Transitional Operations:

Guiding Owners Through Start-up Operations and Regulatory Compliance

Debra C Sharpe, MPH CCHO RBP

Director, Laboratory Services & Compliance, WorkingBuildings, LLC

Craig Reed, PhD, RBP

Deputy Director, Laboratory Operations, WorkingBuildings, LLC

Corporate Headquarters Atlanta, Georgia International Offices London São Paulo Regional Offices Albuquerque Austin Boston Chicago

New York Trenton, NJ Winston-Salem, NC Washington,DC

Fort Lauderdale

Houston

Los Angeles

New Orleans

© 2011 WorkingBuildings

Commissioning

The process of ensuring that systems are designed, installed, functionally tested, and *capable of being operated and maintained to perform in conformity with the design intent*...

- ASHRAE Guideline 1 - 1996

Commissioning Process

A quality-based method that is adopted by an Owner to achieve successful construction projects.

- ASHRAE Guideline 0 - 2005

The economic benefits of commissioning lie in avoiding the added costs associated with non-commissioned facilities.

Benefits to Owners

- Better documentation of the Owner's needs
- Fewer unidentified deficiencies at takeover
- Systems operate at maximum energy efficiency
- Better trained operators
- Saves Money!

Benefits to Designers

- Clearer understanding of Owner's needs reduces redesign work
- Independent design reviews reduce RFIs
- Feedback on actual systems operability lessons learned to take to the next project.

Benefits to Contractors

- Better design documents
- Early identification of issues reduces re-work
- Clear documentation of system functionality at turnover
- Reduced warranty call-backs

When to Use Commissioning

- Technically complicated facilities like laboratories, or health care facilities
- Typical Project Size
 - \$3,000,000+
- Engaged early by the owner is best
 - Pre-design (preferably)
 - Assist in programming
 - OPR Workshop
- Specific tasks defined for each phase

When to Use Commissioning

- Typical Project Scope
 - Mechanical (chillers, boilers, VAVs)
 - Controls (BAS, power monitoring)
 - Electrical (switchboards, transformers, generators)
 - Life Safety (Fire Alarm, emergency lighting)
 - Security (card readers, door alarms, CCTV)
 - Building Envelope

Commissioning Firm Qualifications

- History of the firm
- Evidence that commissioning is a principal enterprise of the firm
- Experience with the type of facility being built
- Commissioning expertise and capability
- Local experience over the last five (5) years on projects of similar size and scope

Commissioning Firm Qualifications

- Prior commissioning reference contacts
- Resumes of key (commissioning) management personnel and their positions
- Professional liability insurance

Commissioning Authority Qualifications

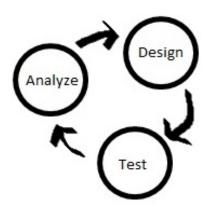
- Minimum 5 years commissioning experience
- Certification by a nationally recognized authority
 - Building Commissioning Association (BCA)
 - University of Wisconsin (Department of Engineering Professional Development)
 - AABC Commissioning Group (ACG)

Cost of Commissioning

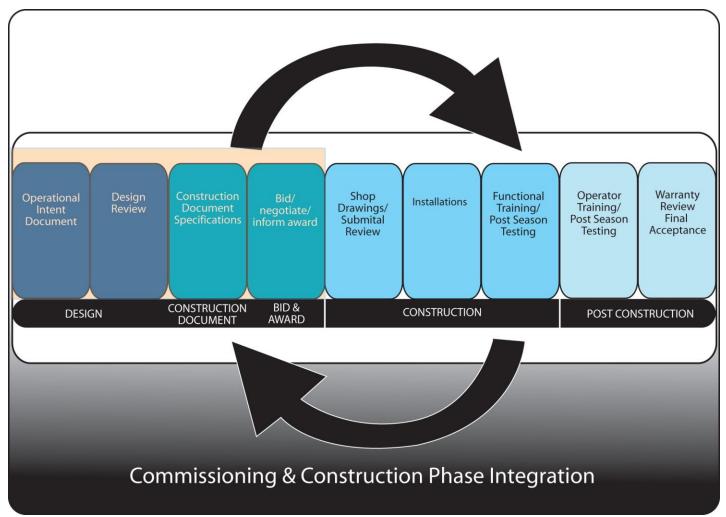
- 0.5% 1.5% of the total construction
- 2% 3% of mechanical construction
- 1% 2% of electrical construction
- Avg \$1.00 per square feet

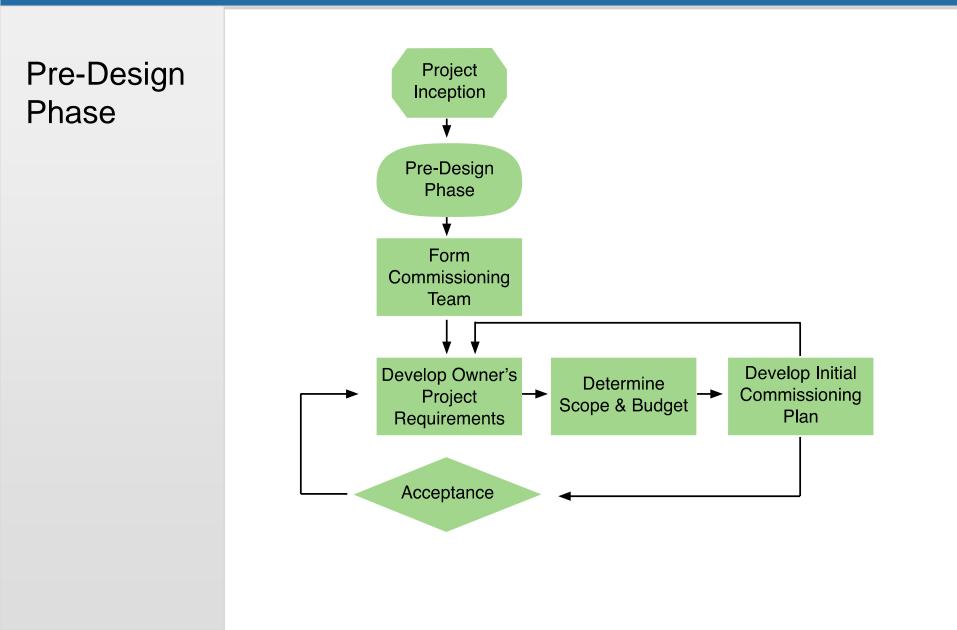
Program Phase

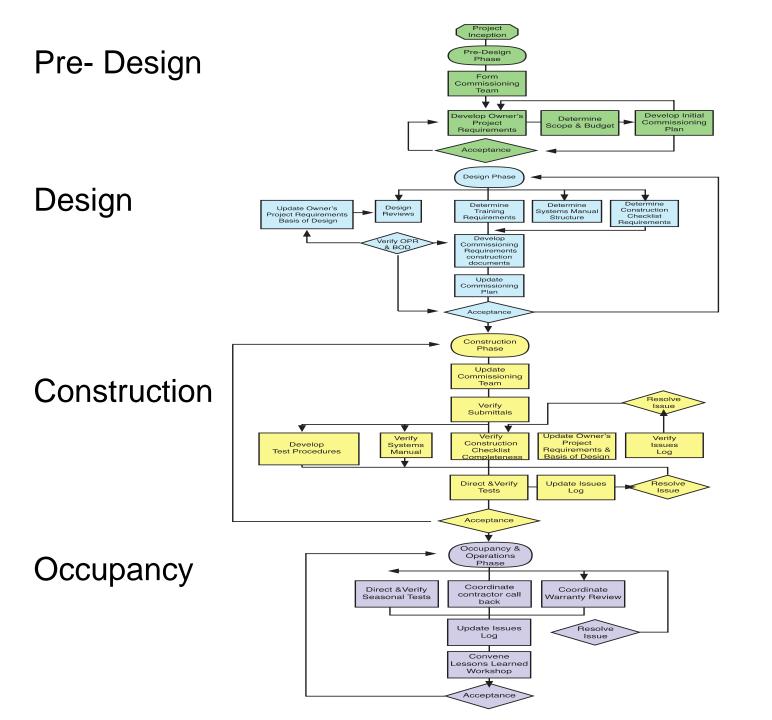
- Owner's **Program of Requirements**
- Documentation of the *Design Intent* Preliminary *Commissioning Plan*



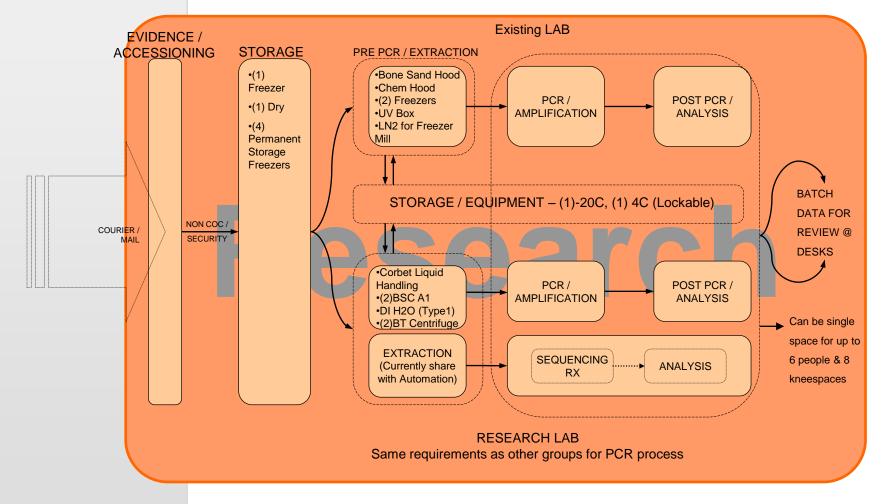
Integrate The Process







Process Flows & SOPs



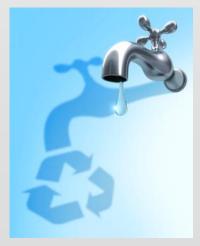


Design Phase Narrative

- Mission, Goals & Meeting Minutes
- Service/Research Definition
- Regulatory Compliance
- Standard Operating Procedures (SOPs)
- Equipment Cut Sheets & Coordination
- Waste Handling
- Materials Receiving
- Inventory Control
- Security
- Staffing & Scheduling
- Service Contracts
- Community Outreach Initiatives
- Existing Utilities & Providers
- Internal Design Standards







Designer Compliance Discussions

- Complexity of the Design
- Can the institution maintain the intended design concept
- Cost of operation the facility
- Ways to reduce cost of overhead and maintenance









Design Phase

- Protocols/PPE
- Security paradigm
- 0&M
- First responder coordination
- Inventory and equipment analysis
- Contract services providers
- Equipment coordination







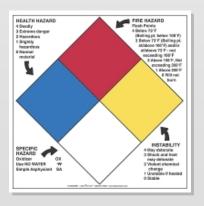




Owner Compliance Discussions

- What agents will be used? In vivo/In vitro
- Volumes & concentrations
- Volumes & types of chemicals
- Work or process flow
- Is this an organization with *"Institutional Control"*?





Owner Compliance Discussions

- Review existing state regulations & identify if they go beyond federal regulations (i.e., waste disposal)
- Review copies of existing policies and procedures
- Review existing operational documents
- Identifying appropriate SOPs, PPE and protocols based on risk assessments





Construction Phase owner

- O&M protocols/PPE
- Community outreach
- First responder coordination
- Contract services providers
- Facilities inspections
- Move management
- Maintaining existing facility







Final Acceptance

- As-built documentation
- Complete commissioning and facility validation
- Complete systems (O&M) manual
- Training documents
- Specified materials inventory
- Off-season testing TBD

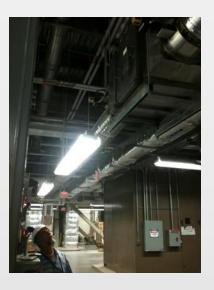






Transitional Phase

- Maintenance & documentation
- RFPs for service contracts
- Move coordination
- Instrument/equipment validation
- User walk-through tours
- Regulatory compliance documents
- Training





Transitional Operations

- Laboratory Commissioning
- Design Review for Compliance
- Protocol Development/Revisions
- Final Stage Operations Oversight
- Building O&M Staff
- Regulatory Compliance Enforcement/ Pre-Inspections
- Move Coordination
- Facility Wide/Multi-Science Protocols







Compliance Coordination

- Biosecurity Plan
- Emergency Response Plan
- Biosafety Manual
- Community Outreach Initiatives
- Protocols
- PPE
- Security
- Maintenance Safety







Compliance Coordination

- Providing Supportive Facility Cx
 Documentation to the Regulatory
 Authorities (i.e., CDC SA Registration)
- Assisting with the Development of Regulatory Documents Policies and Procedures
- Developing and Providing Training to Laboratory and Maintenance Staff
- Meeting with the Regulatory Agencies the community and first responders

Transitional Operations











NJPHEAL



NJPHEAL Vision

- Mission Based Objective 15 Years
- Response to Deteriorating State PH Labs
- Anthrax Incidents after 9/11
- Increased Funding Opportunities
- Available Property Secure Location







Consolidated Lab Services

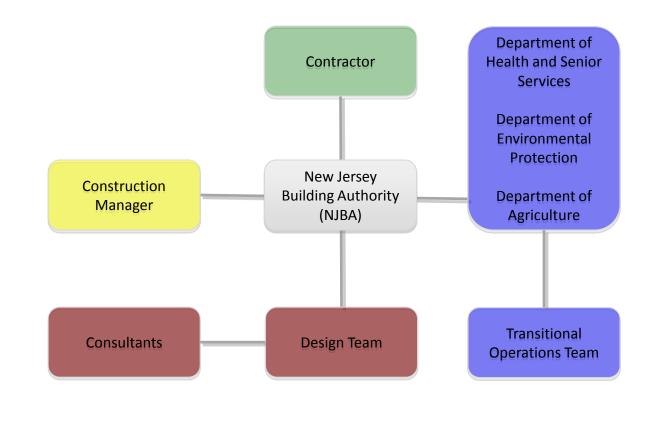
- Clinical Public Health
- Environmental Health
- Animal Health
- Plant Health
- Laboratory Response Network







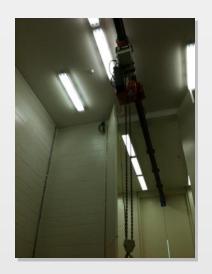
Contractual Structure



Site Location & Security



New Jersey State Police Headquarters Campus







Unique Design Challenges

- Space Types
- Facility Wide Protocols
- 24/7 Operations
- Regulatory Requirements
- Community Relations
- Katrina, China & Inflation
- Move Managment
- Six Years and Counting...







Murphy's Law

- DI Water Leak X 12 (and counting...)
- Condensation flood (AHU Down)
- Sanitary Blockage Flood
- No BSL-3 exhaust fan redundancy
- Installation of separate BSL-3 exhaust fans to maintain static pressure
- Lack of supply and exhaust airflow tracking
- Static dissipating tile shrinkage
- VAV reprogramming
- Long horizontal runs perchloric acid hoods







Lessons Learned

- Users were not adequately involved in the design process
- Centralized leadership was lacking for decision making
- Poor value engineering choices
- Cx agent initially reported to the architect then the owner

Lessons Learned

- Did not adequately review existing compliance structure and documentation
- Ensure all groups understand compliance expectations
- Sharing a facility with different state entities very, very challenging

Conclusions

- Complex & time intensive process
- Expertise is essential
- Involve Cx agent early and report to the owner
- Communication/documentation
- Consolidated leadership with involved stakeholders
- Shared responsibilities
- Informed decision making is key
- Final year is the most difficult