White Glove Test for Safety

Be sure to purchase and wear chemotherapy gloves that have been tested to the correct safety standard

Health care workers know that the last line of defense between them and harmful medications, cleaners, and other chemical agents is personal protective equipment (PPE) like gloves. But what if this apparel is not tested to the preferred safety standard for permeability to hazardous substances like chemotherapy (antineoplastic) drugs?

It's a sobering and valid concern, especially considering that confusion exists in the marketplace about which gloves provide adequate protection. That's because manufacturers today follow two current standards that the American Society for Testing and Materials (ASTM) has in place for testing permeation of glove materials by chemicals. Experts say manufacturers should use the appropriate standard when testing gloves to be used for handling chemotherapy agents. PPE companies that test using the nonpreferred standard may be creating chemotherapy gloves that don't adequately protect the pharmacy personnel, nurses, technicians, and other staff who help maintain the environment of care within health care organizations.

Two standards, one concern

The two current standards for testing chemical permeation of glove materials that some manufacturers follow are: ASTM F739-12, Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact (approved by ASTM in 2012); and ASTM D6978-05 (called D6978)—Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs (reapproved in 2013).[1]

Each standard serves an important purpose. However, D6978 (chemotherapy permeation) is newer and more ideal for testing glove permeation by several different chemotherapy drugs. On the other hand, F739-12 (liquids/gases permeation) is a legitimate but more general standard employed by some manufacturers to test how well their protective clothing materials (including gloves, arm shields, aprons, suits, hats, boots, and respirators) prevent permeation of gases and liquids under conditions of continuous contact. F739-12 (liquids/gases permeation) continues to serve as an important industry standard for agents, like solvents, that are not (in most cases) as toxic as chemotherapy drugs.

There are significant differences between these two standards (*see* Table 1, above), despite the fact that the testing procedures are comparable and both are performed for up to four hours.[1] Glove permeation testing determines the length of time (up to four hours maximum) it takes particular chemicals to penetrate through the glove material—which is called the "breakthrough time." The breakthrough time for D6978 (therapy permeation; the standard for chemotherapy drugs) is verified when the permeation rate reaches 0.01 µg/cm^2/minute; meanwhile, the breakthrough time for F739-12 (liquids/gases permeation; the standard for other chemicals) is determined when the permeation rate reaches 0.1 µg/cm2/minutes.[1] Hence, liquids/gases F739-12 permits a permeation rate 10 times higher than chemotherapy D6978 prior to the gloves failing.[1]

In addition, the chemotherapy D6978 test is carried out at a temperature of 35 + 2º C, as the glove temperature reaches body temperature shortly after they the gloves are put on.[1] By contrast, the liquids/gases F739-12 test temperature matches ambient room temperature (approximately 25º C).[1] This difference is noteworthy because permeation corresponds directly to temperature, and warmer gloves enable greater permeation of the drugs.[2]

Uncertainties and solutions

Some glove makers indicate that they conduct D6978 chemotherapy permeation testing using seven required drugs and two optional manufacturer-selected drugs (*see* Table 2, page 7).[1] However, these manufacturers often reveal breakthrough times based on liquids/gases F739-12, which was not developed for chemotherapy drugs and which has a

Table 1. ASTM Permeation Standards

ASTM Standard	Permeation Rate	Temperature	Drugs
F739-12 (liquids/gases permeation)	0.1 µg/cm^2/min	Room (25º C)	None
D6978 (chemotherapy permeation)	0.01 µg/cm^2/min	35 + 2º C	7 required + 2 optional

Source: National Institute for Occupational Safety and Health (NIOSH). Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings. Cincinnati, OH: CDC, NIOSH; 2004. Accessed Jan 21, 2015. http://www.cdc.gov/niosh/docs/2004-165/pdfs/2004-165.pdf.

Table 2. Required Drugs for Permeation Testing Using the ASTM D6978 (Chemotherapy Permeation) Standard

Drug	Concentration (mg/ml)
Carmustine	3.3
Cyclophosphamide	20
Doxorubicin HCl	2
Etoposide	20
Fluorouracil	50
Paclitaxel	6
ThioTEPA	10
Two optional chemotherapy drugs selected by manufacturer	To be determined based on selected drugs

Source: National Institute for Occupational Safety and Health (NIOSH). Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings. Cincinnati, OH: CDC, NIOSH; 2004. Accessed Jan 21, 2015. http://www.cdc.gov/niosh/docs/2004-165/pdfs/2004-165.pdf.

higher permeation rate and lower temperature parameters.[1] Glove testing done according to liquids/gases F739-12 rather than chemotherapy D6978 can lead to a significant increase in risk of exposure to chemotherapy drugs if these gloves are worn.[1]

"For drugs that do not permeate within the four-hour time limit using ASTM F739-12 [liquids/gases permeation], this may or may not be an issue if health care workers change gloves every 30 or 60 minutes, as recommended in most guidelines," says Thomas H. Connor, PhD, research biologist with the Centers for Disease Control and Prevention and the National Institute for Occupational Safety and Health's (NIOSH's) Division of Applied Research and Technology, Cincinnati, Ohio. "However, for those drugs that permeate gloves in shorter time periods, health care workers could experience dermal exposure to substantially greater quantities of the drugs."

The bottom line concern, Connor says, is that "some manufacturers, unfortunately, are using the best parts of both standards to make their products look safer than they are."

For these and other reasons, federal agencies and professional organizations such as NIOSH, the American Society of Health-System Pharmacists, Oncology Nursing Society, and U. S. Pharmacopeial Convention recommend that health care workers who interact with chemotherapy drugs and other hazardous medications don gloves that have passed chemotherapy D6978's more rigorous standard for permeation testing instead of the liquids/gases F739-12 standard employed for other chemicals.[1]

What you can do

There are several steps that health care organizations and their employees can take to better ensure the safe use of gloves intended for handling of chemotherapy agents.

First, "be aware of the test standards and ensure that gloves that are purchased are tested to the D6978 chemotherapy permeation standard," says Connor. "Chemotherapy gloves that are not tested to the D6978 standard should be avoided by purchasers and workers."

Also, health care organizations should encourage glove manufacturers to abide by all chemotherapy D6978 requirements and report accurate test information on their packaging so that health care workers who depend on these gloves for safety against exposure to chemotherapy and other hazardous drugs can have peace of mind that they are truly protected.

Finally, Joint Commission–accredited organizations need to be sure to follow Environment of Care (EC) Standard EC.02.02.01, "the organization manages risks related to hazardous materials and waste," and its Element of Performance 3, "the hospital has written procedures, including the use of precautions and personal protective equipment, to follow in response to hazardous material and waste spills or exposures."

See "Chemotherapy Glove Use Tips," above, for a summary of NIOSH ideas for using gloves.

Information for this article was taken from a report—co-written by Thomas H.

(continued on page 11)

Chemotherapy Glove Use Tips

Follow these NIOSH recommendations regarding the use of chemotherapy gloves:

- Make sure that gloves are labeled as chemotherapy gloves and that such information is available on the box or from the manufacturer.
- Wear chemotherapy gloves, protective clothing, and eye protection when opening containers to unpack hazardous drugs.
- Wear chemotherapy gloves to prevent contamination when transporting the vial or syringe to the work area.
- Use double gloving for all activities involving hazardous drugs.
- Change gloves every 30 minutes or when torn, punctured, or contaminated. Discard them immediately in a chemotherapy waste container and close the lid.

Source: National Institute for Occupational Safety and Health (NIOSH). Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings. Cincinnati, OH: CDC, NIOSH; 2004. Accessed Jan 21, 2015. http://www.cdc.gov/niosh/docs/2004-165/pdfs/2004-165.pdf.

White Glove Test for Safety
(continued from page 7)

Connor, PhD, research biologist, Centers for Disease Control and Prevention and National Institute for Occupational Safety and Health, Division of Applied Research and Technology, Cincinnati, Ohio; Luci A. Power, MS, RPh, senior pharmacy consultant, Power Enterprises, San Francisco; Firouzan "Fred" Massoomi, PharmD, FASHP, pharmacy operations coordinator, Department of Pharmacy Services, Nebraska Methodist Hospital, Omaha, Nebraska; and Martha Polovich, PhD, RN, AOCN, clinical associate professor, Byrdine F. Lewis School of Nursing and Health Professions, Georgia State University, Atlanta—to be published in early 2015 in Pharmacy Purchasing and Products *magazine. The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health (NIOSH). Mention of any company or product does not constitute endorsement by NIOSH. In addition, citations to websites external to NIOSH do not constitute NIOSH endorsement of the sponsoring organizations or their programs or products. Furthermore, NIOSH is not responsible for the content of these websites. All web addresses in this document were accessible as of the publication date.*

References

1. Connor TH, et al. Permeability testing of gloves and gowns used to handle chemotherapy drugs: Healthcare worker safety demands adherence to the correct ASTM standard. *Pharmacy Purchasing and Products.* In press.
2. Du Pont 2003. How Chemical Mixtures and Temperature Affect Permeation. Technical data sheet. Du Pont de Nemours and Co. 2003. Accessed Dec 31, 2014. http://safespec.dupont.com/safespec/media/documents/mixtures_temp_perm.pdf.

Test your STANDARDS IQ

The Answers

Here are the answers to the questions on page 2. How did you do?

1. **C, every 12 months.** Although health care organizations are not required to have carbon dioxide fire extinguishing systems, facilities that have them must check the equipment every 12 months. For the tests, the organization does not have to discharge the fire extinguishing system, merely verify that everything is in working order. The completion dates of all tests should be documented.
   STANDARDS REFERENCE: EC.02.03.05, EP 14

2. **A, at least one.** To truly test emergency response plans, hospitals should integrate escalating events into their emergency exercises. Escalating events involve incidents that build on each other to create a large-scale emergency that affects the entire community, such as a hurricane that knocks out power, levels the emergency room, and disables both internal and external communication systems.
   For a hospital that offers emergency services, or could expect to receive patients in a communitywide emergency, at least one of the organization's planned exercises must include an escalating event in which the hospital cannot be supported by the local community. Note that the escalating portion of the exercise can be conducted separately from the original drill. In fact, tabletop sessions are acceptable in meeting this requirement and can be a valuable tool in assessing readiness.
   STANDARDS REFERENCE: EM.03.01.03, EP 3

3. **C, larger than 32 gallons.** To reduce the likelihood of fire and preserve life safety, organizations should house their soiled linen and trash receptacles larger than 32 gallons in rooms protected as hazardous areas. Any receptacles smaller than 32 gallons may be placed throughout a facility provided that they do not present a risk to patients, staff, or visitors.
   STANDARDS REFERENCE: LS.02.01.70, EP 2

4. **B, 30 feet.** A Class K–type portable fire extinguisher is designed to form a thick "skin" over a grease fire to contain it until it is truly out. These extinguishers must be located within 30 feet of a grease-producing device, such as a deep fryer, griddle, broiler, or range. A sign near the K-type extinguisher must clearly state that the fire suppression system directly protecting the cooking appliance should be activated first, and then the K-type extinguisher should be used. The Joint Commission would expect staff working in the area to be trained on use of this equipment.
   STANDARDS REFERENCE: LS.02.01.35, EP 9

5. **B, annually.** Hospitals that use Joint Commission accreditation for deemed status purposes must have qualified staff inspect, test, and calibrate nuclear medicine equipment annually. The Human Resources standards outline possible qualifications for the inspector. As with other inspections, organizations should document the dates of nuclear medicine testing.
   STANDARDS REFERENCE: EC.02.04.03, EP 14

The Joint Commission

ECNews

March 2015 Volume 18 Issue 3

Environment of Care | Emergency Management | Life Safety

Asked & Answered

Responding to Your EC Questions

George Mills and other standards experts give authoritative replies

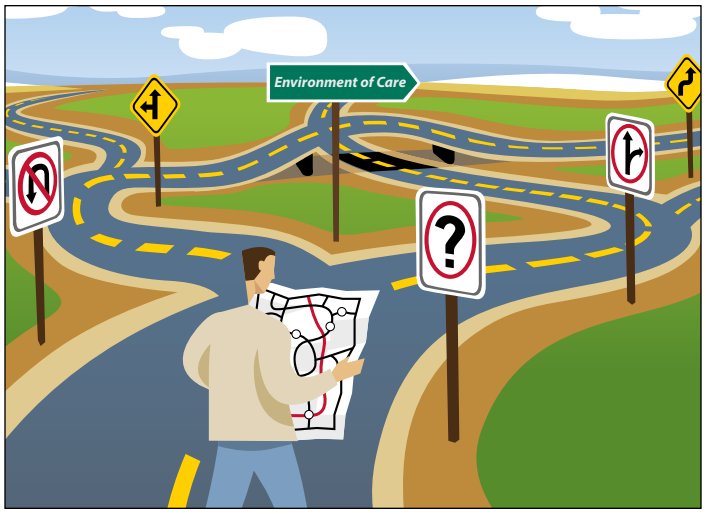
During the course of day-to-day operations, environment of care (EC) professionals inevitably run across issues that raise questions. Often these queries are not unique to one organization, and many facilities can face the same situations. *EC News* recently sat down with George Mills, MBA, FASHE, CEM, CHFM, CHSP, director of engineering, The Joint Commission, and several other Joint Commission experts (see page 10)—to discuss some of the EC-related questions they field. This article offers a brief summary of their responses.

Question: Are bathrooms in public areas required to have emergency call devices?

Answer: The answer to this question depends on the public bathroom's location because certain areas require call devices while others may or may not.

To determine where call devices are needed, organizations should consult Table 2.1-4 in the *FGI Guidelines for Design and Construction of Health Care Facilities* (2010 edition, page 86). Although this table doesn't describe every scenario, it does offer some basic guidance. For example, using the *Guidelines*, you could conclude that a call device is optional in public restrooms located in outpatient waiting rooms, such as those found in a physician's office. However, if a bathroom is located in an outpatient facility's treatment or triage areas, whether specifically in the rooms or in the hallways near the rooms, call devices are required. In addition, if a public bathroom is set in the hallway

(continued on page 3)



Clear answers help keep you on the right road to EC safety.

Inside

Joint Commission Resources

An official publication of The Joint Commission™

Joint Commission Resources

An affiliate of
The Joint Commission

1515 West 22nd Street, Suite 1300W
Oak Brook, IL 60523

Volume 18, Issue 3, March 2015

Send address corrections to: jcrcustomerservice@pbd.com or 877/223-6866.