - Equipment Installation & Calibration
 - Preventative Maintenance & Repair
- Inventory Management Process
 - § Organize Inventory Storage
 - § Record Keeping
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- Module Summary





The Quality System





The Laboratory Instruments / Supplies

- Well maintained instruments and supplies are critical to the operation of any laboratory
 - Assures testing is accurate and reliably available for patient care needs
 - Prevents instrument failures and prolongs life of the instrument





Quality Procurement System

- Ensures instruments and supplies that meet the laboratory's quality requirements are present in adequate quantities for testing at all times
- How do you accomplish?
 - Establish supply chain management plan for the site
 - Monitor and evaluate how supply chain management at each site is working
 - Define problem resolution process when supply or instrument problems occur and improve processes





Quality Procurement System

(Continued)



- How do you accomplish?
 - Define the characteristics and volumes of all critical supply items needed in the laboratory (national list of laboratory commodities may be available)
 - Choose reliable, high quality vendors with ability to meet your needs (primary and alternate)





Quality Procurement System

(Continued)

- How do you accomplish?
 - Put in contract details about critical elements such as how supplies will be delivered and dating of reagents (standing order; deliver via DHL on demand)
 - Maintain a close working relationship with your vendors/suppliers
 - Evaluate your vendor performance at least annually





Equipment Management Plan

- Define responsibility for quality system management - instrument acquisition, contracting, service and repair
- Assign responsibilities for instrument management functions at site level such as:
 - Inventory all instruments on site
 - Write instrument management policies and procedures
 - Produce instrument logs and document all instrument management functions performed





Equipment Management Plan

(Continued)

- Assign responsibilities for instrument management functions at site level such as:
 - Review instrument documentation on a regular basis
 - Implement corrective actions for instrument problems





Equipment Management Plan

(Continued)

- Assign responsibilities for instrument management functions at site level such as:
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Does anyone have
any questions?





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Equipment Management Process



- A process for selecting and maintaining laboratory equipment necessary to meet patient care needs





Equipment Management Process

- Selection and Purchase
- Installation
- Calibration/Method Validation
- Preventative Maintenance
- Troubleshooting
- Service and Repair





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Equipment / Instrument Selection

- Define need/s to be filled - including customer input on testing needs
 - For example, the introduction of ART reveals a need for an automated Hematology analyzer to improve accuracy of cell counts





Equipment / Instrument Selection (Continued)



- Gather information on all potential vendors for instrument or method needed (internet, vendor presentations, colleagues, journals)
- Decide what you want and then measure each vendor against your needs



Vendor # 1



Vendor #
2



Vendor # 3





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Selection Criteria Checklist

- Vendor support and reliability- initial and ongoing
- Availability of service and training support; ease of training
- Instrument, service, and supply cost
- Reagent and control availability; long shelf life

Vendor # 1 Vendor #2 Vendor #3





Selection Criteria (Continued)

- Instrument and environment requirements
 - Power
 - Refrigeration
 - Space (footprint)
 - Environmental considerations
- Instrument quality and stability (how often will QC be needed)

<u>Vendor #1</u>	<u>Vendor #2</u>	<u>Vendor #3</u>
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Selection Criteria (Continued)

- Ease of maintenance and calibration
- Simplicity of operation and ease of training
- Throughput: Stat vs. Batch vs. Random Access
- Heat and noise output

Vendor #1 Vendor #2 Vendor #3





Selection Criteria (Continued)

Vendor #1 Vendor #2 Vendor #3

- Pretreatment and/or manual intervention (need to manually dilute)
- Test Volume and Menu
- LIS connectivity





Selection Costs - Be Careful!

- All instrument selections involve costs:
 - Reagent
 - Lease and purchase
 - Supply and consumable
 - Service





Selection Costs - Be Careful!

(Continued)

- Costs may be incorporated into contracts in the following way
 - Cost per test contract
 - Cost per result reported contract





**What questions
do you have on
instrument
selection, criteria,
and cost?**





Pre-Installation

- Site Leadership's Role
 - Obtain all critical requirements for instrument installation from vendor (back-up power, vacuum/pressure)
 - Get instrument specifications including physical requirements
 - Arrange schedule and timeframe with vendor for the installation
 - Negotiate with vendor on what they will do on-site ahead of time





Pre-Installation (Continued)

- Site Leadership's Role
 - Establish checklist with performance specs
 - Verify package contents on receipt
 - Assure all supplies and resources are available when the vendor arrives to install





Installation

- Vendor's Role
 - Have vendor perform instrument validation and method comparison studies
 - Have vendor help establish reference range
 - Vendor calibrates instrument and runs quality control
 - Vendor trains personnel on all aspects of instrument performance (calibration, QC, data entry) and troubleshooting
 - Vendor leaves records of all studies and instrument manuals





Post-Installation

- Site leadership assesses competency of staff on critical elements of training
- Site leadership establishes instrument maintenance program
- Vendor or internal resources provides ongoing support through service contract





Equipment Calibration

- Vendor performs initial calibration using calibrators and manufacturer's instructions (QC may not be used)
- Vendor trains all staff on calibration procedures
- Management defines frequency and triggers for calibration and writes SOP for calibration





Equipment Calibration (Continued)

- Management assess staff competency on calibration procedures
- Staff performs calibration using calibrator or standard as defined (QC may not be used)
- Calibrators added to supply inventory to assure continuous supply





What questions do you have about installation and calibration?





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A good preventative maintenance program...



- Assures continuous operation of lab instruments with limited downtime
- Assures a high level of performance and quality laboratory results
- Lengthens the life of the equipment
- Decreases expenses of instrument operation
- Improves staff efficiency in producing results and customer satisfaction





Preventative Maintenance

- Preventative maintenance procedures and schedule are defined in vendor manual
- Procedures for maintenance and schedule are refined by each facility based on laboratory needs





Preventative Maintenance

(Continued)

- Defined at intervals - daily, weekly, monthly
- Performed and documented on maintenance records including problem log for instrument issues
- Maintenance records must be reviewed weekly by site leadership to assure completion and adequate function





Function Checks

- Performance checks defined by manufacturer to verify that the instrument is working properly
- Performed daily, weekly, or monthly and documented on function check log
- Examples: background checks, daily temperature checks
- Function check failure must result in troubleshooting





Troubleshooting Equipment Problems

- Troubleshooting occurs when:
 - Function checks are not within tolerance limits
 - QC results are not within tolerance limits
 - System does not seem to be operating properly
 - Laboratory results appear unusual
- Define step-wise troubleshooting procedures for each instrument

Troubleshooting guide is often in vendor





Group Work - Maintenance Schedule



- Work in pairs
- You have received a new BD Facscount analyzer. Determine how you will set up a schedule for maintenance and function checks.





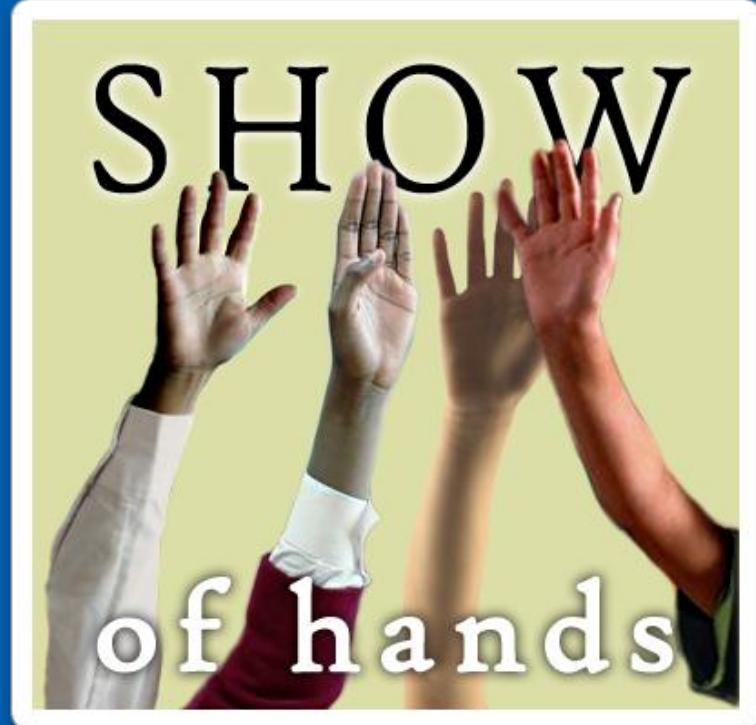
Service and Repair

- Evaluate QC and maintenance records regularly to detect instrument problems early
- Define procedures for obtaining service
- Equipment management procedures should include procedures for obtaining service/repair
- Maintain service and repair logs of all service performed for life of the instrument





What questions do you have about preventative maintenance, service, and repair?





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Inventory Management Process

- A process for maintaining an adequate supply chain (central to local) to maintain uninterrupted service and meet patient care needs





Inventory Management Leads to High Quality Testing



- Ensures consistent availability of supplies and materials, when needed
- Avoids the use of expired reagents and supplies
- Minimizes wastage of expensive supplies





Inventory Management Process

- Organize inventory at site laboratory
- Count and maintain records of inventory
- Requisition/order from central supply/store
- Define reorder quantities/minimum stock level
- Receive and store of supplies
- Define return process (wrong orders)





Facility Storage

- System to organize, secure, and properly store reagents and supplies for laboratory use
- Assess storage requirements of reagents and supplies
- Identify a secure and adequate storage site
 - Locked
 - Free from extreme temperature, direct sunlight, and humidity
 - Free of pests





Facility Storage (Continued)

- Use shelves and bins to organize supplies
- Keep refrigerated supplies in designated well maintained and monitored refrigerators (record temperature daily)
- Organize the supplies carefully





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Organizing the Storage Area

(Continued)

- Store according to temperature requirements
- Store similar items together (controls with controls, calibrators with calibrators)
- Group identical items in smaller groups that are easy to count
- Within each group of similar items, arrange them in alphabetical order





Organizing the Storage Area

(Continued)

- Store all items on shelves (not on the floor)
- Label the shelves with the name of each item in that area of the shelf
- Store all items on shelves with shorter expiry dates at the front
- Check weekly for any expired reagents/supplies and organization of storage





Group Work - Organize Supplies



- Work in pairs
- Discuss how your supplies are currently stored and share ideas for improvement
- Create a list of things you need to change when you return to your lab





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Record Keeping

- Record-keeping is essential to know what you have
- Records will tell you what you have in stock, how much is on the shelf, and when you need to reorder supplies
- Create stock and bin cards for each supply
- Create an inventory list (stock book) of all ordered supplies





Maintain Proper Inventory Records



Stock Card

- Simple, heavy weight cards
- Kept for each item in stock

Stock Book

- Contains listing of all items in the store
- Update monthly after physical count
- Use information from stock cards
- Also called stock





Stock Cards

- Item name (concentration etc.)
- Order/catalog number
- Units
- Price per unit
- Reorder level
- Expiration date
- Special storage requirements





Stock Card: An Example

- Item Name: _____ Unit: _____
- Manufacturer: _____
- Minimum Stock (Re-Order Level): _____

Date	Received From	Issued to	Quantity Received	Quantity Issued	*Balance	Lot #	Signature





Stock Book: An Example

Item Name	Qty (units) Requested	Date Requested	Qty Received	Date Received	Lot #	Expiry Date





Bin Cards

- Make bin card for each item from stock card
- Keep the bin card in front of the item
- Record each supply receipt and removal on the bin card
- Supply receipt should include the date of receipt and quantity received
- When supplies are received or issued, record on the card actual stock on hand
- Make a weekly count of all items in stock





Perform a “Stock/Inventory Count”

What is it?

Physically counting each item in the stock

When is it done? Recommended at the beginning of each month at minimum

Who does it?

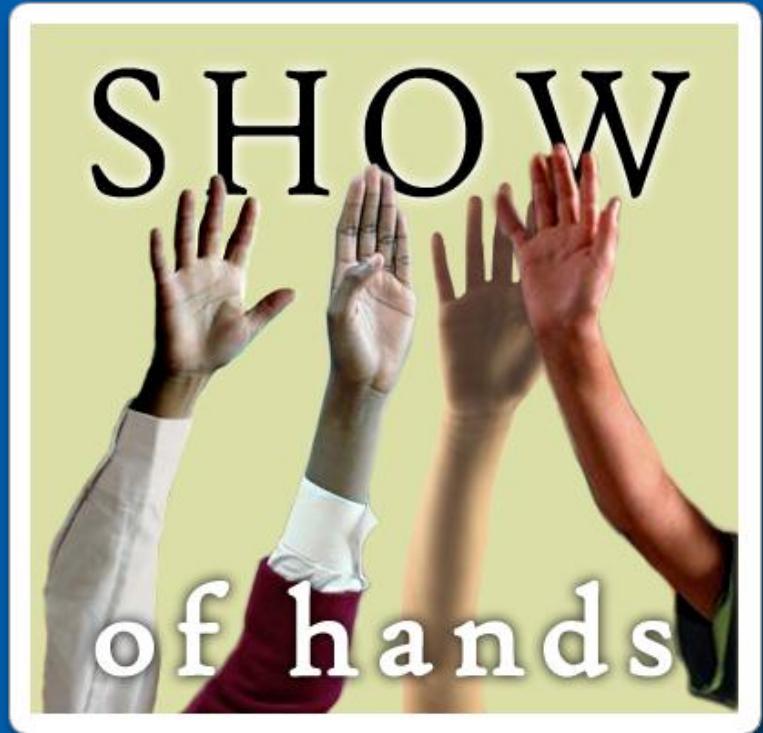
A designated person

All items must be accounted for. Everything that comes in and goes out must be recorded.





What questions do you have about organizing inventory storage and record keeping?





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Requesting Supplies

- Complete requisition form according to defined process
- Accurately complete all required fields
- Maintain documentation on all supplies received from central stores





MINISTRY OF HEALTH AND SOCIAL WELFARE



REPORT & REQUEST FORM FOR LABORATORY SUPPLIES

Facility Code: _____

Facility Name: _____ Type (GOV/NGO/FBO/OTHER): _____

Name of District / Region: _____

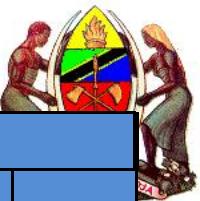
Date Submitted: _____

Reporting Period: Beginning Month: _____ Ending Month: _____ Year: _____

LABORATORY SUPPLIES FOR HEALTH FACILITIES

MSD Code	Supply Item	Unit of Issue	Opening Balance (A)	Received This Period (B)	Lost/ Adjusted (C)	Closing Balance (D)	Estimated Consumed [A+B+C-D] (E)	Quantity Needed [(E÷3)×7-D] (F)	Quantity Requested (G)	Price FY 04 (H)	Cost [GxH] (I)	Approved Quantity (J)	Approved Cost (K)
HIV Diagnosis													
20277006	Bioline HIV1/2 30 tests	Kit											
20271514	Determine HIV 1&2 100 tests	Kit											
	Unigold HIV1 /HIV2 25Tests	kit											
20291345	Vironostika Uniform Ag/Ab 192 tests	kit											
	Vironostika Uniform Ag/Ab 576 tests	kit											
	Enzygnost Anti-HIV 1/2 Plus Plus 192 tests	kit											
	Enzygnost Anti-HIV 1/2												





LABORATORY SUPPLIES FOR HEALTH FACILITIES

MSD Code	Supply Item	Unit of Issue	Opening Balance (A)	Received This Period (B)	Lost/Adjusted (C)	Closing Balance (D)	Estimated Consumed [A+B±C-D] (E)	Quantity Needed [(E÷3)×7-D] (F)	Quantity Requested (G)	Price FY 04 (H)	Cost [GxH] (I)	Approved Quantity (J)	Approved Cost (K)
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Cost Summary

Page	Total Cost	Cost Approved	Additional Funding	Source : Indicate CHF, NHIF, UF etc
1				
2				
Sub-total				
Total cost of additional supplies from Form Blank R&R (if any)				
Total cost of order				
Total available allocation				
Total Supplemental funding Used				

Completed by: _____

Signature: _____

Approved by: _____

Signature: _____





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Reorder Levels

- Reorder level (par level)- the minimum stock level at which you should reorder the item and the amount you should reorder
- To avoid expiration and waste, reorder amount should be the amount likely to be consumed during a period of time
- Identify how frequently your lab received shipments/deliveries (often monthly) in order to factor in lead time





Determine When to Re-order

- Re-order when stock reaches minimum level

Terminology:

- **Minimum stock** - Amount of stock required to support testing operations until additional supplies are received
- **Lead time** - Time between placing an order and receiving it
- **Average usage** - number of test kits used in a given time period





Determining the Reorder Level

- Calculate the average monthly consumption
 - Example: $200 \text{ packs of controls used in last 12 months} / 12 = \text{average monthly consumption}$
- Use a reorder factor for the frequency of delivery based on lead time to receive supplies
- Multiply the average monthly consumption by the lead time. The result is reorder level.





Calculating Reorder Levels

$$\text{Minimum Stock Level} = \text{Maximum lead time in weeks} \times \text{Average Usage}$$

Example:

Maximum lead time = 12 weeks

Average usage/wk = 3 kits

Minimum stock level = $12 \times 3 = 36$ kits

When only 36 kits are left, place an order





Exercise:

Calculating Reorder Levels

$$\text{Minimum Stock/Reorder Level} = \text{Maximum lead time in weeks} \times \text{Maximum Usage}$$

- On average, you use 5 cubes of Isoton a week.
- It normally takes 20 weeks to receive the order you placed.
- You should order more Isoton when cubes are left in the inventory.





Calculating Reorder Levels

(Continued)

- Calculating accurate reorder levels based on consumption and lead time for delivery assures that you will not run out of supplies even if a regular delivery is missed.
- Calculate and note on bin card the minimum reorder level and number of kits/units to reorder for each reagent/supply
- Review annually and adjust reorder levels as needed based on usage





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Receipt and Storage

- Verify the contents of order received with requisition form
- Check that items are in good condition and within expiry dates
- Record the quantity received and date each item was received on stock cards and in stock book





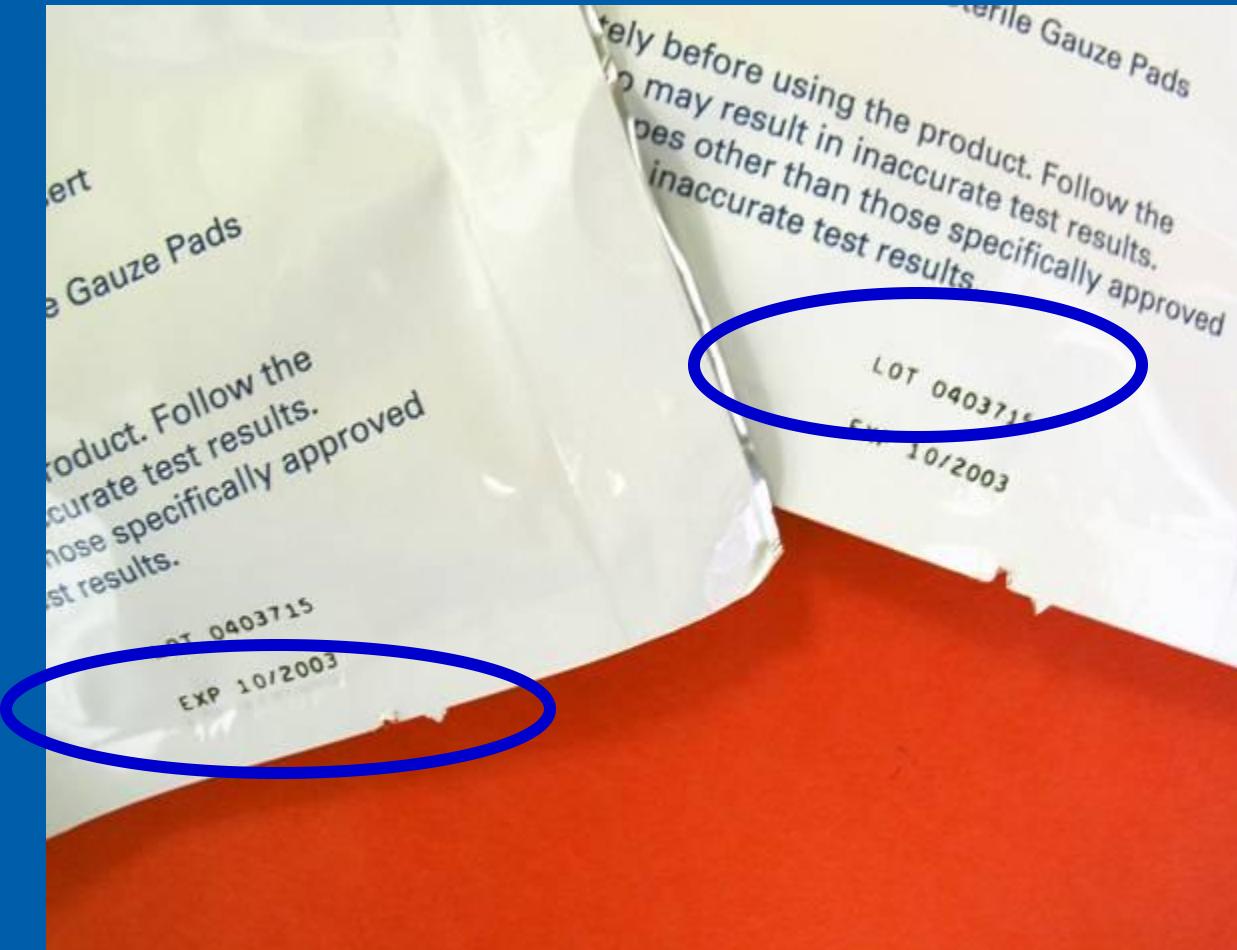
Receipt and Storage (Continued)

- Add quantity received to current stock in inventory
- Label items with receipt date, receiving person's initials and expiration dates
- Store each item behind the existing items in correct bin





Examine Lot Number & Expiry Date





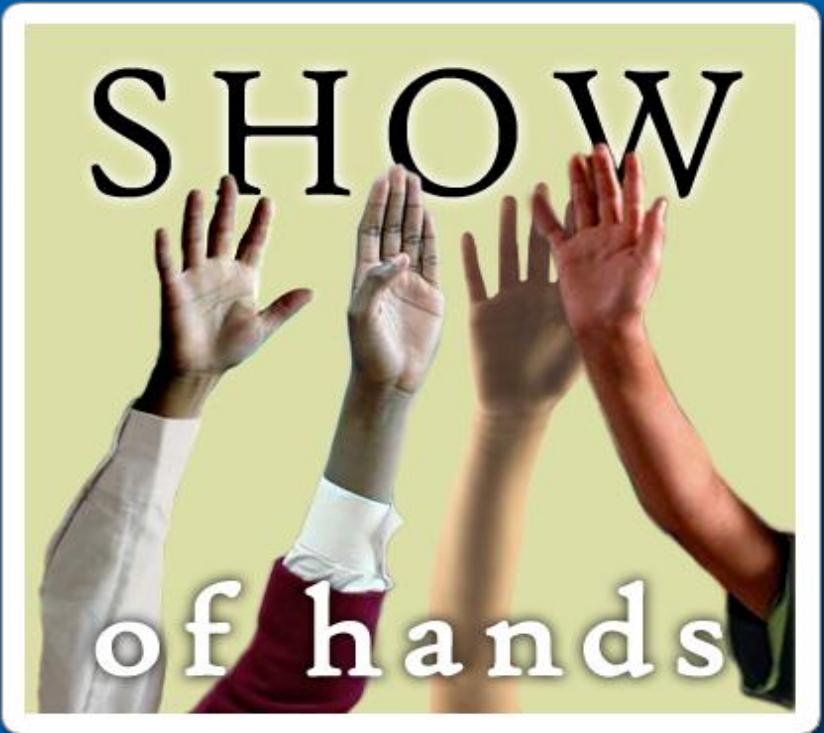
Return Process

- Return items that do not pass inspection on receipt for example:
 - Refrigerated items that are not in a cold pack or maintained at proper temperature
 - Items with any physical damage or deterioration
 - Items with short expiry dates
 - Incorrect orders (short or over-issued, wrong)
- Document all order discrepancies on a report form





What questions do you have about defining reorder quantities and receiving and storing supplies?





Case Study

- You are charged as the site leader with establishing a supply management plan for your site.
- Your site has no defined process in place and the storeroom is a bit disorganized.
- Define the tasks you will perform to improve the situation.





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Summary - Equipment Management

- Selection and Purchase
- Installation
- Calibration/Method Validation
- Preventative Maintenance
- Troubleshooting
- Service and Repair
- Retiring of Equipment





Summary - Inventory Management



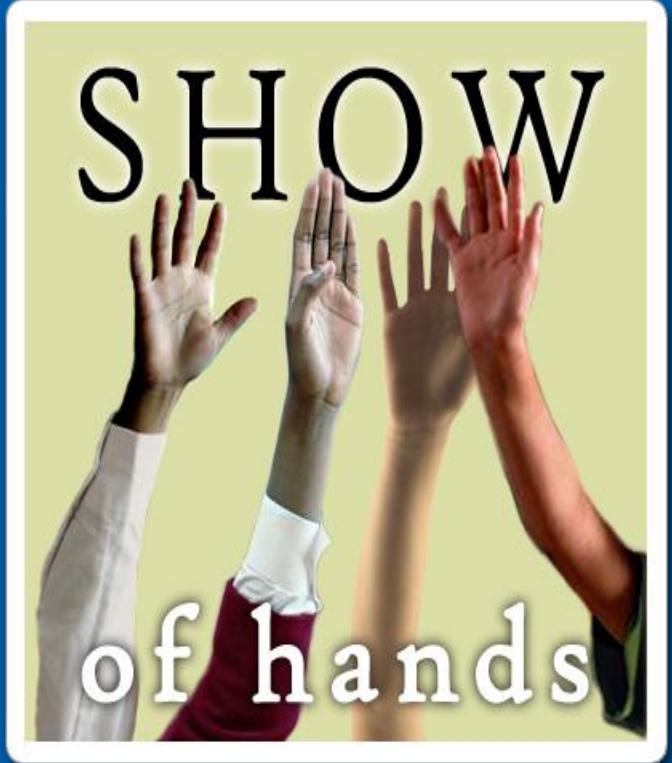
- Organize inventory at site laboratory
- Maintain records of inventory
- Requisition/order from central supply/store
- Define reorder quantities
- Receive and store supplies
- Define return process (wrong orders)





What questions do you have on:

- The Quality System**
- Equipment Management Process**
- Inventory Management Process**





THANK YOU

