Poster #

Virtual CL3 Licensing with the Public Health Agency of Canada During the Pandemic

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INTRODUCTION

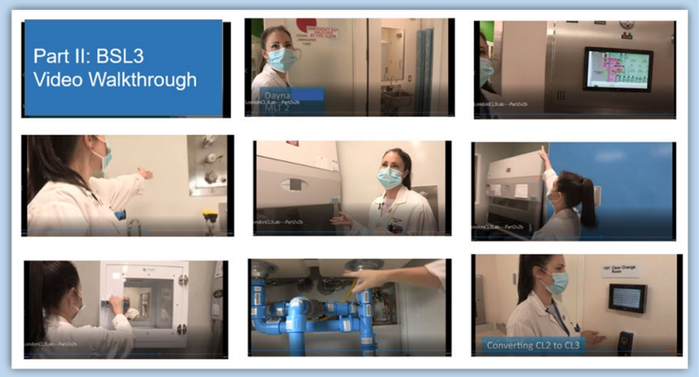
During the COVID-19 pandemic the need for virtual site visits and inspections of laboratory facilities has surged, while the conduct of executing these have become far more difficult. There has been a number of key drivers pushing the need for the virtual environment; risk of downtime and missed targets, reassignment of key individuals to support pandemic response efforts, labor, manufacturing and supply chain impacts, governmental shift in priorities, travel restrictions and other public health measures and government orders. Critically in some jurisdictions, including Canada, new biosafety level three laboratories must be inspected prior to becoming operational in response to the pandemic. To keep up with current project momentum and timelines, virtual site visits can be an effective way to fulfill what was normally achieved through in-person site visits. With that, an open mind and willingness to think outside the box is paramount to success. This paper provides the foundation and best practices of conducting a virtual site visit and inspection (BSL2/ BSL3 public health infectious disease laboratory, approximately 20,000 sq.ft.).

INFORMATION TO BE INCLUDED WITH THE FAILURE TESTING RECORDINGS

In order to be licensed to operate as a Containment Level 3 (CL3 or BSL3) laboratory, a facility must demonstrate compliance with the Canadian Biosafety Standard. While many of the requirements are static and can be demonstrated via the use of photos or are simple dynamic tests that can be adequately demonstrated by video only, confirmation of directional airflow at critical doors and ducted biosafety cabinets during building system failures is a challenging series of tests where both dynamic and steady state results must be confirmed. While all testing for the facility was conducted virtually, this paper focuses on the demonstration and documentation of the failure mode testing. Key information shown in both pre recorded and live streamed failure mode testing included:

- Date failure testing was conducted
- Door or BSC location clearly identified in recording
- Failure test to be conducted
- Baseline visual indication at each door/BSC (e.g. quick demonstration of inward directional airflow or neutral at a critical door or IIB2 BSC in advance of each failure test using a visual aid such as a smoke pencil that does not influence the direction of airflow)
- Start time of test
- Failure testing visual indication at each door/BSC (e.g., using a visual aid such as a smoke pencil that does not influence the direction of airflow)
- End time of test (e.g. typically determined once the HVAC/controls have stabilized)
- Capture visual and/or audible alarms activated during each failure test
- Correlation of results of visual indication, differential pressure loggers, and building automation system records differential pressure trends

BSL3 VIDEO WALKTHROUGH



Also required for licensing and typically demonstrated as part of an in person inspection, are key SOPs as described in the facility's biosafety manual. The following demonstrations were among those presented to the regulator via video:

- Donning of all required PPE as outlined in the Routine Entry into the CL3 Laboratory SOP.
- Doffing of PPE following work with infectious materials as outlined in the Routine Exit from the CL3 Laboratory SOP, including all steps before entering the clean change room.
- Loading the autoclave with representative mixed solid and liquid waste, including placement of biological indicators or sensors.
- Demonstration of general work setup and procedures conducted in the BSC, including steps for removal of materials from the BSC upon completion of work.
- Demonstration of the CL2-CL3 switch over sequence for room 1224, including visuals on the door locking mechanisms and signage to Indicate CL3 mode.

METHODOLOGY

1. Meet with Key Team Members and Discuss Expectations

A series of meetings were held to discuss the required expectations and outcomes of the virtual site visit and follow up inspection. Consider documents, floorplans, and timelines.

2. Consider which Option is the Best Approach for the Site Visit

Virtual site visits can be quite flexible, they can be accomplished through live streaming or a narrated pre-recorded tour of the laboratory facility (scripted narration can be done live or after video completion). An important aspect with live stream video is that it provides details in real time and allows for questions and greater time spent on areas of interest right away. However, with construction methods of containment laboratories the possibility of a poor wi-fi connection resulting in degraded video quality can impact the live stream video tour. A planned and pre-recorded tour can provide an effective review of the entire facility.

3. Consider what Type of Camera or Device to Use

For pre-recorded tours, choose a camera that will capture all parts of the building. For the most part, a consumer grade video camera with memory card is suitable. To minimize vibration, it is preferred that the camera or device be placed on a wheeled cart (or tripod) and rolled in and out of laboratory areas. Alert others that videography is taking place.

4. Planning the Virtual Site Visit

For both types of tours, consider accessibility of laboratory areas and support spaces (e.g., mechanical spaces) and have adequate number of people: minimum one to manage the camera/device, one to go through the story board, a narrator and one to act as the video director.

One of the first aspects for a virtual site visit is to create a story board that would capture and simulate the intent and essential requirements of the physical walkthrough.

4.1 Story Board Planning

- Meet with key team members and the inspector on expectations
- Define the goals and objectives
- Brainstorm ideas
- Create a timeline for the story
- Use photos
- Include notes
- Simulate a dry run

5. Additional Considerations for Failure Mode Testing

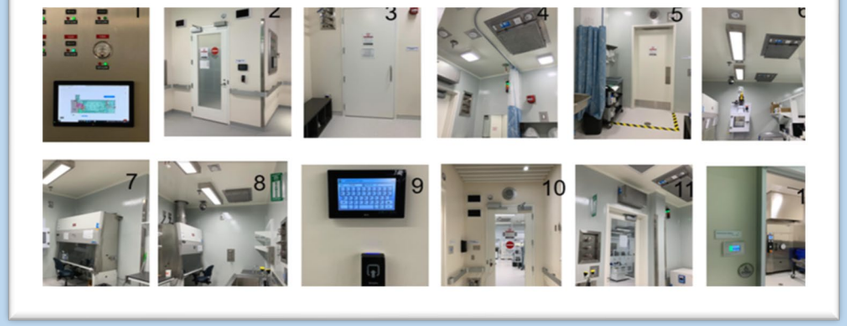
Failure mode testing will require additional participants. Each ducted BSC and critical door is required to be recorded with visual indicator and in this case calibrated differential pressure monitors. For this testing laptop computers with webcams were utilized, negating the need for additional equipment. Also required was a job captain coordinating and live narrating the testing stationed at the Building Automations System workstation, plus a person to simulate each failure scenario. (e.g., to manually "fail" an exhaust fan). The setup was the same for both the pre-recorded and live streamed failure mode testing.

6. Final Recap

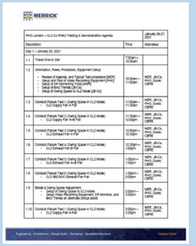
Capturing the facility through video is a considerable undertaking and as noted in the key findings. Each laboratory facility is unique and is presented with different challenges. Despite this, virtual site visits are becoming another way to keep projects moving forward during the pandemic.

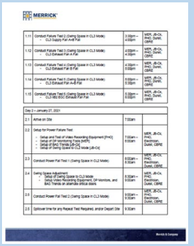
- Meet with key team members and the inspector on expectations
- Consider which option is the best approach for the inspection
- Consider what type of camera or device to use
- Consider pre-recorded walk-throughs and live stream demonstration
- Use a computer, cellphone, tablet, or camera
- For live streaming, consider which platform to use for video sharing (e.g., Zoom, MS Teams, Skype etc.)
- Develop the story board and narration
- Plan details the facility walk through
- Final recap and develop a prototype for each
- Get buy-in from all parties
- Having a skilled editor/videographer is key to ensure the testing is captured and presented effectively
- When live streaming, ensure both the testers and the remotely located observers have adequate bandwidth to ensure nothing is missed

CREATING THE STORYBOARD

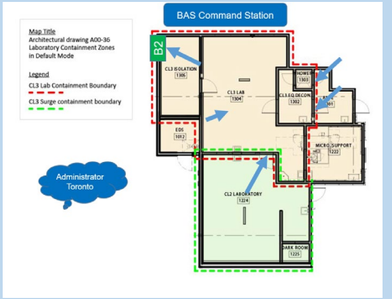


CL3 Failure Mode Testing – The MAIN Event

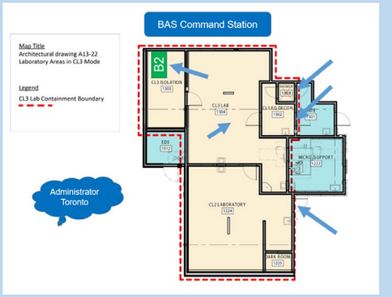




Location of Computers & Command Station CL3 + CL2 Mode



Location of Computers & Command Station CL3 + CL3 Mode



SETTING UP FOR TESTING

- Identify each of the critical doors for IDA smoke demonstration
- Label door with room number, lab layout and test sequence
- Conduct sound checks and visual placement of computer/camera
- Check smoke visualization with meeting administrator
- Use Differential Pressure (DP) monitor at each of the critical doors
- Correlate smoke, DP monitor, BAS DP measurement

KEY TAKE AWAYS

Since virtual site visits are flexible, they can be done through a combination of live streaming and/or a pre-recorded tour of the facility.

1. A combination of pre-recorded (consumer grade digital camera) and live streaming (laptop computer) was used effectively, while live streaming was more efficient in terms of real-time discussion, it was also more challenging due to bandwidth issues.
2. The possibility of a poor wi-fi connection and degraded video quality can impact the inspection during the live stream and video sharing platform. Hard wire connection was preferred over wireless
3. A pre-recorded walk-through can provide an effective review of the facility that was planned out in advance using a story board as the guide. Pre-recording was preferred over live streaming for preparation and archive
4. Video files (e.g., MP4) can be quite large- Cloud based file sharing platform a must.
5. Video – editing is key to make navigating through the video as simple as possible.

CONCLUSION

Virtual site visits and inspections are likely here to stay due to the convenience and time/cost efficiency, however this was the first time and there is some additional refinement to do. It is important to remember that innovation requires collaboration, flexibility within industry to be successful, an owner who has the vision and understands the process and the consultant that understands the importance of success and is willing to do the extra lift. Critically, success also requires a regulator that is will to collaborate and accept new methodologies, and the authors wish to thank the Public Health Agency of Canada for their willingness to engage on this project. The laboratory highlighted in this paper was completed on budget and on time and received government regulatory approval and licensing.