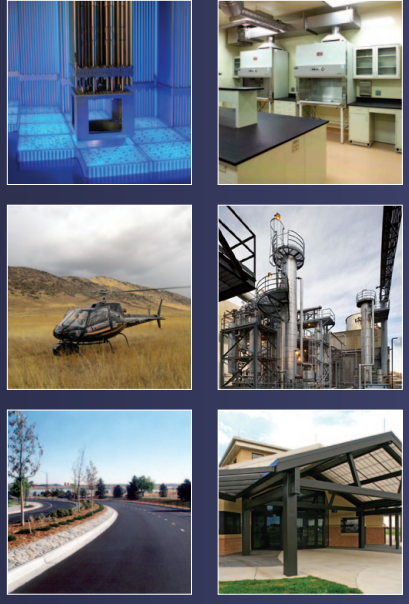

TECHNICAL PAPER

Commissioning the Biocontainment Lab:

Paving the Way for Effective and Trouble-Free Operations

By: Gilles Tremblay

Merrick & Company

Merrick & Company
2450 S. Peoria Street • Aurora, CO 80014-5475
Tel: 303-751-0741 • Fax: 303-751-2581
www.merrick.com

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Abstract

The American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) defines commissioning as *"a quality-oriented process for achieving, verifying, and documenting that the performance of facilities, systems, and assemblies meets defined objectives and criteria."* Originally conceived as an effort to optimize the energy efficiency of large conventional buildings, commissioning (often abbreviated Cx) is taking on an expanded role in biocontainment facilities. Biocontainment facilities are not only among the most costly to operate, but represent those facilities where the proper operation is mission critical for the organization and failures could have substantial consequences for the health and safety of personnel and the larger community. The definition of biocontainment facility is all encompassing and includes everything from outside sensors and controls to the construction of the walls, floors and ceilings and all the associated equipment

This chapter highlights the many differences between conventional and biocontainment facilities from a commissioning and operating perspective, discusses the commissioning process procedure and its costs, and makes recommendations for those designing new facilities. Within this chapter we urge those considering the creation of a new biocontainment facility to strongly consider a) bringing onboard commissioning agents (CxA) with personal experience in biocontainment facilities as opposed to merely conventional facilities, b) getting these experts involved early, in the pre-design stage of the process whenever possible, and c) staying involved in the process with your onsite Operations & Maintenance people in order to optimize your understanding of the complex workings of these facilities. These are the keys to optimizing the opportunities that commissioning can bring to containment lab operations, paving the way to substantial savings in operating costs, protecting research interests and avoiding operating issues every year for decades into the future.

Commissioning the biocontainment lab: paving the way for effective and trouble-free operations

"The Commissioning Process is a quality-oriented process for achieving, verifying, and documenting that the performance of facilities, systems, and assemblies meets defined objectives and criteria."— American Society of Heating, Refrigerating and Air-Conditioning Engineers, Guideline 0-2005. [1]

Consider a conventional building such as a school, commercial building or office, and all of the structures and major systems that need to be put in place before the facility's operational purpose can begin to be realized. These include electricity, water, heat, air conditioning, natural gas, oil, sewage, telecommunications, floors, ceilings, walls, electronic controls, fire safety, security and more. Many of these systems require custom built infrastructure—pipes, ducts, wires—configured on site by different contractors in serial or parallel fashion, often utilizing the same tight spaces. Rarely, if ever, is each team of contractors aware of or concerned about the requirements or perhaps even the existence of the others. Then machinery and equipment—boilers, chillers, fans, pumps, light fixtures—each manufactured in volume by assembly line perhaps half a world away, are shipped in, uncrated and bolted into place. Perhaps they are quality tested individually at the factory before undertaking the shipping process, perhaps not. Perhaps they were tested once as they were uncrated or after installation, just to see if they worked at all, but likely not. And, certainly, they were not tested to see how they worked in tandem with the myriad other systems around them under real world operating conditions.

No wonder then, that, once the keys of an un-commissioned building were turned over to the new owners, the occasional switch would be turned on, only to lead to problems. Subsequent investigation would find a key piece of equipment or infrastructure that was not operating or installed properly, not hooked up, or, sometimes, even missing entirely.

Of course, one would like to think that this was the exception, not the norm. Unfortunately there are many stories suggesting otherwise. Whichever the case, it was certainly true that, even if everything was working, without intervention and fine tuning, there was little possibility that it would be working in an optimized fashion. This was especially the case with the heating and cooling systems; with their reliance upon disparate equipment, miles of ductwork and sensitive electronic sensors, wide fluctuations in temperatures were common both hour-to-hour and room- to-room, with detrimental consequences to both occupant comfort and energy consumption.

This represents some of the drivers that led the U.S. government to mandate that all Federal buildings undergo a commissioning (abbreviated "Cx") process towards optimization of the building's energy efficiency [2]. Many private entities soon followed suit.

Containment labs: significantly more complex than conventional facilities

A number of trends is leading to a clear uptick in the building of higher level biocontainment labs. These drivers include the escalating concerns about threats from biological agents in the wake of 9/11 and the 2001 anthrax scare, the increasing cachet of biocontainment labs among top universities, and the fact that many of the first wave of biocontainment labs, built in the 1950s and 1960s, are reaching the end of their useful life and need to be replaced. This means a clear uptick in the need for effectively commissioning these facilities so that operations can begin and continue in an efficient manner over the long term.

It is important to realize that at this point, commissioning as an industry has not yet developed sub specialties niches, so that much of the commissioning information and expertise is general in nature and applies to the commissioning of conventional buildings. Notably, the commissioning of BSL-3 and BSL-4 biocontainment labs bears little resemblance to the processes developed for conventional buildings. Commissioning BSL-3 and BSL-4 laboratories can be a challenge, since building designers and construction teams also tend to be generalists. Therefore, someone needs to be on the commissioning team who is a biocontainment expert.

Comparing the earlier discussion to a BSL-3 (or higher) biocontainment lab, the challenge—and the chasm between the completion of construction and operations being able to begin—escalates. For example, while there are basic systems in common between conventional buildings and containment facilities—electrical power, heating, air cooling, water service, telecommunications and so on—the number, permutations and subsequent challenges of the interactions between these "familiar" systems is increased an order of magnitude because, in containment applications, many of them need to be redundant. That means *two* independent power sources, *two* independent exhaust fans or air handling systems, *two* waste treatment processes and other redundant systems likely as well. Furthermore, these systems need to work together in varying ways; in some cases, both redundant systems might be running at the same time, at full or low levels. In other cases, one system might be dormant, poised to take over in the case of a failure.

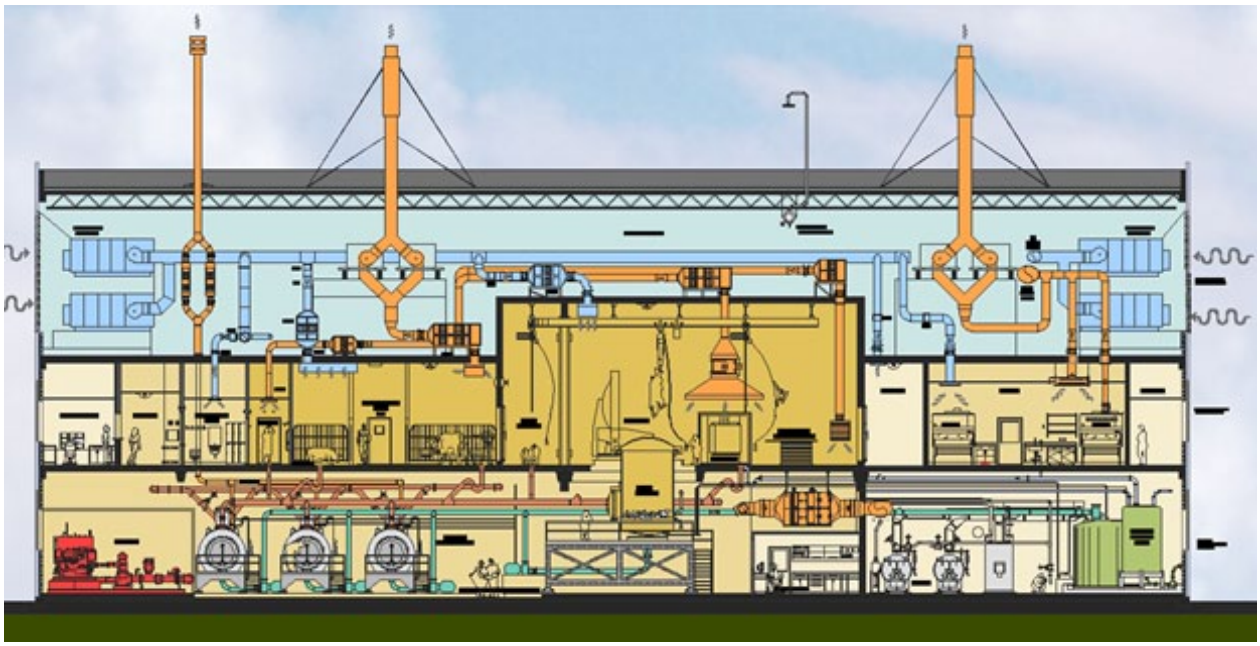

Fig 1 – (Example of BSL3Ag Large Animal Facility)

Also, in a biocontainment facility, unlike any other kind of facility, the lab must be kept at a constant *negative* pressure at a level of approximately -0.05" to -0.1" water column (-12.5 to -25 Pascals), with continuous air movement *into* the contained or "dirty" room and no laboratory air leaking into surrounding spaces, hallways, rooms or outdoors. Maintaining this pressure and directional airflow requires a series of interlinked fans and sensors, as well as a series of back-up devices to guard against the threat of failure. Examples of these are strategically placed uninterruptible power supplies and redundant systems where indicated. In addition, as anyone with experience in high level BSL labs can tell you, some kind of sound attenuation strategy is advisable, since the activity in the ducts related to maintaining the pressure can become distracting to both researchers and their animal subjects.

Testing of failure modes takes on new meaning in biocontainment commissioning, and is perhaps one of the most vital parts of the process. Most importantly, there are a number of key questions which should be addressed. For example, what happens to the directional airflow when there is a power outage or a fan failure, how long does it take for redundant or mitigating systems to kick in, and how long does it take for the desired negative pressure to be re-established? Secondarily, establishing and ensuring the back-up of heating, cooling and basic power such as lighting are important as well, as they would be in any facility.

Significantly unlike other facilities, the biocontainment lab needs to be sealed tight, forming a "containment barrier" that allows no air to escape. Walls, ceilings and floors need to be seamless and monolithic, and the edges and corners where they meet need to be reinforced against leaks, as does every penetration into the room. These include, but are not limited to plumbing pipes, vent ducts, electrical outlets, phone jacks and thermostats. Few, if any pipe fitters, plumbers, electricians and other contractors involved in installing these components and similar infrastructure are familiar with the requirement to make their work airtight. All of these familiar penetrations and more are very commonly identified as leak points in biocontainment lab environments.

Fig 2 – (Typical leak points)

In a biocontainment lab the room must be capable of being sealed tight not only to provide assurance that ambient air not escape but a primary reason it must be sealed is because high level biocontainment labs, unlike typical conventional buildings, must be capable of being decontaminated using a toxic gaseous agent such as chlorine dioxide, formaldehyde or hydrogen peroxide. When these chemicals are in use, it is of course imperative that the vapors not be able to drift into other building spaces, be they adjacent mechanical rooms or wall spaces, hallways or other labs or offices. In addition to ensuring that the room is tightly sealed, it is also vital that all permanent objects and fixtures, from countertops to lamps and more, need to be able to withstand the caustic nature of the gas, and be specified ("spec'd") accordingly.

When a room is sealed as tightly as maximum BSL level labs need to be, and subjected to negative pressures, additional structural issues can come up and need to be mitigated in advance. Although not normally a factor during regular operations, negative pressure in a lab can increase well beyond steady state conditions for a number of reasons. Negative pressure is often increased purposely during the smoke pencil test that is the standard for ensuring that there are no leaks. More damaging however, negative pressure can increase quickly during a system failure in the moments before back-up systems are supposed to kick in and equilibrium is restored. Conventionally installed walls and ceilings cannot stand up to this pressure for long, and the sight of improperly constructed labs "imploding" during testing is, unfortunately, a more common outcome of this process than one would like to think. Although this outcome is not as unfortunate, certainly, as it would be if the issue was not caught in the commissioning process but rather occurred while the lab was in full operation.

Fig 3 – (Exhaust duct implosion when room bubble tight damper tripped closed)

Anyone involved with biocontainment labs also needs to be well versed in effluent treatment, since everything going down the drains needs to be treated before mixing with municipal waste streams. Expertise in HEPA filtration is also needed. HEPA filters on the air exhaust are not mandatory for most BSL-3 labs, and, although mandated for BSL-4 labs, are considered a best practice for all high level containment labs. The reason: extra fail-safe protection against contaminated air escaping during a failure/temporary reversal of the air handling system. BSL-4 labs must also have HEPA filters on plumbing vents for similar reasons. HEPA filters need to be re-certified every year, so testing protocols need to be established that also factor in the method of decontamination that allows for safe testing, and, as a practical matter, HEPA filters in all devices need to be made readily accessible. Seemingly obvious, this is a common design error. Another common design error is failing to compensate for the difference in exhaust static pressure in areas with filters and without, which will cause issues with control-ability of airflow devices, as well as noise issues.

When it comes to security, some of the devices and infrastructure that need to be spec'd and Cx'd —card readers, door interlocks and so on—may be familiar to those versed in commissioning (Cx'ing) contemporary conventional commercial and office spaces; but, depending on the BSL level, other types of systems and practices may not be. These may include biometric identity devices, perimeter fencing, the maintenance of a blast zone, double door entry, blast-resistant building materials and so on. Further, there needs to be knowledge about specific security needs in the freezer areas where select biological agents are likely stored.

Fire security systems in a biocontainment facility also have special requirements that professionals designing, commissioning and operating them should understand. For example, unlike a typical office building, water from the sprinkler systems, as determined through risk assessments, might not be allowed to run into hallways or other rooms, or into standard drains. That might mean the specification of sloped floors, strategically placed floor drains and a treatment/decontamination system capable of handling the potentially huge influx of water without a potentially disastrous backup. Insights into these kinds of emergency and failure scenarios tend to only come with real world experience.

Similarly, in a multi-lab environment, decisions need to be made about the relative degree of isolation achievable by each lab. For example, if one lab needs to be shut down for testing, repair, certification or decontamination, do the owners want the flexibility to keep the other labs operational? Decisions need to be made, weighing the need for continuing operations with the extra cost that installing separate systems and isolation dampers and similar devices will entail. This concept is another that is not well understood among designers, contractors, CxAs and other professionals more familiar with conventional facilities than biocontainment labs. We see the isolation question remaining unconsidered in a large number of facilities. This severely impacts operations for the entire lifecycle, and is more expensive to mitigate down the road.

If much of these design concepts (i.e.…the redundant systems, the sealed room design, the constant negative pressure, the extensive failure testing, the corrosive-resistant finishes, the pit-falls of unfamiliar equipment and

situations) are likely to be all but unknown to the commissioning agents that just completed a primary school or a department store, the specialized equipment that is the *raison d'être* of the containment lab will likely be even more so. Certainly, commissioning such items as carcass treatment equipment, tissue digesters, biocontainment cabinets, and animal feeding and watering systems would be outside the expertise and likely, comfort levels, of the general commissioning community, as would the redundant breathing air systems, and specialized chemical shower systems mandatory for BSL-4 facilities.

Further, it is vital that the commissioning team—as well as any other group involved with building the new containment lab—be familiar with and have intimate understanding of the protocols the future lab will ultimately need to follow. Many of the protocols such as those described herein are dictated in "Biosafety in Microbiological and Biomedical Laboratories (BMBL-5th Edition)" [4]. The BMBL is the CDC/NIH publication that establishes the design criteria for every biocontainment facility in the United States and for most of those in many other parts of the world. Some other countries utilize similar guidelines or those published by the World Health Organization. Lack of familiarity with the real world application of the guidelines is a key driver of overdesigning some systems and under designing others.

For many, there are also a number of regulatory concerns that likewise drive the need for specialized experience and expertise. For example, new labs that conduct research using certain select biological agents listed by the United States Department of Agriculture (USDA) or the Centers for Disease Control (CDC) must undergo a verification and registration process before beginning operations, and expert commissioning can be key to meeting this challenge. *"The BSL-3 facility design, operational parameters and procedures must be verified and documented prior to operation. Facilities must be re-verified and documented at least annually."* – BMBL 5th Edition, pg45, BSL-3 D15 [4]. Similarly, facilities related to projects funded by the National Institutes of Health (NIH) have their own sets of requirements that must also be taken into account.

One of the key challenges within the biocontainment industry is the understanding and application of directional airflow and pressure gradients at the containment boundary. *"The laboratory shall be designed such that under failure conditions the airflow will not be reversed."* BMBL 5th Edition, pg43, BSL-3 D9 [4]. This concept, which has been a moving target in the past, represents one of the most critical criteria that needs' to be planned for in the design phase, proven during the commissioning process and maintained during the operational phase. The CxA can play an important role in negotiating this minefield and implementing a *sustainable* long term operational solution.

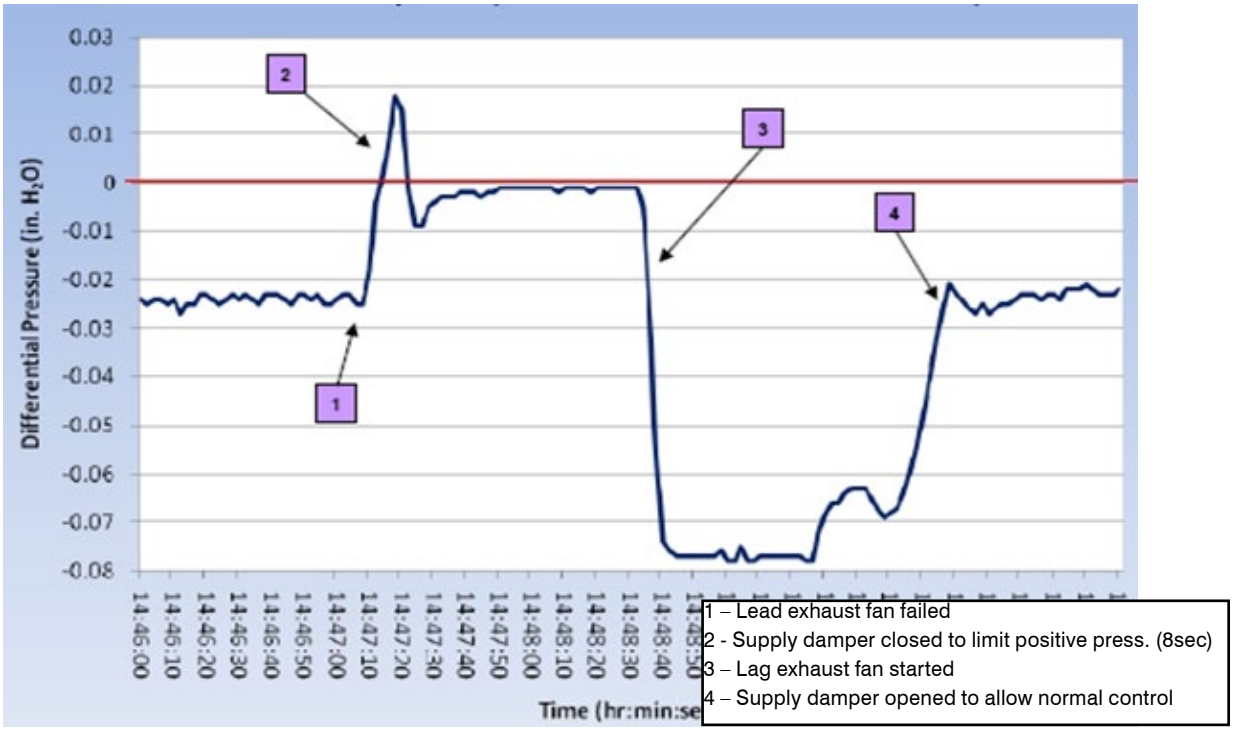

Fig 4 – (Pressure trending of laboratory space during fan failure testing to optimize system performance and alleviate airflow reversals)

With these vast differences between conventional and biocontainment facilities, it is important to remember that, again, in the current environment, most of the procedural details and information currently available on commissioning from the commissioning industry refers to a wide array of conventional buildings and would not in great measure apply to biocontainment lab commissioning. Those planning to be involved with the building and operating of new biocontainment facilities need to be aware of this fact in order to avoid accepting inaccurate information and advice and making inaccurate assumptions.

Biocontainment commissioning starts in the design phase

Historically, commissioning of conventional buildings has been considered primarily a "back end" service, with CxAs called in cold toward the end of the construction process, the building previously sight unseen. This usually worked out satisfactorily, since the focus was primarily on energy efficiency and air quality, concerns universal in scope utilizing a finite range of familiar equipment. In containment labs, where the performance of the building itself is mission critical, specialized equipment is the norm, complexity is high and safety is a grave concern, the issues, challenges and procedures are different, and the paradigm must be as well.

In fact, in biocontainment applications, it is potentially most advantageous in terms of both schedule and cost for CxAs to be involved early, in the pre-design phase. This is especially true if the CxAs involved bring *personal* real world biocontainment commissioning experience to the project. In this transitional phase, as the commissioning industry gets up to speed on biocontainment, there are many instances where specific individuals at a commissioning company might have experience with biocontainment, leading the company to claim biocontainment experience. In reality, the actual CxAs assigned to the job, may be, more generalist in experience like the vast majority of CxAs currently, and personally unfamiliar with the intricacies and complexities of the biocontainment lab, suggesting, at best, a steep learning curve.

In addition, many commissioning companies, while admitting a lack of experience in commissioning biocontainment facilities, will tout their experience with commissioning clean rooms, which are a far more common type of facility, as a "similar" type of challenge. Not that someone with clean room experience could not potentially also do a fine job in commissioning a biocontainment facility, but it is important to note (and presumably they will realize this, and quickly) that a clean room in many ways is the *exact opposite* of a biocontainment facility. In a clean room, the effort is placed on blowing everything *out* of the room, with constant *positive* air pressure applied, a very different kind of technical challenge. Some of the need for redundancies and fail safes may be similar, but, as with any other kind of facility that one could possibly imagine, the specialized equipment will be wholly unfamiliar.

While the need for containment commissioning experts currently outstrips the supply, it is assumed here that most future owners of biocontainment labs will seek out CxAs with personal biocontainment experience, or at least engage those with *active* and *continuous* conduits to such expertise in their own organizations. Thus they can avoid commissioning generalists with no biocontainment experience, lest they find themselves in the costly and time-consuming (and perhaps *ironic*) situation of being guinea pigs.

Getting these professionals involved in the pre-design stage and encompassing their feedback helps ensure that the optimal lab design and proper equipment for biocontainment purposes is spec'd in all cases to best meet the owners' research and budgetary requirements, as well as true performance and regulatory demands and the need for accessibility, repairability and testability. This is no small matter. General commissioning industry statistics suggest that nearly 60% of control system failures can be traced back to the design and specification phase, a statistic that would likely be even higher if only the more complex biocontainment facility were considered. Furthermore, appropriate involvement of experiences biocontainment commissioning professionals allows any inevitable errors (including less than optimal design points) to be mitigated on paper, when they are still fast and inexpensive to fix thus flagging of potential issues requiring real world lab operating experience.

It is important to realize that the later, construction-side commissioning process generally ensures that everything planned in the design phase is installed properly. However, it does *not* necessarily formally ensure that what was planned in the design phase achieves the optimum specification, much less the correct specification, for the biocontainment facility.

As part of design-side commissioning, the CxA also creates the commissioning plan for the construction phase of the project, as well as all related training plans and documentation. The agent will provide feedback into life cycle cost modeling, and help the owners make decisions accordingly. The agent will help procure equipment that might have long lead times. This agent will provide guidance in scheduling outside certifications for systems

such as biosafety cabinets and HEPA filters, which also need to be proactively scheduled upfront to avoid future bottlenecks.

This phase also begins the commissioning team's relationship with the owner. As the common link through the pre-design, design, construction and post-construction phase, the CxA becomes the owner's defacto eyes and ears. Asas independent experts, CxA is best able to safeguard the owners interests. The agent also becomes the point of continuity and "historical knowledge" and is an integrating force during the entire process, especially in the hand-offs between the design and construction phase, and the construction and occupancy phase, when the design and construction teams have long since "left the building." Add in the fact that commissioning in the design phase as well as the construction phase ultimately costs no more than the design team doing it themselves, these benefits, as we shall see later, are essentially "free."

The construction phase: commissioning's "heavy lifting"

The field phase of commissioning usually begins towards the end of the last year of construction, while construction is still going on, allowing for parallel work plans that optimize schedules, as well as allowing for faster mitigation of issues as they arise, since construction personnel are still onsite. It continues until after construction is complete and all contractors have physically left the building.

Construction phase commissioning entails roughly four escalating elements, focusing in order on the component, the system, the systems in tandem, and whole building operations. Efforts are conducted with the philosophy that the earlier in the process an issue is discovered, the faster and easier it can be fixed, and the less impact there will be to scheduling and cost. Everything is fully documented, and it is primarily this documentation that is scrutinized by the CDC and most other authorities in their review processes.

Component Verification—ensures that equipment coming in is as spec'd, is installed properly and has appropriate tags, valves and lockouts in place. This can start as early in the construction process as practical.

System Tests—ensure that each system functions optimally under all operational parameters. If a system passes, it is documented and then prepared to be part of integrated system test. If it doesn't pass, it needs to be remediated and then retested.

Integrated System Tests—test how systems operate in tandem. One of the most vital parts of these efforts is failure testing, considering the potential dynamics and pitfalls on an integrated level; if power is stopped, do the air handling, controls and all other interrelated systems react as they should? Do they respond automatically or do they get locked out and require manual intervention? How long does it take? If a device fails or acts in abnormal fashion, how do other interrelated components react? It is inevitable that systems will occasionally fail, but great pains need to be taken to ensure that they fail correctly. Ensuring this is the case for every system is complex, and is an iterative, trial and error process.

Another major aspect of this period is the fine tuning of the sensors and control loops that run the building environment, including temperature, pressure and air flow. Before commissioning, these almost always display sporadic, and often dramatic fluctuations. This is likewise a trial and error process to optimize these vital systems in tandem with all building operations.

It is important to note that integrated system tests cannot begin until all contractor activities are complete; they must however be available to mitigate issues as they come up.

Facility Operation System Test (FOST)—All aspects of the building must operate without a hiccup for a continuous two-four week period; as errors are found, they are mitigated, and the clock starts again.

Systems undergoing commissioning in the biocontainment lab often include, but are not limited to:

- Room Integrity
- Communication Devices
- Door Interlocks/Access Control/Security
- Directional Airflow/Pressure Gradients
- Autoclave & Barrier Devices
- Backflow Prevention Devices
- Emergency Generator and UPS backup
- Effluent Decontamination System

- Tissue Digesters
- Biological Safety Cabinets
- HEPA Filters/Housings
- Supply & Exhaust Ductwork
- Building Automation System Controls (Normal & Emergency Modes)

It is hoped that the owners, or, more specifically, the onsite Operations & Maintenance (O&M) people who will ultimately be responsible for the day to day operations of this facility, will become active participants throughout the process, and a good biocontainment CxA will encourage and enable this. The more the actual operators understand about the operations of the building, under normal conditions certainly, but also under emergency conditions, the more effective they will be going forward. Having the O&M personnel involved during the commissioning process is an invaluable training tool for the facility staff to understand how a facility of this type is meant to function. This is perhaps most true during the testing of failure modes. Understanding how systems and equipment will be operated and maintained in a biocontainment facility, with the supporting protocols and procedures, is a critical aspect that needs to be defined earlier rather than later. An experienced CxA can help with this during the design phase and ensure its carried into the operational phase which becomes even more important if the O&M group has not been engage early enough in the process to fully understand some of the operational parameters which can include: redundant operation, isolation, decontamination and testing requirements of the specialized systems and equipment.

System Operational Characteristics (Y)es (N)o (T)BD	AHU	Exhaust Fans	Room/Labs	HEPA Filtration	Plumbing	Electrical	Special Systems
Scheduled Maintenance	Y	Y	T	T	T	Y	T
Redundant/By Pass Capabilities	Y	Y	N	Y	T	Y	T
Safeties/Interlock	Y	Y	N	N	N	Y	T
Able to be Isolated/Shutdown	Y	Y	T	Y	T	Y	Y
Decontamination Requirements	N	T	Y	Y	T	N	T
Testing and Calibration	Y	Y	Y	Y	N	T	Y
Information Management Requirement	Y	Y	Y	T	N	T	Y
SOP Dependant	Y	Y	Y	Y	T	T	Y
Biological Verification	N	T	Y	Y	T	N	Y
Annual Re-verification	T	Y	Y	Y	N	T	Y

Fig 5 – (Determining operational characteristics early on)

It should be noted that Federal agencies might have a “life sciences building expert,” but in most university and corporate environments, this function may be separated. Non federal sites may have life science experts familiar with the imminent research to be performed, and building managers, facilities managers, engineering managers and other professionals familiar with conventional building operations. However, fewer, if any professionals personally familiar with the specific operations and maintenance of BSL-3 and higher biocontainment labs are found in these environments. A situation where the CxAs have left and the assigned O&M people brought in later, with none of them ever having even seen much less been involved with the operations of a high level biocontainment facility is unfortunately not an uncommon one. Owners and CxAs should work together to avoid it.

During the entire process, a collaborative relationship among the owners, the commissioning team and the construction team is vital. Many construction companies welcome the efforts of the CxAs, seeing them as a way to reduce liability; avoid future warranty callbacks; remove some of the time and expense of the quality control responsibility from their shoulders; help them catch errors in their earlier, less costly incarnations; and provide

expert insights into a lucrative construction specialty they might not yet be expert in. Other construction teams are not as welcoming, and frankly, the relationship between the CxAs and the construction agents is fraught with potential pitfalls, as their goals can, unfortunately, sometimes be seen to be at odds. The contractors often perceive that their primary responsibility is to finish on time and on budget, and they are often under tremendous pressure to do so; the commissioning team, as owner advocates, has the responsibility to make sure that the job is done right, which is not always the same goal.

To help alleviate issues, upfront scheduling and planning for commissioning activities in detail is vital—i.e. not just having a single line that says "commissioning" somewhere on the schedule. (This is another way that incorporating commissioning early into the design process can help ensure a more efficient experience going forward.) In addition, owners need to impress upon the construction team that the CxAs should receive their full cooperation at all times.

As the commissioning activities commence, contractors need to be available to attend to any issues in conjunction with the commissioning personnel. Their work should not end when they leave the facility; their work should end at the same time commissioning is finished: when all systems are fully tested and confirmed functional and the commissioning report validates that the building is ready for operations. Sign-offs and payments should be scheduled accordingly, if possible.

Sometimes, construction companies will have their own commissioning divisions and offer to add commissioning to their service to the facility or they may offer to hire a third party who would then, of course, be beholden to the contractor. For perhaps obvious reasons, this has not proven to be the most effective means of establishing a seamless reporting structure to the client. Frankly, many consider it a conflict of interest akin to having a fox guard the henhouse. Most will agree that, in order to be most effective and transparent, the CxA should be independent reporting only to the owners; in particular when managing the issues that will arise and assigning them to the appropriate party for resolution whether it is the designer, constructer or even the owner/user.

After the FOST test is completed successfully, the CxA can turn over the keys and allow beneficial occupancy to the new owner; however, in most climates the CxA must return in the opposite season to test the heating or cooling systems, as the case may be, under natural conditions. In addition, many of the systems in the list above require ongoing certification or compliance testing by the appropriate regulatory agencies, often on an annual basis. Many owners usually call in the CxA to help prepare for successful outcomes of these tests through a *re-commissioning or verification* program, although it is hoped that, at least after the first several years, local O&M personnel are sufficiently up to speed on the workings of the facilities to prepare without outside assistance. As the 50+ year useful life of the facility draws to a close, the owners will also likely require the special expertise of a *de-commissioning agent* to help decontaminate and prepare the facility for closing.

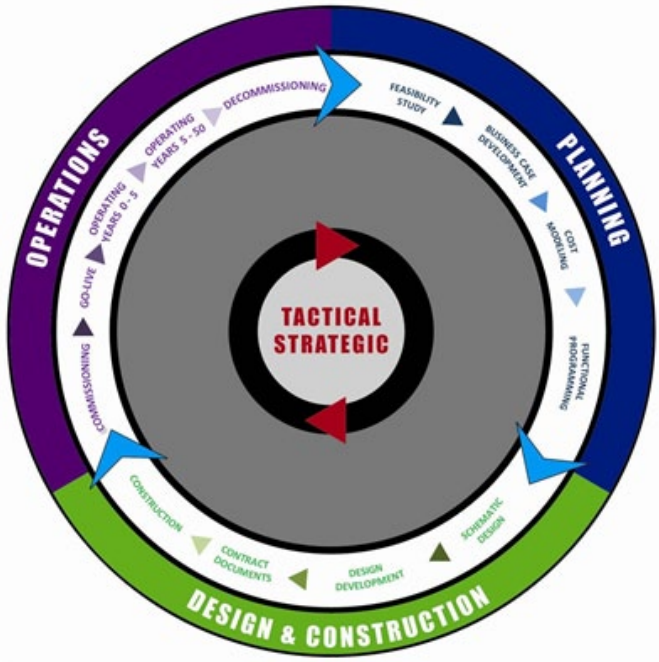

Fig 6. (Commissioning through the life-cycle of a facility)

Containment lab commissioning cost considerations

The short answer to the question "how much does commissioning cost?" is "commissioning doesn't cost, it pays." Industry statistics suggest that, in conventional facilities, optimizing systems can lower annual operating costs by up to 20%. And, considering the significantly higher complexity and operating costs—not to mention risks—associated with biocontainment facilities, full commissioning is not only a virtual necessity in today's environment, it is a smart investment as well; one that should appropriately be thought of with payback in mind.

In working toward a more specific answer, it is noted that, as is the case with much else currently written about commissioning, the commonly seen cost "rules of thumb" fall unfortunately flat when one considers commissioning of a biocontainment facility as opposed to the commissioning of a conventional building. Ballpark commissioning estimates geared toward offices and commercial buildings are often based on "square footage," since it assumed that most of these spaces have the "same" equipment and infrastructure, with larger facilities simply having proportionally more of it. This logic doesn't follow in containment facilities, since every lab space is so different and a scenario where a smaller, fully optimized lab with maximum specialized equipment that costs significantly more to both build and commission than a larger lab with less stringent requirements can be readily imagined. In addition the HVAC, plumbing and electrical systems for a biocontainment facility can represent over 50% of the project cost in relation to the architecture which is outside the norm of typical commercial buildings. For these reasons, the best rules of thumb for costs associated with commissioning biocontainment facilities are based not on square footage but as a percentage of total building costs.

Construction Phase Commissioning Costs	
Commissioned Systems	**Commissioning Costs**
HVAC and controls	2.0% to 3.0% of total mechanical costs
Electrical Systems	1.0% to 2.0% of total electrical costs
HVAC, controls and electrical	0.5% to 1.5% of total construction cost
Source for the first two line items: Ron Wilkinson, ASHRAE Journal, Feb. 2000. Third line: PECI	

Fig 7 (Typical construction phase commissioning costs for non-biocontainment project)

Full commissioning services are inclusive of, the agents involved in the pre-design stage of the new biocontainment facility continuously through design, and construction, handling facility operations system testing, working with contractors to mitigate issues and handing the keys over to the new occupants. The best estimates currently place commissioning costs fees at 1.5%-2.0% or higher of total ground-up building costs.

It is interesting to note that a small percentage, perhaps only 10%-20% of the overall Cx cost, represents the difference between getting biocontainment expert CxAs involved early in the design phase, as opposed to bringing them on only later, in the late construction phase, when it would be too late to mitigate changes on paper and changes must be made in the field, to the detriment of cost plans and time schedules. Further, this small percentage is not really an added out-of-pocket cost, since the design firm would be charging this amount or more if they were assigned, by default, to perform design phase commissioning tasks such as creating the commissioning plan and test protocol documents. They would likely be doing so, however, without the benefit of having biocontainment commissioning expertise.

To further put the figure of 1.5%-2% of total building costs in perspective, it is again misleading to look at it with a conventional building mindset. In conventional buildings, construction costs loom large as a high percentage of total life cycle costs. In a biocontainment lab scenario, where a) facilities are built with longer operating life cycles in mind, presumably half a century or more and b) annual operating and maintenance costs are significantly higher—perhaps 300% or more—than those of conventional buildings, ongoing operating costs tend to *dwarf* construction costs, perhaps by a factor of 10 to 1 over the facility life time. This points not only to the modest cost of full commissioning in relation to the overall investment, but the fact that, with commissioning's proven ability to mitigate hidden errors and efficiency robbers and optimize systems so that owners benefit from lower operating costs every year going forward, that such benefits will likely be even stronger in a biocontainment facility than in a conventional building in terms of the operating dollars to be saved.

Summary

It is understood that biocontainment facilities are costly to construct and operate; and are constantly subjected to regulatory demands and public scrutiny. The commissioning process can be leveraged to implement and support a sustainable operational program that meets all the demands of a biocontainment facility. Some of the key aspects to take from this discussion are:

- Commissioning saves costs over time both in operational costs and up-time in program research.
- Commissioning biocontainment lab requires different expertise than general buildings; and these experts should be involved early – ideally during the pre-design phase.
- Commissioning includes independent systems and systems working together with varying operational characteristics.
- Early involvement of the O&M group during design, construction and commissioning program.

These are the keys to optimizing the opportunities that commissioning can bring to containment lab operations, paving the way to substantial savings in operating costs, protecting research interests and avoiding operating issues every year for decades into the future

# # #

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