

[High Priority] - H0635 : [COVID-19] Use of Automatic Chemical Disinfection Systems May Lead to Chemical Exposure and Equipment Damage [ECRI Exclusive Hazard Report]
Medical Device Hazard Report

Published: Tuesday, July 21, 2020

UMDNS Terms:

- Environmental Disinfection Systems [27285]
- Environmental Disinfection Systems, Chemical, Hydrogen Peroxide Vapor [27286]

Geographic Regions: Worldwide

Suggested Distribution: Clinical Laboratory/Pathology, Critical Care, Emergency/Outpatient Services, Infection Control, Oncology, OR/Surgery, Orthopedics, Pediatrics, Pulmonology/Respiratory Therapy, Diagnostic Imaging, Risk Management/Continuous Quality Improvement, Facilities/Building Management, Dentistry/Oral Surgery, Ophthalmology, Internal Medicine, Point-of-Care Coordination, Staff Education, NICU, EMS/Transport, Pharmacy, Central Sterilization Reprocessing, Materials Management

Problem:

1. The COVID-19 pandemic has increased interest in automatic chemical disinfection systems that could be used in healthcare, industrial, and commercial settings.
 1. Organizations may buy and implement these systems without full knowledge of the requirements for safe and effective system use.
 2. Misuse of automatic chemical disinfection systems can result in human chemical exposure and potential damage to sensitive devices, equipment, and items.
2. There are currently two types of automatic chemical disinfection systems:
 1. Hydrogen peroxide vapor (HPV) room decontamination systems:
 1. These systems disperse a controlled amount of hydrogen peroxide gas to further decontaminate manually cleaned and disinfected porous (e.g., fabrics) and non-porous surfaces (e.g., medical equipment) within an enclosed, unoccupied space.
 2. The total time for HPV treatment is several hours.
 2. Chemical fog room disinfection systems:
 1. These systems disperse a controlled amount of chemical fog (i.e., a suspension of liquid droplets in a gas) to provide supplemental disinfection of manually cleaned and disinfected non-porous surfaces (e.g., solid countertops) within an enclosed, unoccupied space.
 2. The total time for chemical fog treatment is approximately one to two hours.
3. Safe use of automatic chemical disinfection systems requires the following:
 1. Operation in enclosed, unoccupied spaces
 2. Preparation of enclosed, unoccupied spaces (e.g., sealing HVAC vents, smoke detectors, and doors)
 3. Operator training to safely and effectively set up, operate and monitor automatic chemical disinfection systems
 4. Devices, equipment, and items that are compatible with HPV or chemical fog
4. Potential consequences of automatic chemical disinfection system misuse during HPV or chemical fog treatment include:
 1. Human chemical exposure (e.g., hydrogen peroxide, peroxyacetic acid, quaternary ammonium compounds) can occur if:
 1. HVAC vents, smoke detectors, and outer door(s) to enclosed spaces are not sealed.
 2. An operator prematurely enters the enclosed space.
 2. Unknown system efficacy unless appropriate chemical and biological monitoring is performed.
 3. Damage, discoloration, or material degradation of incompatible devices, equipment, or items.

ECRI Recommendations:

ECRI is not aware of conclusive clinical evidence for chemical fog room disinfection efficacy. Some healthcare, industrial, and commercial organizations will decide to purchase and use automatic chemical disinfection systems despite the lack of evidence of system efficacy in these settings. For those organizations, ECRI provides the following recommendations:

Before purchasing automatic chemical disinfection systems:

1. Determine who will administer the organization's automatic chemical disinfection system program. The program administrator's responsibilities include:
 1. Establish metrics for safe and effective system use (e.g., operator training and competency assessment method; type, placement, and frequency of chemical and biological indicator use; frequency of operator audits; frequency of system inspection and preventive maintenance [IPM]).
 2. Develop an emergency action plan for emergent entry of enclosed spaces undergoing chemical disinfection (e.g., notification of the local Hazmat team, adherence with applicable OSHA requirements for staff personal protective equipment, including an organization respiratory protection program (1,2)).
 3. Conduct training and competency assessments of system operators.
 4. Perform periodic operator audits and provide just-in-time coaching as needed.

5. Schedule IPM of automatic chemical disinfection systems.
6. Schedule calibration of handheld chemical sensors if needed.
2. Make a list of the enclosed spaces that will undergo automatic chemical disinfection (i.e., a chemical disinfection room list).
3. Make a list of the sensitive devices, equipment, and items that are within the listed rooms.
 1. For each item on the list, review the device/equipment/item instructions for use (IFU) or consult with the manufacturers of those products to ensure that HPV or chemical fog use is acceptable.
4. Determine who will operate automatic chemical disinfection systems.
5. Consider how automatic chemical disinfection systems will affect staff workflow and room turnaround time.
6. Estimate the capital and consumable costs of using automatic chemical disinfection systems for the listed rooms at the desired frequency (e.g., once per day).

During implementation of an automatic chemical disinfection system program:

1. Upon hire and at least annually, provide system operators with education, hands-on training, and competency assessment of the following:
 1. Room preparation and system set up:
 1. Manually clean and disinfect environmental surfaces (e.g., devices, equipment, items).
 2. Manually dry or air dry surfaces.
 3. Operators should adhere to the automatic chemical disinfection system IFU:
 1. Seal HVAC vents, cover smoke detectors, and open cabinets/drawers/doors.
 2. Place chemical and biological indicators as specified by the automatic chemical disinfection system program.
 3. Set up the mobile system or activate the stationary system installed in the room.
 4. Seal all doors to the room using tape.
 5. Place a hazard sign at the sealed door(s).
 6. Initiate the disinfection cycle on a remote controller or tablet.
 7. Use a handheld chemical sensor to verify that there is no chemical leakage around the outer room door(s).
 2. Room breakdown after system use:
 1. Remove tape and sign(s) from sealed door(s).
 2. Open the sealed door(s), and use a handheld chemical sensor to verify that the chemical concentration is less than the OSHA permissible exposure limit (3) before room entry.
 3. Unseal HVAC vents, uncover smoke detectors, and close cabinets/drawers/doors.
 4. Remove chemical and biological indicators, process biological indicators if needed, and document results as specified by the automatic chemical disinfection system program.
 3. Chemical safety:
 1. Specify how to safely handle chemical solutions used in automatic chemical disinfection systems.
 2. Always remain outside an enclosed space that is undergoing automatic chemical disinfection treatment.
 4. Monitor automatic chemical disinfection system efficacy:
 1. Highlight the importance of chemical and biological monitoring.
 2. Interpret and document the results of chemical and biological monitoring.
 3. Determine how to respond to failed chemical and biological indicators (e.g., whom to contact).
2. Perform operator audits at the frequency specified by the automatic chemical disinfection system program.
 1. Provide just-in-time coaching as needed.
3. Keep a supply of chemical and biological indicators that operators can access.
4. Maintain documentation of chemical and biological monitoring as needed.
5. Schedule IPM of automatic chemical disinfection systems according to the system manufacturer's recommended IPM frequency.
 1. Ensure that the recommended IPM method is followed.
6. Schedule calibration of handheld chemical sensors if needed.
7. Monitor ongoing costs of the automatic chemical disinfection system program, such as operator and administrator time, costs of consumables (e.g., chemical disinfectant, chemical and biological indicators), and costs of room downtime.

Background:

1. ECRI has received several questions related to the safety and efficacy of the two types of automatic chemical disinfection systems used in healthcare, industrial, and commercial environments.

1. HPV decontamination systems use hydrogen peroxide solutions that are EPA-approved [chemical sterilants](#) . These sterilants have labeled indications for sterilization of clean, dry porous and non-porous surfaces when used according to HPV room decontamination system IFUs.
2. Chemical fog room disinfection systems should specify the use of EPA-approved disinfectant solutions. These products have labeled indications for adjunct disinfection of clean, disinfected, dry, non-porous surfaces when used according to chemical fog room disinfection system IFUs.
2. WHO does not recommend the use of automatic chemical disinfection systems in healthcare and non-healthcare settings (4):
 1. In indoor spaces, routine application of disinfectants to environmental surfaces by spraying or fogging (also known as fumigation or misting) is not recommended for SARS-CoV-2.
 2. Spraying or fogging of certain chemicals, such as chlorine-based agents and quaternary ammonium compounds, is not recommended because of adverse health effects on workers in facilities where these methods have been used.
 3. Spraying environmental surfaces in both healthcare and non-healthcare settings with disinfectants may not be effective in removing organic material and may miss surfaces shielded by objects, folded fabrics, or surfaces with intricate designs.
 4. If disinfectants are to be applied, use of a cloth or wipe that is moist with disinfectant is recommended.
3. A CDC guideline states that “more research is required to clarify the effectiveness and reliability of fogging, UV irradiation, and ozone mists to reduce...environmental contamination” (5).
4. A recent ECRI assessment determined that the clinical evidence for chemical fog room disinfection efficacy is inconclusive (6):
 1. The effectiveness of chemical fog room disinfections to reduce HAI rates “cannot be determined from available evidence consisting of 1 systematic review (SR) of very-low-quality studies at high risk of bias. The SR suggests HPV [hydrogen peroxide vapor and fog] may reduce infections caused by vancomycin-resistant enterococci, but no statistical difference in infection rates was found for *Clostridioides difficile* (*C. diff*) or methicillin-resistant *Staphylococcus aureus*. However, findings need further validation in additional, higher-quality studies. Two clinical guidelines make no recommendations for or against use of HPV [hydrogen peroxide vapor and fog] systems for preventing HAIs.”

References & Source Documents:

1. Occupational Safety and Health Administration (OSHA). Occupational Safety and Health Standards. Number 1910: Personal Protective Equipment [online]. [cited 2020 July 8]. Available [here](#) .
2. Occupational Safety and Health Administration (OSHA). Occupational Safety and Health Standards. Number 1910.134: Respiratory Protection [online]. 2011 June 8 [cited 2020 July 8]. Available [here](#) .
3. California Division of Occupational Safety and Health Administration (OSHA). Table AC-1 Permissible Exposure Limits for Chemical Contaminants [online]. 2011 June 8 [cited 2020 July 8]. Available [here](#) .
4. World Health Organization. Cleaning and disinfection of environmental surfaces in the context of COVID-19 [online]. 2020 May 16 [cited 2020 July 8]. Available [here](#) .
5. Centers for Disease Control and Prevention, U.S. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 [online]. 2019 May [cited 2020 July 8]. Available [here](#) .
6. ECRI. Hydrogen Peroxide Room Disinfection for Preventing Healthcare-associated Infections. 2020 Apr 15 [cited 2020 July 8].

Comments:

- This alert is a living document and may be updated when ECRI receives additional information.

Source(s):

- 2020 Jul 20. ECRI researched report