

Fogging and Misting Shower Performance for Reduction of Exposure During Protective Clothing Removal

Martin Axon

Principal Occupational Hygienist

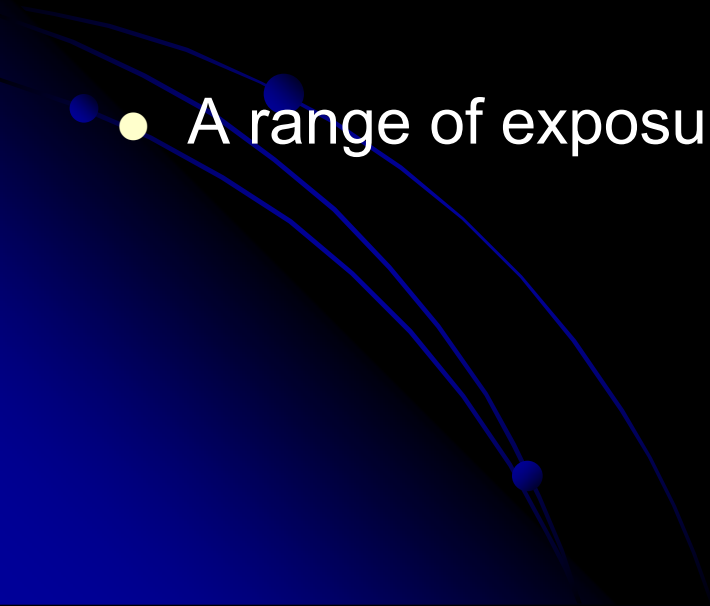
SafeBridge Europe, Limited

Mountain View, CA • New York, NY • Europe (UK)

www.safebridge.com

In collaboration with PBSC Ltd and Eisai Inc.

Background to Project

- Pharmaceutical industry handles active pharmaceutical ingredients (APIs) designed to cause a physiological effect if absorbed by the body.
 - APIs that cause effects at low doses may be considered “occupationally potent”
 - A range of exposure controls can be applied
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Layers of Control

- Layers of control can include:
 - Primary control at source
 - Secondary control – a contained facility
 - Tertiary controls - personal protective equipment (PPE)
 - This PPE will often include a disposable coverall
 - Administrative controls – e.g. procedures and techniques – applies to all controls

Primary Control



- Example 1 - materials with OELs ranging from 5,000 – 100 $\mu\text{g}/\text{m}^3$ can potentially be controlled by local exhaust ventilation.
- Example 2 - materials with OELs below 10 $\mu\text{g}/\text{m}^3$ usually require contained operations (isolators, contained transfer systems etc. are recommended).

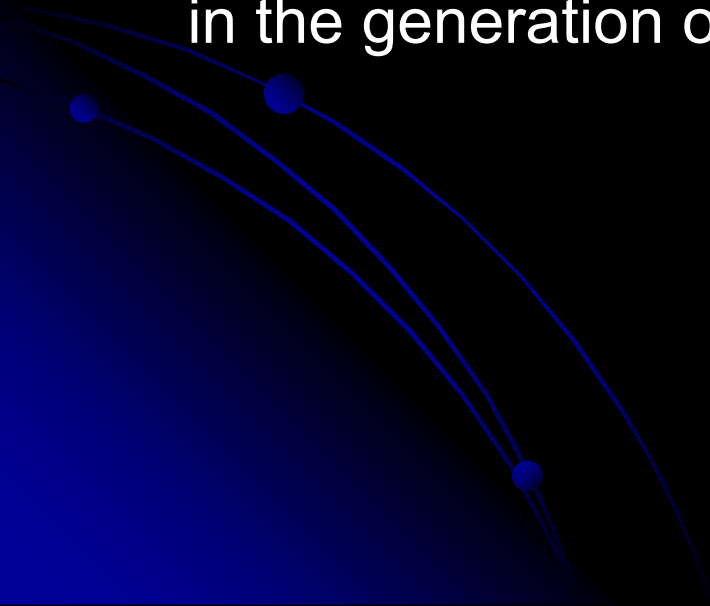
Secondary Control

- Secondary control can be provided by the facility and may include:
 - Processing room under negative pressure
 - Dilution ventilation and directional airflow
 - HEPA filtration of process room air, no recirculation
 - Airlock and changing room
 - Decontamination shower
 - Moved away from air shower installations beginning in 1990s

Combination Shower



Tertiary Control

- Personal protective equipment (PPE)
 - Disposable coverall and maybe other PPE
 - As the operator/s leave the process suite the PPE will be removed
 - If contaminated with API, removal of the PPE will result in the generation of airborne API
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Disposable Coverall

Tyvek 'Classic'



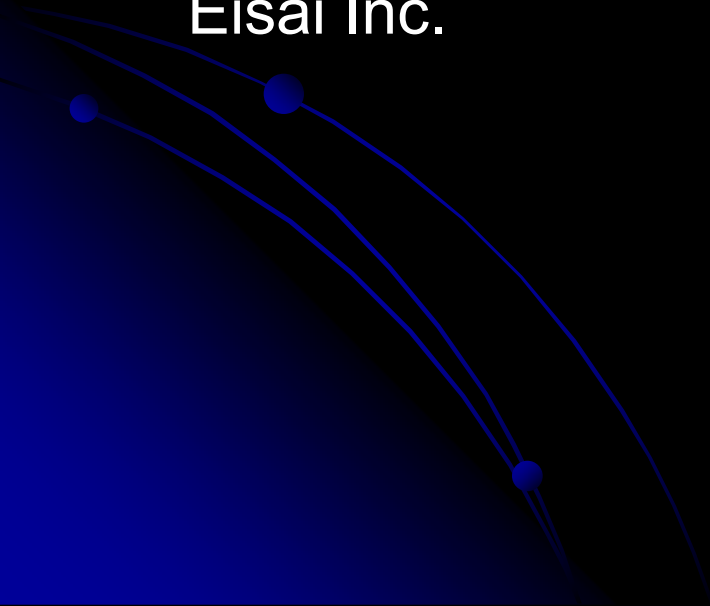
Washable Coverall Combination

Washable polyester suit
and PAPR



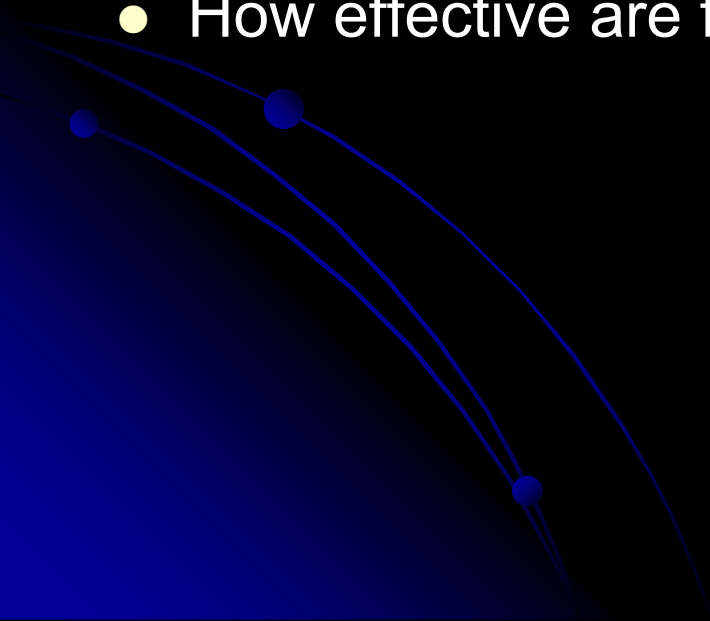
Evaluation of Shower Effectiveness

- Concept for fogging and misting showers presented at a Pharmaceutical Safety Group meeting in the early 1990's.
- Opportunity arose to generate new data working in collaboration with a vendor (PBSC Ltd.) and their client Eisai Inc.



Operation of Fogging and Misting Showers

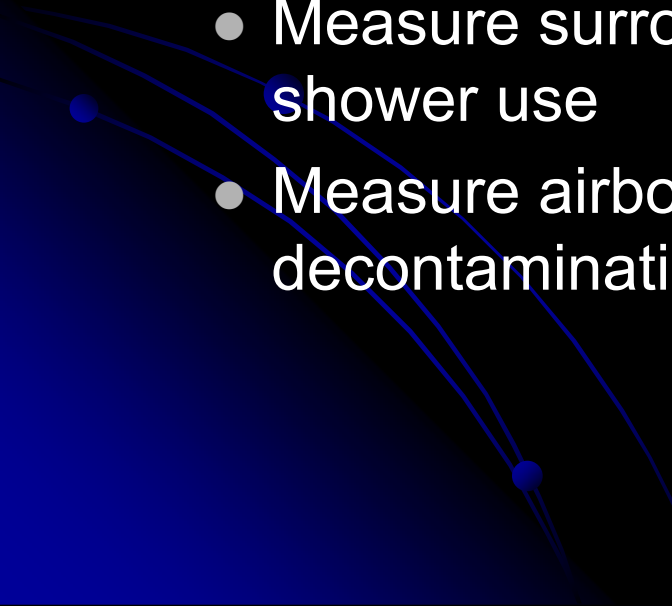
- Fogging shower - water droplets 5 – 10 μm diameter.
- Misting shower - water droplets 20 – 50 μm diameter.
- How effective are fogging/misting showers?



Objectives

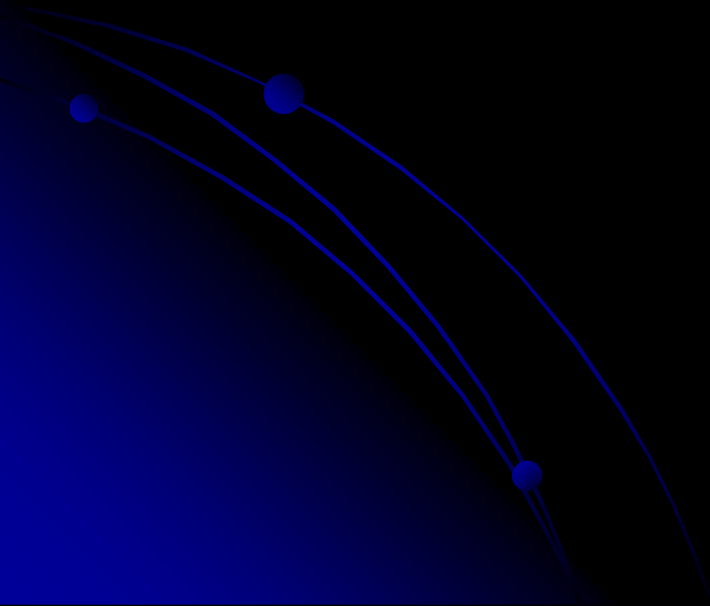
- Provide data on the decontamination effectiveness of a fogging and/or misting shower
- Evaluate the extent of decontamination of two types of suit
- Evaluate the suppression of airborne API powder during suit removal
- Overall – evaluate if effective to keep degowning area clean.

Develop Method

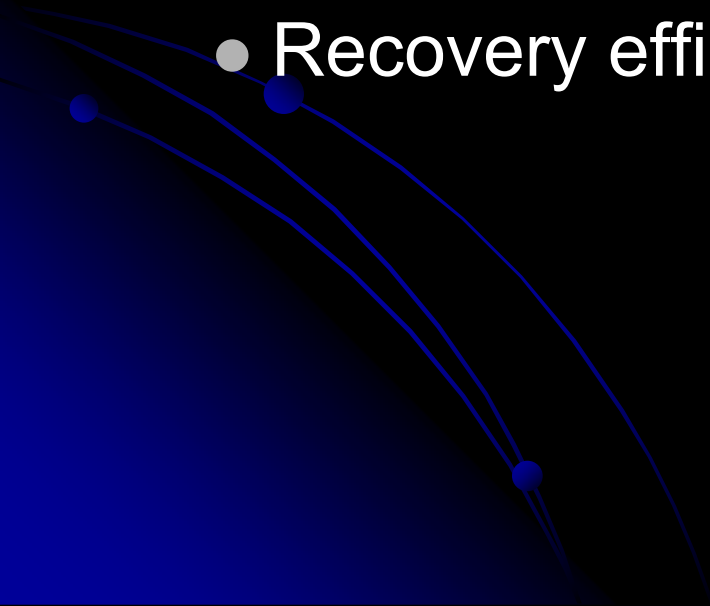
- How do you evaluate decontamination and airborne suppression?
 - Surrogate API used for safety
 - Before and after comparison
 - Artificially contaminate the suit
 - Measure surrogate on the suit before and after shower use
 - Measure airborne concentrations with and without decontamination
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Approach Used

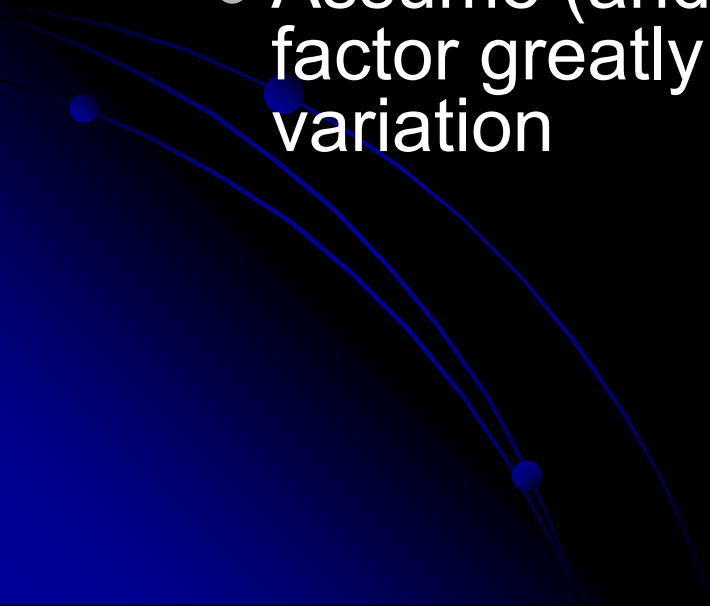
- Patches at defined locations
- Suits are artificially contaminated with a surrogate API
- Surrogate is applied to the patches while the suit is worn by an operator



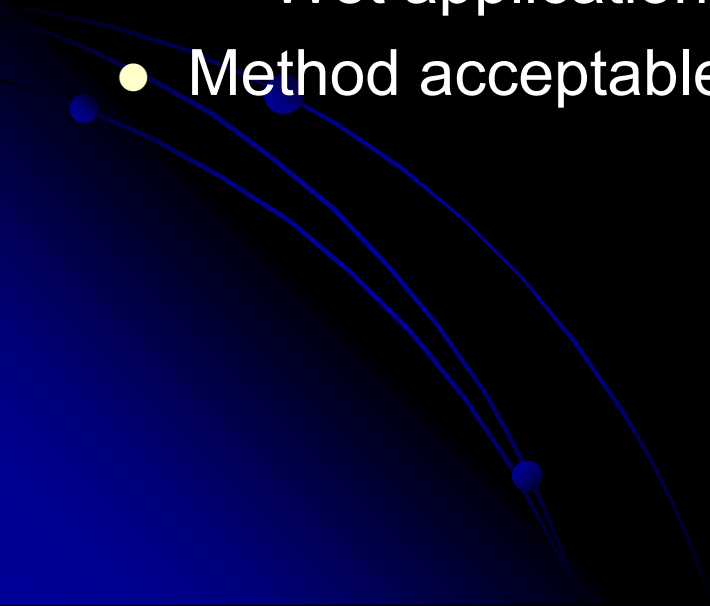
Challenges

- Amount applied to patch unknown
 - Amount applied to patch variable
 - Can't measure the actual amount applied before showering
 - Recovery efficiency?
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Solutions

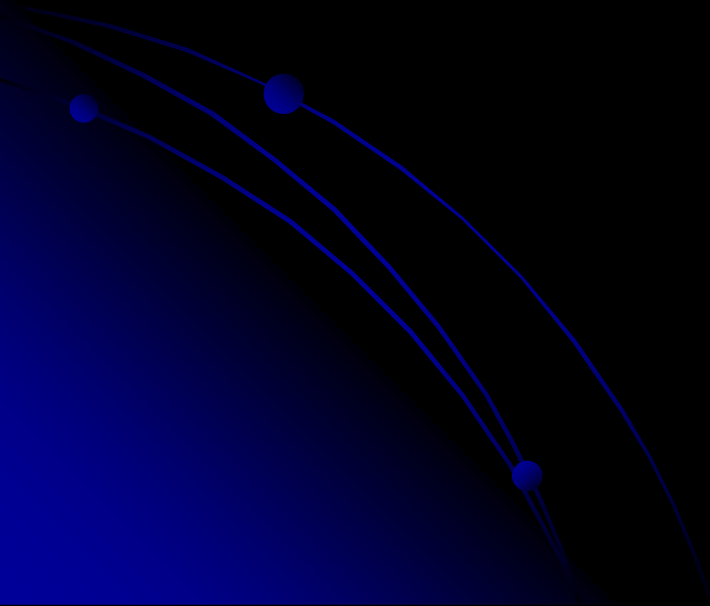
- Validate surface recovery efficiency
 - Apply surrogate to two sets of suits.
 - Measure first set before
 - Measure the second set after
 - Assume (and hope) that the decontamination factor greatly exceeds the application variation
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Results of Validation

- Method validation (air and surface) and analysis by SafeBridge AIHA accredited industrial hygiene analytical laboratory in California.
 - Dry and wet recoveries validated
 - Dry application: 11 – 84 mg, 67 – 109 % recovery
 - Wet application: 0.2 – 10 mg, 91 – 104 % recovery
 - Method acceptable
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Surrogate Application

- Same person throughout (except first evaluation – demonstration by SafeBridge occupational hygienist)
- Chest, knee, armpit, head, shoulder
- PAPR – side of head, bib

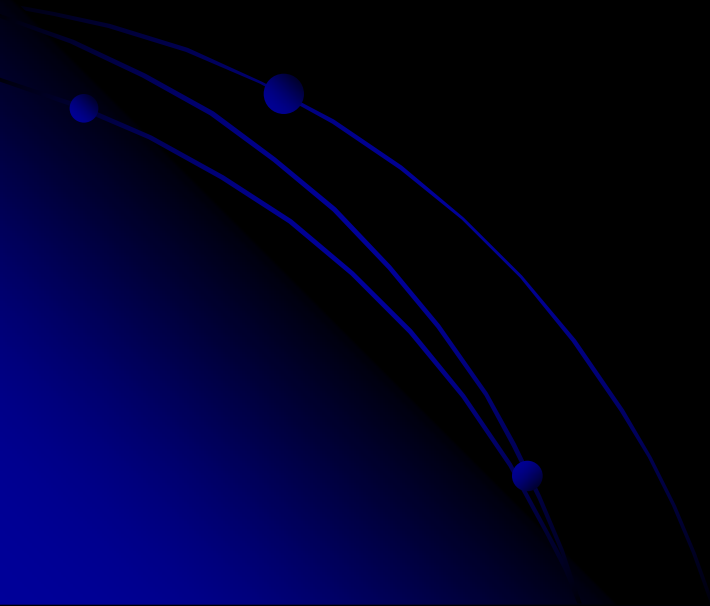


Patch Locations

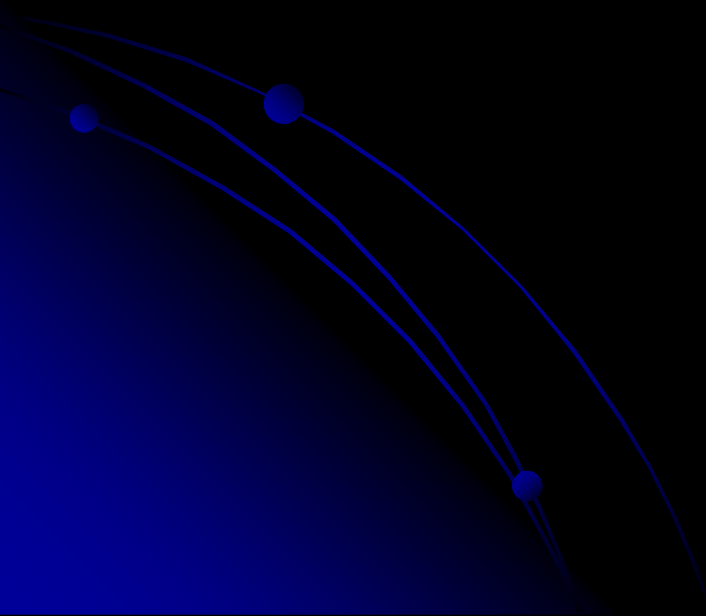


Surrogate Application

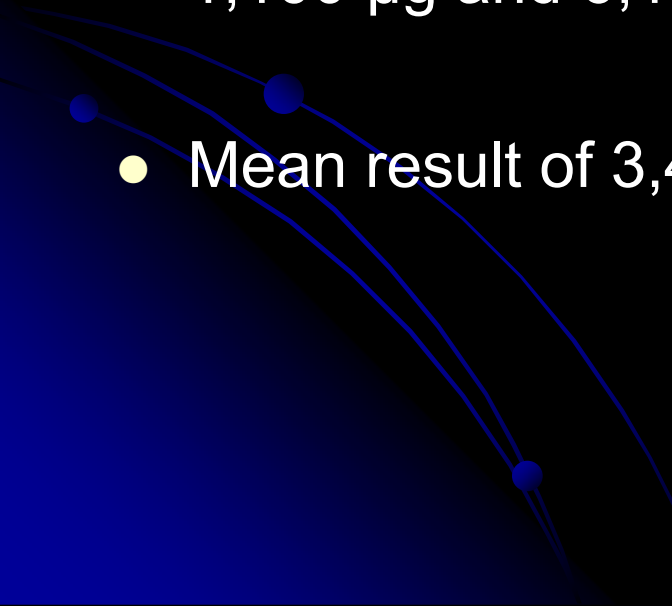
- VIDEO HERE



Removal of Patches



Results for Patch Application Recoveries

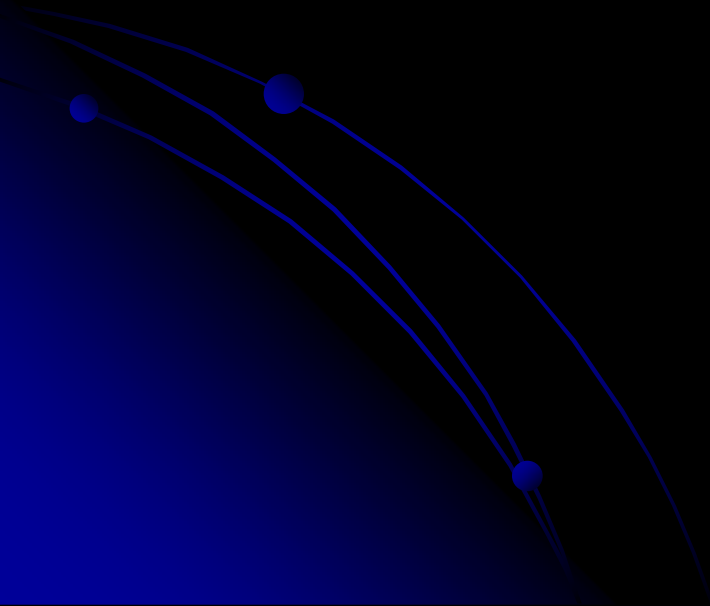
- Surrogate applied to patches while the suits worn by the “operators”.
 - The amount recovered from the patches ranged from 1,100 μg and 6,150 μg .
 - Mean result of 3,400 μg used
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Study Design - Variables Evaluated

- Two types of disposable suit material, plus PAPR
 - Tyvek or polyester
- Fogging/misting or fogging only
- Effect of operator position when showering
 - Direct or indirect
- Variables selected to meet clients objectives

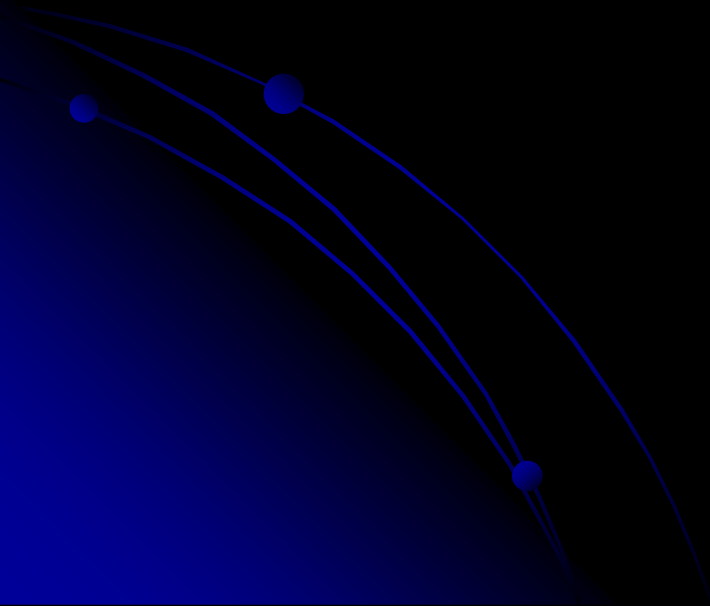
Study Design – Fixed Parameters

- Water shower
- Fogging – 30 seconds, 23 litres/hr
- Misting - 60 seconds, 228 litres/hr
- Operator movements in shower
- Patch locations, defined body locations



Showering Technique

VIDEO TO GO HERE



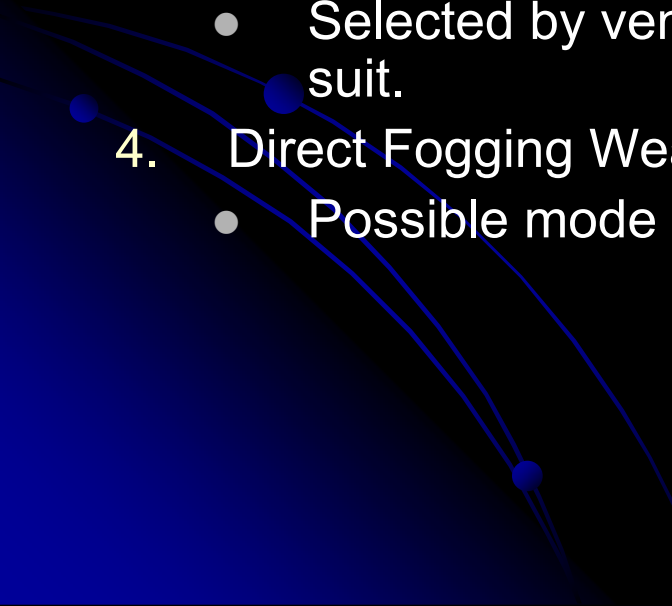
Suppression of Airborne API VIDEO



Results – Air Monitoring

- Without Showering – Tyvek Ensemble
 - Overall, area and personal samples in change cubicle (n=14), **mean = 88.6 $\mu\text{g}/\text{m}^3$** , range = 19 – 349 $\mu\text{g}/\text{m}^3$.
- Without Showering – Washable Suit Ensemble
 - Overall, area and personal samples in change cubicle (n=14), **mean = 54.4 $\mu\text{g}/\text{m}^3$** , range = 21.4 – 249 $\mu\text{g}/\text{m}^3$.
- No difference statistically, **mean = 72 $\mu\text{g}/\text{m}^3$**

Test Modes for Airborne Suppression

1. Direct Fogging/Misting Wearing Tyvek
 - Selected by vendor - most likely mode of operation for potential customers.
 2. Direct Fogging/Misting Wearing Washable Suit
 - Anticipated mode of shower use by Eisai
 3. Indirect Fogging Wearing Tyvek
 - Selected by vendor - worst case conditions for most popular suit.
 4. Direct Fogging Wearing Washable Suit
 - Possible mode of shower use by Eisai
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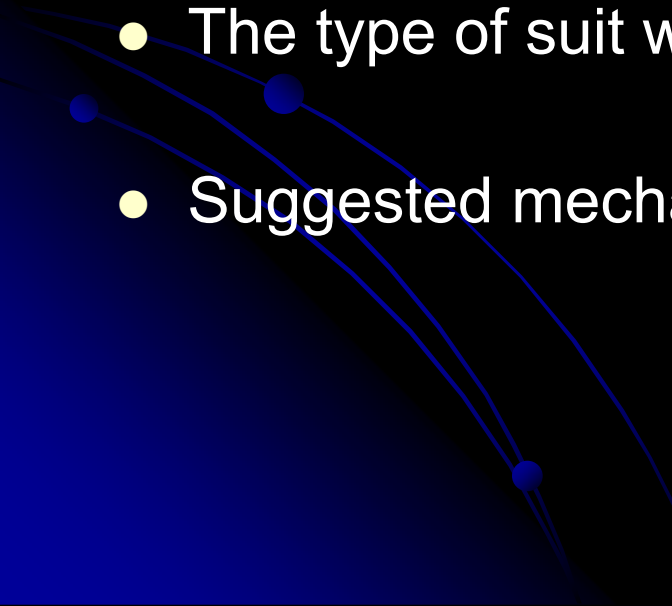
Airborne Results After Showering

- Mean result without showering – 72 $\mu\text{g}/\text{m}^3$.
- 1. Direct fogging/misting wearing Tyvek
 - Mean result < 0.09 $\mu\text{g}/\text{m}^3$.
- 2. Direct fogging/misting wearing washable suit
 - Mean result < 0.1 $\mu\text{g}/\text{m}^3$.
- 3. Direct fogging wearing washable suit
 - Mean result < 0.16 $\mu\text{g}/\text{m}^3$.
- 4. Indirect fogging wearing Tyvek
 - Mean result < 0.11 $\mu\text{g}/\text{m}^3$.

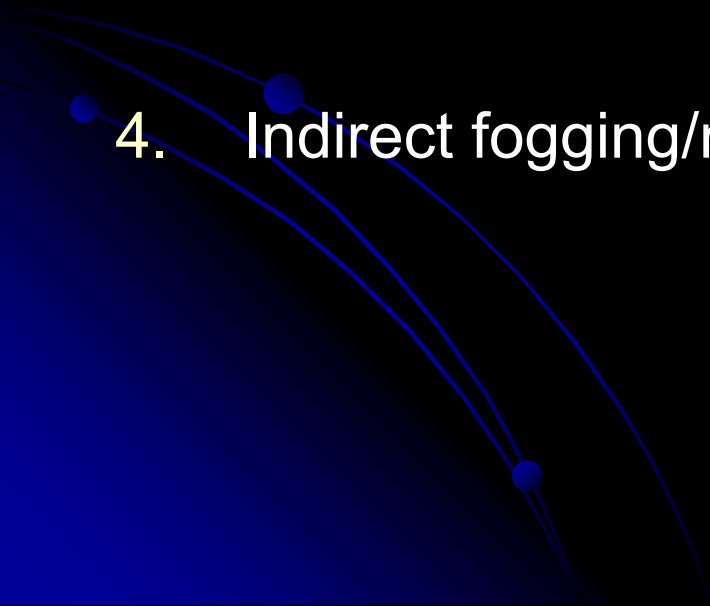
Summary of Suppression Results

1. Direct fogging/misting wearing Tyvek
 - Suppression > 800 times reduction
2. Direct fogging/misting wearing washable suit
 - Suppression > 730 times reduction
3. Direct fogging wearing washable suit
 - Suppression > 440 times reduction
4. Indirect fogging wearing Tyvek
 - Suppression > 640 times reduction

Conclusions for Suppression

- The shower appears to be very effective at suppressing airborne releases during removal of coveralls.
 - Shower mode doesn't appear to affect outcome
 - The type of suit worn doesn't appear to affect outcome
 - Suggested mechanism
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Test Modes for Decontamination

1. Direct fogging/misting wearing Tyvek
 2. Direct fogging/misting wearing washable suit
 3. Indirect fogging/misting wearing Tyvek
 4. Indirect fogging/misting wearing washable suit
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Decontamination Results After Showering

- Mean patch contamination before: 3,400 μg

1. Direct fogging/misting wearing Tyvek

- Mean patch loading 33 μg

2. Direct fogging/misting wearing washable suit

- Mean patch loading 11 μg

3. Indirect fogging/misting wearing Tyvek

- Mean patch loading 2,730 μg

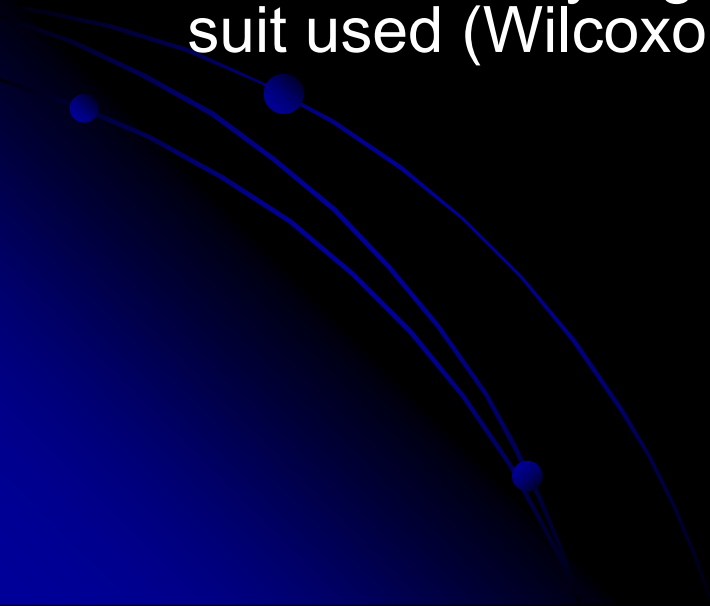
4. Indirect fogging/misting wearing washable suit

- Mean patch loading 442 μg

Summary of Decontamination Results

1. Direct fogging/misting wearing Tyvek
 - Decontamination: 104 times reduction
2. Direct fogging/misting wearing washable suit
 - Decontamination: 309 times reduction
3. Indirect fogging/misting wearing Tyvek
 - Decontamination: 1.3 times reduction
4. Indirect fogging/misting wearing washable suit
 - Decontamination: 8 times reduction

Conclusions for Decontamination

- The effectiveness of suit decontamination highly dependent on the shower mode (direct or indirect).
 - Unlike airborne suppression, for decontamination the operator needs to be in the direct path of the shower.
 - No statistically significant difference due to the type of suit used (Wilcoxon signed rank test).
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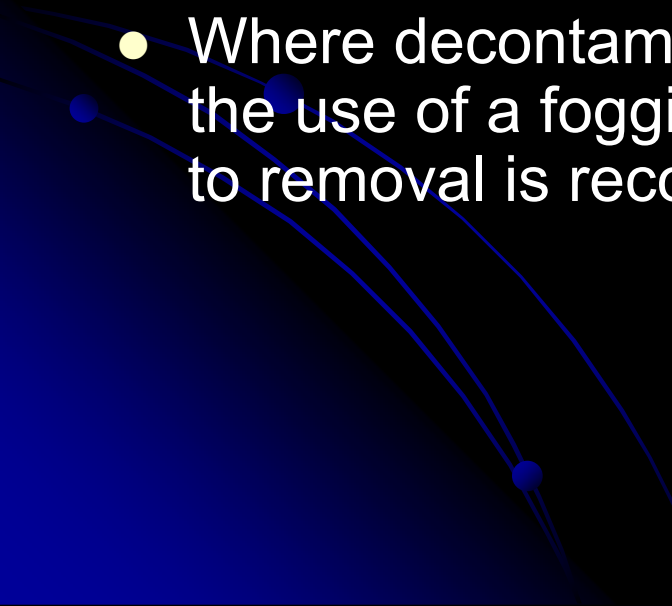
Other Findings

- Decontamination of PAPR
 - After direct f/m shower, mean = 380, range 0.5 – 2,240 μg (n = 6)
 - After indirect f/m shower, mean = 3,150, range 0.8 – 7460 μg (n = 6)
 - 8 times lower than the notional application when using direct f/m shower and 1.1 time lower than the notional application using indirect f/m shower
 - Fewer samples and highly variable results
- Water penetration of suits
 - Tyvek suit – some penetration in all shower modes except indirect fogging
 - Washable suit – no penetration observed in any mode

Summary of Findings

- The findings apply to the design of shower tested. They may not apply to other APIs, types of shower or suit material.
- Suppression of airborne API - no difference between shower type, mode of operation or type of suit worn.
- Decontamination - the use of misting/fogging shower in the direct mode appears to provide significant decontamination.
- PAPR decontamination was highly variable.
- Tyvek suits leaked in all modes except indirect fogging. Protected seam Tyvek suits are available.

Recommendations

- Based on this work, where there is the potential for a PPE ensemble to become contaminated during production operations the use of a fogging shower is recommended prior to removal to reduce the potential for airborne exposure to the API.
 - Where decontamination of a PPE ensemble is required the use of a fogging/misting shower, in direct mode, prior to removal is recommended.
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Limitations

- Shower is not a substitute for other controls
- Please refer to full report
 - Available from peterbloomer@pbsc.co.uk
- Seek advice prior to selecting shower

