



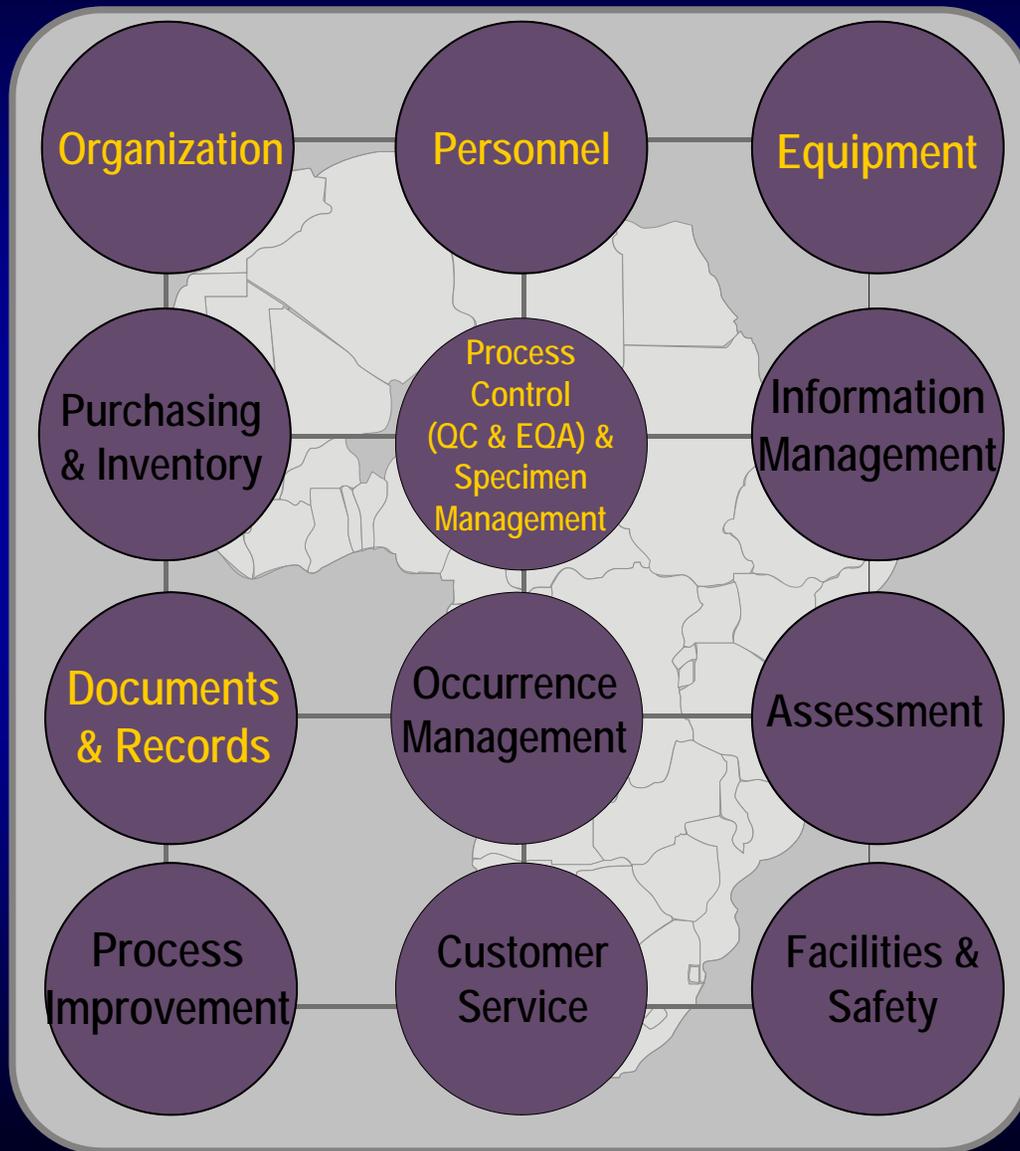
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Equipment



SAFER • HEALTHIER • PEOPLE™

The Quality System



Problem Scenario #1

- You're in the middle of performing ELISAs and the reader fails. You don't have a documented procedure for troubleshooting, the maintenance log has not been updated for 2 years, and the manufacturer's instructions are missing.
- What should you do? Why?

Functioning Equipment is Vital for:

- Producing reliable test results
- Minimizing instrument breakdown
- Lowering repair costs
- Preventing delays in reporting test results
- Maintaining productivity

A Good Equipment Program Achieves

- Maintaining a high level of performance
- Lengthening instrument life
- Reducing interruption of services due to breakdowns and failures
- Improving customer satisfaction
- Improving the technologist's confidence and knowledge

Basic Laboratory Equipment

- Microscope
- Balance/scale
- Centrifuge
- Micropipette
- Spectrophotometer
- Refrigerator
- Freezer
- Autoclave
- Hot air oven
- Incubator
- pH Meter
- Water bath
- Washer
- Shaker / rotator
- Vortex

Equipment Management

- Selection
- Acquisition
- Installation
- Calibration / Validation
- Maintenance
- Troubleshooting
- Service and repair
- Retiring equipment / disposition

Equipment Management Oversight

- Assign responsibilities for all activities
- Train all personnel on equipment management requirements and responsibilities
- Monitor equipment management activities by:
 - Routinely reviewing all records
 - Ensuring all procedures are followed
 - Updating procedures, if necessary

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Selection Criteria

- Use
 - Matching equipment with service provided
- Performance characteristics
- Facility requirements
- Cost
- Supply of reagents
- Ease of operation
- Warranty
- Availability of manufacturer technical support
- Service Contracts

Selection Criteria

- Location in the laboratory
 - available space, accessibility
- Safety

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Acquiring Equipment

- Purchase, Lease, or Rent
 - Central acquisition
 - Bulk procurement
- Donor provided
- Conditions of contract

Acquiring Equipment

- Contract considerations:
 - Parts Manual
 - Installation
 - Operators' Manual
 - Trial period
 - Contents of service contracts

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Installation Checklist

- Prior to installation:
 - verify physical requirements have been met
 - Safety checks, electrical, space, ventilation, water supply, ambient temperature, etc.
 - confirm responsibility for installation

Installation

- Upon receipt:
 - verify package contents
 - do not attempt to use prior to proper installation
- If required, ensure the equipment is installed by the manufacturer

Installation

- After installation
 - Establish inventory record
 - Define conditions
 - Develop and implement protocols for calibration, performance verification, and operating procedures
 - Establish maintenance program
 - Provide training for all operators

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Equipment Calibration

- Perform initial calibration
 - Calibrators or standards
 - Follow manufacturer's instructions
- Determine frequency of routine calibrations

Performance Validation

- Validate the performance of new equipment prior to use
 - Test known samples, analyze data
 - Establish stability/uniformity temperature controlled equipment
 - Check accuracy/precision for pipettors
 - Check centrifuge rpms

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Maintenance Program

- Systematic and routine cleaning, adjustment, or replacement of instrument and equipment parts
 - Performed periodically, daily, weekly, monthly

Example:

- Cleaning optical lenses
- Thermostat adjustments
- Changing motor brushes

Function Checks

- Monitoring of instrument parameters to verify that that your equipment is working according to the manufacturer's specification
- Performed periodically- daily, weekly, monthly
- Performed after major instrument repair

Example:

- Daily monitoring of temperatures
- Checking wavelength calibration
- Checking autoclave indicator paper

Implementing a Maintenance Program

- Assign responsibility
 - Oversight of all laboratory equipment
 - Individual responsibilities
- Develop written policies and procedures
- Train staff
- Keep records

Implementing a Maintenance Program

- Create a record for equipment inventory
 - Name, Model #, Serial #
 - Location in lab
 - Date purchased
 - Manufacturer and vendor contact information
 - Warranty, expiration date
 - Spare parts

Implementing a Maintenance Program

- For each piece of equipment:
 - Establish routine maintenance plan
 - Establish required function checks
 - Develop a list of spare parts

Implementing a Maintenance Program: Spare Parts

- Establish and maintain an inventory of most frequently used spare parts. Include in record of inventory:
 - Spare parts per equipment
 - Part number
 - Average use
 - Minimal # of items to be stored
 - Cost and date of ordering
 - Dates of entry and issuance of part from inventory stock
 - Balance of items remaining in inventory

Implementing a Maintenance Program: Documents

- Develop written procedures for all equipment
 - Concise step-by-step instructions for performing maintenance and function checks
 - Include guide for troubleshooting
- Establish maintenance records to track:
 - function checks and routine maintenance
 - calibration
 - manufacturer's service

Sample Records

- Charts
- Logs
- Checklists
- Graphs
- Service Reports

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Troubleshooting

- Check manufacturer's instructions
- Determine source of problem
 - Sample problem
 - Reagent problem
 - Equipment problem
 - Check electrical supply
 - Check water supply
- Make one change at a time

When In-house efforts fail:

- Do NOT use equipment that does not function properly
- Options for testing:
 - Refer to nearby laboratory
 - Obtain backup instrument from central stores
 - Store samples appropriately
- Seek help from manufacturer or other technical expert
- Place a malfunction notice on equipment

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Service and Repair

- Schedule service that must be periodically performed by the manufacturer
- Options
 - Centrally service small equipment, e.g., microscopes, washers, pipettes
 - Team of biomedical service technicians

Equipment Documentation

- Develop a problem log record for each piece of equipment
 - Date problem occurred, removed from service
 - Reason for breakdown or failure
 - Corrective action taken
 - Date returned to use
 - Change in maintenance or function checks

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Retiring Equipment / Disposition

- When?
 - When experts indicate not repairable
 - Outmoded, will replace with new equipment
- Why?
 - Prevent inaccurate test results
 - Free up valuable space
 - Hazardous
- How?
 - Salvage any useable parts
 - Consider biohazard, follow safety disposal procedures

Benefits of a Maintenance Program

- Safety
- Fewer interruptions of work
- Lower repair costs
- Elimination of premature replacement
- Less standby equipment
- Identification of high maintenance cost
- Reduction of variation in test results
- Greater confidence in the reliability of results