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A Review of Testing and Performance Certification of Modular and Mobile BSL 3 Laboratories

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Introduction and hypothesis/objectives:

Several BSL 3 laboratory configurations have been placed and tested in various locations around the world including Africa, Asia, and America. Laboratory layouts, systems integration, performance characteristics, and risk based assessment as applied to the BSL 3 laboratories "failure mode testing" is provided and discussed.

These BSL 3 laboratories are very unique due to the varying locations and stresses under which each of the BSL 3 laboratories continuity of performance must be assured.

Several different BSL3 laboratories, some with performance histories and some new to the field, will be reviewed lending to the discussion of what the test data suggests, and ponders the question of is there more testing and how much might be needed for a higher level of assessment and level of confidence.

Materials and methods:

Standard technique and equipment was used with additional supportive techniques using equipment commonly available. Current guidelines and recommendations are used including the BMBL (5th edition), Canadian Laboratory Biosafety guidelines (3rd edition), WHO Laboratory Biosafety manual (3rd edition), with additional information from the Australian Guidelines for Certification of Facilities/Physical Containment Requirements.

Each location and user/country has specific compliance regulations, rules and references. In additional to this inherent baseline, additional testing and data provides more assessment guidance lending more tools for the certification process and the goal of substantiating a safe working environment for the corresponding biological agent risk groupings as well as unknowns.

Results:

Results obtained from the certification testing, e.g. operational differential pressure relations and ventilation flow characteristics under various environmental conditions will be provided with consideration of both primary and secondary engineering controls.

As an will be explored due to the high variability of environmental dynamics, will be characterized, equipment placement due to the physical requirements and constraints

Discussion/conclusions:

Data resulting from environmental and operational conditions, static and non-static, with the associated HVAC systems dynamics and technologies, provide good insights for the safety level of confidence sought.

However, considerations to these very same conditions, weather, HVAC technologies and interface, could reasonably provide an enhanced level of operational safety. Flow rates as well as differential pressures can be adjusted in many circumstances to optimize on some of the variability of the environmental conditions.

More simple physical and HVAC designs with more defined and simplified technologies would achieve a higher level of operational considerations as well as ease of field and services support.

Testing for Laboratory Performance

...based upon **"risks" and ability to apply appropriate methods for the "determination of performance."**

The discussion below is a ***partial list*** of questions in answer the questions such as; ***Does it work & are we safe?***

Developmental criteria is developed from guidelines, standards, user needs, and regulations.

How can they be optimized, within each user setting?

*Engineering risks, systems controls, HVAC BMS, normal and failure mode analysis..These are essential to understand and quantify, but, D***o they tell us enough?***

*Risk based analysis uses the assessment of the perception of risks. These risks assumptions are dependant upon laboratory operations, primary and secondary barriers, personnel, training, emergency preparedness, etc., and experience(s). Algorithms and modeling are very important, in addition to the determination criteria used.

Relating this subjective information to the "provable" data is a continual challenge for those in the position of providing a tested and safe laboratory environment based upon the compiled risk assessments, and available laboratory based information.

In the end, it is about trying to do better, ***what can we do better?***

Considerations...

- What are "normal laboratory risks, how are they determined?"
- What about dropping cultures, exit through the lab door –
- question - What is the effect of the aerosol, assuming the aerosol is released,
- What is the effect of the door? An aerosol with the motion of the door, personnel?"
- Can you verify this by "smoke tests?"
- Can it be done better?
- Can you quantify a door test" - air reversal ???

Is the laboratory tightness or how leaky? Engineered leakage Vs unintended leaks?

Leaks due to external influences [overdriven seals]? Wind, barometric shifts…

Location and validation of sensors?

More, more, more.

Engineering controls verification….(considerations)

HVAC – BMS "How smart is smart?"

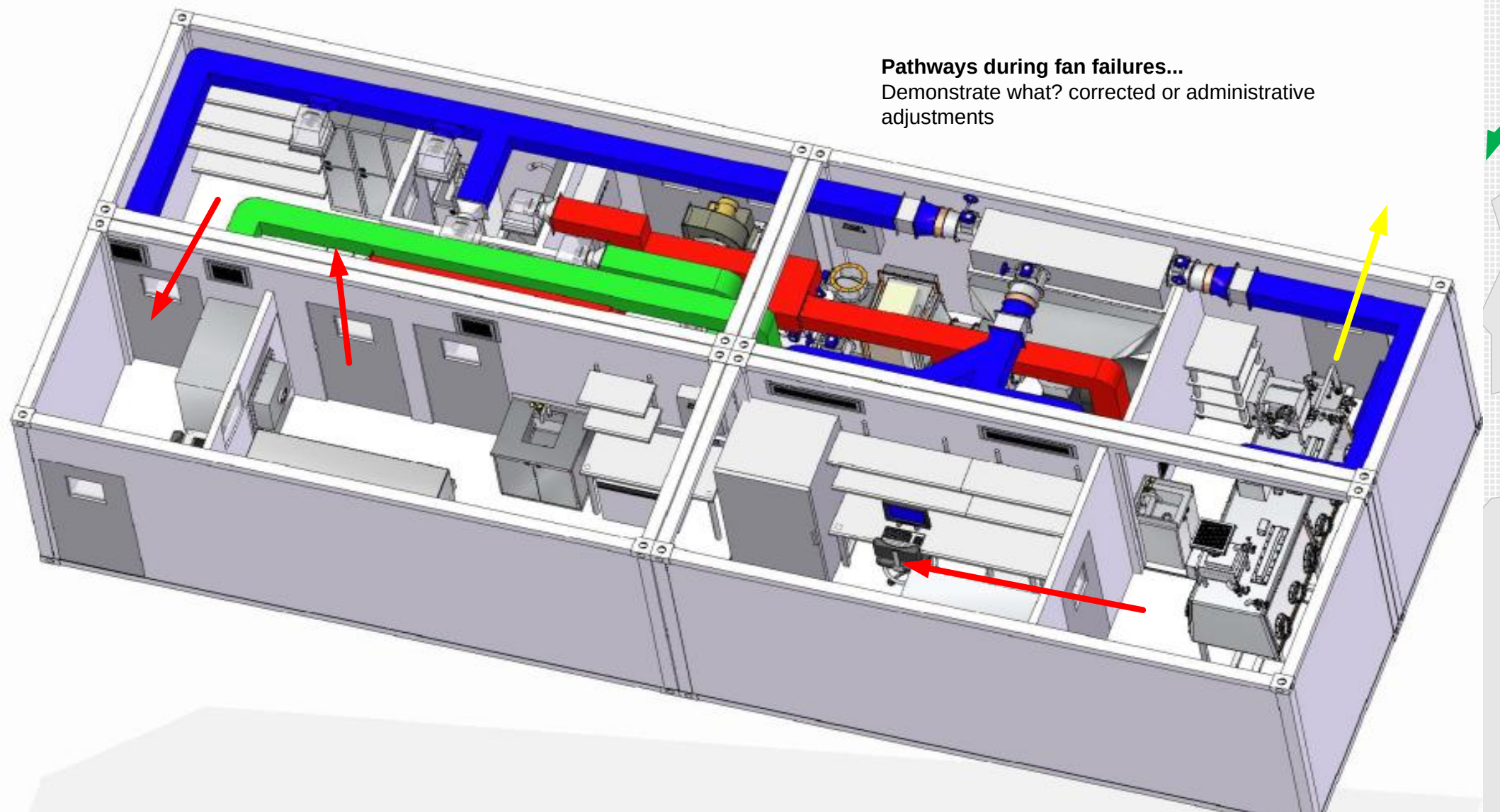
- Supply
- Exhaust
- Ducts
- Diffusers
- Valves
- Doors

Testing of the Containment Barrier/Envelope Integrity (considerations)

Airflow Volumes: Rates for mathematically derived air changes (cleandown) rates
How accurate of a representation are these?

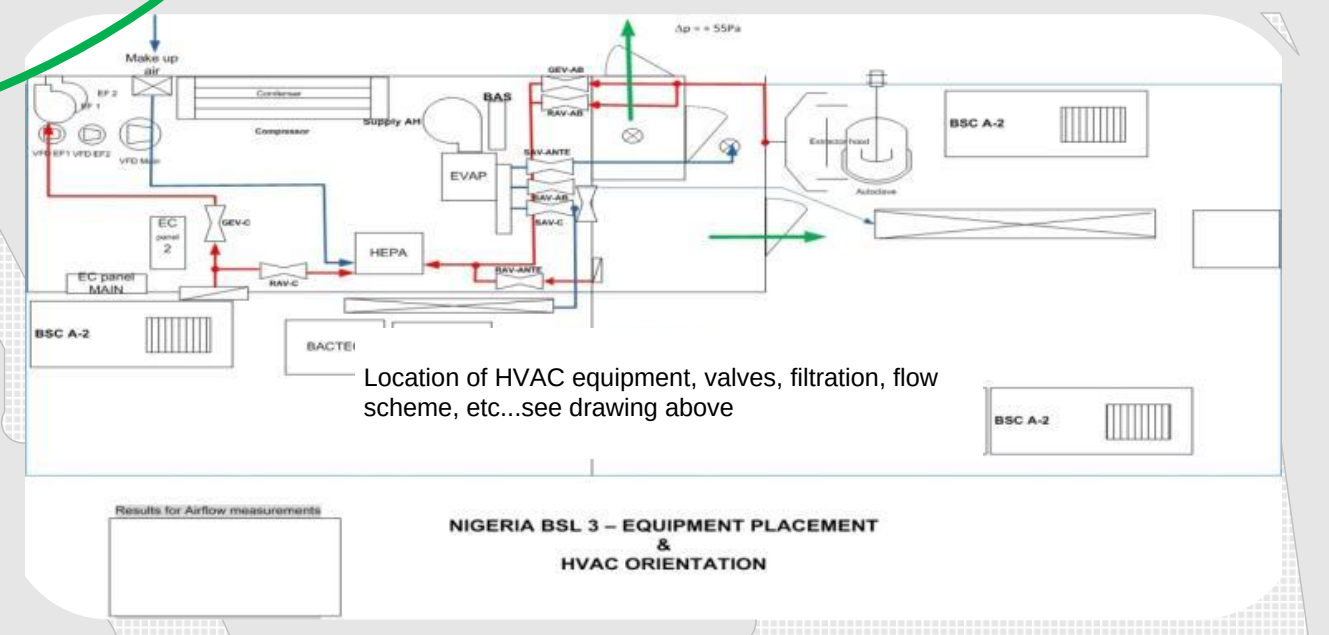
- Additional Testing…
-
- Electrical Testing
-
- Temperature control and validation
-
- Plumbing
-
- Biosecurity
-
- Life Safety Code
-
- Others

Biosafety Level 3 Mobile Laboratory


Pathways during fan failures...
Demonstrate what? corrected or administrative adjustments

Biosafety Level 3 Modular Lab

So, is it safe?

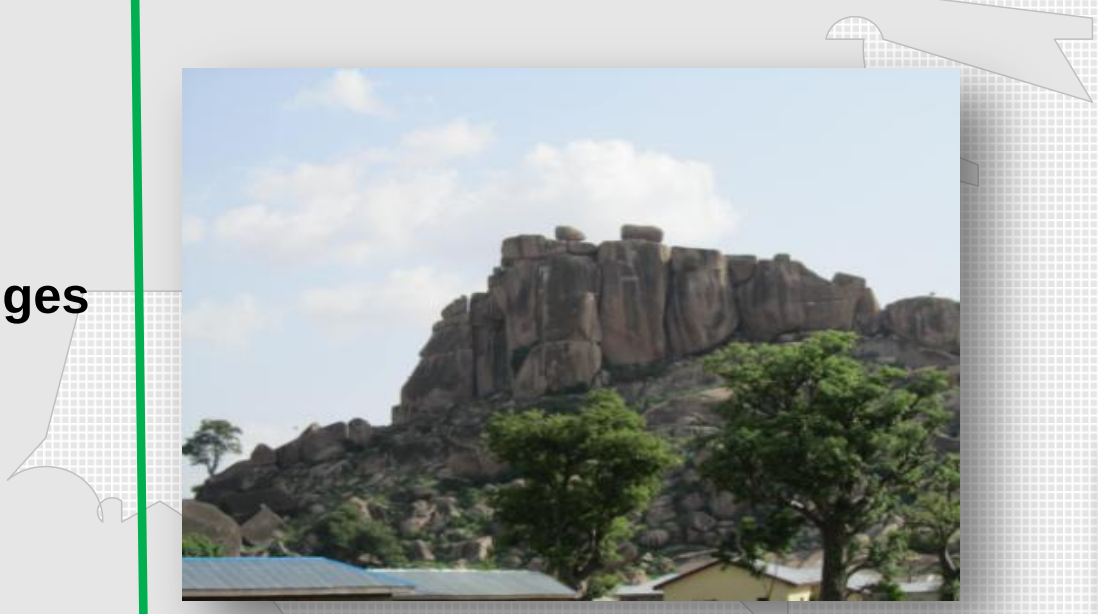


Location of HVAC equipment, valves, filtration, flow scheme, etc...see drawing above

NIGERIA BSL 3 – EQUIPMENT PLACEMENT
&
HVAC ORIENTATION

?

Location and Climate challenges



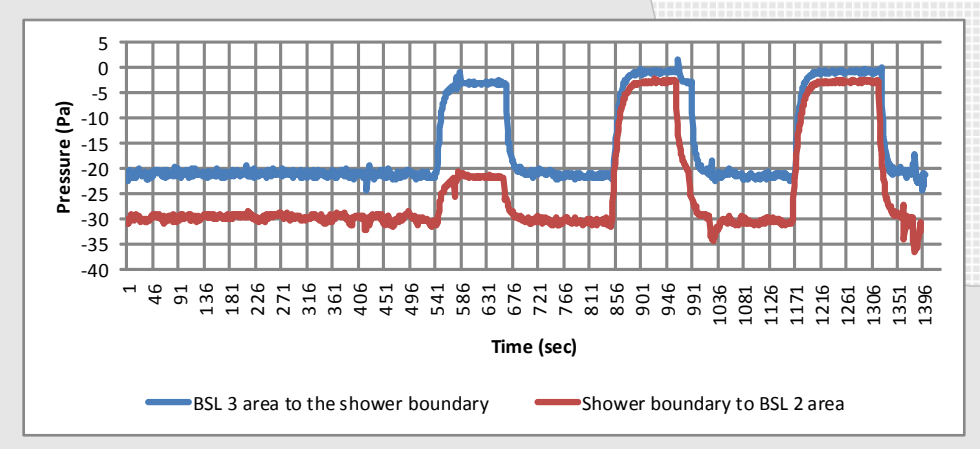
Where the lab lives... has much to do with how it operates;
How does it operate at different times of the year?,

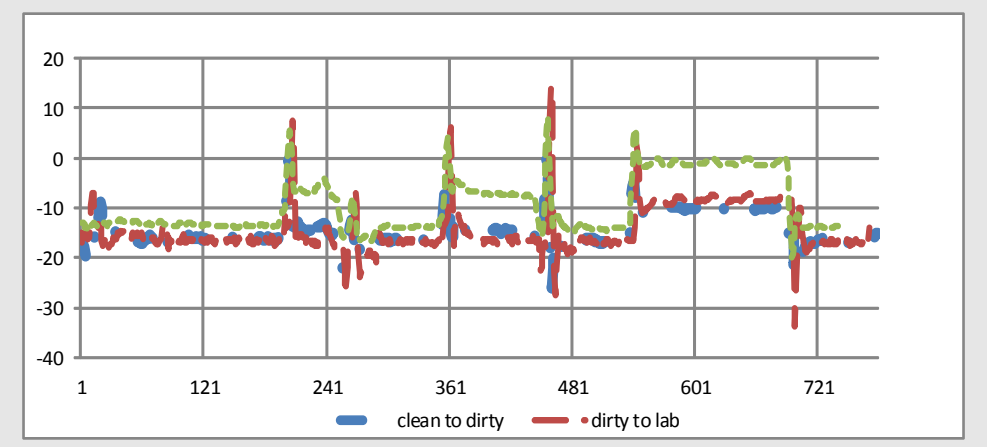
There are, often, a wide range of environmental challenges - **Above**, a laboratory being set-up in sub-Saharan Africa, the "Hamataan" sub-Sarahan dust storm – which lasts weeks and weeks and presents wind and dust challenges.

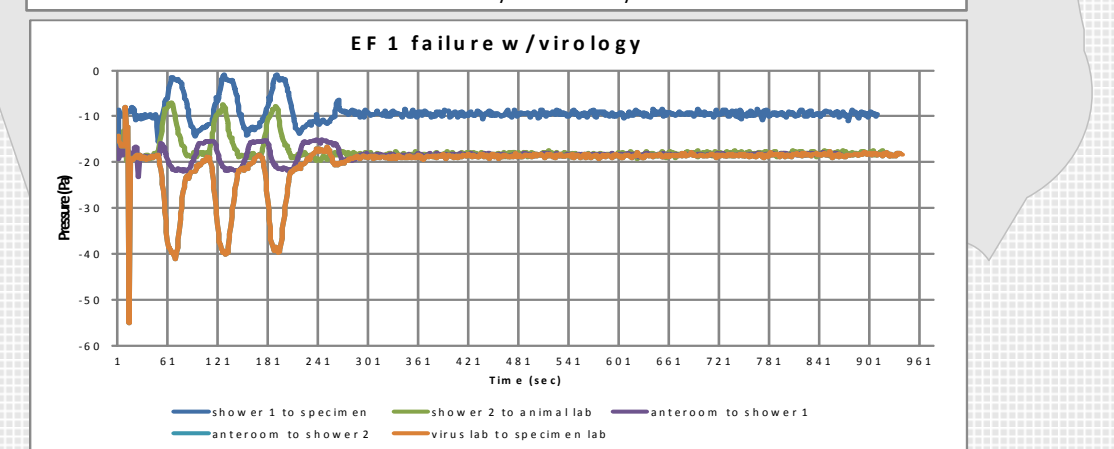
Facilities – HVAC systems w/control(S) (BMS)

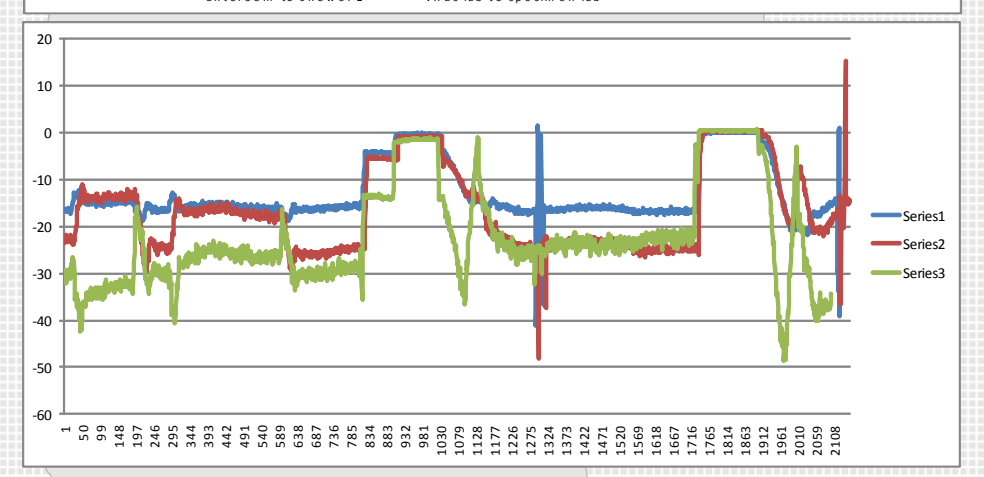
Partial Listing of Tests as Shown Below:

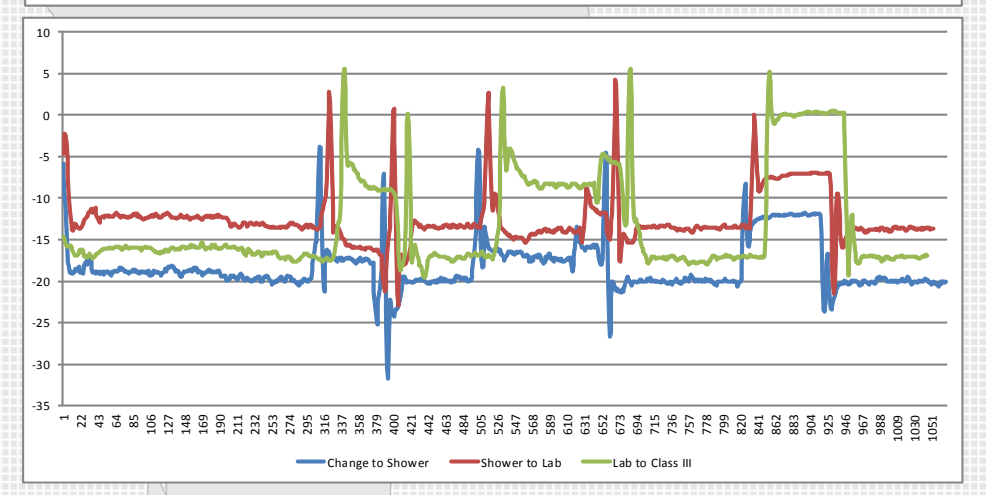
- Start -up
- Shut Down
- Exhaust Fan Failure
- Supply Fan Failure
- Chiller Failure….others











The charts above are actual results from different laboratories.

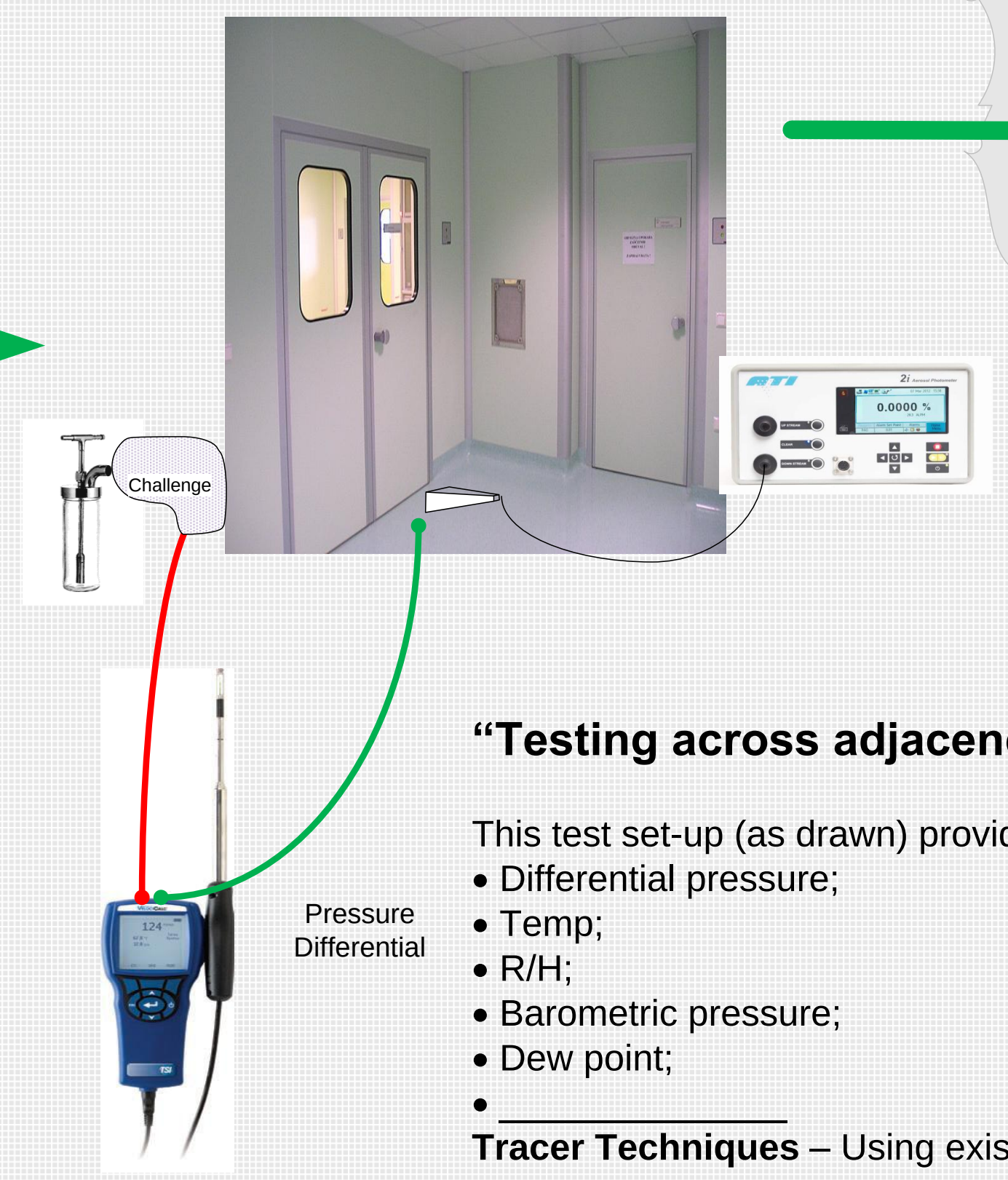
Some of the data represent the initial data leading to further and in depth review and resolution of issues...to a successful project.

They are a result of many "things" present and within the charts, and, in some cases, complex.
Some of these contributors include the:

- Systems controls (BMS), the computer drive sequences (dependant on several skill sets including the programmers,
- Ability to understand the essential control orientation/sequencing of the system (systems logic),
- Ability to address and adapt to the electro-mechanical process and mechanical responses inherent with the component selections during the project

Testing doors – Interior – Exterior

What are the influences – door size, differential pressure, airflow rate/volume, environmental[climate impact]



Example of test:

Data/results from challenge across areas – Test result obtained where good. Qualification of % leakage with test method = HEPA filter Leak test w/acceptance of 0.01% of upstream concentration [all equipment calibrated and adjusted for test scenario]

Upstream @ challenge 67 μg/l polydispersed PAO [Laskin generated]; and/or 2μ size [Collison generated]

Downstream @ 0.000 % of challenge [door closed – normal operational mode (PAO), differential pressure
Failure mode @ 0.0016% of applied challenge – AHU failure w/restart [Restart of the HVAC is very likely to demonstrate transient pressurization – may not constitute actual "reversal" as per BMBL 5th.

"Testing across adjacencies using common equipment."

This test set-up (as drawn) provides:
- Differential pressure;
- Temp;
- R/H;
- Barometric pressure;
- Dew point;
- ______________

Tracer Techniques – Using existing, field proven equipment.

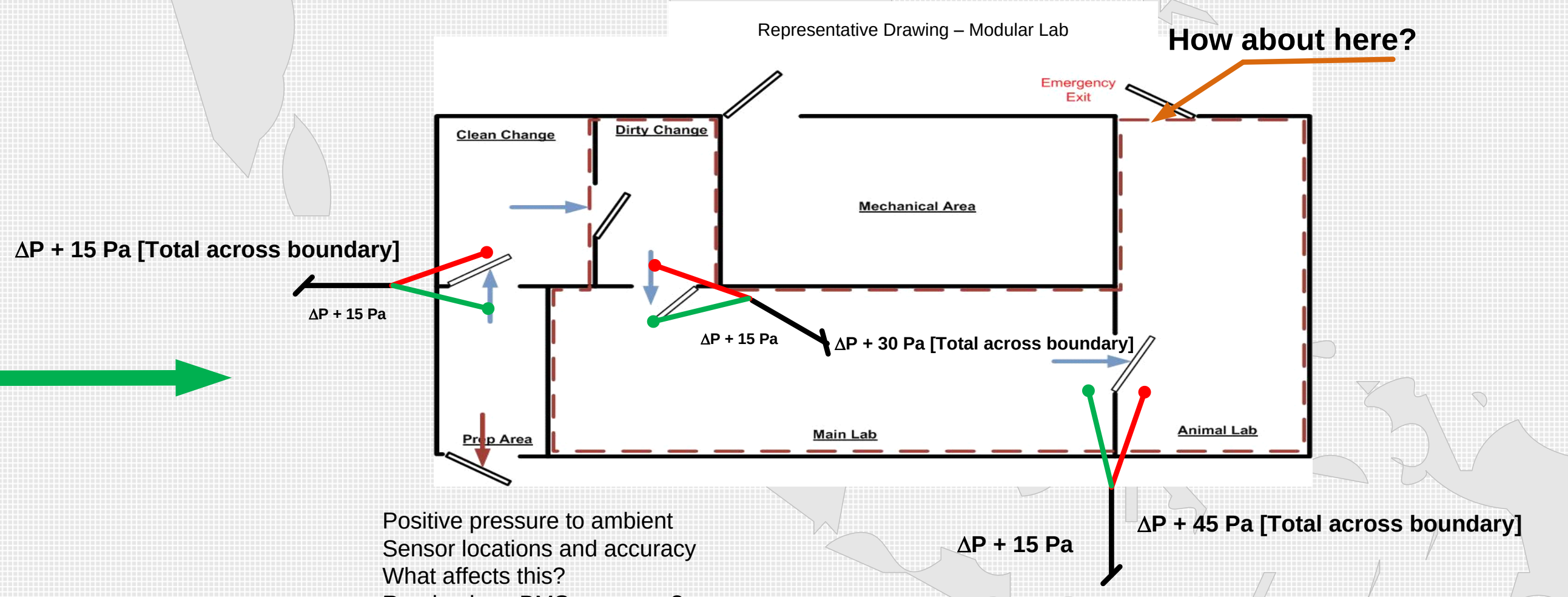
- Upstream concentration for Collison Nebulizer
- Pick-up of aerosol challenge downstream as applied to "conditions of test"
- Helium can also be used

ALL TEST RESULTS ABOVE CAN BE RECORDED AND QUANTIFIED

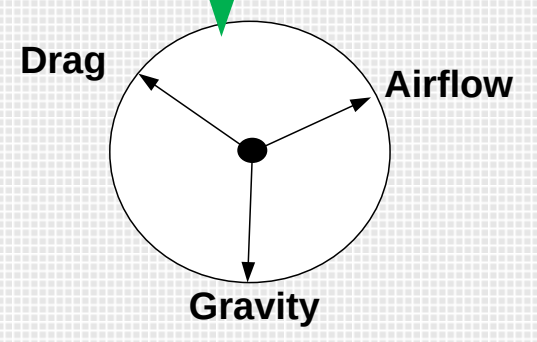
Results: from testing and in-situ adjustments, as a result from some of the additional test techniques and operational insights, have had positive results, leading to successful projects.

While much focus is placed upon differential pressures, airflow volumes have been shown to be just as important e.g., opening and closing doors, the retention or displacement of aerosols in front of or behind the doors, carriage/transport of airborne constituents entering and exiting the doors, and conformance to the intent of regulations applied or laboratory needs as written and often implied (interperted).

Differential Pressures Testing
Cascading pressures between areas



Positive pressure to ambient
Sensor locations and accuracy
What affects this?
Read only or BMS response?



Remember , is about the air.

Particles falling in still air; general equation $v_T = t_p g$
So, what about dynamic airstreams?

So how do the different methodologies, spreading in homogenous turbulence, particle motion, dimensional scales, turbulence on ability to spread work and can be field reviewed?

What does it mean?

Conclusions:

Additional testing methods are powerful for the determination of the "Level of Confidence" needed with any BSL 3 Laboratories, as well as other laboratories, located in widely varying situations. These issues become more apparent within the project scope and missions assigned to mobile and modular BSL3 projects.

As operational needs become identified and more pronounced, the ability to look and quantify these needs provides more "tools in the toolbox" with the processes and determinations for developing proper operational facilities. It is important to realize that modular and mobile laboratories have additional challenges, above those generally found in a fixed laboratory.

As issues and items become better identified, relative to this type of modern laboratory, stakeholders must develop an awareness to many of the nuances which have and can be observed and planned for. By carefully approaching the different locations, needs, user criteria, as well as providing "realistic risk based supplemental and operational criteria", mobile and modular laboratories will provide a leading role [testability rendering a high operational confidence level] within the unique geographical territories and the developing and continual biological safety challenges.

Additionally, as "lessons learned" are better implemented, the balance between the "state of the art" technology and what will and does work (through repeatable, adaptive and viable test methodologies) will provide proper biosafety safety with many of the existing and developing programs.