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

Equipment

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

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

**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

**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)?
**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)

**Establish acceptance criteria**
- Annually check over range of "tare" (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 weights

**Equipment SOP/Log priorities**

<table>
<thead>
<tr>
<th>GREEN LIGHT</th>
<th>RED/EXPIRED DATES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repetitive use in GLP Studies</td>
<td>Single use, borrowed</td>
</tr>
<tr>
<td>Generates, measures assesses, environmental Inspection, cleaning Maintenance, Test/Calib/Stand</td>
<td>Only one study</td>
</tr>
<tr>
<td>Failure affects study outcome or integrity; results in lost data</td>
<td>No maintenance required, if it breaks throw it out</td>
</tr>
<tr>
<td>Importance</td>
<td>Failure of little importance</td>
</tr>
</tbody>
</table>
Requirements for Equipment SOPs

- Instrument Specifications
- Definitions (if applicable)
- Materials, methods, and schedules for routine:
  - Inspection (checking hoses, nozzles, lines, pressures, levels)
  - Cleaning
  - Maintenance (generally based on operator's 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

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

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, Hobe's thermometers)

WCQTI/Pac Rim
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 log 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

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

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!!!!!!