Facility and Equipment Maintenance

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Overview

- Facility Maintenance
- Equipment Maintenance

Facility Specifications

Drawing on our design talk from earlier…

- If possible: documentation of construction
  - Correspondence with architects, their plans & specifications, construction agreements
  - Correspondence with FDA, if applicable
  - Correspondence with internal facilities management

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Facility Specifications

During construction:

- Monitoring of:
  - Materials used in construction
  - Design changes
  - Damage occurring during construction
  - General inspections
  - Continued correspondence and progress reports

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Facility Specifications

Upon completion of construction

- Documentation of:
  - Final walk-thru checklist
  - Resolution of checklist items
  - Qualification/Validation of critical items:
    - Air handling system
    - Temperature and humidity controls
    - Card key access system
    - Automated LN2 delivery system
    - Alarm systems
    - Emergency power and back-up systems
  - Final hand-off of new laboratory: date of start-up of operations

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Facility Operations

Once in production…

- Documentation of critical systems
  - Quality Control semi-annually
    - Air handling system
    - Emergency power and back-up systems
    - Alarm systems
  - Quality Control more frequently than1x/month
    - Temperature and humidity controls
    - Viable and non-viable particle counts
    - Air pressure differentials
    - Automated LN_2 delivery system
  - Ongoing monitoring of the physical condition of the laboratory

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Facility Operations

- Preventative maintenance and deviation management: Documentation!!!
  - Preventative maintenance
    - Any servicing performed on the facility such as replacement of HEPA filters or temperature checks or adjustments
    - Safety inspections
    - Electrical checks
  - Deviation Management
    - Any repairs due to facility damage or failure such as air handling vents needing to be replaced
    - Sticking doors, cracks in wall due to settling of foundation, etc!
  - Ask for documentation of everything!

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Equipment Overview

- Purchase
- Installation
- Qualification
- Validation
- Maintenance
- Retirement
- Document control

Equipment Purchase

- When purchasing equipment, think of long-term use.
- Compare products.
- Ask trusted colleague for advice.
- Buy a clinical product if available

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Receipt of Equipment

- Documentation of:
  - Date of receipt and initials of accepting tech entered into ordering log book or other inventory system
  - Inspection of packaging
  - Any evidence of visible physical damage

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Unpacking equipment

- Assistance of factory vendor representative, if major equipment
- Documentation of:
  - Correct equipment shipped
  - All accessories present
  - Inspection of equipment
  - Any evidence of visible physical damage

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Internal Asset Control

- Notify Clinical Engineering
  - Perform electrical and safety testing
  - Asset management
    - Computerized equipment inventory
    - Preventive maintenance schedule
  - Control tag placed on instrument indicating it has passed inspection

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Documentation

Type of Equipment:_____

Equipment	Manufacturer	Model number	Vendor

Date ordered_____ Tech:_____ *Attach copy of Purchase Req.

Receipt

Date of Receipt:_____ Time of Receipt:_____ Carrier:_____

Inspection of Packaging ☐Acceptable ☐Unacceptable (see F42) Tech:_____

Entered into Inventory Log Book ☐ Tech:_____

Installation

Unpacking performed by:_____

Factory Vendor/Service Rep present: ☐ No ☐Yes, Name_____

Inspection of Equipment ☐Acceptable ☐Unacceptable (see F42) Tech:_____

Inspection of Accessories ☐Acceptable ☐Unacceptable (see F42) Tech:_____

Clinical Engineering

Clinical Engineering contacted: Date:_____Time:_____Tech:_____

Electrical and Safety Assessment ☐Acceptable ☐Unacceptable (see F42) Tech:_____

Asset Management Inventory Number _____ PM Due _____

Signature of Tech Completing Form:_____Date: _____

Director Analysis: Initial Installation ☐Acceptable ☐Unacceptable (see F42)

Director Comments: _____

_____

_____

Laboratory or Medical Director Signature:_____Date:_____

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Installation of Equipment

- Position in logical area
- Plug into dedicated circuits or emergency power if necessary
- Install according to manufacturer's instructions
- Assure proper start up and general operation

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Priority of Equipment

- Determine priority level
  - Critical piece of equipment

  or
  - One of many

Priority	Equipment
A	Cytometer
A	Hematology Analyzer
A	Scientific Balance
A	Biological Safety Cabinets
A	Floor model Centrifuge
A	Cell washer
A	LN2 Transport Container
A	LN2 Vial Vessel
A	Cryogenic Control Management & Fill System
A	LN2 Vessels (1 -> 5)
A	Cell Separator
A	Control Rate Freezers
A	Heat Sealer
A	Active Blood Bank Refrigerator
A	Sterile Connecting Device
A	Transplant Water Baths
A	Particle Monitor
A	Centrifuge inserts for CBUs
B	Serofuge
B	Dry Shipper
B	Fluorescent Microscope
B	Brightfield Microscope
B	Pipettors
B	Quarantine Blood Bank Refrigerator
B	Vial Coolers
C	CO_2 Incubator
C	-70 Freezer
C	Clean Room Fridge
C	Clean Room Freezer
C	Stopwatches and Timers
C	Thermometers

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Equipment Qualification

Lab “rules” (SOP)

- Laboratory equipment that is to be used for assay validation must be qualified according to a pre-approved protocol prior to the start of method validation.

- A document of the instrument qualification is to accompany any resulting method validation report.

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Qualification Plan

The Qualification Plan must be documented prior to performing any tests

- Principle
- Goal
- Reagents and Supplies
- Procedure
  - Manufacturer's Tests
  - Internal Tests
- Target Values/Acceptance standards
- Result Reporting
- Quality Control
- References and Appendices

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Manufacturer's Tests

Determine manufacturer's tests prior to instrument release

Examples:

- Electrical testing
- Calibration
- Reproducibility
- Carryover

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Internal Tests

Determine required tests prior to lab instrument release, document in Qualification Plan, prepared specifically for each new piece of equipment, and depends on critical nature of equipment

Examples:

- Linearity
- Accuracy and Precision
- Stability
- Cross-validation

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Qualification Testing

Qualification:

- Testing performed according to specifications.
- Record test results in a spreadsheet or database, as appropriate.

When critical equipment:

- Run in parallel on other qualified machinery in lab (if replacement or an additional unit).
- Run in parallel with other certified laboratories (when a new piece of equipment).

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Documentation Review

- Review of Qualification Plan and specified parameters
- Compilation of test results
- Statistical analysis of test results
- Summary of test results
- Report prepared by technologist detailing the results of the qualification

- Laboratory Director reviews all documents and signs off on Qualification, specifying an implementation date.
- The Equipment Qualification Report is placed into the appropriate Equipment Binder.

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Equipment Binder

- Each Binder contains five sections and is specific to equipment type. (*e.g.* Centrifuges, Microscopes, Refrigerators)
  - Procedures (QC, maintenance, cleaning, calibration)
  - QC Results
  - PM Documentation
  - Deviation Management (failures, malfunctions, accidents, service calls)
  - Validations (qualifications, method validations and manufacturer's manuals)

At this point we meet as a group to discuss Method Validation and required QC Procedures with the Laboratory Director. These documents will also be filed in the Equipment binder once complete and approved.

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