Evaluation of Nine Positive Pressure Suits for Use in the BSL-4 Lab

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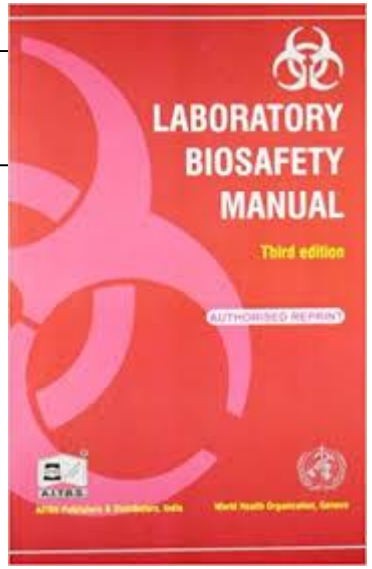
Containment Level 4 (CL4/BSL-4)

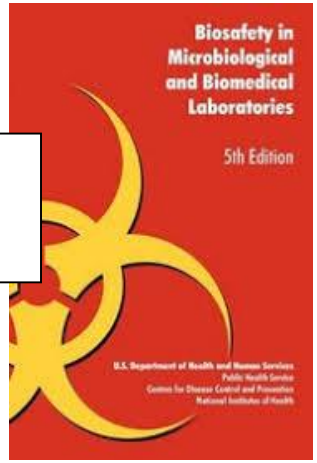
- **Risk Group 4 Agents**: Pathogens that pose high risk to the health of individuals or animals and a high risk to public health.
  - Effective treatment and preventive measures not usually available.
  - Risk of disease spread to animal populations ranges from low to high depending on pathogen.
- **Cabinet Laboratories**: Use a series of Class III Biosafety Cabinets to handle infectious material.
- **Suit Laboratories:** much more complicated from facility standpoint - stringent requirements for dedicated non-recirculating ventilation systems, waste handling systems & processes, building automation systems, chemical showers

Positive-Pressure Suits… What's in a name?

Personnel who enter the suit area are required to don a one-piece, positively pressurized, HEPA-filtered, supplied-air suit. Air to the suit must be provided



"full-body, air-supplied positive-pressure personnel suit." (BMBL)



9.1.5.2 Positive-Pressure Suits

Positive-pressure suits provide the maximum full-body coverage (i.e., head-to-toe) to protect from the containment zone environment, and include integral boots, gloves, and headpiece. Breathable air is provided through a supplied air hose connected to the suit, which creates a positive pressurization within the suit. Integrity testing is conducted to demonstrate that suits are gas tight (i.e., no tears or leaks) and able to maintain a fixed positive pressure when inflated.

Positive-Pressure Suits

- Very few criteria define type of suit for BSL-4 lab use
- Models commonly utilized include:
  - **Type 1C**: Gas-Tight encapsulating suit with breathable air and positive pressure supplied by a remote airline (EN 943-1:1995), or
  - **Type III PPE:** ventilated protective clothing against particulate radioactive contamination (EN 1073-1:1998)
- Market dominated by three major manufacturers
- Varying shelf life
- Desire for improved models among BSL-4 community
- Substantial costs and potential airflow incompatibility prohibitive for laboratories to evaluate new alternatives

Are alternative, more robust and comfortable suit models available for use in the BSL-4 laboratory and large animal cubicle?

Are they compatible with the Chemical Shower?

Suit Study

Four new models of Positive-Pressure suits purchased

+

Three additional models on loan from companies or collaborators

+

Two Suits currently used at NCFAD

=

Largest cross-sectional comparison of positive-pressure suits for BSL-4 use

Questions

1. Do all suit materials withstand chemical shower disinfectant?
2. Do BSL-4 personnel show a strong preference for a particular suit model?
3. Do different suits expose users to different CO_2 levels? Standard vs emergency situations?

Characteristics of Suits Included for Study

Suit	Airflow Requirement	Construction Material	Glove System	Visor	Exhaust Valves
1	360 - 440 L/min	polyester fabric with Viton coating & butyl undercoat	Locking cuff dry glove system	180°	Back of hood (2) + back (3)
2	360 - 440 L/min	butyl-coated polyester fabric	Locking cuff dry glove system	180°	Back of hood (2) + back (3)
3	360 - 440 L/min	PVC-coated polyester fabric	Locking cuff dry glove system	180°	Back of hood (2) + back (3)
4	360 - 440 L/min	neoprene-coated polyester fabric	Locking cuff dry glove system	180°	Back of hood (2) + back (3)
5	450 – 950 L/min	PVC-coated fabric	Tape	180°	Hood (1) + Upper back (1)
6	141.5 - 254.8 L/min	Chlorinated Polyethylene	Tape	300°	Legs (2) & Upper back (2)
7	220 – 475 L/min	PVC-coated polyamide fabric	Bayonet glove ring system	180°	Back of hood (4)
8	220 – 475 L/min	polyamide fabric with inner PVC layer and outer Viton - butyl coat	Bayonet glove ring system	180°	Back of hood (4)
9	78 – 702 L/min	PVC-coated fabric	Tape	360°	Back of hood (4)

Glove Systems

Locking Cuff System
(Suits 1-4)

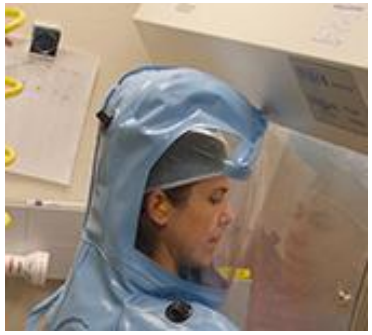
Bayonet Glove System
(Suits 7&8)

External Taping Method
(Suits 5,6 & 9)

Visors

Suits 1-4

Suit 5



Suit 6

Suits 7&8

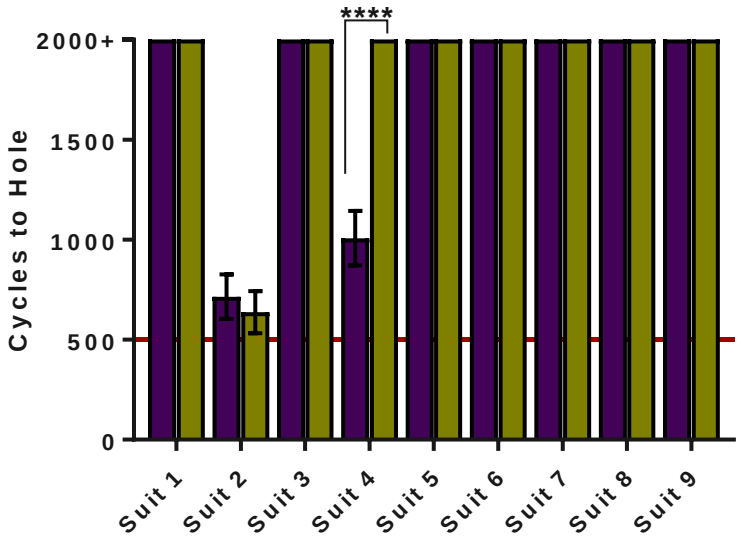
Suit 9

1. Effect of Chemical Shower Disinfectant

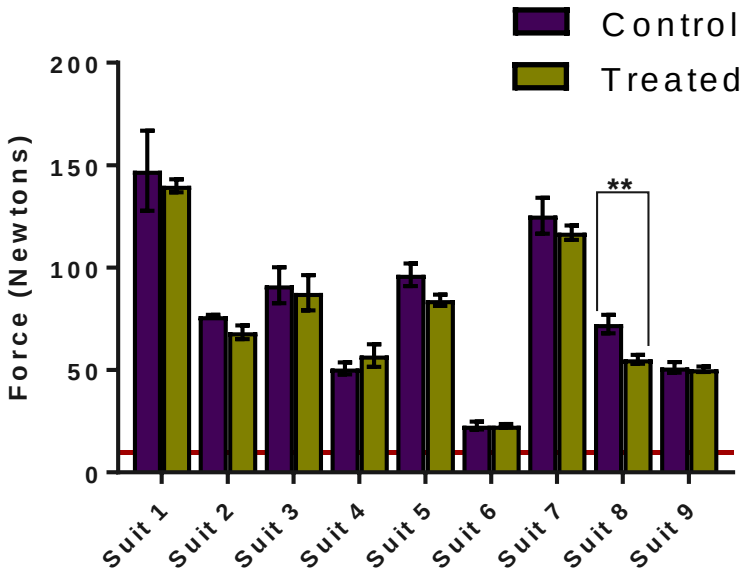
- Chemical Shower process at Winnipeg Lab:
  - 5% Micro-Chem Plus™: 2 mins
  - H_2O Rinse: 3 mins
- Experimental Setup:
  - Submerge suit swatches in 5% Micro-Chem solution for 5 days (= 2 chemical showers daily x 5 years)
  - Test mechanical resistance of treated vs controls according to international standards:
    - Abrasion (EN 530:2010)
    - Puncture (ISO 13996:1999)
    - Flex-cracking (ISO 7854:1995)

(In conjunction with University of Alberta's Protective Clothing and Equipment Research Centre)

Abrasion Resistance



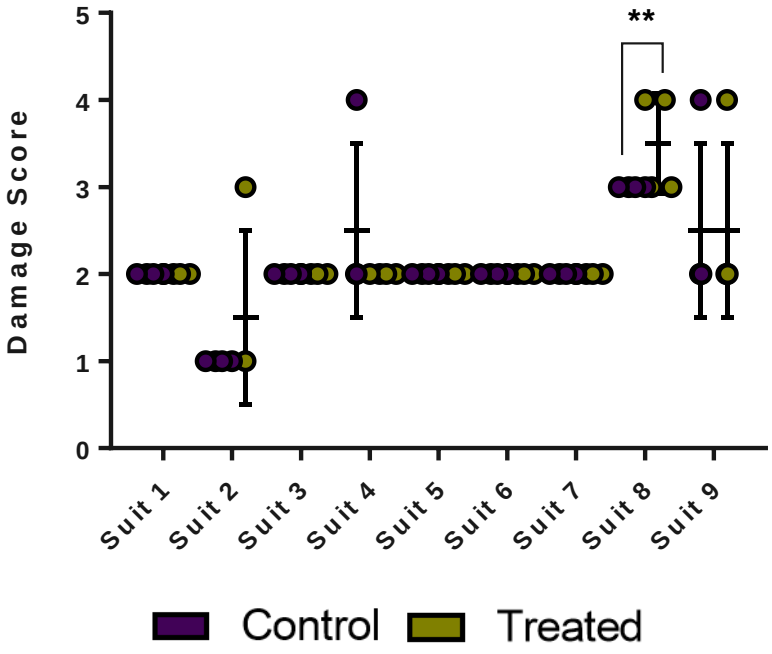
Puncture Resistance



- All Suit materials, treated or not, surpassed performance requirements for Class 1C garment rating (>500 cycles to hole and >10N force)
- 5% Micro-Chem had no significant effect on resistance to abrasion or puncture, with exception of Suit 8 (Viton-Butyl coating)
- Micro-Chem **enhanced** resistance to Suit Material #4 (neoprene) in both tests

Flex-Cracking Resistance

- Suit 2 material (Butyl) had small hole by 15,000 Cycles
- After 40,000 cycles - no differences between controls and treated swatches for 6/8 remaining suits
- Slight increase in damage scores for MicroChem-treated Suit 8 (Viton-Butyl-coated fabric)
- Higher damage Score for **control** of Suit 4 (neoprene)



Part 2. Personnel Preference

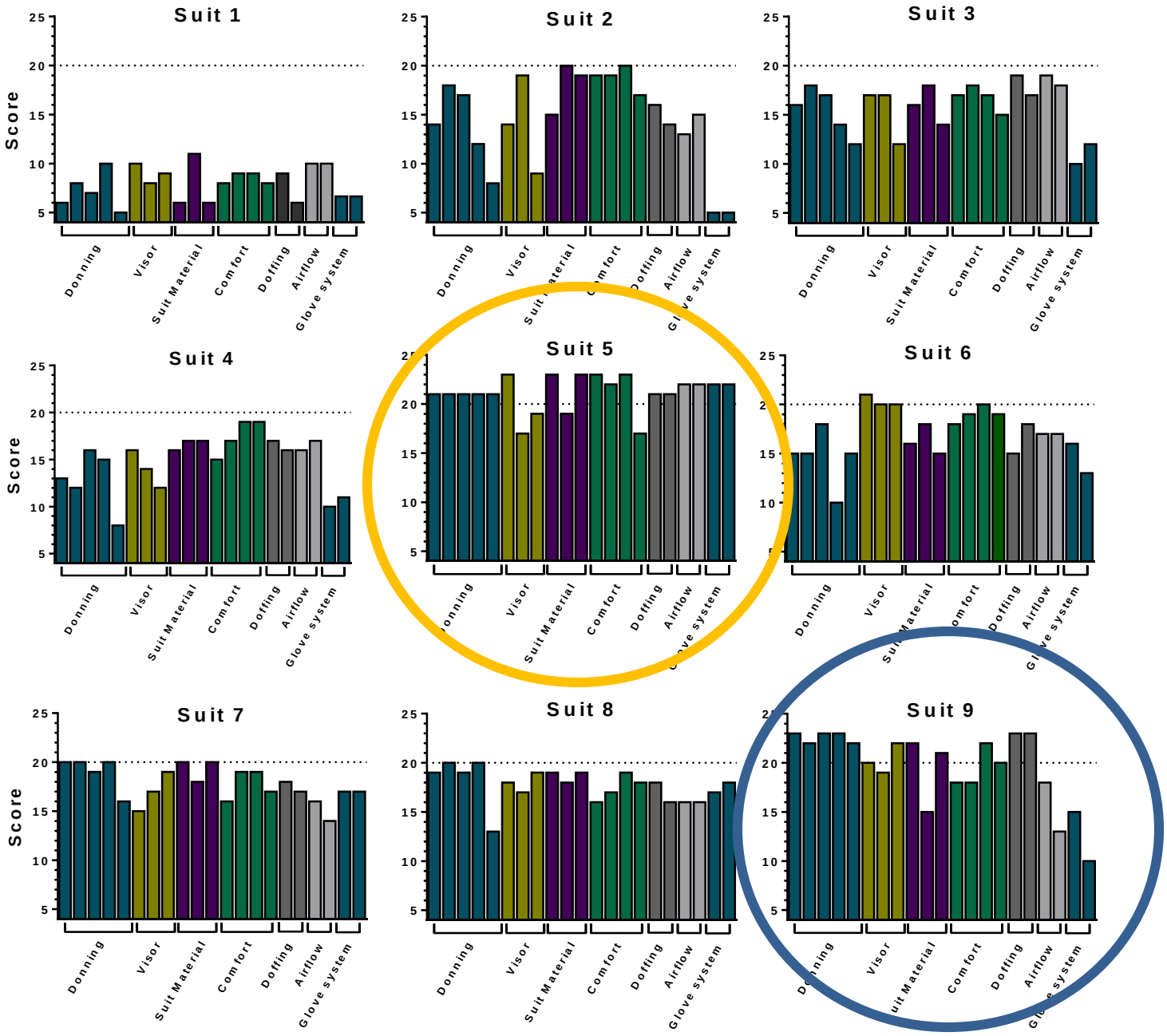
- Participant-driven, present and past members of Special Pathogens Unit
- BSL-4 training lab at JC Wilt Infections Disease Research Inst.
- Compressed air adjusted for each suit (20% above min) based on manufacturers' requirements
- Mock BSL-4 scenario:
  - Attempt glove change
  - Connect and disconnect to airdrops
  - Move about laboratory
  - Carry items to and from sink
  - Work in Biosafety Cabinet
  - ***Visual alarms***

Suit Survey

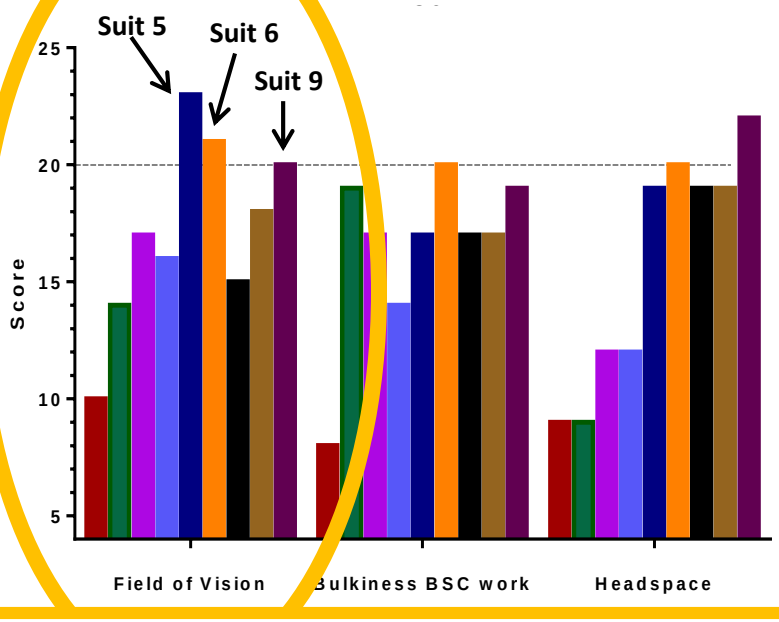
- 21 questions, broadly covering seven topics:
  - Donning & doffing procedure, suit material, visor, overall comfort, airflow and glove system
- Completed immediately post-doffing by each participant
- N=5 per suit
- Verbal rating scale, later converted to numerical values
- Scores of 20 or higher considered good

1. How would you rate the donning process?

	1 Not at all Easy	2 Slightly Easy	3 Fairly Easy	4 Easy	5 Very Easy	TOTAL
Overall Donning Process	p	g	xby			14
Donning of suit - Leg area			xgpy	b		18
Donning of suit - Arm area			gpy	xb		17
Donning of suit - Head area		xbg	py			12
Zipping suit shut	xgp	b	y			8


Suit 1
Suit 2
Suit 3
Suit 4
Suit 5
Suit 6
Suit 7
Suit 8
Suit 9
Score
25
20
15
10
5
Donning
Visor
Suit Material
Comfort
Doffing
Airflow
Glove system

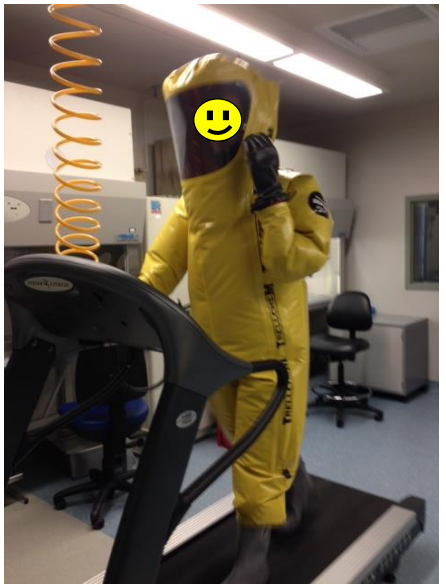
VISOR

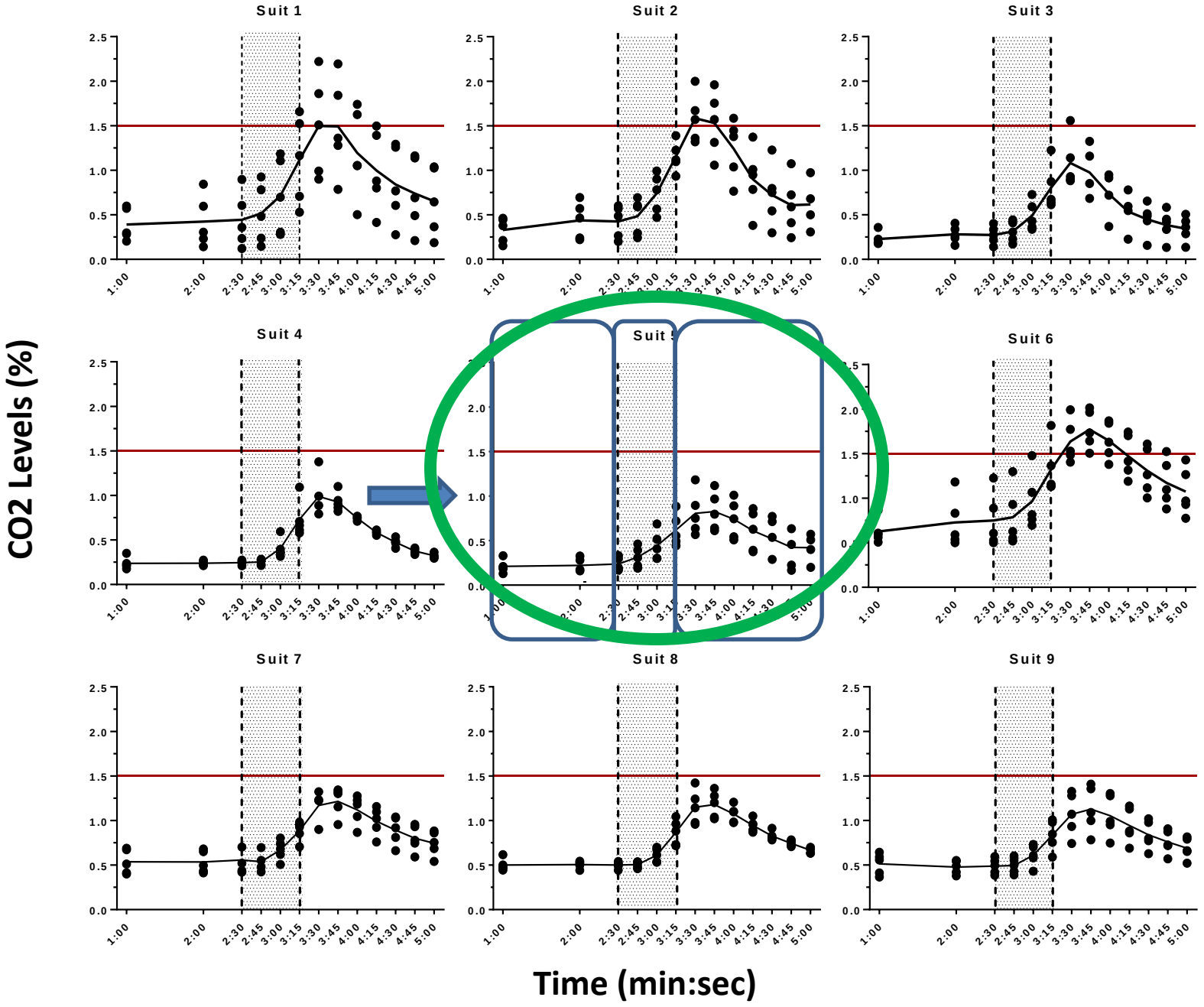


Important Note: Only 3 top-scoring suits had acceptable field of vision. Significant delays in visual alarm recognition with other models.

3. User Microenvironment

- Analysis of CO2 accumulation during light exercise (treadmill @ 1.5 mph)
- Five minutes of walking, disconnect from supply air at 2:30 mark and reconnect at 3:15
- Real-time monitoring with portable CO2 monitor via Bluetooth connection




Suit 1
Suit 2
Suit 3
Suit 4
Suit 5
Suit 6
Suit 7
Suit 8
Suit 9
CO2 Levels (%)
Time (min:sec)

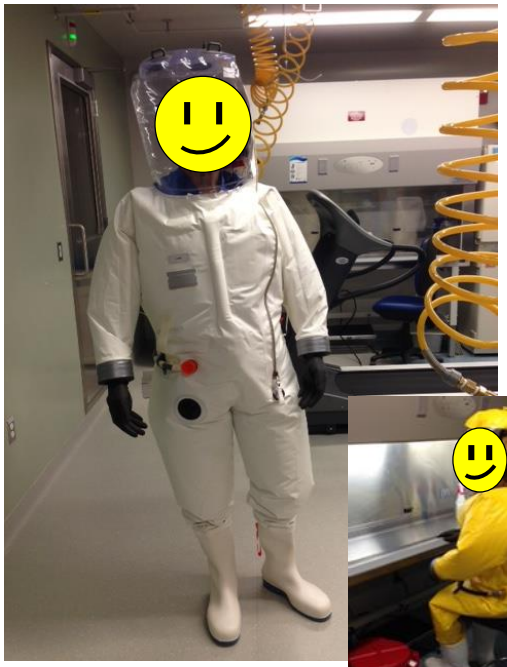
Suits for the Animal Cubicle: Quick Note

- Mock-Hot pig experiment set up to allow staff training opportunity in cubicle without BSL-4 agent risk
- Only two suits compared due to airflow incompatibility for other models with building compressor settings
- **Blue suits preferred**:
  1. Greatly reduced bulkiness for tight cubicle spaces
  2. Blood more easily removed from blue suit than yellow

     {Interestingly, Parks *et al.* noted higher reductions in log cfu with blue suit compared to yellow suit in study of chemical shower effectiveness…(Parks *et al., Applied Biosafety* 18(4) 2013)}

Suit Study - Results

- **Effect of 5% Micro-Chem**? Insignificant for suits used at NCFAD, potential incompatibility of butyl-coated fabrics
- **User Preference?** Suit 5, followed by Suit 9
- **New Models?** Suits 1-4 and 7-8 deemed unsuitable for BSL-4 lab (peripheral vision and gloving issues)
  - Air system revamp may permit future use of Suit 5 at Wpg lab (high airflow requirement)
- **Microenvironment?** All suits provided safe working environments for CO2 exposure while connected to supply air and even brief periods of disconnect



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Mat Pinette
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Evaluation of Nine Positive Pressure Suits for Use in the Biosafety Level-4 Laboratory

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Abstract

Positive pressure suits are the most recognizable feature of Biosafety Level 4 (BSL-4) laboratories, protecting users both through delivery of umbilical-fed HEPA-filtered air and by providing a positively pressurized microenvironment with respect to the surrounding laboratory space to minimize the possibility of exposure resulting from compromised suit integrity. While many positive pressure suits utilized in the chemical and radiation protection industries could be considered for BSL-4 use, the substantial costs and potential incompatibilities with facility settings prevent many labs from investigating novel alternatives. In the present study, 9 positive pressure suits from 5 different manufacturers were critically assessed for their suitability in the BSL-4 laboratory. Material resistance and compatibility with 5% Micro-Chem Plus™, CO_2 exposure levels, and overall user preference were assessed through a combination of objective and subjective testing. Results demonstrated that exposure to 5% Micro-Chem Plus™ had no deleterious effects on the mechanical properties of most suit materials, though some potential incompatibility was observed with butyl fabrics. Real-time monitoring of CO_2 levels inside the suits showed a great deal of variation between models, however all suits provided a microenvironment where users were exposed to CO_2 levels below 1% during normal activity and less than 2% during periods of disconnect from supply air. Finally, survey results from study participants indicated a strong preference for suits with light construction material, 360-degree visibility, high delivery airflow and gloves that require fixation by taping. By combining the present results with facility-specific factors, laboratories will be better equipped to consider new models that best suit their needs.

Keywords

positive pressure suits, biosafety level 4, personnel protective equipment, laboratory biosafety, CO_2 exposure

Biosafety Level 4 (BSL-4) laboratories are highly complex containment facilities where a combination of engineering, reveals that there are in fact very few criteria that define what type of suit can be worn in BSL-4. Neither the WHO Labora-