Review of Necessary Practices for EPA Submission of a Hospital Disinfectant Using Good Laboratory Practice (GLP) Disinfectant Study Summaries of a Hospital Disinfection System

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Disclosures:
Tomi Environmental Scientific Advisory Board; Trinity Health System Employee
All Opinions are expressed are my own
**A New Approach:** The First EPA Registered Solution + Equipment Combination that Provides the Unique Technology of Hydrogen Peroxide Ionization called SteraMist™.

**The iHP™ Process:**

[Diagram of the iHP™ process]

The EPA registered 7.8% Hydrogen Peroxide BIT™ Solution converts to iHP™ after passing through an atmospheric cold plasma arc. iHP™ contains a high concentration of Reactive Oxygen Species (ROS) composed mostly of Hydroxyl Radicals. ROS damage pathogenic organisms through oxidation of proteins, carbohydrates, and lipids. This leads to cellular disruptions and/or dysfunction and allows for disinfection/decontamination in the targeted areas and large spaces.
The iHP™ Process

- The SteraMist™ converts the BIT™ solution into a Reactive Oxygen Species (ROS) after passing through an atmospheric cold plasma arc.
- \( H_2O_2 \) converted by plasma science.
- iHP™ contains a high concentration of Reactive Oxygen Species (ROS) composed mostly of Hydroxyl Radicals.
- Does not contaminate the environment with any toxic by-products.

All Hospital Disinfectants Must Be EPA Registered

All disinfectants and pesticides marketed for use in United States must meet safety requirements as described in OCSPP 810.2200, (1) Applicability.

It addresses testing to demonstrate the effectiveness of antimicrobial pesticides bearing claims as disinfectants, fungicides, virucides, and tuberculocides. (EPA 712-C-07-074)

<table>
<thead>
<tr>
<th>Organism</th>
<th>Study Title</th>
<th>Study Completion Date</th>
<th>EPA Product Performance Guidelines</th>
<th>EPA Product method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pseudomonas aeruginosa (ATCC 15442)</td>
<td>Efficacy of a Disinfectant Applied to a Room via a Fogging, Mist or Vaporizing Device for Disinfection AOAC Germicidal Spray Method</td>
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<td>Modified Method AOAC 961.02</td>
</tr>
<tr>
<td>Methicillin Resistant Staphylococcus aureus-MRSA (ATCC 33592)</td>
<td>AOAC Germicidal Spray Method</td>
<td>04 MAR 2015</td>
<td>OCSP8 B10.2200</td>
<td>Modified method AOAC 961.02</td>
</tr>
<tr>
<td>Clostridium difficile (C. diffl) spores (ATCC 43598)</td>
<td>Efficacy of a Disinfectant Applied to a Room via a Fogging, Mist or Vaporizing Device for Disinfection of C. difficile spores AOAC Germicidal Spray Method</td>
<td>16 SEP 2015</td>
<td>OCSP8 B10.2100</td>
<td>QCT2 Method: ASTM E2197. ASTM E2839</td>
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<tr>
<td>H1N1 Influenza A (ATCC VR-1469)</td>
<td>Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces and Surfaces and Disinfection of H1N1 Influenza Virus AOAC Germicidal Spray Method</td>
<td>02 MAR 2015</td>
<td>OCSP8 B10.2200</td>
<td>ASTM E1053</td>
</tr>
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<td>Salmonella enterica (ATCC 10708)</td>
<td>Efficacy of a Disinfectant Applied to a Room via a Fogging, Mist or Vaporizing Device for Disinfection of Salmonella AOAC Germicidal Spray Products Test Method Modified for Handheld Spraying Device AOAC Germicidal Spray Products Test Method Modified for Use with a Fogging Device and Viruses</td>
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Note: MB methods from EPA are specifically referenced in OCSP8 citations and are not separately listed.
Process of getting EPA Registered is a difficult, time consuming, and expensive.

1. Find an Accredited Lab
2. Receive an EPA approved Protocol
3. Run R&D Tests
4. Run GLP Tests

Process Continued…

5. Pass GLP Tests
6. Receive Final Report
7. Submit Revised Registration and Final GLP Report Studies to the EPA
8. Discuss, Review, and Edit Revised Registration with the EPA
9. Wait 90 days for Review
Methods: In the Dip Studies...

• Study carriers are inoculated with specific organisms with three different lots of disinfectant, one lot being older than 60 days old; 60 carriers per organism are used, and dipped into solution, per specified time.

Results

• With 59/60 carriers being negative for the organism after disinfectant treatment to be considered acceptable.

In Aerosolized Studies... per EPA Defined Protocol

• For each bacterial and viral organism, the cultures are grown per protocol.
• Coated onto carriers, usually glass microscope slides.
• Carriers are inoculated, and dried per protocols.
Protocols Continued...

- Sprayed solution is applied to the carriers using the Equipment for 5 seconds/ 0.0929 m² (1ft²) at 24 inches with a contact time of 7 minutes or solution is fogged to fill a space with a contact time of 15 minutes.

- Technology is fairly temperature and humidity independent. Humidity is held at 16.7-27% relative humidity and temperature is held at 20 ± 2 °C depending on organism being tested.

- The carriers are transferred using sterile technique to neutralizing solution, incubated and examined for growth.

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GLP Tables for Disinfectant

<table>
<thead>
<tr>
<th>Test Organism</th>
<th>Test Substance</th>
<th>Sample Dilution</th>
<th>Number of Carriers</th>
<th>Confirmed as Test Organism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pseudomonas aeruginosa (ATCC 15442)</td>
<td>Binary Ionization Technology® (BIT™) Solution Batch# OJ30A1</td>
<td>Ready to Use</td>
<td>60</td>
<td>0</td>
</tr>
<tr>
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| Clostridium difficile spores - CFU on Filter: CFU/Carrier (Log_{10}) |
|---------------------------------------------------------------|------------------|--------------------|---------------------|
| Binary Ionization Technology® (BIT™) Solution Lot: OJ30A1     | Average Log_{10} <0.00 | Log_{10} Reduction: >6.33 |                    |
| Binary Ionization Technology® (BIT™) Solution Lot: OJ02A1     | Average Log_{10} <0.08 | Log_{10} Reduction: >6.42 |                    |
| Binary Ionization Technology® (BIT™) Solution Lot: OL11A1     | Average Log_{10} <0.03 | Log_{10} Reduction: >6.47 |                    |
Other GLP Studies for Disinfectants

- TES01120614. FLU A for H1N1 pages 3---12 modifications included (7);
- TES01030716.RDT page 3 for *Mycobacterium bovis* (8);
- Protocol Number P1619 pages 25---38 for *Salmonella enterica* and protocol modifications page 10 (10);
- Microchem Laboratory Protocols NG7535 for *Norovirus* (11).

Other GLP Studies for Disinfectants

“THE GOLD STANDARD”

- Protocol MRID 488313---03 (field study) pages 2---4 for *Geobacillus stearothermophilus spores* (9);
In Conclusion...

- The EPA aerosolized studies are very difficult to perform as compared to dip test technology where carriers are simply immersed in the disinfectant solution for a period of time and evaluated.

- These studies are the first to demonstrate the combination of disinfection solution and the effect of the dispersal method with the **RESULTING EFFECT ON THE KILLING EFFICACY FOR MULTIPLE ORGANISMS.**

Thank you!