UNC HEALTH CARE

Risk-Assessment Worksheet

Issue: Off-label use of >2% glutaraldehyde chemical germicide utilizing a 20-minute immersion at 20°C (20/20) after a standard cleaning protocol is sufficient to achieve high-level disinfection

Assessment Date: March 18, 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 use of a standard cleaning protocol in conjunction with a 20-minute, 20°C >2% glutaraldehyde immersion will achieve high-level disinfection.

Suggested Questions	Benefit	Risk
What is the impact on patient care delivery?	There are no data demonstrating benefit of utilizing an extended immersion time of 45-minutes at 25°C to achieve high-level disinfection. Numerous scientific studies and professional organizations† support the efficacy of >2% glutaraldehyde for 20-minutes at 20°C in conjunction with adequate cleaning prior to achieve high-level disinfection. Score - 5	There is no risk associated with the transmission of pathogens utilizing the 20/20 protocol, assuming adequate cleaning prior to disinfection. There are no published studies of transmission of infection when guidelines have been followed. Score – 1
How does the issue affect the staff?	In order to achieve adequate high-level disinfection by utilizing the label prescribed method would require 45-minutes, resulting in more staff time spent disinfecting scopes without a patient benefit. Score = 5	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. Score - 1
What is the impact on HAIs	There have been no published reports of cross-transmission of pathogens when current guidelines‡ have been followed.	There are no data that demonstrate improved infection prevention and a reduction in HAIs with a 45-minute immersion at 25°C in the absence of adequate cleaning.

	Score - 5	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?	By shortening the duration of exposure of endoscopes to chemical sterilants/high level disinfectants (HLD) we will shorten the turn-around time for a scope without affecting patient safety. Score - 5	Extending exposure of endscopes to chemical sterilants/HLD will increase the cost of all endoscopic procedures by slowing the reprocessing time and requiring the purchase of additional devices to maintain current demand. Extended exposure also reduces the use-life which may result in increased maintenance and replacement cost. 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?	Decreased immersion time of endscopes in chemical sterilants/HLD will extend the useful life of an endoscope by reducing moisture damage and corrosion associated with increase exposure time and temperature as the label prescribes. Score - 5	Following the labeling protocol causes a shortened use-life of endoscopes due to prolonged immersion of endoscopes which may increase moisture damage and corrosion. Score - 1
What is the impact on internal physical systems?	NA	NA

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 current FDA labeling claims of 45 minutes at 25°C.

Regulatory Analysis: The Joint Commission

Joint Commission incorporates by reference the 2008 CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, Recommendation 7O: Federal regulations are to follow the FDA-cleared label claim for high-level disinfectants. The FDA-cleared labels for high-level disinfection with >2% glutaraldehyde at 25°C range from 20-90 minutes, depending upon the product based on three tier testing which includes AOAC sporicidal tests, simulated use testing with mycobacterial and in-use testing. *Category* IC.

The Food and Drug Administration
The FD&C Act grants FDA authority to regulate devices as defined in 21 U.S.C. §321(h). Under section 321(h), the term "device" includes an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory that is intended to cure, mitigate, treat, or prevent disease in man, or is intended to affect the structure or any function of the body of man.

Liquid chemical germicides intended for use in conjunction with a variety of articles that fit within the statutory definition of "device," such as operating instruments, medical examining tables, hospital scales, and other hospital equipment, also fall within the definition of "device" because they are considered accessories to these devices.

In regulation liquid chemical germicides used with devices, FDA is exercising its responsibilities under the FD&C Act for ensuring that devices are safe and effective for their intended uses. The FD&C Act provides enforcement authority to FDA to pursue regulatory actions, including seizure, injunction, prosecution, and civil penalties.

Management Data: No adverse or sentinel events or other data suggests a problem with the current CDC/HICPAC guideline or UNC Health Care policy of using an adequate cleaning protocol in conjunction with >2% glutaraldehyde chemical germicide at 20°C for 20-minutes to achieve high-level disinfection.

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

†, ‡ References:

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