Biocontainment Laboratory Operational Planning:
Methodology For Blending Design And Operations

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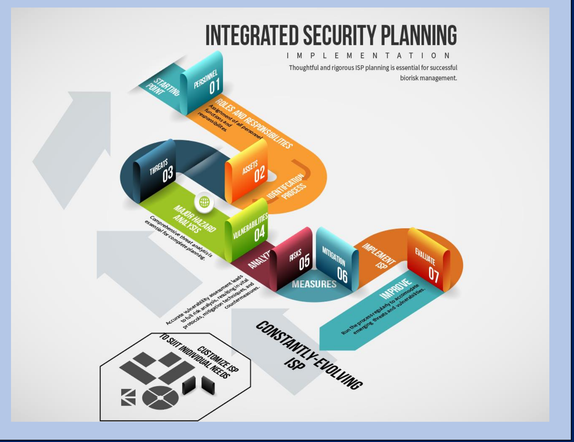
INTRODUCTION

Operational planning of biocontainment laboratories is a critical element to ensure the transition from design and construction to steady-state operations is strategic, organized, efficient, and minimizes risks. Failure to strategically design operational planning can incur significant costs and delays achieving readiness, increasing the time between the end of construction and the beginning of true science operations. This is particularly important for biorisk management programs, which represent a significant vein that runs through all aspects of laboratory management systems. This presentation will detail a process for systematic and strategic planning of biocontainment laboratory operations to support closing the gap that exists between facility handover and initiation of operations. Scenarios from major laboratory projects will be highlighted to demonstrate the validity of the operational planning process and how it reduces the start-up time and cost to achieve science, research, and diagnostic missions. Attendees will benefit from learning the stepwise process of operational planning, the development of strategic tools to gather programmatic requirements, a novel systems of tracking progress during the operational planning efforts, and tactics to support the critical role of biorisk management as a foundational element of laboratory readiness. This will result in a detailed understanding of how to plan biocontainment laboratory operations during the design and construction process to achieve more rapid and efficient mission implementation, using biosafety and biosecurity programs as a foundation.

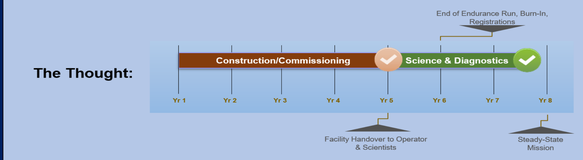
CASE STUDY:
A New National Laboratory with Augmented Biocontainment Capabilities

Currently, a new National Laboratory is nearing the end of construction completion, ushering in the ramp-up on commissioning. For the past few years a significant operational planning effort has been in place to support the stand-up which will include significant BSL3 and BSL4 capabilities. Because many of these capabilities are new, a comprehensive operational planning approach was adopted to ensure that both facilities and programs were developed concomitantly. Of importance is the registration for Tier 1 agents under the Federal Select Agent Program (FSAP), which without, would result in delayed operations. The operational planning process took this into account and ensured a process to engage regulators and future users toward a common registration strategy.

Operational planning of this laboratory also afforded the opportunity to design an integrated risk and threat management approach that spans biorisk management, security, EHS, laboratory operations, facility management, and others. Given the complexity and magnitude of operations, this integrated approach represents a novel way to manage institutions risks and threats.



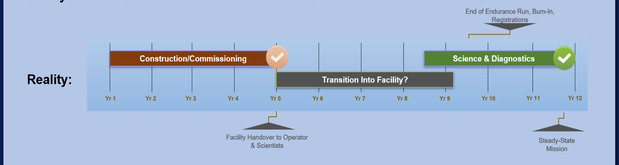
WHAT IS STRATGEIC OPERATIONAL PLANNING?



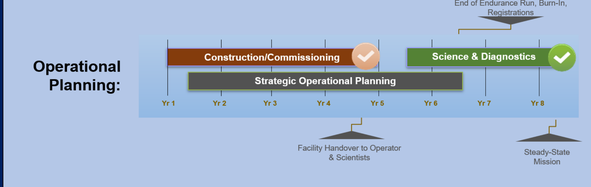
The central dogma of laboratory design is:

Laboratory Planning → Design → Construction → Commissioning

This pathway is facility-centric and lacks a dedicated process for planning how the laboratory will operate once commissioning is complete. Failure to properly plan facility operations often results in significant delays of science, research, and/or production following laboratory handover. These delays incur substantial institutional costs.



Strategic Operation Planning leverages tools and management programs to achieve comprehensive integration for all design, construction, commissioning, and stand-up laboratory operations that will reduce cost and time required to achieve facility operational readiness. It is most successful when executed **concurrent** with design, construction, and commissioning activities.



Integrated Design and Operational Planning

Facility Design

Operational Program Design

Basis of Design

Strategic Science Plan: Operational Modeling

Visioning

Define How The Laboratory Will Operate At And Beyond Steady-State

- **Define the mission, partners, relationships** (*Executive Team, Project Management Organization, Science Mission, and Stakeholder Relationships*)
- **Define the culture of accountability** (*Quality, Regulatory compliance, Safety & Security, and Risk & Threat Management*)
- **Define critical laboratory management programs & systems, and how they interface** (*EHS, Biosafety & Biosecurity (Biorisk) Management, Occupational Health, Animal Care & Use, Security, IT, Administration*)
- **Define Procedures and Training Management Systems**

Conceptual Design

Requirements Development: Requirements Package

Requirements Gathering

Define Detailed Requirements For All Critical Laboratory Programs

- **Information Technology**
- **Science and Diagnostics Programs**
- **Construction and Commissioning Interface**
- **Training and Procedure Programs**
- **Lab Management Programs**
- **Regulatory Compliance**
- **Transitioning-In Activities**

- Work directly with end-users to ensure all requirements are captured and catalogued, as well as determine and integrate any necessary changes implemented between design and operational phases

Detailed Design

Program Development: Developing Operational and Transition Plans

Planning

Use The Operational Model And Requirements Packages To Develop Customized Operational Plans To Determine Precisely How To Build In Individual Actions, Owners, Steps, And Risks Associated With Transitioning Into The New Laboratory

- Operational and transition plans will be highly dependent on the integrated master schedule

CA/CX and O&M

Plan Implementation

Execution

- **Transition Plan goes to the POC responsible for the big move**
  - Answers who, what, when, where, how for the facility transition
  - Reads like a detailed SOP and includes checklist elements that tie back to the transition schedule
- **Operational Plan goes to a discipline lead (e.g., Biosafety Officer, Facilities Manager, EHS Director, etc.)**
  - Should be able to build out the discrete program elements (policies, procedures, guidelines, training, manuals)
  - Should address milestones and checkpoints to coordinate with other programs (e.g., Biorisk Management with EHS; Facilities Management with IT)

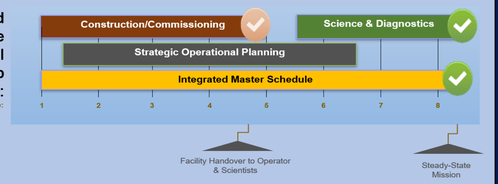
PROJECT MANAGEMENT APPROACHES & TOOLS

Integrated Master Schedule (IMS)

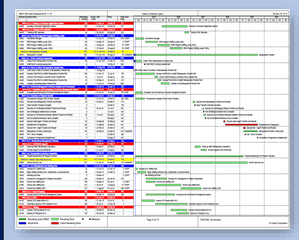
Provides The Scaffold For Milestones, Metrics, And Progress

- Incorporates inputs from all stakeholders and implementers, across all phases of facility stand-up
- Serves as the single sheet of music that everyone is working off of, planning against, and sharing with stakeholders
- Is rooted in durations and logic (not manually-entered dates) which can allow your schedule to be responsive and accurate
- Generates a critical path of activities where most schedule risk resides
- Allows the project to be resource-loaded from start-to-finish for budgeting and utilization purposes
- Links construction milestones to operational planning activities and science stand-up tasks
- Can be used to generate progress reports and hold POC's accountable

An Integrated Master Schedule Incorporates All Stand Up Activities:



Past Performance



- Populated operational planning activities across over 15 technical domains
- Integrated milestones from facility design, construction, and commissioning phases
- Incorporated science program stand-up activities such as phased experiments, pathogen transport, and Select Agent registration
- Reports live changes to start/end dates when schedule risks are realized
- Displays peaks and valleys in resource utilization and budget requests across all phases

Operational Planning Reduces Operational Risks

- **Vision builds transparency and accountability across the enterprise:**
  - *Concurrence from day one*
- **Removes ambiguity from transition process:**
  - *Succinctly establishes who, what, when, how*
- **Reduces time and cost to stand-up into steady-state:**
  - *Application of PM tools provides real-time info*
- **Allows a structured process to ask, "What's possible?"**
  - *Primary consideration for technology integration and IT architecture*
- ***Ensures SCIENCE is integrated effectively!***

Operational Model	Requirements	Planning	Execution

1. Operational Model provides vision and scaffold for lab programs
2. Requirements Packages define expectations of all users
3. Integrated Master Schedule, Operational and Transition Plans define interdependencies, actions, and owners
4. Execution is driven by all of the above, achieving practical, accountable transition toward steady-state

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