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Cycle Development of Vaporized Hydrogen Peroxide (VHP) Under Room Exhaust Conditions in the CL3 Laboratory

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Learning Outcomes

1. Develop effective VHP decon cycle evolving beyond current industry practices
2. Identify requirements for validation of VHP decon under slight exhaust conditions
3. Conduct VHP validation under slight exhaust conditions
4. Establish trim valve and exhaust settings to be programmed in at the push of a button

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Objective

- To establish the parameters of a VHP decon cycle that can be run during hours of normal business operation under slight room exhaust

Introduction

VHP decontamination advantages:

- excellent material compatibility;
- carried out at low temperature, ambient pressure;
- results in non-toxic by-products

Four (4) phases of VHP run

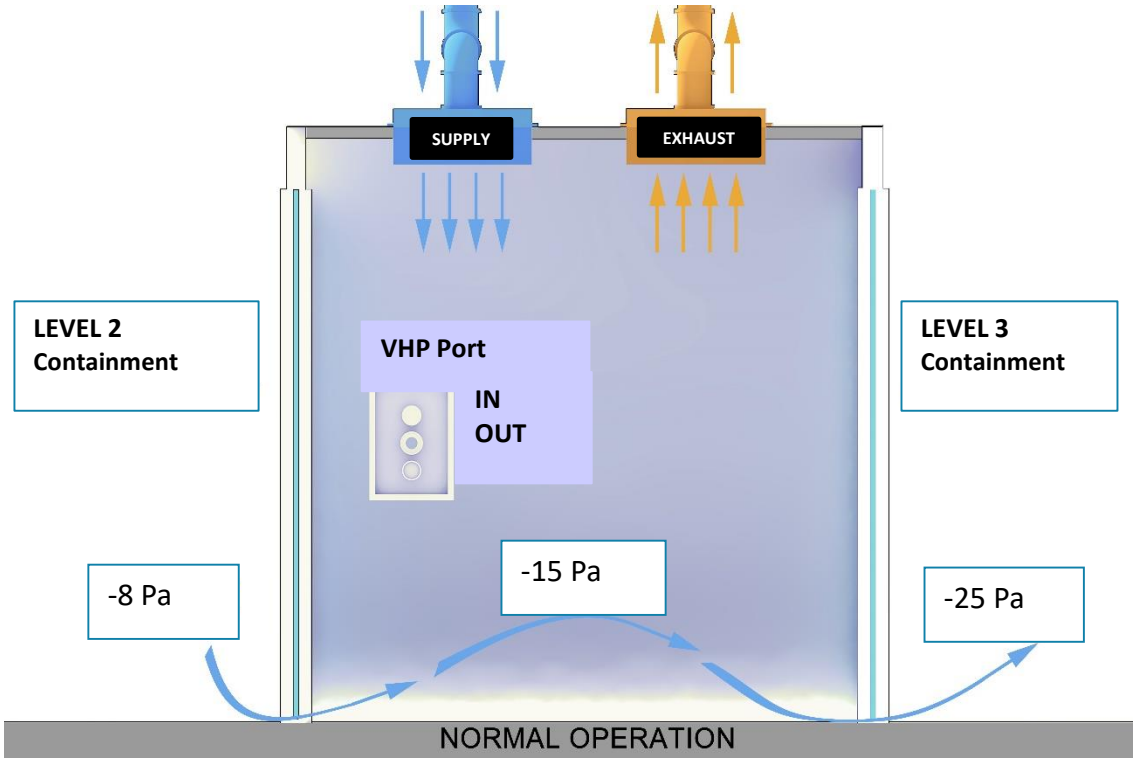
1. dehumidification
2. conditioning
3. decontamination
4. aeration

Background

- A 350ft^3 decon room on the perimeter of the CL3 equipped with a trim valve

- Trim valve allows small amount of VHP to exhaust
  - inward directional airflow maintained
  - VHP leak into adjacent space prevented
- PHOL strives to evolve beyond current practice
  - establish decon method that may safety be run during business hours with minimal impact to CL3 operations

NORMAL Operation



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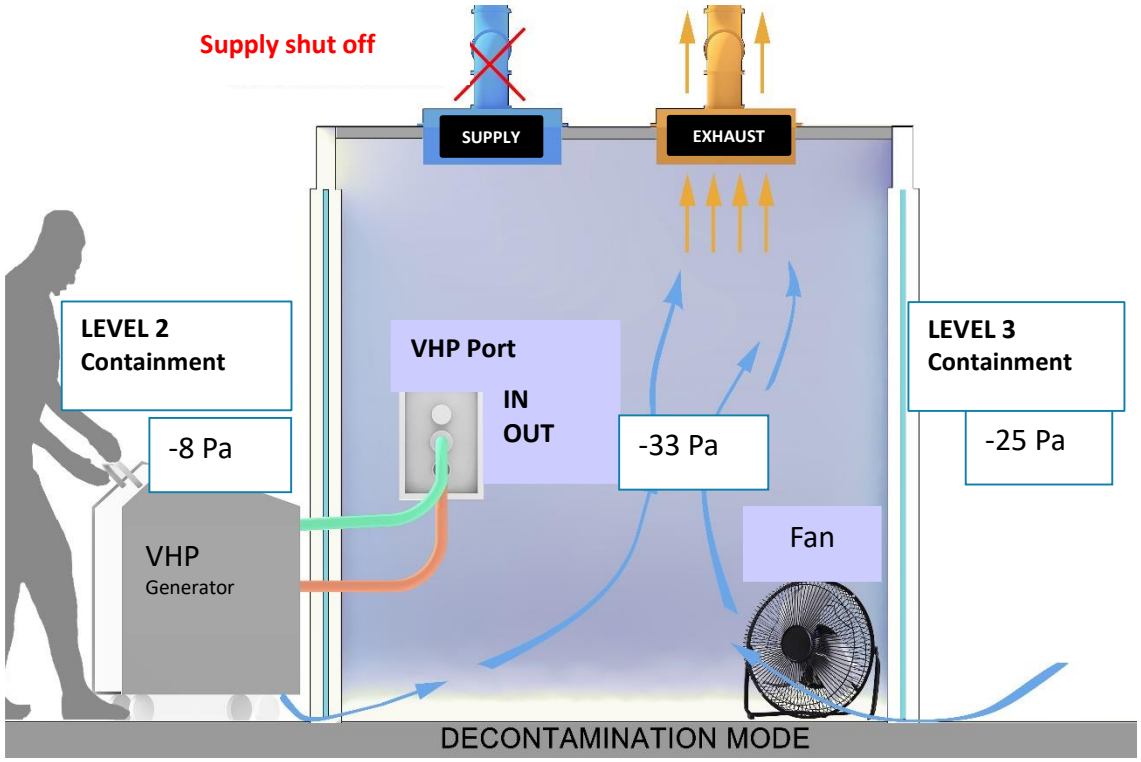
DECON Mode



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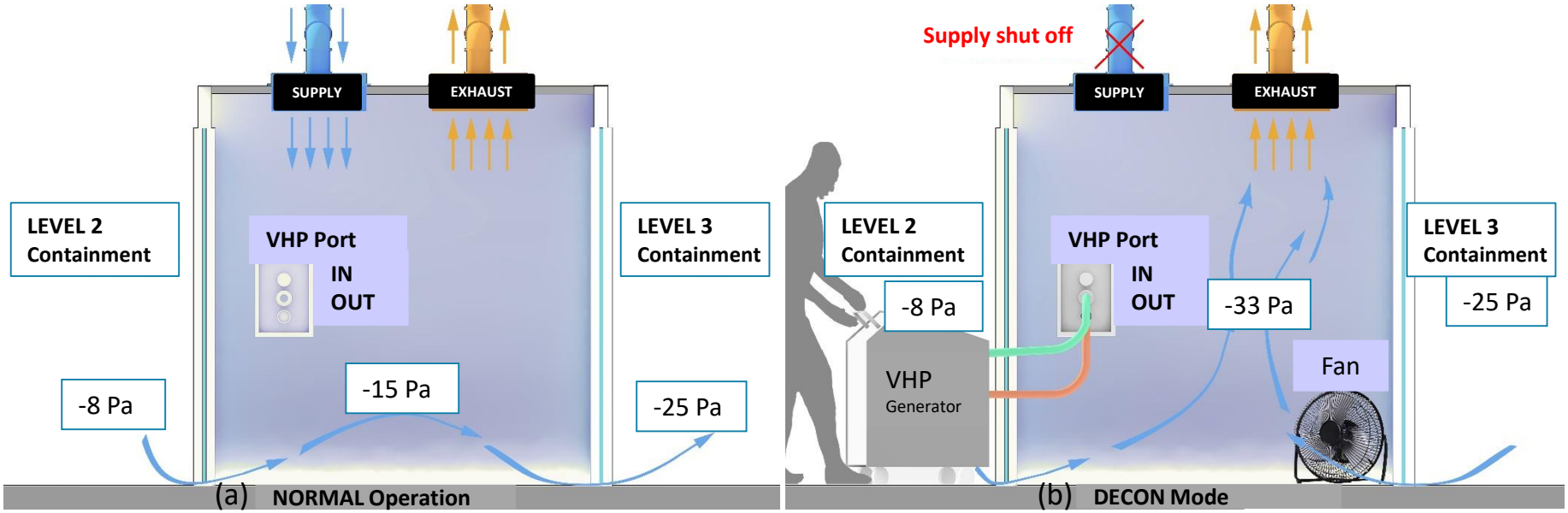
NORMAL vs. DECON Modes



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Materials

- Steris VHP 1000ARD

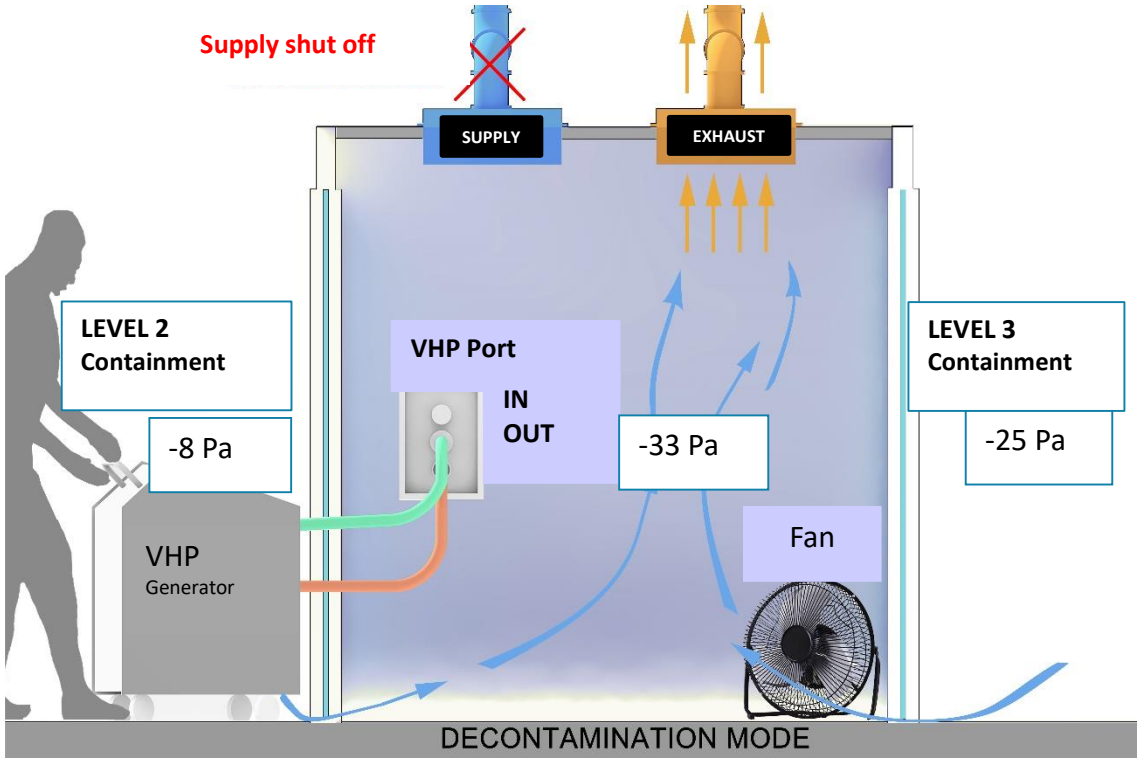
- Vaprox 35% H_2O_2
- Chemical Indicators (CI)
- Biological Indicators (BI) and media tubes
- Drager H_2O_2 Monitor (ppm)
- Triscale sensor
  - Enclosure temp.
  - % relative humidity
  - Vaprox [H_2O_2]

Methods

- Port VHP generator to decon room
- Inlet/return ports in room mismatched to generator fittings
  - VHP generator using 35% H_2O_2 installed inside decon room

Methods

Decon room settings were programmed as shown:



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Methods

- Eight (8) BI and 8 CI were placed in 'worst case scenario' locations

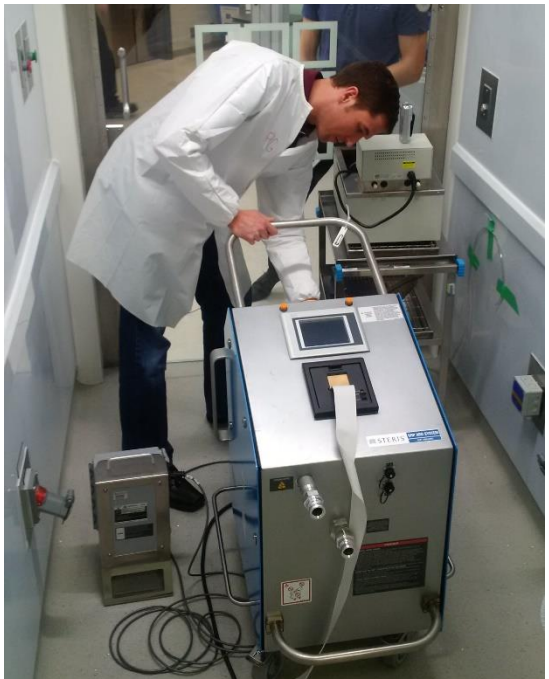
Indicator	Location
1	Rear upper right wall (near room exhaust)
2	Right wall centre
3	Front lower right wall
4	Front wall centre
5	Front upper left wall (near equipment for decon)
6	Left wall centre
7	Rear lower left wall
8	Rear wall centre

- BI - validate sterility assurance level (SAL)
- CI - demonstrate VHP distribution
- One fan was included for maximum VHP mixing

Methods

Four VHP runs were performed:

- 1st run to develop initial parameters, test integrity of decon room for leakage, assess VHP distribution with CIs;
- runs 2 and 3 to revise cycle parameters;
- 4th run to establish final cycle parameters



Methods

Cycle development considered complete when:

1. all cycle parameters are determined;
2. SAL validation process demonstrates a 6 log reduction of *G. stearothermophilus* spores;
3. final VHP concentration level of ≤1 ppm;
4. when the cycle is reproducible

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Run 1 – Initial Cycle Parameters

- Initial parameters calculated using manufacturer's instructions[1]
- Room isolated from HVAC system
- CIs used, no [VHP] monitoring as cable was unavailable

Parameter/ Phase	Dehumidifi -cation	Condition- ing	Decontami- nation	Aeration	Extended Aeration
Time, hh:mm	00:10	00:05	00:30	00:05	As needed
Airflow, SCFM	20	20	20	20	Variable
Injection Rate, g/min	n/a	11.0	3.5	n/a	n/a
Humidity, mg/L	9.6	n/a	n/a	n/a	n/a

[1] VHP Cycle Development Guide (Steris Corp. Mentor OH)

Run 1 – Results

- Cycle started normally
- Significant leakage at CL3 door latch @ 10 min into decon phase -> run was aborted
- CIs showed adequate colour change

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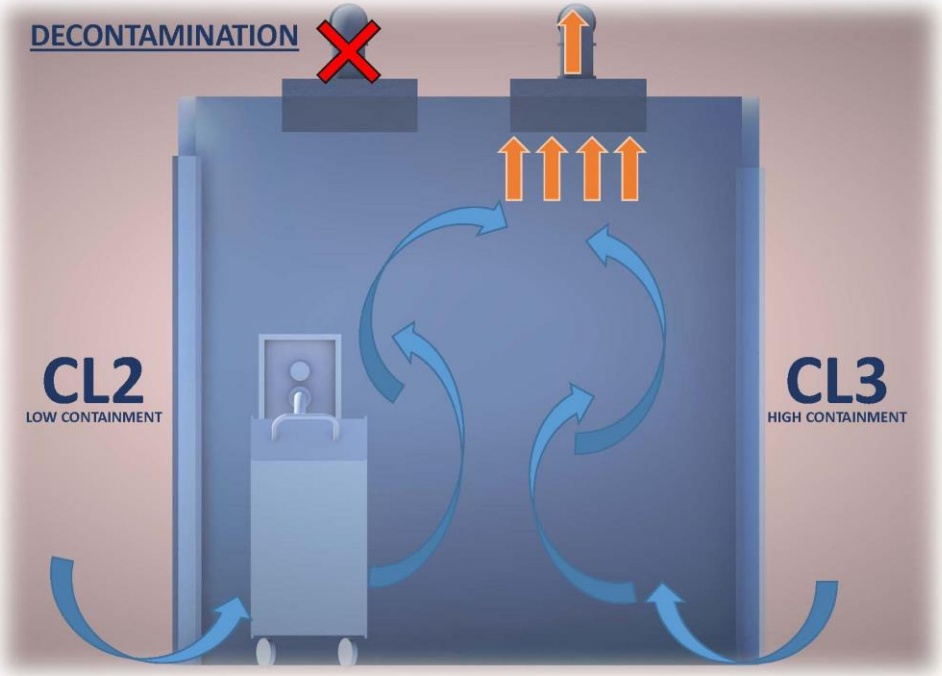
Run 2 – Revised Cycle Parameters

- CIs and [VHP] monitoring
- Triscale sensor placed on decon room floor next to ARD
- Room adjusted to run at slight –ve pressure
- No change in cycle parameters from run 1



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Run 2 – Results

- Dehumidification phase -- easily reached 5.5 mg/L humidity, humidity target lowered from 9.6 to 6.9 mg/L for next runs
- Conditioning phase -- [VHP] = 205 ppm by end
- Decon phase -- [VHP] peaked at 800 ppm @ 22 min into phase
  - *Condensation* noted on CL3 door, [VHP] decreased and settled at 750 ppm by end of phase
- Aeration phase -- residual VHP = 1.5 ppm @ 2 hours in
- CIs well turned, CI closest to decon room exhaust was slightly less turned

Note on condensation

- Condensation of VHP has –ve consequence on material
- B.P. of H_2O is 100°C and H_2O_2 is 150°C
- H_2O will boil off before H_2O_2
- H_2O_2 will condense out in more concentrated form

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Run 3 – Revised Cycle Parameters

- Dehumidification phase lowered from 9.6 to 6.9 mg/L
- Conditioning phase ↑ from 5 to 10 min; injection rate ↓ from 11 to 10 g/min
- Decon phase time ↑ from 30 to 40 min; injection rate ↓ from 3.5 to 3.2 g/min
- CIs and [VHP] monitoring; decon room under slight –ve pressure

Parameter/ Phase	Dehumidifi -cation	Conditioni ng	Decontami- nation	Aeration	Extended Aeration
Time, hh:mm	00:10	00:10	00:40	00:05	As needed
Airflow, SCFM	20	20	20	20	Variable
Injection Rate, g/min	n/a	10.0	3.2	n/a	n/a
Humidity, mg/L	6.9	n/a	n/a	n/a	n/a

Run 3 – Results

- Cycle started normally
- Conditioning phase -- [VHP] = 470 ppm by end
- Decon phase -- Condensation noted on CL3 door @ 12 min into phase, [VHP] = 940 ppm
  - Injection rate lowered to 3.0 g/min and [VHP] settled to 750 ppm
  - @24 min into phase, injection rate returned to 3.2 g/min
- Run completed with no issues…. but….
- Aeration phase -- residual VHP = 4.2 ppm @ 3 hours in
- CIs well turned

Run 4 – Final Cycle Parameters

- Conditioning phase ↓ from 10 to 8 min
- Decon injection rate ↑ from 3.2 to 3.5 g/min
- CIs, BIs and [VHP] monitoring; decon room under slight –ve pressure
- Water bath on cart placed in decon room with own BI

Parameter/ Phase	Dehumidifi -cation	Conditioni ng	Decontami- nation	Aeration	Extended Aeration
Time, hh:mm	00:10	00:08	00:40	00:05	As needed
Airflow, SCFM	20	20	20	20	Variable
Injection Rate, g/min	n/a	10.0	3.5	n/a	n/a
Humidity, mg/L	6.9	n/a	n/a	n/a	n/a

Run 4 – Results

- Cycle proceeded w/o issue
- Decon phase-- Some condensation noted on CL3 door @ 10 min into phase, subsided throughout rest of run
- Aeration phase -- residual VHP = 1.2 ppm @ 2 hours in
- CIs well turned
- BIs collected, transferred to media vials, incubated at 55-60°C for 7 days
  - No BI showed growth at 7 days

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Chemical indicators (CI)

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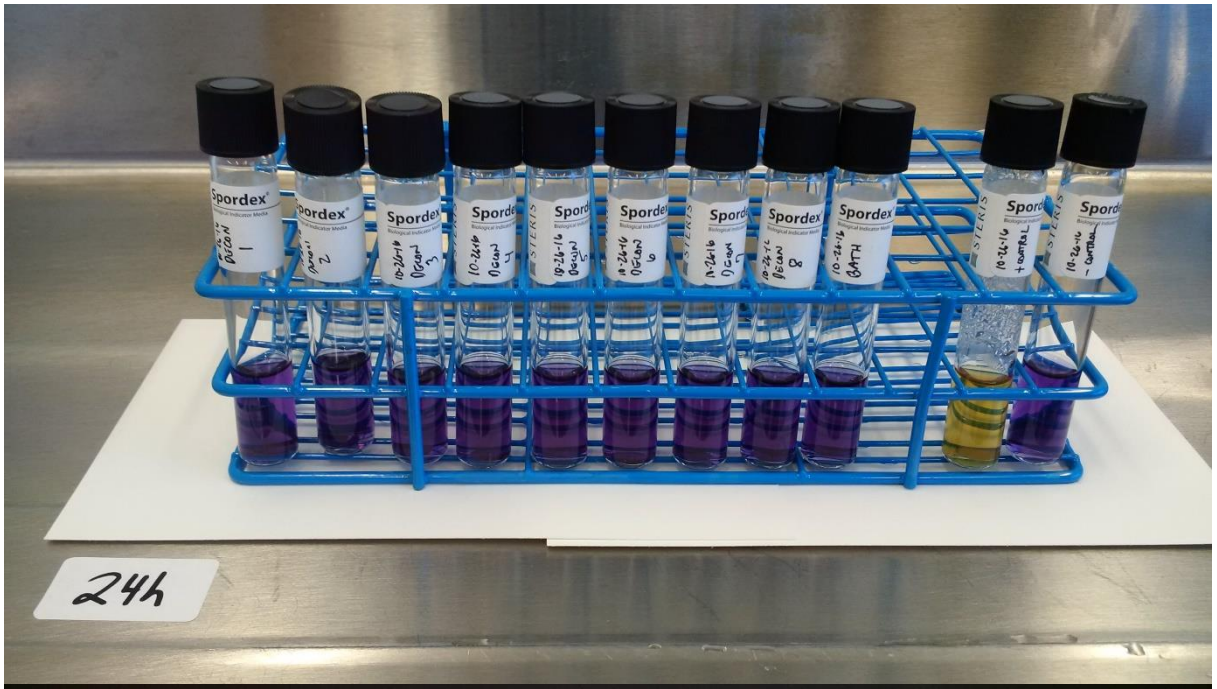
Biological Indicators (BI)



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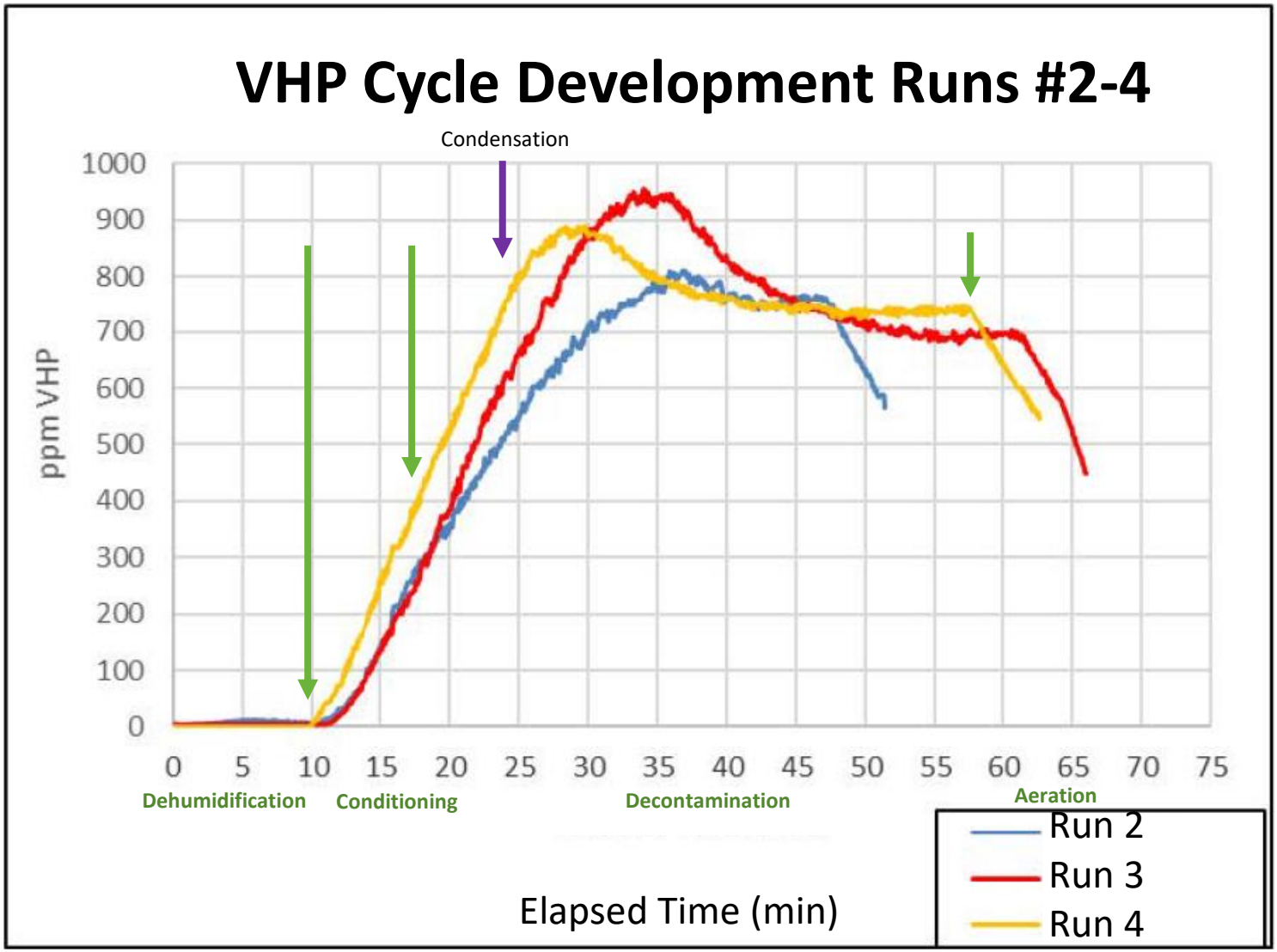
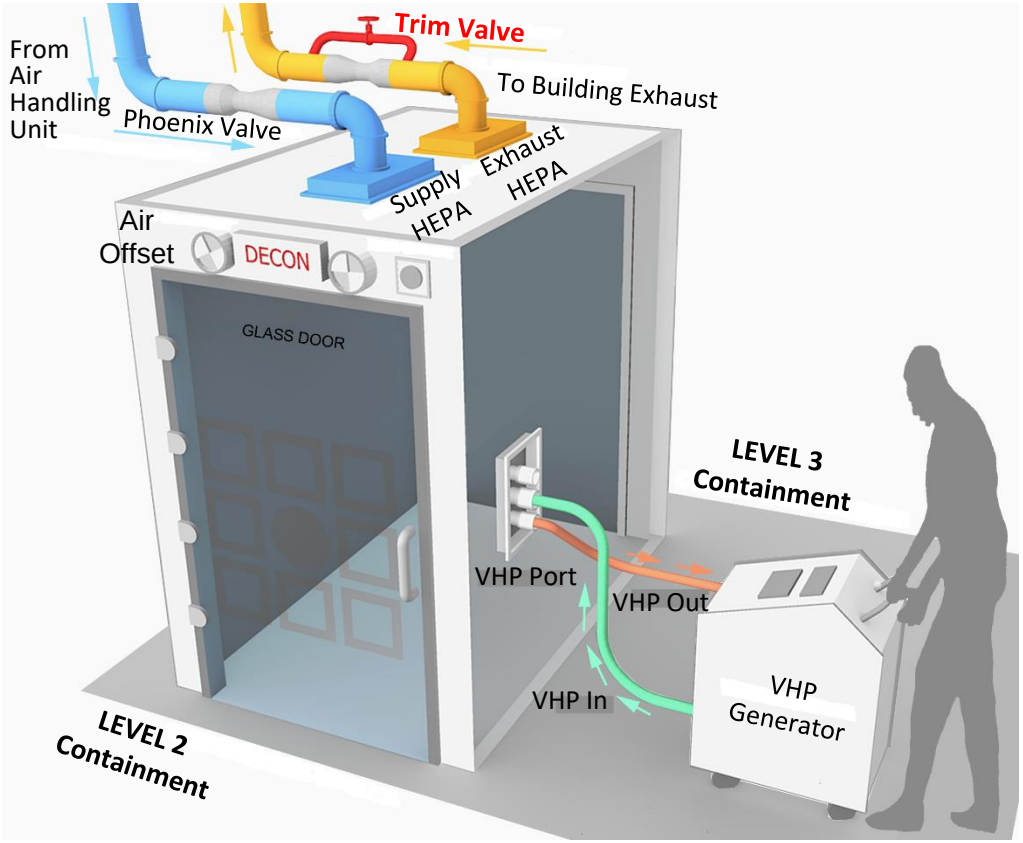

VHP Cycle Development Runs #2-4
Condensation
ppm VHP
1000
900
800
700
600
500
400
300
200
100
0
0 5 10 15 20 25 30 35 40 45 50 55 60 65 70 75
Dehumidification
Conditioning
Decontamination
Aeration
Elapsed Time (min)
Run 2
Run 3
Run 4

Discussion

- SAL validation did pass with the current room set-up

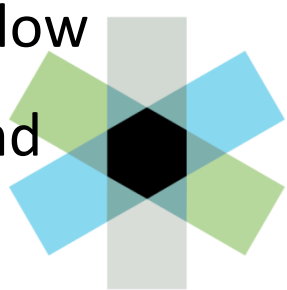
- VHP generator inside decon room not consistent with the intended use of decon space
- Further runs required once correct size of inlet/return ports are installed
  - verify cycle parameters and reproducibility with typical airflow and VHP mixing

Intended set-up of decon room



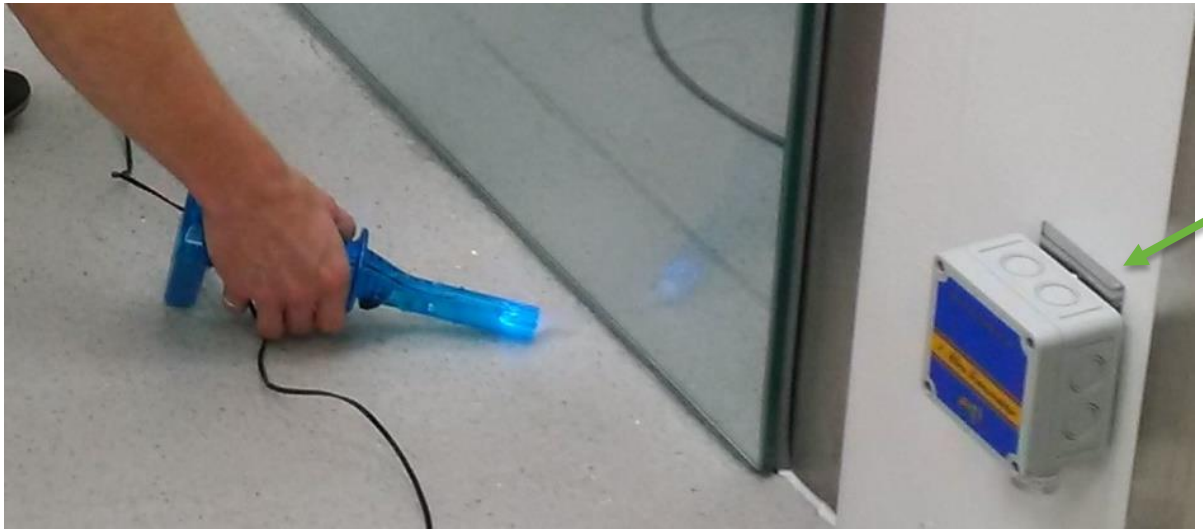
Safety notes

- VHP sensors strategically installed and connected with the Building Automation System (BAS)
  - Two VHP sensors permanently installed in decon room to monitor [VHP] on the BAS throughout a run
- Triscale sensor connected to the generator to monitor real-time [VHP]
- Trim valve setting maintains inward directional airflow
- If VHP leaks outside of decon room, alarm will sound (audible and visual), alerting user to abort run



Decon mode

- Smoke pencil demonstrating inward direction airflow when room in decon mode setting



VHP sensor connected with the BAS

Conclusions

- Validation of decon technologies and procedures in containment labs is essential to ensure effective decon of infectious material

- Although successful in decon and safety, cycle parameters developed here require optimization when generator is ported to the decon room as originally designed

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Acknowledgements

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