



Position Statement Regarding the Use of Alcohol-Based Surgical Skin Preparations

Based on numerous inquiries and requests from both hospital and ambulatory surgical center providers, the department is issuing this position statement regarding the use of alcohol-based pre-operative antimicrobial skin preparations.

Both the Hospital Licensing Rules, under 25 TAC §133.143(a), and the Ambulatory Surgical Center Rules, under 25 TAC 135.42(a), state:

"Flammable germicides. Flammable germicides shall not be used for preoperative preparation of the surgical field."

The literal interpretation of the rule would prohibit the use of any alcohol-based surgical skin preparation. However, it is not the intent of the department to establish rules that will prohibit the use of new and more effective products and technology, as long as there is evidence to support that they are safe for the patients that we are charged to protect. The Department recognizes the demonstrated efficacy of these alcohol-based skin preparation products in preventing surgical wound infections. Literature also supports that when qualified, trained operating room staff follow appropriate precautions and procedures, the use of these products can be safe in the surgical environment.

The Department plans to review and revise these rules in the near future. In the interim period, facilities who choose to utilize an alcohol-based surgical skin preparation should not be cited for a violation of the above referenced rules, provided all of the following conditions are met:

- 1) Only self-contained, single-use, pre-measured applicators may be used to apply alcohol based surgical skin preparations.
- 2) All product safety warnings and guidelines must be followed in using the product.
- 3) The facility must have detailed policies and procedures outlining the safety precautions related to the use of the products, which at a minimum must address:
 - Minimum drying times and staff responsibility for ensuring prep is dry.
 - Prevention of pooling and actions to be taken if pooling occurs.
 - Prohibition of draping until product is thoroughly dried
 - Limitations related to use of ignition sources only after prep drying is assured.
 - Any other specific requirements and precautions as specified by the product manufacturer must be incorporated into the facility policy.
 - Policies shall also address staff recourse should a physician issue an order that compromises the safe use of the product.

Alcohol-Based Surgical Skin Preparations
Position Statement

- 4) At a minimum, the facility must include the following documentation in the patient's clinical record:
 - Time the prep was applied and signature of staff applying the solution.
 - Time the prep was determined to be dry and the signature of the staff person who made the determination.
 - Documentation that absence of pooling was verified, or if pooling occurred, corrective actions taken, and signature of responsible staff person.
 - Time draping was applied and staff initials.
 - Time procedure was initiated and staff initials.

- 5) All staff responsible for the application of alcohol based surgical preps, and all staff working in a surgical environment where these preps are utilized, must have attended training on the use of the products and the appropriate safety precautions. Documentation verifying staff participation in training must be maintained in personnel training records.

- 6) The facility must outline the process for investigating and addressing any violation of the policies and procedures related to the use of alcohol-based surgical skin preparations.

- 7) Any occurrence of fire in the surgical suite must be reported to the Department within one (1) business day. The cause of the fire must be investigated and a corrective action plan must be developed.

Issued September 28, 2004