Proposed TIA
NFPA 99, 2005 edition

13.4.1.2.2 Germicides and Antiseptics.
13.4.1.2.2.1 Medicaments, including those dispersed as aerosols, shall be permitted to be used in anesthetizing locations for germicidal and antiseptic purposes, for affixing plastic surgical drape materials, for preparation of wound dressing, or for other purposes.
13.4.1.2.2.2* Flammable liquid germicides or antiseptics used in anesthetizing locations, whenever the use of electro-surgery, cautery or electrosurgery a laser is contemplated, shall be nonflammable packaged to ensure controlled delivery to the patient in unit dose applicators, swabs, and other similar applicators.).
13.4.1.2.2.3 Whenever the application of flammable liquid germicides or antiseptics is employed in surgeries where the use of electro-surgery, cautery or a laser is contemplated, time shall be allowed to elapse between application of the germicide or antiseptic and:

a) The application of drapes to permit complete evaporation and dissipation of any flammable vehicle remaining, and
b) The use of electro-surgery, cautery or a laser to ensure the solution is completely dry and to permit thorough evaporation and dissipation of any flammable vehicle remaining.

13.4.1.2.2.4 Any solution-soaked materials shall be removed from the operating room prior to draping or use of electro-surgery, cautery or a laser.
13.4.1.2.2.5 Pooling of flammable liquid germicides or antiseptics shall be avoided.
13.4.1.2.2.6 A preoperative "time out" period shall be conducted prior to the initiation of any surgical procedure using flammable liquid germicides or antiseptics to verify that a flammable germicide or antiseptic:

a)application site is dry prior to draping, and use of electro-surgery, cautery or a laser, and
b) that pooling of solution has not occurred, or has been corrected, and
c) any solution soaked materials have been removed from the operating room prior to draping and use of electro-surgery, cautery or a laser.

(C) 13.4.1.2.2.7 Whenever flammable aerosols or antiseptics 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.
13.4.1.2.2.8 Health care organizations shall establish policies and procedures outlining safety precautions related to the use of flammable liquid or aerosol germicides or antiseptics used in anesthetizing locations, as required in Section 13.4.1.2.10 whenever the use of electro-surgery, cautery or a laser is contemplated.

A.13.4.1.2.2.2 Some tinctures and solutions of disinfecting agents provide significant clinical benefits in reducing the risk of surgical infections. However, they 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~~. To control this risk, flammable germicides or antiseptics that are used when electro-surgery, cautery or a laser is contemplated should be packaged to ensure controlled delivery to the patient (e.g., unit dose applicator, swab, etc.) in small volumes appropriate for single application.

A.13.4.1.2.2.5 If pooling occurs, wick excess solution and allow the germicide or antiseptic to completely dry.

Substantiation:

The Issue

The American Society for Healthcare Engineering of the American Hospital Association is dedicated to providing and maintaining safe environments for our patients and staff. We believe that certain environmental risks are inherent to essential clinical procedures utilized to render patient care; but these risks may be properly managed and potential hazards mitigated through standardized procedures implemented by experienced and highly trained staff. Representatives from clinical practice, infection control, manufacturing, hospital administration, and a federal regulatory agency have developed this TIA. Its intent is to clear up language that has remained unchanged in NFPA 99 for over 25 years and has fallen behind the common surgical practices and products that are currently utilized in hospitals throughout the US.

The issue is not a simple one as operating rooms of hospitals and ambulatory care settings are busy and hectic places yet they are a sanctuary for the healing of millions of people every year. The medical procedures and supporting preparation that takes place in these rooms can be hazardous to the health of the patient and staff therefore every precaution must be taken by the operating room team to safeguard the environment by closely following established procedures. Section 13.4.1.2.2 on germicides is not written with strong enough language to provide health care staff and regulators with the opportunity to provide this safe environment when alcohol based skin prep is employed. Recent events have questioned the use of alcohol skin prep when cautery electro-surgery, or lasers are contemplated. The dilemma in today's operating room environment is that cautery, electro-surgery, or lasers are commonplace and will be used or readied for use in 90% or more of surgical procedures. The alcohol skin prep is significantly more efficient and importantly, more effective in preventing surgical infections than aqueous solutions. Therefore, the newly proposed language is to strengthen the procedural elements of using flammable germicides instead of eliminating them as a clinical tool.

"As to the issues, alcohol based products are no more dangerous in the OR than a scalpel, laser, oxygen, or drapes. Banning them will hinder effective surgery. The key to preventing surgical fires is to ensure that the staff knows the hazards and how to minimize their risks." Mr. de Richemond, Associate Director, ECRI

The Fix

This TIA extensively increases the awareness of the risk from fire when alcohol skin prep is employed and electro-surgery, cautery, and lasers are contemplated. The risk is not in the volume of material, spilling, or mishandling of the skin prep but in trapping pooled solution under a surgical drape and then igniting it with a heat source. A thoroughly dry site additionally ensures that no vapors remain. To this extent, the TIA has added language to strengthen the clinical protocols used in the surgical preparation process. This has been accomplished by adding:

1. Application of alcohol skin prep shall be from a unit dose style of applicator.
2. Expanding and emphasizing the critical need for appropriate drying time before surgical drapes are applied or a heat-producing source is employed.
3. The removal of solution-soaked material from the area to avoid a potential oversight.
4. A procedure to deal with the pooling of solution. This should not be an issue if the paragraph on unit dose application is enforced.
5. A policy mandating a "time out" period prior to the draping or use of electro-surgery, cautery, or lasers. This procedure is similar to the Joint Commission's new standard on wrong-side surgeries and, mandates an "all clear" be announced by a selected staff member.
6. Reemphasizes the existing NFPA 99 language requiring a periodic hazard assessment be performed of the surgical procedures and the OR environment.

With the severe strengthening of the skin prep surgical protocols and the mandatory addition of a "time out", the hazard of using alcohol based germicides and antiseptics are being effectively managed.

Clinical Background

Prevention of Surgical Site Infection

Scope of the problem: According to the *CDC Guideline for Guideline for Prevention of Surgical Site Infection (SSI), 1999,* "in the United States alone, there were an estimated 27 million surgical procedures are performed each year. (13)The CDC's National Nosocomial Infections Surveillance (NNIS) system, established in 1970, monitors reported trends in nosocomial infections in U.S. acute-care hospitals. Based on NNIS system reports, SSIs are the third most frequently reported nosocomial infection, accounting for 14% to 16% of all nosocomial infections among hospitalized patients. (14) Of these SSIs, two thirds were confined to the incision, and one third involved organs or spaces accessed during the operation. When surgical patients with nosocomial SSI died, 77% of the deaths were reported to be related to the infection, and the majority (93%) were serious infections involving organs or spaces accessed during the operation" [Note: see appendix for citation references]

Skin prepping: The entire purpose of skin prepping in the OR, as close to the time of incision is to ensure the best possible patient outcome, i.e., prevention of surgical site infection. There is agreement based on epidemiological evidence. That "most surgical site infections originate from the patient's own skin, mucous membranes or viscera. When mucous membranes or skin is incised, the exposed tissues are at risk for contamination with endogenous flora (58)" - even though we must- and do- maximize all other environmental parameters to reduce exogenous or other sources of contamination. The use of alcohol has been established as the 'gold standard' for prevention of surgical site infection because of its speed in 'kill' or cidal activity against microorganisms.

Clinicians are aware of the hazards of alcohol and would agree that if there were safer and equally effective agents for surgical preps they would willingly consider substitutes. Among the other commonly used antiseptic agents today are iodophors (e.g., povidone-iodine), chlorhexidine gluconate (CHG) in aqueous solutions, or solutions of these in alcohol (termed tinctures.) However, even the aqueous formulations involve some use of alcohol during skin cleaning.

According to the *CDC Guideline,* "no studies have adequately assessed the comparative effects of these preoperative skin antiseptics on SSI risk in well-controlled, operation-specific studies." Hence the *complete removal* of alcohol in any form constitutes an unacceptable risk for increased surgical site infection and has never been attempted. The most common practice is using aqueous formulations with alcohol skin wipes, alcohol alone, or tinctures of iodophors or CHG. The fact remains that the clinical community simply *does not know the unintended consequence of complete alcohol removal because no one has been willing to risk development of SSI.* Application outside of the operating room and moving the patient later—once the site is dry is not good for the patient and increases risk of recontamination. How these products are typically used in teaching and training is described by a well-known authority in surgical infectious diseases:

> **Dellinger, E Patchen, *Surgical Infections, Surgical Infections and Choice of Antibiotics* 15th Edition 1997; W.B. Saunders Company.**
> "Skin Preparation. The skin is an important source of organisms contaminating surgical wounds. Two methods can be recommended to prevent skin organisms from entering the wound. First, the time-honored technique is to scrub the entire operative area of the patient for 5 to 7 minutes with a germicidal detergent solution and then paint the region with an antimicrobial solution of either tincture of iodine, povidone-iodine, or chlorhexidine. An alternative way to isolate the skin from the wound is to use an antimicrobial incise drape applied to the entire operative area, with the incision made through the plastic. Before the incise drape is applied, the skin should be scrubbed for 1 minute with a 70% solution of alcohol or a solution of 2% iodine in 90% alcohol to kill surface bacteria…. the technique of drape application, including cleansing of surface fat and debris from the skin and application only to a dry surface, becomes important for its success."

Alcohol: As noted before, alcohol is the 'gold standard' 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."[1]

Other antiseptic agents –iodophors; chlorhexidine gluconate (CHG):
Tinctures: Iodophors or CHG have a persistent antimicrobial efficacy on skin flora (i.e., continuing kill action after the alcohol evaporates). They are most effective as tincture. 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 iodophors or CHG once the site is dry. The combination improves cidal activity, faster drying of the solution on the skin and a continuing cidal action of the antiseptic whether an iodophor or CHG. Further, use of a tincture enhances the incise drape adhesion, which can dramatically reduce infection risks by protecting the wound from normal surgical fluids (blood, saline etc) since it dries so quickly.

Aqueous: Aqueous formulations must be dry to be effective for cidal activity, but take prolonged time to dry—10-15 minutes. If tinctures are *not* used, then alcohol swabs are used to remove prep residue prior to applying the drape in order to decontaminate the skin as close to incision time as possible. Further, many patients are allergic to iodophors or CHG and prolonged contact with the aqueous solutions may lead to skin 'burns'

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.

Risk management

Prior experience with managing the risk for fire recognizes that there are many sources of fire risk—other combustible fuels such as the patient's own hair, (face, scalp, body) and GI tract gases - as well as endotracheal tubes, breathing circuits, airways and masks, as well as, prepping agents including alcohol, linens, dressings, various ointments, gloves,

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[1] Fry, Donald E. *Surgical Infections, Antiseptics in Surgery*, 1st Edition1995, Little, Brown and Company.

tubing, and tourniquet cuffs and other materials that may not be flammable in an environment that is not oxygen or nitrous oxide enriched.

ECRI, an independent non-profit health services research organization, has published several articles on preventing, preparing for and managing surgical fires and in its Guidance Article*: A Clinician's Guide to Surgical Fires - How They Occur, How to Prevent Them, How to Put Them Out* **implicitly** recognizes that the this must be done to minimize or even eliminate a very predictable risk—that of surgical site infections. The steps recommended by ECRI and endorsed by the Joint Commission on Accreditation of Healthcare Organization in their prior Sentinel Alert on preventing fires in the OR are incorporated into the proposed TIA.

ASHE proposes including key practices to ensure these protocols are recognized and implemented by calling for a time out before introducing a source of ignition (e.g., electro-surgery, cautery or laser) thus permitting the optimal skin preparation, reducing risk of SSI yet minimizing risk of fire.

Appendix:

Excerpt: Guideline for Prevention of Surgical Site Infection, 1999 Alicia J. Mangram, MD; Teresa C. Horan, MPH, CIC; Michele L. Pearson, MD; Leah Christine Silver, BS; William R. Jarvis, MD; The Hospital Infection Control Practices Advisory Committee AJIC Volume 27, Number 2 *Guideline for Prevention of SSI 99* pp.107-108

Table 6. Mechanism and Spectrum of Activity of Antiseptic Agents Commonly Used for Preoperative Skin Preparation and Surgical Scrubs

Agent	Mechanism of Action	Gram-Positive Bacteria	Gram-Negative Bacteria	Mtb	Fungi	Virus	Rapidity of Action	Residual Activity	Toxicity	Uses
Alcohol	Denature proteins	E	E	G	G	G	Most rapid	None	Drying, volatile	SP, SS
Chlorhexidine	Disrupt cell membrane	E	G	P	F	G	Intermediate	E	Ototoxicity, keratitis	SP, SS
Iodine/ Iodophors	Oxidation/ substitution by free iodine	E	G	G	G	G	Intermediate	Minimal	Absorption from skin with possible toxicity, skin irritation	SP, SS
PCMX	Disrupt cell wall	G	F*	F	F	F	Intermediate	Good	More data needed	SS
Triclosan	Disrupt cell wall	G	G	G	P	U	Intermediate	E	More data needed	SS

Abbreviations: E, excellent; F, fair; G, good; Mtb, Mycobacterium tuberculosis; P, poor; PCMX, para-chloro-meta-xylenol; SP, skin preparation; SS, surgical scrubs; U, unknown.
Data from Larson E.[176]
*Fair, except for *Pseudomonas* spp.; activity improved by addition of chelating agent such as EDTA.

c. Patient skin preparation in the operating room
Several antiseptic agents are available for preoperative preparation of skin at the incision site (Table 6).

The iodophors (e.g., povidone-iodine), alcohol-containing products, and chlorhexidine gluconate are the most commonly used agents. No studies have adequately assessed the comparative effects of these preoperative skin antiseptics on SSI risk in well-controlled, operation-specific studies.

Alcohol is 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.12 Alcohol is readily available, inexpensive, and remains the most effective and rapid-acting skin antiseptic.(176) Aqueous 70% to 92% alcohol solutions have germicidal activity against bacteria, fungi, and viruses, but spores can be resistant.(176,177) One potential disadvantage of the use of alcohol in the operating room is its flammability.(176-178) Both chlorhexidine gluconate and iodophors have broad spectra of antimicrobial activity.(177,179-181) In some comparisons of the two antiseptics when used as preoperative hand scrubs, chlorhexidine gluconate achieved greater reductions in skin microflora than did povidone-iodine and also had greater residual activity after a single application.182-184 Further, chlorhexidine gluconate is not inactivated by blood or serum proteins. 176,179,185,186 Iodophors may be inactivated

by blood or serum proteins, but exert a bacteriostatic effect as long as they are present on the skin. (178,179)

Before the skin preparation of a patient is initiated, the skin should be free of gross contamination (i.e., dirt, soil, or any other debris). (187) The patient's skin is prepared by applying an antiseptic in concentric circles, beginning in the area of the proposed incision. The prepared area should be large enough to extend the incision or create new incisions or drain sites, if necessary.(1,177,187) The application of the skin preparation may need to be modified, depending on the condition of the skin (e.g., burns) or location of the incision site (e.g., face). There are reports of modifications to the procedure for preoperative skin preparation which include: (1) removing or wiping off the skin preparation antiseptic agent after application, (2) using an antiseptic-impregnated adhesive drape, (3) merely painting the skin with an antiseptic in lieu of the skin preparation procedure described above, or (4) using a "clean" versus a "sterile" surgical skin preparation kit.(188-191) However, none of these modifications has been shown to represent an advantage.

C.CDC RECOMMENDATIONS

1. Preoperative

a. Preparation of the patient

8. Thoroughly wash and clean at and around the incision site to remove gross contamination before performing antiseptic skin preparation. *Category IB*
9. Use an appropriate antiseptic agent for skin preparation (Table 6). *Category IB*
10. Apply preoperative antiseptic skin preparation in concentric circles moving toward the periphery. The prepared area must be large enough to extend the incision or create new incisions or drain sites, if necessary. *Category II*

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