

28 Pa. Code §569.35 (7) Non-Flammable Agents in Surgical Suite

Structured Exception

Recommendation

The Department permits use of alcohol-based skin preparation solutions under certain conditions that minimize the potential for alcohol to be a fire hazard.

Clinical evidence/support for this exception

As the third most commonly reported nosocomial or hospital-acquired infection, surgical site infections can cause considerable morbidity. Several antiseptic agents are available for preoperative preparation of skin at the incision site. Iodophors (e.g., povidone-iodine), alcohol-containing products, and chlorhexidine gluconate are the most commonly used agents (CDC, 1999). According to CDC, using alcohol-based preparations is strongly recommended as an intervention to prevent surgical site infection. Alcohol-based preparations are defined by the FDA as having one of the following active ingredients: ethyl alcohol, 60% to 95% by volume in an aqueous solution, or isopropyl alcohol, 50% to 91.3% by volume in an aqueous solution. Alcohol is readily available, inexpensive, and remains the most effective and rapid-acting skin antiseptic. Aqueous 70% to 92% alcohol solutions have germicidal activity against bacteria, fungi, and viruses, but spores can be resistant.^{1,2}

One potential disadvantage of the use of alcohol in the operating room is its flammability. CMS reported in their January 12, 2007 memo to Directors of Survey and Certification that alcohol-based skin preparations, if improperly applied, may be a fire hazard. Such dangerous situations can occur if the solution wicks into a patient's hair or linens or pools on the patient's skin. Alcohol vapor can also become trapped under the surgical drapes and channel into the surgical site, where heat producing devices such as electric cautery devices can serve as ignition sources and start a fire. However, CMS says that "in light of alcohol's effectiveness, there is a need to balance the risks of fire related to use of alcohol-based skin preparations with the risk of surgical site infections."³

Thus, healthcare facilities that use alcohol-skin preparation in anesthetizing a location should follow appropriate policies and procedures, such as the ones outlined in this exception process that limit the potential of alcohol to be a fire hazard.

Minimum requirements for this exception:

- A. Facilities must limit use to only those alcohol-based skin preparation solutions that:
 - are prepackaged to ensure controlled delivery to the patient in unit-dose applicators, swabs or other similar applicators; and
 - provide clear and explicit manufacturer/supplier instructions and warnings. The instructions for use shall be carefully followed.

- B. Facilities must establish procedures to ensure that:
 - the skin preparation solutions that contain combustible agents do not soak into the patient's hair or linens;
 - the skin preparation solution is completely dry prior to draping and inspection of the

prepped area to confirm it is dry prior to draping;

- the patient's medical record includes documentation that the above has occurred prior to the surgical procedure.

Documentation to be provided to the Dept by the facility:

- A. Facility policies and procedures for use of skin preparation solutions that contain combustible agents, including:
- Procedures for use of skin preparations that contain combustible agents in anesthetizing locations where electrocautery, laser or other sources of ignition may be present in order to reduce the risk of fire associated with the use of combustible skin preparations.
 - Content and documentation of annual mandatory education provided to all staff, including the physician staff, involved in the use of surgical skin preparations that contain combustible agents.
 - Documentation of notification to the facility's general liability carrier regarding use of surgical skin preparations that contain combustible agents any response by the insurance carrier.
- B. Serious event reports of any incidents or operating room fires when combustible skin preparation agents have been used, if there is patient harm; reports of an infrastructure failure where there is no patient harm under the Pennsylvania Patient Safety Reporting System (PA-PSRS). *(This is an ongoing requirement)*

Related Exceptions

None.

Footnotes:

1. Digison, Mary. "A Review of Anti-septic Agents for Pre-operative Skin Preparation." *Plastic Surgical Nursing*.27 (4), 2007. Pp. 185-189
2. Herman, Mich; Lepor, Herbert. "Skin Preparation for the Prevention of Surgical Site Infections: Which Agent is Best?" *Reviews in Urology*. 11(4), 2008. Pp. 190-195
3. Eddinger, D.; Zimmerman, M. "Use of Alcohol-based Skin preparations in Anesthetizing Locations". *CMS Memorandum to State Survey Agency Directors*. January 12, 2007.