Why are Opening New BLS-3 and BSL-4 Facilities Often Delayed by Years?

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Or a Better Title?

- The Challenges of User Expectations & Requirements vs the Architect & Engineer Specifications & Direction vs Management Goals & Budget vs Safety & Regulatory Requirements in Designing, Commissioning & Opening for Use Any High Containment Facility!

All is not a Patagonia

Sometimes it’s Antarctica

A Few Definitions

- BSC – Biological Safety Cabinet
- BSO – Biosafety Officer
- BSL – Biosafety Level from 1 (lowest) to 4 (highest)
- FH – Fume Hood
- HVAC – Total Ventilation System
- A&E – Architect & Engineer
- T&B – Test & Balance
- VE – Value Engineering

Why the Operational Delay?

- Many BSL-3 & BSL-4 facilities, on average, are delayed 1-2 years (Many longer)
  - User expectations
  - Systems designed against budget vs use
  - Regulatory requirements
  - User changes due to science & direction
  - No clear “written” guidance

Facility Design vs User Needs

- Challenges of the final product
  - Commissioning against design or new expectations?
  - Regulatory agency now involved with more stringent expectations?
  - Why is there never enough air reserve & capacity?

The Basics Have Not Changed

- Single pass air – (filtration Risk Assessment)
- Sustained directional air flow – from clean to most dirty (cold ⇨ warm ➡ hot)
- Solid, impervious floors, walls & ceilings
- Capable of being decontaminated
- Multiple self closing doors – (Air Lock?)
- Certification capable (AAALAC)
- Commissioning against expectations

Case Study

- Multi-story, multi-wing biological & chemical research facility
  - Significant flammable solvent volumes
  - Recombinant DNA & other biological agents
  - Radioactive isotopes
  - Tight budget restraints

Who Wants What?

- The users want lots of working space with all the bells & whistles
  - Be able to use large volumes of chemicals
  - Be protected from mixing chemicals & biologicals
  - BSCs, Fume hoods & autoclaves near by
- The management - low cost
  - Cuts out a fan bank (VE)
  - Allows common plenum (VE)
  - Removes the only freight elevator (VE)
  - Assumes flammable solvent volumes can be controlled by safety person & users
  - Eliminated autoclave canopies over all units

Design Issues due to VE

- Major air capacity issues
- Building so positive the doors will not close without an effort
- No freight elevator & only one people elevator available for all three wings
- All fume hoods ganged with the main facility exhaust
- Door grills creating a significant fire issue

Can This Facility be Commissioned?

- Not enough exhaust fans
- Current fans running at maximum
  - Burning out within 2-4 months on average
- Hallways becoming the “common plenum”
- Sustained directional air flow not possible
- Other issues
  - Not all deck to deck walls
  - Too many wall & door openings for air transfer purposes rather than a controlled ducted system

Case Study

- BSL-3 Laboratories
  - Multiple entry layers starting with BSL-2
  - Cold, warm & hot areas
  - Multiple users per area
  - Subject to significant regulatory oversight with the expectation for “zero tolerance positive pressure” even when passing through a doorway with a cart

Who Wants What?

- The users want lots of working space with all the bells & whistles
  - Be able to move from lab to lab without disrupting air capture
  - Be protected from all agents
  - BSCs, Fume hoods & autoclaves within the facility
- The management wants low cost
  - Minimum HVAC – not enough air
  - A&E direction without user needs
  - Work flow issues not considered
  - Commissioned without activity
  - Assumed Regulators would be happy

Design Issues

- A&E fell short of understanding what “sustained directional airflow” really meant
- Exhaust ducts placed directly over hot lab doorways on the warm side & over ducted & stand alone Biosafety Cabinets
- Multiple supplies with few exhausts per laboratory (B2 cabinet expected to exhaust for a small laboratory)

Can This Facility be Commissioned

- A balancing & control nightmare
- Was not designed for the regulatory expectation of zero tolerance air reversal
- Baffling all the badly placed exhaust & supply vents & closing excess supplies
- Depending upon ducted BSC & Autoclave canopy for additional exhaust

Show Stoppers

- Some common Challenges to Certification & Commissioning
  - Not enough air
  - Not enough controls or inadequate controls
  - No test ports
  - Poor seals all around
  - Changing expectations
  - Regulators will not accept

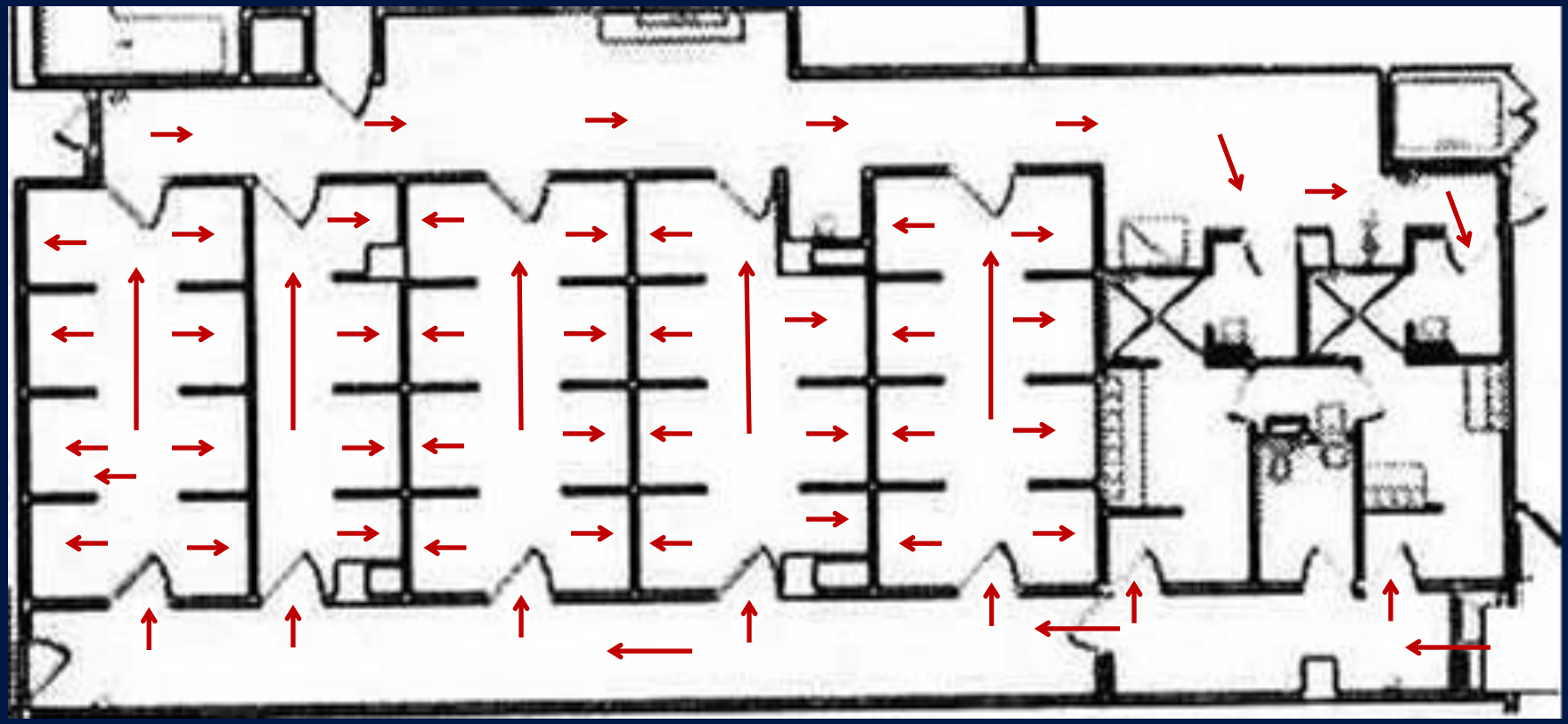
More Examples

- Multiple 100% exhaust ducted biosafety cabinets ganged with the fume hoods & building exhaust
  - Opening or closing the fume hood disrupts the airflow & alarms the BSC
  - Opening & closing room doors has the same effect
  - Control system cannot adjust for the change

Examples Continued

- Air lock vs multiple entry layers
  - Air locks expensive
  - Can you accomplish the same without?
  - Maintenance aspects
  - Overall reliability & control
  - Risk Assessment must be completed
- Regulatory required?

User Requires & Expects the Following Air Flow within this ABSL-3



What Can You Do?

- Users & Maintenance Personnel
  - Get involved
  - Spell out your specific needs
  - Document the specifications
  - Refer to regulations where they impact – get them involved for support of requirements
  - Settle for a smaller footprint vs allowing HVAC value engineering
  - Don’t settle for a facility that cannot be maintained

What Can You Do?

- Safety
  - Do your homework – understand both the user & construction team needs
  - Educate the management team
  - Sell the necessity of involvement from the early design through operational readiness
  - Be the liaison to all parties

What Can You Do?

- Certifiers
  - If you are already a vendor – try to input to the design/construction team
  - Can't get to the team – then get to the BSO
  - You can end up with a certification nightmare if the entity planners do not understand

What Can You Do?

- Commissioning Agents
  - If you have been involved at the start – don't fear being heard
  - If you know you will be the agent – get to the BSO or design/construction team
  - Savvy entities will involve the agent from the beginning

Too Late the Facility is at 75-100%

- Suggestions:
  - Be honest – if the facility cannot be certified or commissioned in its current configuration – tell them so
  - Ask what the Regulatory requirements are (NIH/CDC?)
  - Suggest solutions to the problems – even redesign as needed
  - Don’t just certify or commission for that moment in time! It will not last once the facility is in operation.

Thoughts from Both Sides

- Users
  - Feel they explained themselves completely
  - Assumed the construction team knew & understood their terminology
  - Assumed the construction team knew & understood the regulations that applied to the work
- A&E
  - Feel user expectations were not reasonable
  - Feel users did not explain properly
  - Feel users kept making changes
  - Needed documented detailed specifications agreed to by both sides

Personal Experience

- Major issues common to many facilities
  - Early calculations done without considering all the potential equipment – all active & in use
  - Early T&B conducted without all large air, water and heat users on line
  - T&B in general conducted without activity
  - Commissioning done without activity information
  - Excess air capacity is the first to go via Value Engineering & cost control
  - Did not understand Regulatory Requirement

Is There a Solution?

- Most important components
  - Initial meetings with users, A&E, commissioning agent, safety, management & maintenance (those who must keep it up & running)
  - Complete & very detailed specification list & **why**
    - Signed off by all parties
    - Include specific regulations where applicable
  - Users & safety represented (with authority) on the construction team throughout the process

A Final Thought

- The Ancient Inca Indians had engineering skills, calendars & time dials
- They even controlled air flow!

Machu Picchu, Peru

Questions?

Gentoo Penguins, Falkland Islands