

# **Regulatory Advisory**

*A service to members, advisories are produced whenever there is a significant development that affects the job you do in your community.*

## **Use of Alcohol-based Surgical Prep Solutions ASHE Analysis of NFPA 99 and Guidance Articles**

### **A Message to ASHE Members:**

Surgical fires — fires that occur on or in a surgical patient — happen only rarely, but their consequences can be grave. They can kill or seriously injure patients, injure surgical staff, and damage critical equipment. The risk of surgical fires is present when ever and wherever surgery is performed, whether in an operating room (OR), a physician’s office, or an out patient clinic<sup>1</sup>.

This opening statement, from *A Clinician’s Guide to Surgical Fires*, highlights the need for an understanding of risk of surgical fires, the fundamental principles of how fires start, how they can escalate, and how they can be prevented. Ignition sources from cautery or lasers, usage of flammable and combustible products, and an enriched oxygen atmosphere all contribute to the risk of fire. Each of these elements plays an important role in the care of the surgical patient and therefore *managing the risk of each element*, rather than removing any single element is the key to preventing surgical fires.

In response to a recently reported surgical fire, ASHE members have reported that some Authorities Having Jurisdiction (AHJ’s) have determined that alcohol based surgical prep solution may not be utilized in surgery. This determination is based on their interpretation of NFPA 99 – Standard on Healthcare Facilities. ASHE feels that NFPA 99 does not prohibit the use of alcohol based surgical prep solutions. In fact, NFPA 99 specifically addresses germicidal solutions in surgery and provides *conditions for their safe use*.

### **ASHE Recommendations:**

- **Hospitals and other healthcare facilities should be allowed to continue utilizing alcohol surgical prep solutions to prepare patients for surgery by optimizing conditions to prevent surgical infections, provided that the usage is consistent with the labeling and instructions of the product.**
- **Hospitals and other healthcare facilities utilizing alcohol surgical prep solutions should assess current procedures and develop protocols that ensure and document that the applied solution is thoroughly dry before introducing any source of ignition.**

These recommendations are based on ASHE’s interpretation of NFPA 99, guidance from ECRI, and guidance from JCAHO’s Sentinel Events Alert. Each of these documents should

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<sup>1</sup> A Clinician’s Guide to Surgical Fires, HEALTH DEVICES 32 (1), January 2003

be referenced when developing or evaluating organizational policies and procedures regarding prevention of surgical fires.

### **NFPA 99 – 1999 Edition - Code Analysis**

NFPA 99, Chapter 12 (Hospital Requirements), Part 12.4.1 (Anesthetizing Locations), Section 12.4.1.2.2 Germicides:

(A) Medicaments, including those dispersed as aerosols, shall be permitted to be used in anesthetizing locations for germicidal purposes, for affixing plastic surgical drape materials, for preparation of wound dressing, or for other purposes.

(B) Liquid germicides used in anesthetizing locations, whenever the use of cautery or electrosurgery is contemplated, shall be nonflammable.

(C)\* Whenever flammable aerosols are employed, sufficient time shall be allowed to elapse between deposition and application of drapes to permit complete evaporation and dissipation of any flammable vehicle remaining.

\*Appendix Clarification - A.12.4.1.2.2(C) Some tinctures and solutions of disinfecting agents can be flammable, and can be used improperly during surgical procedures. Tipping containers, accidental spillage, and the pouring of excessive amounts of such flammable agents on patients expose them to injury in the event of accidental ignition of the flammable solvent.

### **ASHE Analysis:**

Section 12.4.1.2.2 addresses the use of germicides in anesthetizing locations of hospitals. The three sentences (A, B, and C) are all interrelated parts of this single paragraph. Extracting sentence B as an absolute statement, without consideration of sentences A and/or C takes the information out of context. Sentence C is a modifier of sentence B. This becomes apparent when reading the three sentences together (A, B, and C) as they would appear as a paragraph in a book. When read in that light, sentence C becomes a modifier of sentence B to establish the conditions to be met when flammable aerosols are used in anesthetizing locations where cautery or electrosurgery is contemplated:

*Medicaments, including those dispersed as aerosols, shall be permitted to be used in anesthetizing locations for germicidal purposes, for affixing plastic surgical drape materials, for preparation of wound dressing, or for other purposes. Liquid germicides used in anesthetizing locations, whenever the use of cautery or electrosurgery is contemplated, shall be nonflammable. Whenever flammable aerosols are employed, sufficient time shall be allowed to elapse between deposition and application of drapes to permit complete evaporation and dissipation of any flammable vehicle remaining.*

Sentence C is further clarified in the appendix. An inconsistency does exist as sentence C specifies flammable aerosols while the appendix identifies that “solutions of disinfecting agents can be flammable”. This inconsistency should not lead to an interpretation that sentence C only applies to aerosols and excludes liquids. The concern that this entire section addresses, ignition of flammable vapors, can occur whether the solution is packaged as an aerosol or a liquid; therefore sentence C should be interpreted as describing conditions for the use of flammable germicides whether they are delivered via aerosol or liquid.

**Guidance Article: *A Clinician's Guide to Surgical Fires - How They Occur, How to Prevent Them, How to Put Them Out***

ECRI, an independent non-profit health services research organization, has published several articles on preventing, preparing for and managing surgical fires. This guidance article is a comprehensive look at the causes, risk factors, and operational techniques to prevent surgical fires. ECRI has reported that 50-100 surgical fires, defined as those fires that are on or in the patient, occur annually in the United States. The fuels in these fires are multiple and include the patients own hair (face, scalp, body) and GI tract gases. Other combustibles include, but are not limited to, anesthesia components (endotracheal tubes, breathing circuits, airways, masks), prepping agents including alcohol, linens, dressings, various ointments, gloves, tubing, and tourniquet cuffs and other materials that may not be flammable in an environment that is not oxygen or nitrous oxide enriched.

Rather than prohibiting specific products to reduce the risk of fire, the guidance article offers ways that the risk of surgical fires can be mitigated through effective management all each of the key patient care elements that could contribute to fires. The section titled "Minimizing Fuel Risks" specifically identifies during surgical prep:

- Be aware that alcohol-based preps are flammable.
- Avoid pooling or wicking of flammable liquid preps.
- Allow flammable liquid preps to dry fully before draping; pooled or wicked liquid will take longer to dry than will prep on the skin alone.
- Use a properly applied incise drape, if possible, to help isolate head and neck incisions from O<sub>2</sub>-enriched atmospheres and from flammable vapors beneath the drapes. Proper application of an incise drape ensures that there are no gas communication channels from the under drape space to the surgical site.

ASHE's interpretation of NFPA 99 section 12.4.1.2.2 is consistent with ECRI's guidance

**Joint Commission - Sentinel Event Alert • Issue 29 - June 24, 2003**

Joint Commission's sentinel event alert is consistent with ASHE's interpretation of NFPA 99 and the ECRI guidance article in its focus on understanding and mitigating fire risks rather than prohibiting patient care products. "The basic elements of a fire are always present during surgery and a misstep in procedure or a momentary lapse of caution can quickly result in a catastrophe," says Mark Bruley, vice president, Accident and Forensic Investigation, ECRI. "Slow reaction or the use of improper fire-fighting techniques and tools can lead to damage, destruction or death." Bruley notes that virtually all surgical fires are preventable and that their impact can be lessened through an understanding of fire and how to fight it. The alert goes on to state that health care organizations help prevent surgical fires by informing staff members, including surgeons and anesthesiologists, about the importance of controlling heat sources by following laser and ESU safety practices; *managing fuels by allowing sufficient time for patient prep*; and establishing guidelines for minimizing oxygen concentration under the drapes.

### **The Role of Alcohol in Lowering the Risk of Surgical Site Infection**

Alcohol is an important tool in the hospital operating room environment, proven to lower the risk of surgical site infection. “Alcohol is one of the oldest antiseptics, and remains one of the most effective, outperforming virtually all other antiseptics.... Alcohol is bactericidal and cheap, and does not damage human skin. It kills vegetative bacteria both by denaturing proteins and by interfering with bacterial metabolism. Fungi and viruses are also destroyed by alcohol, but bacterial spores can be resistant. Although alcohol rapidly evaporates, damaged organisms continue to die after a single brief exposure..... While all alcohols are bactericidal, higher-molecular-weight alcohols are more bactericidal. Other subtle differences between alcohols exist, but the single most important factor is concentration, since all alcohols must be diluted with water to effectively denature proteins. Both ethyl and isopropyl alcohols are in common clinical use, usually in concentrations of 70-90% .... The World Health Organization recently designated alcohol as the ‘gold standard’ against which all skin antiseptics should be judged.”<sup>2</sup>

There are other commonly used antiseptics –iodophors and chlorhexidine gluconate (CHG)- that have a *residual* effect on skin flora (i.e., continuing kill action after the alcohol evaporates). They are available as aqueous solutions or tinctures (alcoholic based solutions). The added value of tinctures (at varying concentrations of alcohol) is the “instant” action of alcohols as noted above, combined with the continuing residual activity of an iodophor or CHG. The combination improves residual activity, faster drying of the solution on the skin and a continuing residual action of the antiseptic whether an iodophor or CHG. Therefore it is essential to provide the full spectrum of options for skin antisepsis in order to optimize all factors that may prevent surgical site infection.

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March 18, 2005

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<sup>2</sup> Fry, Donald E. *Surgical Infections, Antiseptics in Surgery*, 1<sup>st</sup> Edition 1995, Little, Brown and Company.