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# Performance Standard for the AOAC Use-dilution Methods

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# Disclaimer

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## Antimicrobial Policy & Guidance Documents

The Registration Policy Documents section is organized to include relevant sections of the [Code of Federal Regulations](#) (as references), internal [Guidance/Guidelines](#), [Letters](#) (containing guidance or relevant information), [Protocols](#), [Science Policy](#), and [Templates](#) for registrants' use.

- [Code Of Federal Regulations \(CFR\)](#)
- [Guidance / Guidelines](#)
- [Letters](#)
- [Protocols](#)
- [Science Policy](#)
- [Templates](#)

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### Code Of Federal Regulations (CFR)

- [40 CFR part 152 & 40 CFR part 156](#) -- Antimicrobial Registration Requirements
- [40 CFR part 158](#) -- Data Requirements

### Guidance / Guidelines

- [Lower Certified Limit Testing Guidance](#) (5 pp, 104 KB) (Please direct comments to Mark Perry at [perry\\_mark@epa.gov](mailto:perry_mark@epa.gov))
- [UDM Performance Standard Revision Document](#) (3 pp, 94 KB)
- [Crosswalk Table for Non-public-Health Guidelines](#)
- [Fragrance Notification Pilot Program](#) (9 pp, 47 KB)
- [Guidelines for Voluntary Disclosure of Antimicrobial Ingredient Information on Company Websites and/or Labels](#)
- [Use of Disinfectants and Sanitizers in Heating, Ventilation, Air Conditioning, and Refrigeration \(HVAC&R\) Systems](#) - Supplemental Guidance
- [Antimicrobials Used in the Fermentation of Fuel Ethanol](#) - Clarification of Jurisdiction
- [Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus \(Formerly called Swine Flu\)](#)
- [Guidance on what the net contents statements should contain for antimicrobial wipe/ towelette products](#)
- [Guidance for the Efficacy Evaluation of Products with Sporidical Claims against \*Clostridium difficile\*](#) - This document provides the Agency's guidance for efficacy testing to obtain a label claim against the spores of *Clostridium difficile*
- [This is a response to questions concerning existing C. diff claims](#) (Vegetative form) on antimicrobial product labels.
- [Barrier Products Clarification Document](#) - Guidance on what is needed for an Agency barrier determination.
- [Use of the Term "Shock" on Non-pesticide Labeling \(PDF\)](#) (3 pp, 118 KB) - This document further clarifies what claims can be made for non-pesticide shock products.

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# Scope

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- ⦿ The new performance standard criteria only apply to liquid products tested with the UDM against *S. aureus* and *P. aeruginosa*.
- ⦿ UDM requirements for testing *Salmonella enterica* are not impacted.
- ⦿ For limited and broad spectrum disinfectant claims, the new performance standard for *S. aureus* applies.
- ⦿ The new performance standard criteria are applicable to data used to support new registrations, label amendments, data call-ins issued by the Agency, and in post registration testing.

# Background

- The current versions of AOAC Methods 955.15 and 964.02 were posted by AOAC in September, 2013 and should be used for testing.
- The revised AOAC methods are posted online at:  
[http://www.aoac.org/imis15\\_prod/AOAC/Default.aspx](http://www.aoac.org/imis15_prod/AOAC/Default.aspx)
  - Official Methods of Analysis (2013) 19th Ed., AOAC INTERNATIONAL, Gaithersburg, MD, AOAC Use-dilution Method 955.15. *S. aureus*.
  - Official Methods of Analysis (2013) 19th Ed., AOAC INTERNATIONAL, Gaithersburg, MD, AOAC Use-dilution method 964.02. *P. aeruginosa*.
- Standard Operating Procedure for AOAC Use Dilution Method for Testing Disinfectants (MB-05-12), EPA Office of Pesticide Programs, Microbiology Laboratory, Environmental Science Center, Ft. Meade, MD,  
<http://www.epa.gov/pesticides/methods/atmpa2z.htm>

# Background

- A reassessment of the method's performance standard was conducted utilizing the best available data and statistical methodology to analyze the UDM's variability.
- To support revisions, the EPA, in collaboration with MSU, submitted three manuscripts to the JAOAC Int. for technical review and approval. The manuscripts describe:
  - the outcome of a 2009 UDM collaborative study,
  - a statistical model for assessing performance standards of disinfectant test methods, and
  - the use of statistical modeling to reassess the UDM performance standard.

# New Performance Standard

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- ⦿ Each microbe should be tested three times.
- ⦿ Each test should be conducted against a separate batch of product for a total of three batches.
- ⦿ All three batches should be at the lower certified limit (LCL) of the active ingredient(s).
- ⦿ Each of the three tests should be conducted on a different day.
- ⦿ Testing at a single lab is acceptable.
- ⦿ Sixty carriers are required per test, without contamination in the subculture media.

# New Performance Standard

- The performance standard for *S. aureus* is 0-3 positive carriers out of sixty.
- The performance standard for *P. aeruginosa* is 0-6 positive carriers out of sixty.
- To be deemed an effective product, the product must pass all tests (6) for both microbes.
- The Agency will monitor the outcome of the new performance standard criteria as data are generated, and if necessary, adjust the performance standard at a later date.



# New Performance Standard

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- Example: for 955.15 – September 13, 2013
  - (h) Performance standard.— 3 positive (growth) carriers out of 60 tested. Conduct three separate UDM tests, one test conducted per day. All tests must meet the performance standard. Testing at a single laboratory is acceptable.
  - Note: A hospital-level disinfectant product (as defined by the U.S. EPA) must pass both *S. aureus* and *P. aeruginosa* tests to be deemed effective (a total of six tests).

# References

- Tomasino, S.F., Parker, A.E., Hamilton, M.A., & Hamilton, G.C. (2012) Performance of the AOAC Use-dilution method with Targeted Modifications: Collaborative Study. *J. AOAC Int.* **95** (6), 1618-1628
- Parker, A.E., Hamilton, M.A., & Tomasino, S.F. (2013) A Statistical Model for Assessing Performance Standards for Quantitative and Semi-quantitative Disinfectant Test Methods. *J. AOAC Int.* **97** (1) 58-67
- Tomasino, S.F., Parker, A.E., & Hamilton, M.A. (2013) Use of Statistical Modeling to Reassess the Performance Standard for the AOAC Use-dilution Methods (955.15 and 964.02). *J. AOAC Int.* **97** (1) 68-77

# Questions/Comments

