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Cycle Development of Vaporized Hydrogen Peroxide Decontamination Under Negative Room Exhaust Conditions in Containment Level 3 Laboratory

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Abstract

Introduction: The cycle parameters for vaporized hydrogen peroxide (VHP) decontamination were developed under negative room exhaust conditions. A 350ft^3 decontamination (decon) room is situated on the perimeter of our containment level (CL) 3 laboratory. Operation of VHP under a slight exhaust will facilitate the process of safely running VHP during normal business hours without compromising laboratory testing activities.

Method: The set-point and control of the trim valve on the decon room was adjusted throughout VHP cycle development so that air will move into the decon room from the adjacent spaces and out of the facility through the trim valve during a VHP cycle.

Results: Four VHP cycles were run, fully turning all chemical and biological indicators in three runs. Non-typical airflow and VHP mixing inconsistent with the envisioned use of the decon room was observed.

Conclusions: The VHP decon cycle development was successful; however, continual adjustment and further runs are required once all hard-ware is available.

Objective

The aim of this work was to establish the parameters of a VHP decontamination cycle that can be run during hours of normal business operation under slight room exhaust.

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Introduction

VHP decontamination is a preferred method as it has excellent material compatibility, can be carried out at low temperature and ambient pressure, and results in non-toxic by-products. A VHP run typically consists of 4 phases: dehumidification; conditioning; decontamination; and aeration.

A 350ft^3 decon room is situated on the perimeter of the CL3 at Public Health Ontario Laboratory (PHOL). The decon room is equipped with a trim valve to allow a small amount of VHP to exhaust from the room while ensuring inward directional airflow and preventing leakage of VHP into adjacent space (Fig. 1). With this design, PHOL strives to evolve beyond current procedures to establish a decontamination method that may safety be run during normal hours of operation while the CL3 lab is in use.

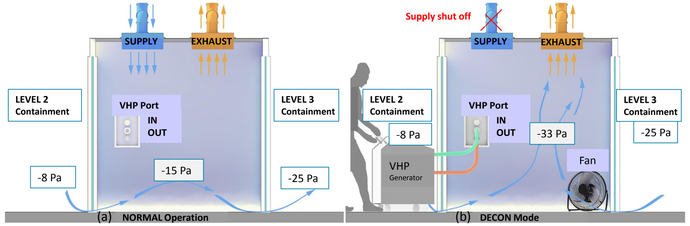


Figure 1. Decon room in (a) normal operation (b) decontamination mode

Materials and Methods

As the inlet/return ports in the room were mismatched to the generator fittings, the VHP generator using 35% H_2O_2 was installed in the decon room as shown in Fig. 2. Decon mode room settings were programmed (Fig. 1b).

Eight biological (BI) and chemical (CI) indicators were placed in worst case locations, to validate sterility assurance level (SAL) and demonstrate VHP distribution, respectively. One fan was included for maximum VHP mixing.

Four VHP runs were performed: run 1 to develop initial parameters; runs 2 and 3 to revise parameters; and run 4 to establish final cycle parameters. Cycle development will be 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.

Figure 2.
Decon room with VHP generator and fan

Results

Initial parameters were calculated using the manufacturer's instructions[1]. Cycle 1 was run at ambient pressure (Table 1). At 10 min into the decontamination phase, significant leakage was detected on the CL3 side at the door latch. The run was aborted. CIs showed adequate colour change.

The room was set to decon mode. Cycle 2 was run as per Table 1. Condensation was noted on the CL3 door at 22 min into the decon phase. Two hours of extended aeration resulted in a VHP residual reading of 1.5 ppm. The CIs were well turned.

Parameter \ Phase	Dehumidification	Conditioning	Decontamination	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

Table 1. Initial cycle parameters for runs 1 and 2

The third run with revised parameters was run (Table 2). Condensation was noted on the CL3 door at 12 min into the decon phase. The VHP residual was 4.2 ppm after 3 hours of extended aeration. The CIs were well turned.

Parameter \ Phase	Dehumidification	Conditioning	Decontamination	Aeration	Extended Aeration
Time, hh:mm	00:10	00:10	00:40	00:05	00:00
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

Table 2. Revised cycle parameters for run 3

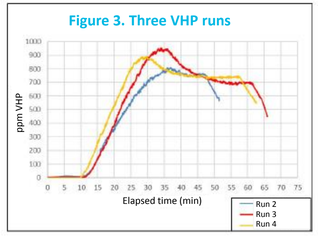
BIs and CIs were included in the final run (table 3). Condensation was noted at 10 min into the decon phase which subsided throughout run. At 2 hours of extended aeration, the VHP residual was 1.2 ppm. CIs were well turned. BIs were incubated at 55-60° C for 7 days with positive and negative controls. No BIs showed growth.

Parameter \ Phase	Dehumidification	Conditioning	Decontamination	Aeration	Extended Aeration
Time, hh:mm	00:10	00:08	00:40	00:05	02:00
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

Table 3. Final cycle parameters, run 4

The three full cycle runs are depicted in Figure 3.

Figure 3. Three VHP runs



Discussion

The placement of the VHP generator in the decon room was not consistent with the intended use of the space. Once the correct size of inlet/return ports are installed further runs will be needed verify cycle parameters and reproducibility with typical airflow and VHP mixing as shown below in Figure 4.

The SAL validation passed with the current room set-up.

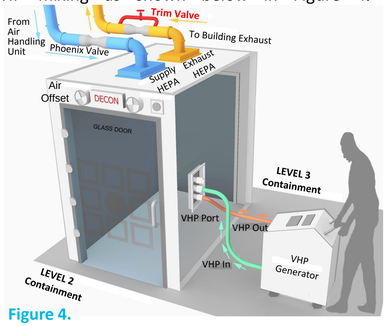


Figure 4.
Intended set-up of Decon room

To ensure safety of staff in the labs, VHP sensors were strategically installed and connected with the Building Automation System (BAS). The trim valve setting maintains inward directional airflow (Fig. 5). Should VHP leak outside of the decon room, an alarm will sound, and the user will be alerted to abort the run. Additionally, a Triscale sensor is connected to the generator to monitor real-time [VHP] along with two VHP sensors permanently installed in the decon room to monitor [VHP] on the BAS throughout a VHP decon run.

Figure 5.
Smoke pencil demonstrating inward direction airflow when room in decontamination mode setting

Conclusions

Validation of decontamination technologies and procedures in containment laboratories is essential to ensure effective decontamination of infectious material. Although successful in terms of both decontamination and safety, the cycle parameters developed in this investigation will require optimization once the generator is ported to the decon room as per the original design.

References

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

Acknowledgements

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