



### Risk-Assessment Worksheet

Issue: Off-label use of one minute contact times for low-level surface disinfectants used on noncritical environmental surfaces and noncritical patient care equipment

Assessment Date: March 15, 2011

Scoring: Low = 1      Moderate = 3      High = 5

Team Members: Bill Rutala, Vickie Brown, David Weber, Kirk Huslage, Becky Brooks, Tina Adams, Brenda Featherstone, Lisa Teal, Emily Sickbert-Bennett, Maria Gergen.

Meeting Actions: Team members evaluated the evidence and determined that off-label 1 minute contact times was sufficient to disinfect noncritical environmental surfaces and noncritical patient care equipment in a healthcare environment

Suggested Questions	Benefit	Risk
What is the impact on patient care delivery?	There are no data demonstrating an infection prevention benefit of a 10 minute contact time for surface disinfection. More than a dozen articles* demonstrate the ability of EPA-registered disinfectants to inactivate HA pathogens (e.g., MRSA, VRE, CONS) with a contact time of $\leq 1$ minute. Additionally, data demonstrate that our surface disinfectant (QUAT) continues to have significant antimicrobial activity that extends beyond the wet time on a surface. That is, our surface disinfectant has sustained antimicrobial effectiveness (i.e., >6 hours) against HA pathogens when left on the surface. Score - 5	There are no demonstrated risks to utilizing a 1 minute contact time for surface disinfection. No HAIs have ever been attributed to non-critical environmental surfaces and noncritical patient care equipment. Score – 1
How does the issue affect the staff?	In order to achieve a contact time of 10 minutes, as recommended by the labeling on many disinfectants, the disinfectant would need to be applied up to 5 times as the typical drying time of a	Requiring staff to follow label directions for actions with no proven benefit to employee or patient safety may serve to reduce efforts proven to improve patient outcomes.



	water-based disinfectant is 1.5-2 minutes. Using a 1 minute contact time will result in more staff time available for patient care. Score = 5	Score - 1
What is the impact on HAIs	Multiple scientific studies have demonstrated the efficacy of hospital disinfectants against pathogens causing healthcare-associated infections (HAI) with a contact time of less than 1 minute Score - 5	There are no data that demonstrate improved infection prevention with a 10 minute contact time vs. a 1 minute contact time.  Score - 1
How does the issue affect any visitors, volunteers, and so forth?	NA	NA
What is the impact on public safety?	NA	NA
What is the financial impact of the issue on the organization?	The use of a 1 minute contact time for non-critical surfaces results in more staff time spent caring for patients and less exposure to the deleterious effects of the disinfectant. Score - 3	There are no EPA enforcement action on healthcare facilities for "off-label" use of surface disinfectants. There have been citations reported from regulatory agencies such as CMS.  Score - 3
What is the impact on the physical structure, including buildings, departments, units, or other areas?	NA	NA
Does the issue affect the exterior environment, including access, exit from buildings, grounds, rest areas, and so forth?	NA	NA
What is the impact on equipment, including its use, function, serviceability, and so forth?	Less use of disinfectants on noncritical environmental surfaces and noncritical patient care equipment will prolong the useful life, serviceability and function of these surfaces and equipment due to the deleterious effects of the disinfectants. Score - 5	Prolonged use of germicides may have a deleterious effect on the equipment's use, function, and serviceability. Some germicides (alcohol and chlorine) can cause deterioration of rubber, plastics, and metals. Score - 1
What is the impact on internal physical systems?	NA	NA



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Total Benefits Score = 23

Total Risk Score = 7



**Meeting Actions:** The team members scored each point as outlined, and concurred that there is no advantage to utilizing EPA-registered disinfectants at the recommended contact time of 10 minutes for disinfection of non-critical environmental surfaces and noncritical patient care equipment.

**Regulatory Analysis:** The Joint Commission

Joint Commission incorporates by reference the 2008 CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, Recommendation 5K: Disinfect noncritical surfaces with an EPA-registered hospital disinfectant according to the label's safety precautions and use directions. Most EPA-registered hospital disinfectants have a label contact time of 10 minutes. However, many scientific studies have demonstrated the efficacy of hospital disinfectants against pathogens with a contact time of at least 1 minute. By law, the user must follow all applicable label instructions on EPA-registered products. If the user selects exposure conditions that differ from those on the EPA-registered product label, the user assumes liability for any injuries resulting from off-label use and is potentially subject to enforcement action under FIFRA. *Category II, IC.*

The Environmental Protection Agency

Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires all pesticides and disinfectants distributed and sold within the United States to be registered (licensed) by the EPA. Before the EPA may register a disinfectant/pesticide under FIFRA, they must demonstrate efficacy against the targeted organisms using the AOAC published methods and, according to specifications "will not generally cause unreasonable adverse effects on the environment". FIFRA also gives the EPA the ability regulate use through labeling, packaging, composition and disposal.

**Management Data:** No adverse or sentinel events or other HA infection data suggests a problem with the current policy of using at least a 1 minute contact time for disinfection of non-critical environmental surfaces and noncritical patient care equipment.

**Follow-up Plan:** Incident reports will be monitored for any issues and if any identified, this policy will be reviewed.

**Approval:** The following leadership bodies have reviewed this risk assessment and adopted the position indicated. During this review, each leadership body has concluded that this position is in the best interest of the patient.

Leadership Body	Date of Approval
Hospital Infection Control Committee	

\* References:

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14. Springthorpe VS, Grenier JL, Lloyd-Evans N, Sattar SA. Chemical disinfection of human rotaviruses: efficacy of commercially-available products in suspension tests. J. Hyg. (Lond). 1986;97:139-61.
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