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

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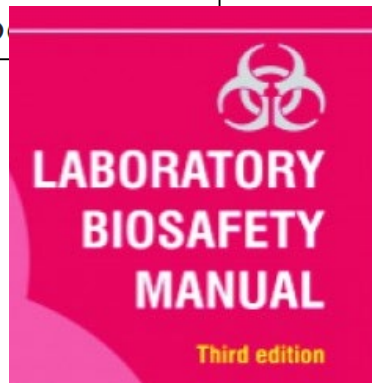
BSL-4 Laboratory

- Biosafety Level (Containment Level) 4 Laboratories = maximum biocontainment
- Combination of enhanced engineering controls, specialized biosafety equipment, and maximum level of operational practices
- Two configurations: Class III cabinet Laboratories vs Suit Labs
- Suit laboratories predominate over Class III cabinet laboratories in North America and expanding globally
- Suit Labs: Personnel wear positive-pressure suits with externally supplied HEPA-filtered breathing air at all times within the laboratory

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 b

"full-body, air-supplied positive-pressure personnel suit." "a positive pressure suit supplied with HEPA filtered breathing air."



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.

Canadian Biosafety Handbook (CBH) – 2nd Edition

Positive-Pressure Suits

- Very few criteria define type of suit for BSL-4 lab use
- No BSL-4 PPE standard, instead:
  - **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
- Desire for improved models within BSL-4 Lab community
- Limited published data available
- 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?

Suit Study

Inclusion of Nine different models = Largest cross-sectional comparison of positive-pressure suits for BSL-4 use

Specific Questions to Address:

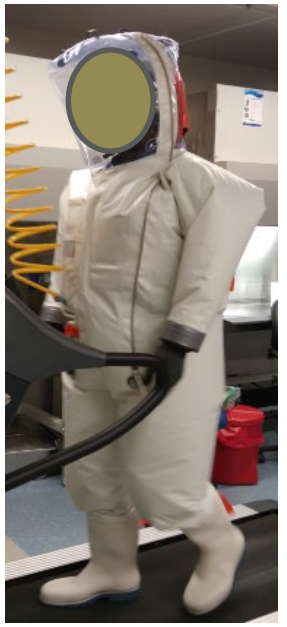
1. **Does exposure to chemical Shower disinfectant harm suit material?**
2. **Do BSL-4 laboratory personnel show a strong preference for a particular suit model?**
3. **Do suits differ measurably in microenvironments?**

Suit 1

Suit 2

Suit 3

Suit 4

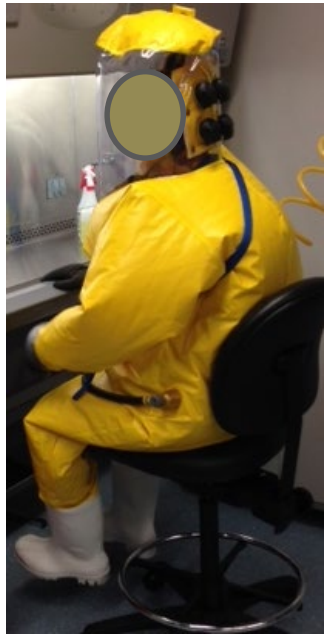


Suit 5

Suit 6

Suit 7

Suit 8



Suit 9

Differentiating factors

- Body material
- Airflow requirement
- Airflow distribution
- Exhaust valves (number, placement)
- Visor design
- Zipper design (length & placement)
- Glove systems:

Locking Cuff System


Bayonet Glove System


External Taping Method

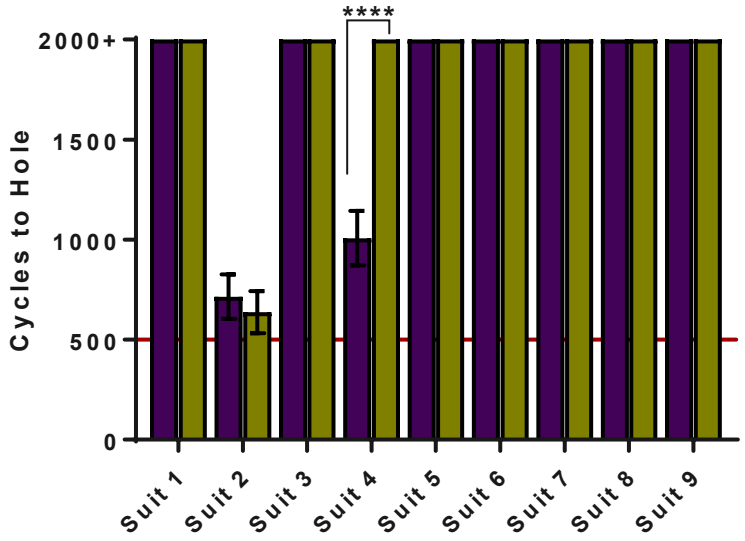
1. Effect of Chemical Shower Disinfectant

- **Chemical Shower process at CSCHAH**:
  - 5% Micro-Chem-Plus: 2 mins
  - H2O Rinse: 3 mins
- **Experimental Setup**:
  - Submerge 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)

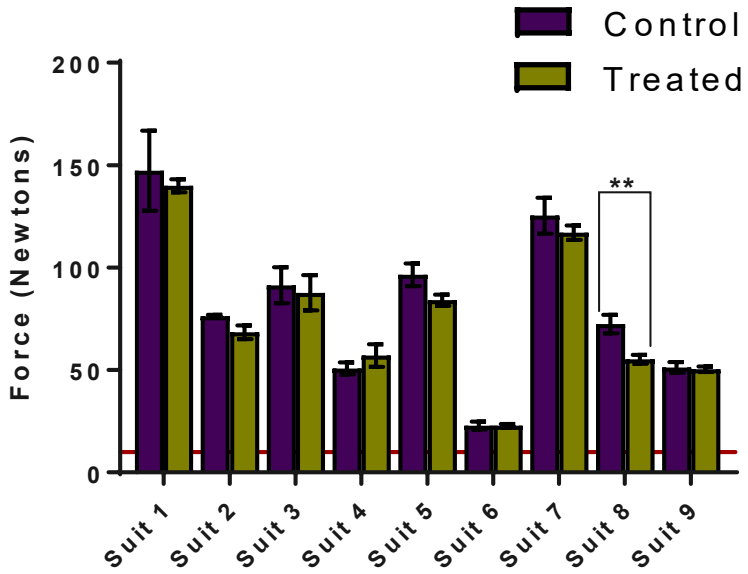
(In conjunction with University of Alberta's Protective Clothing and Equipment Research Centre)

Results - Effect of Chemical Shower Disinfectant on Suit Material

Abrasion Resistance



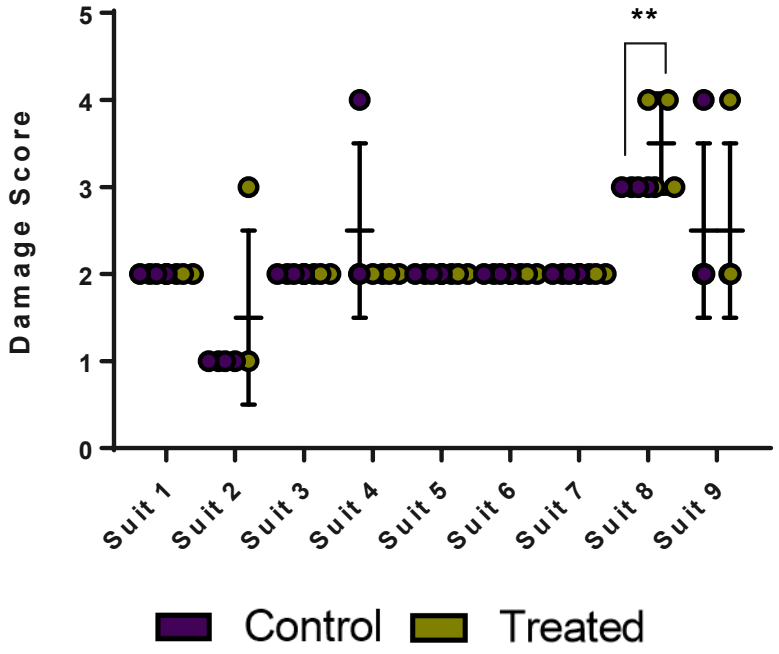
Puncture Resistance



- 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 - Suit Study

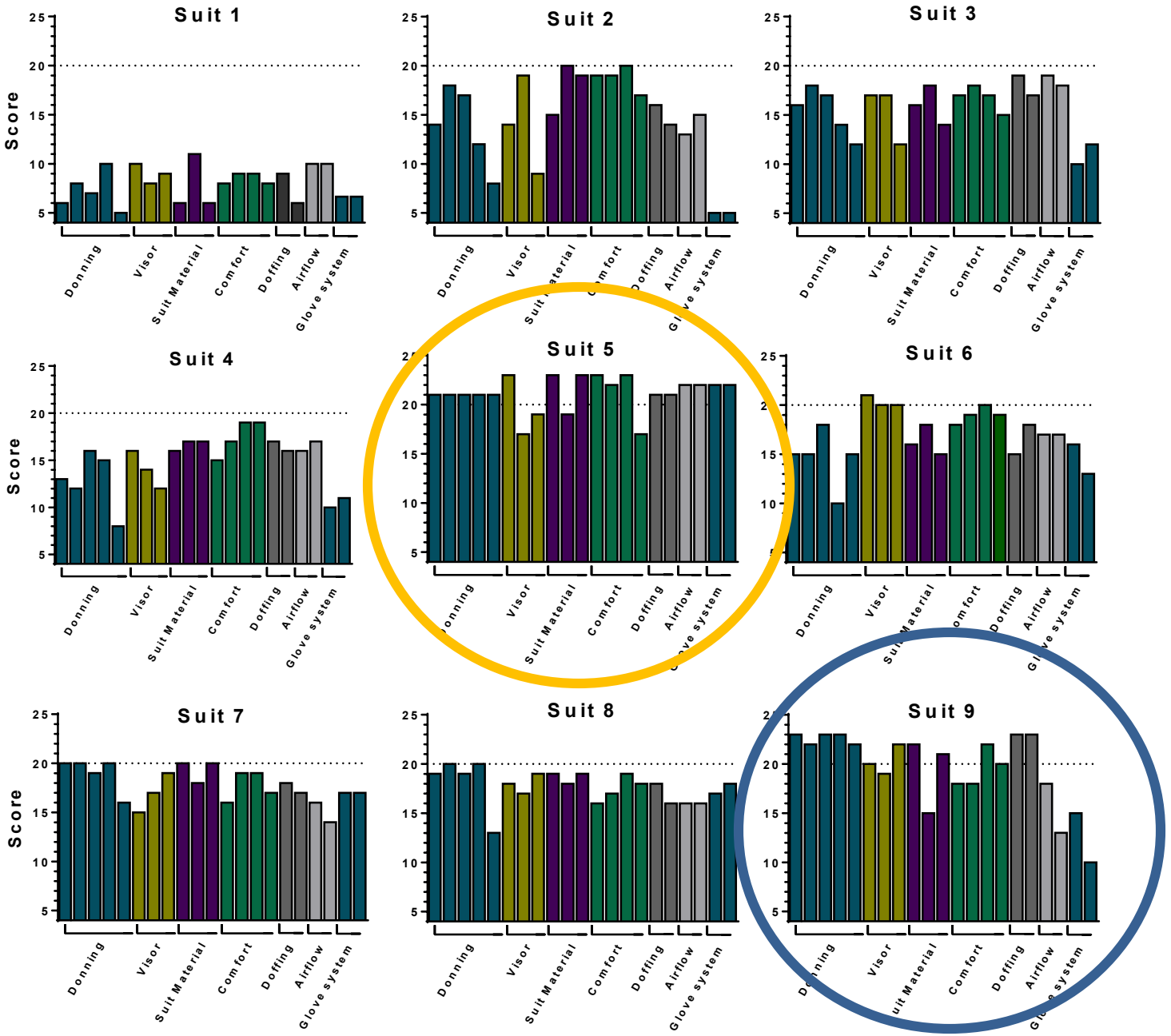
- Participant-driven in BSL-4 training lab, present and past members of Special Pathogens Units
- Compressed air adjusted for each suit (20% above min) based on manufacturers' requirements
- Mock BSL-4 scenario:
  - Attempt glove change
  - Connect and disconnect to airdrops
  - Move about laboratory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

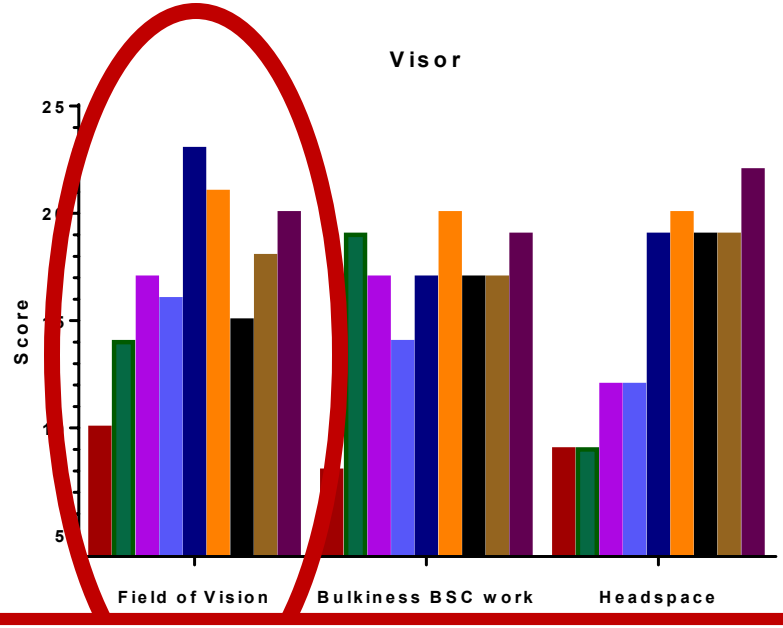
Suit Survey

- 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, 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

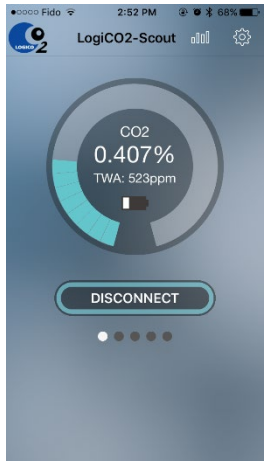

Suit 1
Suit 2
Suit 3
Suit 4
Suit 5
Suit 6
Suit 7
Suit 8
Suit 9
Score
25
20
15
10
5
Donning
Visor
Suit Material
Comfort
Doffing
Airflow
Glove system

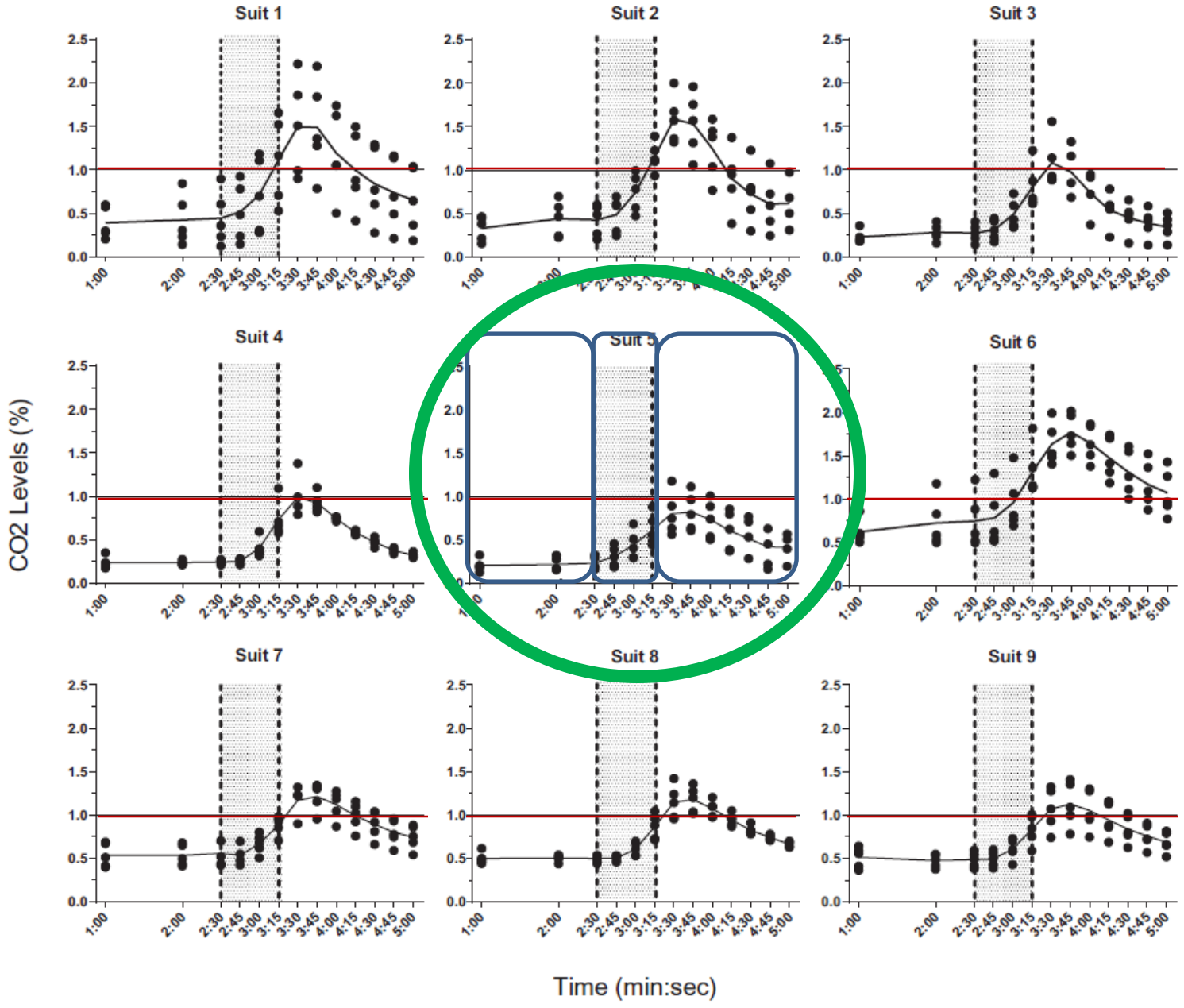


Important Note: Only 3 Top scoring suits had suitable field of vision. Significant delays in visual alarm recognition with other models.

3. Suit Microenvironment

- Analysis of CO_2 accumulation in visor area of suit 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 CO_2 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 Large 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 (Suit 6 and 9) compared due to airflow incompatibility for other models with compressor settings
- **Blue suits preferred**:
  1. Greatly reduced bulkiness for tight cubicle spaces
  2. Blood more easily removed from Suit 6 than Suit 9

     {Interestingly, Parks *et al.* noted higher reductions in log cfu with Suit 6 compared to Suit 9 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 currently in use, potential incompatibility with 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)
- **Microenvironment?** All suits provided safe working environments for CO_2 exposure while connected to supply air and even brief periods of disconnect
- **Changes as a result??** Not yet…

Thank You

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- Canadian Food Inspection Agency
- Peter Marszal, Jay Krishnan, Les Wittmeier, Edwin Ledesma, Don Whitworth, Todd Cutts, Kelly Anderson & Tracy Drew
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Greg Smith
Brad Pickering
Brad Collignon
Graham Casey
Nikesh Tailor
Matt Suderman
Mat Pinette
Cory Nakamura
Glenn Clark
Chandrika Senthilkumaran
Andrea Kroeker
Yohannes Berhane
Shawn Babiuk

Characteristics of Suits Included for Study

Suit	Airflow Requirement	Body	Zipper	Glove System	Visor	Exhaust Valves
1	360 - 440 L/min	Double-faced polyester fabric coated with Viton® coating & butyl undercoat	Downward closing, fitted vertically on right hand side	Locking cuff dry glove system	180°	Back of hood (2) + back (3)
2	360 - 440 L/min	Double-faced, butyl-coated polyester fabric	Downward closing, fitted vertically on right hand side	Locking cuff dry glove system	180°	Back of hood (2) + back (3)
3	360 - 440 L/min	Double-faced, PVC-coated polyester fabric	Downward closing, fitted vertically on right hand side	Locking cuff dry glove system	180°	Back of hood (2) + back (3)
4	360 - 440 L/min	Double-faced, neoprene-coated polyester fabric	Downward closing, fitted vertically on right hand side	Locking cuff dry glove system	180°	Back of hood (2) + back (3)
5	450 – 950 L/min	Reinforced PVC-coated fabric	Downward-closing with exposed teeth	Tape	>300°	Hood (1) + Upper back (1)
6	141.5 - 254.8 L/min	20 mil (0.5mm) Chlorinated Polyethylene	Upward closing OEB pressure sealing zipper with closure lips covering teeth.	Tape	300°	Legs (2) & Upper back (2)
7	220 – 475 L/min	Polyamide fabric coated with PVC on both sides.	Gas tight, downward closing, chloroprene rubber coated zipper with splash guard.	Bayonet glove ring system	180°	Back of hood (4)
8	220 – 475 L/min	Antistatic butyl rubber with Viton® on top.	Gas tight, downward closing, chloroprene rubber coated zipper with splash guard.	Bayonet glove ring system	180°	Back of hood (4)
9	78 – 702 L/min	PVC-coated fabric	Downward closing, fitted vertically on right hand side	Tape	>300°	Back of hood (4)