Equipment and Logs

Equipment GLP Requirements

- Equipment used in the generation, measurement, or assessment of data and equipment used for facility environmental control shall:
  - Be of appropriate design and adequate capacity to function according to protocol
  - Be suitably located for operation, inspection cleaning and maintenance

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Equipment

- Equipment shall be adequately inspected, cleaned, and maintained.

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"The contact points must be dirty...just click it up and down a few times."

■ **Equipment used for the generation, measurement, or assessment of data shall be adequately tested, calibrated, and/ or standardized.**
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EQUIPMENT

Standardization- comparing against similar equipment (use of 3 thermometers to determine variation at different points) or make repeated measurements and determine deviation from mean

Calibration - Use of materials with known or certified values (usually involves adjustments)

Verification/Testing – assuring a piece of equipment is operating correctly

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Equipment

■ Points to Consider
  - How true to accurate does the measurement need to be?
  - What is going to be done with the data?
  - How much data are you willing to lose?
  - How likely is the piece of equipment to malfunction?
  - What is the consequence of equipment malfunction?
  - Are you calibrating or just verifying (checking)?

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BALANCES/SCALES-Example

- **Verification recommendations**
  - Reproducibility checked by calculating SD of 10 repeated measurement of same weight
  - Off-center error checked by recording weight of object in center of pan then 1/2 way toward each outer edge - should be no difference
  - Annually check over range of balance with multiple weights (external servicing recommended)

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BALANCES/SCALES - example

- Establish acceptance criteria
- Annually check over range of "tares (10-100g)", establish linearity
- "Checks" done prior to use, bracketing weight range or over range of balance
- Use class S weights (stainless steel)
- Verify "working" brass weights with 3 stainless steel

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Equipment SOP/Log priorities

GREEN LIGHT		RED/YELLOW LIGHT
Repetitive use in GLP Studies	FREQUENCY	Single use, borrowed Only one study
Generates, measures assesses, environmental	FUNCTION	Mixes, houses, cleans
Inspection,cleaning Maintenance, Test/Calib/Stand	USE REQUIREMENTS	No maintenance required, if it breaks throw it out
Failure affects study outcome or integrity; results in lost data	IMPORTANCE	Failure of little importance

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Requirements for Equipment SOPs

- Instrument Specifications
- Definitions (if applicable)
- Materials, methods, and schedules for routine:
  - Inspection (checking hoses, nozzles, lines, pressures, level)
  - Cleaning
  - Maintenance (generally based on operators manual and good science)
  - Testing (validation, alarms, balance checks)
- Calibration/standardization (analytical equipment, thermometers, pipettors, balances, etc...)
- Operation
- Component testing
  - Weather stations
- Responsible persons
- Remedial actions in case of malfunction
- Troubleshooting

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Suggested Equipment SOP Format

- **Title**
- **Scope**
- **Definitions**
- **References**
- **Instrument Specifications**
- **Inspection**
- **Testing**
- **Cleaning**
- **Maintenance (materials, methods, schedules - daily, weekly, quarterly, yearly or winterizing)**
- **Calibration/standardization**
- **Validation/verification procedures**
- **Component testing**
- **Operation/use**
- **Remedial actions in case of malfunction**
- **Troubleshooting**
- **Responsible persons**

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Requirements for Equipment Maintenance Logs

- **Routine Maintenance Documentation:**
  - **Inspection (checking hoses, gas lines, pressures, etc.)**
  - **Maintenance (as detailed in SOP)**
  - **Testing (alarm systems, balance checks)**
  - **Calibration/ standardization (balances, sprayers, Hobo's thermometers)**
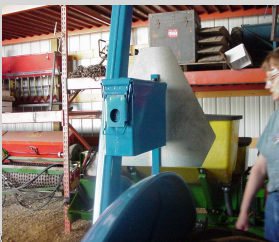
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Requirements for Equipment Maintenance Logs

- **Routine Maintenance Documentation:**
  - **Must contain dates of operations**
  - **Must specify whether SOPs were followed**
  - **Cleaning**
    - » **Not required to be documented in equipment logs by GLP**
    - » **If not documented in equipment log, should be documented in study records**
    - » **Routine cleaning - logs**
    - » **Specific study cleaning-study records**
    - » **Critical for equipment used by several people**

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Requirements for Equipment Maintenance Logs

- **Documentation of non-routine maintenance and repairs:**
  - Nature of defect
  - How and when defect was discovered
  - Remedial actions taken in response to defect

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Helpful Hints for Equipment Compliance

- Use forms that support SOP requirements for all routine maintenance procedures
- Use forms that "key" for required GLP elements for non-routine maintenance
- Keep calibration data on facility forms and in logs
- Use a three ring binder or ACCO binder (clasp) and include SOP in the equipment log
- Archive originals when pages are full; photocopy in log
- Army ammo boxes are nice welded to the tractor/sprayer
- **COMPUTERS ARE EQUIPMENT!!!!!!!**

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QUESTIONS??????

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