



C-33 - HIGH CONTAINMENT LABORATORIES (BSL-2, BSL-2+, & BSL-3)	
I	<u>General Criteria</u>
A	The purpose of this Guideline is to establish the criteria for Design and Construction of Level 3 Biological Safety Laboratories (High Containment Laboratory) at UNC-Chapel Hill. In addition to these criteria, any High Containment Laboratory shall conform to the latest edition of Biosafety in Microbiologic and Biomedical Laboratories (BMBL) and National Institute Health (NIH) Design Requirements Manual (DRM) in effect at the start of construction.
B	A high containment laboratory shall be designed to allow it to perform independently of other building systems. This is to allow normal building maintenance to occur without disruption to lab operations. Additionally, systems critical to lab operation shall be redundant. Reliability, longevity, and low maintenance shall be the primary building system goals.
C	At project close out a verification statement signed by all members of the Design Team will be submitted to the University stating that any high containment laboratory included in the project scope meets the requirements stated in IA. In addition, a Risk Assessment shall be completed prior to opening and after any modifications to a lab,
D	All building system equipment (HVAC, plumbing, controls) that will require regular maintenance shall be accessible to maintenance personnel without having to enter the laboratory space and shall not have the potential for exposure to pathogens/agents. External services shall have emergency shut off external to lab.
E	All mechanical, electrical, IT (including cables in telecom closet) and security equipment serving the high containment laboratory/suite shall be specifically labeled throughout the building.
F	All building system equipment shall at minimum be installed according to the manufacturer's recommended installation instructions.
G	A laboratory system description shall be provided for all laboratories/suites. This document shall be updated anytime a laboratory is modified. The system description shall include the follow sections; General Description, Subsystems and Major Equipment, Operations and Maintenance, Periodic Testing, Drawings and Tables, and Attachments. UNC has adopted this format for system descriptions documents. This will be a living document that supports the operations and maintenance of the laboratories/suites for the life of the laboratories/suites.



H	The close out process (e.g., delivery of laboratory system description, operations & maintenance manual, commissioning report, test and balance report, and training of building operations staff) will be completed within 30 days of the final acceptance of the modified laboratory, prior to the re-introduction of the agent into the lab space.		
II	<u>Architectural</u>		
A	Containment Zones (Refer to Figures 1 and 2): Containment zones shall be identified on plans.		
	1	Primary Containment Zone (PCZ):	The PCZ has live agent present. All air is HEPA filtered by Biological Safety Cabinet (BSC) prior to exhaust either by direct ducting or room exhaust. The PCZ is within the Secondary Zone.
	2	Secondary Containment Zone (SCZ):	A SCZ may have live agent present... All air is exhausted to the outside and is HEPA filtered.
	3	Tertiary Containment Zone (TCZ)	A TCZ never has live agent present. All air is exhausted via HEPA filtered room exhaust or to a higher containment zone. Examples of Tertiary zones include but are not limited to Anterooms, changing rooms and showers, etc.
B	The laboratory shall be separated from areas that are open to unrestricted traffic flow within the building.		
C	Access through two (2) self-closing doors to reach the inner laboratory is the minimum requirement. The outer door shall be a self-locking security door.		
D	A clothing change room (anteroom) shall be included in the passageway between the two self-closing doors. Adequate space for a hands-free sink, pass-through autoclave, and shelves for protective equipment and lockers shall be provided. The anteroom should have shower in\shower out capability.		
E	The shower and hand washing sinks should have the capability to be plumbed for effluent decontamination.		



F	The entry doors shall be designed to accommodate moving large equipment into and out of the laboratory.	
G	Air pressure status shall be visible both from the hallway and the anteroom to provide assurance upon entry that all rooms are under negative pressure.	
H	Each lab in SCZ shall have a hands-free or automatically operated sink available for hand washing.	
I	All laboratory surfaces (walls, floors, ceilings) shall be designed to be easily cleaned and decontaminated.	
	1	Bench tops shall be impervious to water and be chemical and heat resistant. Cabinets shall not be constructed of wood.
	2	Floors shall be monolithic/seamless or with welded seams and covered up the wall 4 inches. The floors shall be continuous under permanent casework.
	3	Ceilings shall be monolithic (no removable tiles).
	4	Walls and ceilings shall be painted with durable glossy acrylic or epoxy paint with adequate coverage to provide a “no pinholes evident” finish.
	5	All laboratory furniture must be capable of supporting anticipated loads and uses and, shall be made of non-porous material (including chairs). Adequate spacing shall be provided between benches, cabinets and equipment to allow for cleaning and decontamination.
	6	All penetrations (including electrical and plumbing) into the laboratory shall be sealed per the DRM sealant table. All penetrations and junction boxes within the lab shall be sealed.
J	No outside windows are recommended to be present in the laboratory.	
K	All high containment laboratory doors shall have full length door stops and the doors provided with adjustable door sweeps.	



L	All refrigerators, freezers, animal caging systems and incubators used to store high containment laboratory agents shall be located within the inner laboratory (SCZ) and equipped with a locking mechanism. Freezers shall be monitored 24/7 and page out if they fail.	
M	Ceiling access doors are not recommended. If required, ceiling access doors in the laboratory shall have gas-tight gaskets and piano hinges.	
N	A pass-through autoclave with a functioning door interlock shall be available in the laboratory.	
	1	Autoclaves shall be large enough to accommodate large equipment.
	2	Steam isolation shut off valve shall be outside of the lab.
	3	An autoclave shall have a built-in effluent decontamination cycle.
	4	The drain for the autoclave shall be in the SCZ (lab) side of the lab.
	5	Any autoclave steam relief valve discharge and condensate drain shall discharge to the SCZ (lab) side of a pass-through autoclave and not the anteroom or exit areas.
	6	A bioseal shall be used to create a seal between the autoclave and the SCZ (lab) wall between the lab and anteroom.
	7	Access for autoclave repair shall be outside of the SCZ.
	8	A canopy hood over the autoclave is required to contain heat and steam from the anteroom side of the autoclave.
	9	Clean side autoclave doors shall not open directly onto a public corridor
O	A Class II Type A or Type B Biological Safety Cabinet (BSC) shall be available in the laboratory/suite.	
	1	BSCs shall be installed so that the room supply and exhaust air does not interfere with proper operation. Additionally, BSCs shall be located away from doors, high traffic laboratory areas and not directly across from each other.
	2	Cabinets must comply with, be installed and certified in accordance with latest version of NSF/ANSI 49.



	3	If a cabinet is ducted the internal supply fan in the biosafety cabinet and remote exhaust fans shall be interlocked so that the supply fan in the cabinet shuts off whenever the exhaust fan fails.
	4	Class II Type A thimble ducted cabinets are not allowed.
P		Vacuum lines shall be independent of the building vacuum. Local vacuum lines must be protected with HEPA filters.
Q		An eyewash station shall be in each laboratory.
R		Provide space near the lab or in the building for storing critical spare parts such as belts and motors as well as tools such as a ladder.
S		The space above a lab shall be sealed such that a leak does not flood into the lab. Thresholds shall be provided on doors to keep minor floods from entering or exiting the anteroom or lab.
III		<u>Electrical</u>
A		Cast electrical boxes are recommended for outlets.
B		All components of the HVAC system (supply and exhaust), alarms, emergency lighting and laboratory outlets for essential equipment (Biological Safety Cabinets, freezers, autoclave, etc.) shall be on a backup power system. All high containment laboratory equipment and controls on backup power shall be supplied backup power through a closed transition transfer switch.
C		All components will have labeling to identify what panel and breaker is used, see Facilities Lab Maintenance Notification Procedure for labeling standards.
D		Backup power to the lab and associated systems shall be on dedicated circuits from the generator. These shall be in compliance with Article 700 of the NEC.
E		Light fixtures shall be surface mounted and designed to maintain gas tight requirements.
F		At least one light fixture in the inner lab and one in the anteroom shall be equipped with battery backup. Battery location cannot be within the light fixture.
G		BAS controllers and BSCs shall have UPS with a run time of at least 120 seconds. The UPS provided for the BAS controller and the A2 BSC's must divert back to normal power if the UPS fails.



H	Electrical panels serving high containment laboratories shall be located in locked electrical or mechanical rooms. Circuit breakers shall not be located within the SCZ (lab).
I	VFDs shall be selected and programmed to ride through (maintain microprocessor power) momentary power interruptions (such as open transitions during generator tests) of up to 3 seconds (???) and catch motors on the fly spinning down after an interruption.
IV	<u>HVAC\BAS Controls</u>
A	The laboratory shall be designed to have directional airflow from the hallway, through the TRZ into the SCZ.
B	The dedicated supply and dedicated exhaust system for the laboratory shall be completely separate from other building HVAC systems.
C	The air supply and exhaust systems must be interlocked to prevent reversal of the directional airflow and positive pressurization of containment area in the event of an exhaust system failure.
D	The pressure relationship of SCZ, TCZ, and corridor shall be actively controlled by laboratory grade supply and lab exhaust terminal valves. Blade damper style terminal boxes are not permitted.
E	The brand, generation, and software tools for the high containment laboratory BAS shall be the same as that used throughout the building.
F	Digital readout /visual monitoring devices that indicate directional airflow are required in the laboratory. These air pressure monitoring (APM) devices shall have audible alarms to indicate HVAC system failure. The devices shall be equivalent to Tek-Air Systems Iso-Tek Space Pressurization Monitor (SPM-2200) or Paragon SP-3000. The range of the room APM shall be from 0.25 to -0.25 INWC. There shall be a strobe light in main lab for APM alarms.
G	The APM shall have a dry set of contacts for alarming and analog outputs to enable remote monitoring via the Building Automation System (BAS) and UNC Police.
H	The exhaust system shall be designed with redundant 100% capacity exhaust fans, N+1. Exhaust systems shall be designed to allow fans to operate simultaneously. Failure of the either fan will cause the other fan to increase in speed to maintain design air flow in minimum time to maintain lab pressurization.



I	All general exhaust fans shall have dedicated variable frequency drives (VFD) with manual bypass capability to enable fan operation even when the VFD fails.
J	Each ducted BSC may require a redundant exhaust fan depending on design.
K	BSC controllers should be provided with one digital output. The BSC digital output will be for an alarm input to the BAS. (Refer to Table 1)
L	All exhaust ductwork shall be welded stainless steel, gas tight to allow for decontamination. Round ducts are recommended. Leakage tests of the ductwork should be done as part of the commissioning process. All welds, gaskets, penetrations or seals on exterior surfaces of ducts shall be able to sustain air pressure for 20 minutes and be free of soap bubbles at 4 inches WG and the gas leak rate should not exceed 2×10^{-8} cubic feet per minute (CFM). (reference ductwork leakage testing in the Mechanical and Plumbing section of the UNC guidelines)
M	Consideration shall be made for uninterrupted straight lengths of ductwork to enable accurate airflow measurements.
N	Manual, accessible, gas-tight isolation dampers are required in the air supply and exhaust ducts for the laboratory.
O	A switch labeled "Emergency Supply Air Shutdown," which will de-energize the air handler via a safety circuit (not BAS logic), shall be located in the anteroom and in the main lab.
P	Environmental room sensors (e.g. T-stat) shall not have local user adjustment features. The associated room air supply terminal unit shall be provided with a discharge air sensor, which along with the room sensor shall be used in a cascade loop to limit space temperature swings.
Q	Any high containment laboratory room housing an autoclave, served by an HVAC system that is capable of humidification, or housing any other device using steam shall have a room humidity sensor. Humidity Sensors shall be installed in the exhaust duct; not the lab.
R	The supply duct shall include sensors and logic to shut down the humidifiers upon a loss of humidity control.
S	The supply side of the air distribution system shall be designed with redundant full capacity fans. If both fans are in a common air handling unit they will be partitioned to allow servicing without loss of supply air.



T	<p>All exhaust air from the laboratory shall be HEPA filtered. HEPA filters shall be located as close as possible to the containment barrier penetration. HEPA filters shall be rated for 99.99 efficiency at 0.3 microns. These filters shall include provisions for bag-in/bag-out filter replacement. HEPA filters shall be located with consideration to replacement and testing procedures. Consideration shall be given to provide redundant filter banks in case of unplanned laboratory shutdowns. HEPA filters should be zoned so that shutdowns can be coordinated.</p>	
	1	<p>Test ports and isolation dampers shall be installed on both sides of the filter to allow for filter testing and decontamination.</p>
	2	<p>Valved ports with magnahelic gauges shall be installed to measure pressure drop across the filter and fans. These shall be separate gauges for the filter and fan sections.</p>
	3	<p>Clearance should be maintained around the filter housing to allow for filter changes.</p>
	4	<p>Polydisperse Dioctyl Phthalate (DOP) filter test is required to insure that HEPA filters or the areas around the filter do not leak. There should be 10 duct diameters upstream of the HEPA filter for good mixing.</p>
	5	<p>All exhaust discharge shall be vertical. The stack should be at least 10 feet above the roof surface or have a stack with a smaller diameter trailing end to produce higher velocity flow to avoid re-entrainment by the building, and should be increased in elevation when necessary to avoid the influence of surrounding structures. The discharge must be a minimum of 25 feet from the intake.</p>
U	<p>All HVAC equipment failures, including exhaust and supply fans, shall alarm through the building automation system to the Energy Management Control System (EMCS) shop. APM alarms shall be sent to the UNC Police and EMCS. Refer to Figures 1 & 2 and Table 1 for alarms and notification.</p>	
V	<p>The BAS shall include a Local Control Station (LCS), with all graphics and controls hosted locally such that full BAS functionality including 1 minute sample rate trending exists in the building when internet connectivity to the outside is lost.</p> <p>A second (redundant) fully functional LCS with a documented manual change over process is required if LCS serves a gateway/server function.</p>	



W	The BAS network for the High Containment Laboratory shall be physically separate from the other parts of the building BAS network such that network problems in one area do not affect the other areas and problems may be isolated.
X	Building automation systems shall maintain operational set points during all loss of power events and return to normal operations.
Y	For each High Containment Laboratory, any general room exhaust, BSC, and any autoclave hood exhaust flow shall be measured by the BAS. Total room exhaust shall be summed and the total room exhausts flow tracked by the room supply flow to ensure proper room CFM offset and pressurization control. Both the supply and exhaust air terminals shall be under the same controller. Refer to UNC HVAC standards for lab control requirements.
Z	HVAC control panels are best located in locked electrical or mechanical rooms. If a panel must be located in a public space, it must be locked.
ZA	System shall include a hard wired interlock to shut down the supply air ventilation system in the event that status of the exhaust fans is lost.
ZB	For suites of labs, a master status panel (refer to architectural section) is required to be visible from the anteroom to the suite for visual status of all air pressure monitors.



V	<u>Plumbing</u>
A	An eye wash shall be available in the inner laboratory. An “Eyewash” sign must be posted near the eyewash.
B	Provide exterior access to isolation, mixing and other valves for domestic hot and cold water supply cutoff.
C	Water service to the laboratory shall be protected by backflow prevention devices to prevent contamination of areas exterior to the High Containment Laboratory. Backflow prevention devices shall be installed outside of the lab and in an accessible location.
D	Provide redundant reduced pressure backflow prevention specific to High Containment Laboratory to prevent contamination of non-High Containment Laboratory piping.
E	An emergency shower is required in the TCZ (anteroom).
F	Trap Primers are prohibited. All traps shall be extra deep (>6 inches).
G	Natural gas cannot be plumbed into the laboratory.
H	All piping for effluent shall be double walled pipe.
I	If compressed gas will be needed for experiments, it is recommended that piping should be run into the SCZ from a manifold in a gas cabinet outside the SCZ.
J	The effluent decontamination process is determined by the science of the laboratory. A location for effluent decontamination shall be designated and designed.
K	The agent and chemicals used for decontamination in the laboratory must be taken into consideration when selecting construction materials.
VI	<u>Security\Life Safety</u>
A	A strobe light fire alarm and a fire alarm pull station are required in the laboratory. The strobe light shall be visible in all locations of the laboratory.

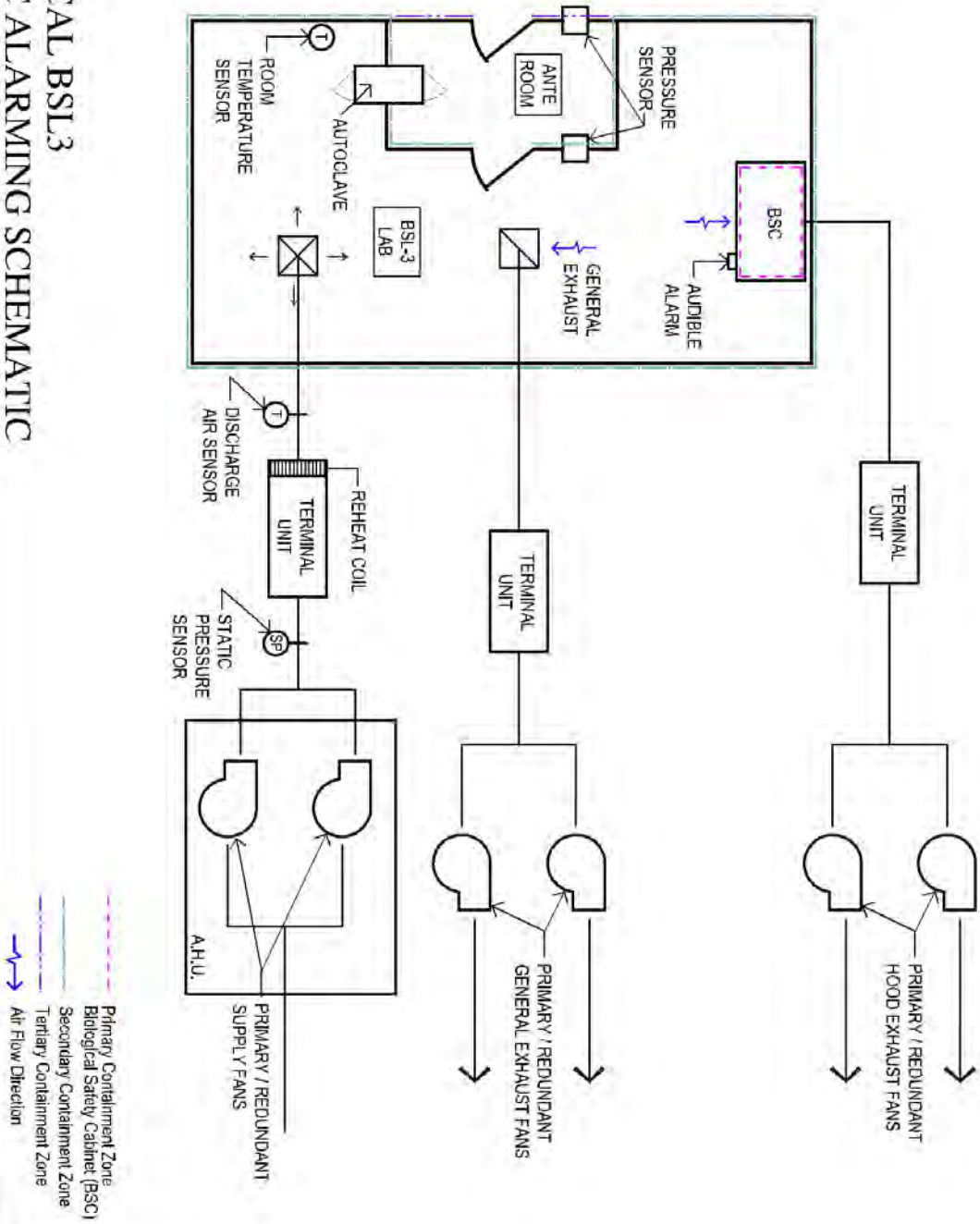


B	The laboratory shall be secured by electronic locks and/or combination locks, accessible only by authorized personnel.	
C	A keycard access system shall be required for tracking entry into the lab.	
D	A telephone that functions during power outages shall be available in the inner lab and anteroom for emergency purposes.	
E	The anteroom and inner laboratory doors should be electronically interlocked to prevent both from being opened at the same time.	
F	<u>Additional Life Safety Requirements for Select Agent Labs</u> A minimum of three security barriers where each security barrier adds to the delay in reaching secured areas where select agents and toxins are used or stored. One of the security barriers must be monitored in such a way as to detect intentional and unintentional circumventing of established access control measures under all conditions (day/night, severe weather, etc.) The final barrier must limit access to the select agent or toxin to personnel approved by the HHS Secretary or Administrator, following a security risk assessment by the Attorney General.	
	1	Provide and install a keycard swipe recorder outside the main laboratory door and inside the main laboratory door to record entry and exit from the lab.
	2	Provide and install a keycard access on the door leading from anteroom to the laboratory proper.
	3	All keycard use shall record the time and date of entry or exit and the name of keycard owner.
G	A Knox-box, accessible by emergency responders, shall be installed at the entrance to the main door of the lab for holding keycard to the secure lab/suite. Based on security requirements a Knox-box may also be required in the stairwell.	
H	In the event of a fire alarm, the combination and electronic locks on the laboratory's main door will continue to function and keep the laboratory secure (i.e., fire alarm secure).	
I	Video surveillance shall monitor hallway entrance to the select agent laboratory. The most recent forty five days of video shall be stored on a digital recorder with removable media.	



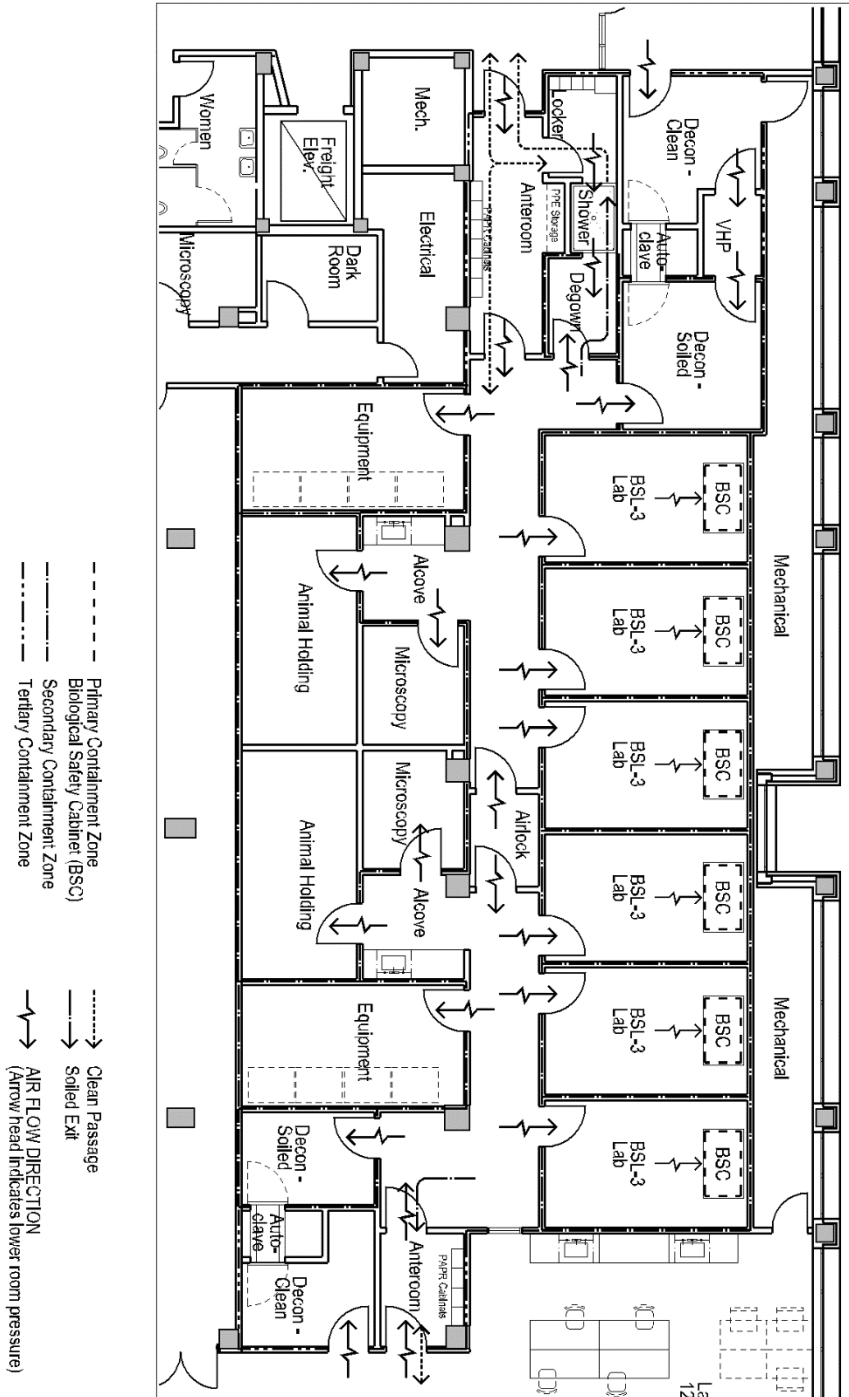
VII	<u>Commissioning</u>
A	The High Containment Laboratory and all supporting systems shall be commissioned by an independent commissioning provider. A commissioning plan shall be submitted for approval by Facilities Services and The Environment Health and Safety Department. During the commissioning process; the system description will be verified and validated.
VIII	<u>Exception Process</u>
	If during the design and construction phase the requirements of this document cannot be met, it is required that a written explanation is provided documenting why and what alternative approach was agreed to. This document will require the signoff of the Department of Environment, Health and Safety, Facilities Services, and all members of the Design team.

TYPICAL BSL3
HVAC ALARMING SCHEMATIC
FIGURE 1





TYPICAL BSL3
MULTIPLE LABS
FIGURE 2





UNC-Chapel Hill BL3 Lab Alarming Standards

Table 1

Item	Condition	Notify			Alarm Limits	Alarm Text	Notes
		DPS	Audible	EMCS			
1	Anteroom to Lab High Pressure	x	x	x	Differential Pressure > -0.005 inWG (field verify)	Bldg xx Room xx BL-3 Secondary Containment Zone High Pressure	Provide local audible alarm after condition exists for 30 seconds. Provide 45 second delay prior to initiating alarm to EMCS and DPS. Field verify delay and high limit.
2	Anteroom to Lab Low Pressure			x	Differential Pressure < -0.15 inWG (field verify)	Bldg xx Room xx BL-3 Secondary Containment Zone Low Pressure	Provide 45 second delay prior to initiating alarm. Field verify low limit.
3	Anteroom to Hall High Pressure	x	x	x	Differential Pressure > -0.005 inWG (field verify)	Bldg xx Room xx BL-3 Tertiary Containment Zone High Pressure	Provide local audible alarm after condition exists for 30 seconds. Provide 45 second delay prior to initiating alarm. Field verify delay and high limit.
	Anteroom to Hall Low Pressure			x	Differential Pressure < -0.15 inWG (field verify)	Bldg xx Room xx BL-3 Tertiary Containment Zone Low Pressure	Provide 45 second delay prior to initiating alarm. Field verify low limit.
4	Ducted Cabinet Face Velocity Alarm		x		80 FPM	N/A	Provide audible alarm at cabinet. Provide 15 second delay on alarm.
5	Ducted Cabinet Terminal Unit			x	Designer to call. Low equivalent to 80FPM. Alarm when flow drops below.	BL-3 Ducted Cabinet airflow too low. Check for fan failure.	
6	Ducted Cabinet primary exhaust fan			x	Pressure switch or CT indicates fan failure.	Bldg xx EF-x BL-3 primary exhaust fan failure for ducted BSC. Confirm operation of redundant fan. Investigate power failure, belt breakage, motor failure.	
7	Ducted Cabinet backup exhaust fan	x		x	Pressure switches indicates fan failure of both primary AND backup exhaust fans.	Bldg xx EF-x BL-3 primary AND backup BSC exhaust fan failure	
8	Room Temperature (non animal holding)			x	Deviation from setpoint by 1 degF	Check air handler and reheat valve.	
9	Room Temperature (animal holding)	x		x	Deviation from setpoint by 1 degF	Bldg xx Room xx BL-3 High Temperature (animal holding)	
10	General Exhaust airflow			x	Deviation from setpoint by 10%	Bldg xx Room xx BL-3 General Exhaust airflow differs from setpoint. Check exhaust fan operation and terminal box operation.	
11	General Exhaust primary fan			x	Pressure switch or CT indicates fan failure.	Bldg xx EF-x BL-3 primary exhaust fan failure for general exhaust. Confirm operation of redundant fan. Investigate power failure, belt breakage, motor failure.	
12	General Exhaust backup fan	x		x	Pressure switches indicates fan failure of both primary AND backup exhaust fans.	Bldg xx EF-x BL-3 primary AND backup general exhaust fan failure	
13	Supply air low static pressure	x		x	Static Pressure Setpoint - Actual Static pressure > 0.2 inWG	Bldg xx EF-x BL-3 supply air static pressure low	
14	Air Handler primary supply fan			x	Pressure switch or CT indicates fan failure.	Bldg xx SF-x BL-3 primary supply fan failure for ducted cabinet. Confirm operation of redundant fan. Investigate power failure, belt breakage, motor failure.	
15	Air Handler backup supply fan	x		x	Pressure switches indicates fan failure of both primary AND backup exhaust fans.	Bldg xx EF-x BL-3 primary AND backup supply fan failure	
16	Room Temperature on airflow heaters	x		x	TD-Dim Edwards and Doug Fleming	Bldg xx Ultra-low freeze high temperature	
17	Animal Cage system failure	x		x	Failure	Bldg xx Room xx BL-3 Animal Cage xx failure	
18	Door Access-Unauthorized access attempt	x		x	Unauthorized access	Bldg xx Room xx BL-3 Unauthorized entry	
19	Door Access-Door left ajar	x		x	Door left open too long	Bldg xx Room xx BL-3 Door left open	Provide 30 second delay prior to initiating alarm. Field verify delay.
20	BJPRA Box	x		x	Notify when access is gained to the box	Bldg xx BL-3 BJPRA Box accessed	

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