

**tyco**

Healthcare



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Merrily Gere  
Connecticut Department of Environmental Protection  
Bureau of Air Management  
Engineering and Enforcement Division  
79 Elm Street  
Hartford, CT 06106-5127

**Re: Comments on the Proposed Revisions to RCSA §22a-174-20**

Dear Ms. Gere:

United States Surgical, Division of Tyco Healthcare Group LP (USS) appreciates the opportunity to provide comments on the Department's proposed revisions to RCSA §22a-174-20. USS is a diversified medical device manufacturer, which utilizes a number of solvents at various stages in our manufacturing operations in North Haven. Our comments primarily concern RCSA §22a-174-20(jj), which deals with spray application equipment cleaning.

In §22a-174-20(jj)(3)(A), the Department lists a number of operations and industries which are exempt from the requirements of this subsection. Based on the complexities of our manufacturing processes and the fact that we are subject to the stringent requirements of the U.S. Food and Drug Administration (FDA), USS requests that "medical device manufacturing" be added to this list. Any changes to our operations may invoke separate requirements to conduct additional expensive, time consuming validations and/or toxicity testing of the surgical products. Without this regulatory change, we would be severely limited in our ability to comply with this proposed rule while continuing to remain competitive in a declining economic market.

Within §22a-174-20(jj), the Department proposes to implement several options for the cleaning of the spray application equipment. Three (3) of the five (5) options given require the use of a "cleaning solvent with an applied VOC content that does not exceed 50 grams per liter (0.417 lb/gal)." In two (2) of these options [§22a-174-20(jj)(4)(B) and (D)], the low-VOC cleaning solvent is used in a relatively "closed" system to minimize emissions. USS requests that the requirement for the use of a "cleaning solvent with an applied VOC content that does not exceed 50 grams per liter (0.417 lb/gal)" be removed

from these two (2) specific applications [§22a-174-20(jj)(4)(B) and (D)] using a “closed” system. This request is based on the following:

- We feel that the reduction in solvent emissions with the use of the low-VOC cleaning solvent versus any other solvent would be minimal in the “closed” systems.
- The low-VOC cleaning solvent may not be able to adequately clean the spray application equipment in a timely manner, placing an additional financial burden on the regulated community.
- In the event a new solvent needs to be used during cleaning, the introduction of the foreign material to an established, validated manufacturing process will require the need to expend resources to conduct additional, extensive, quality testing. Again, the financial burden to conduct this expensive and time consuming process will fall upon the regulated community.

In light of our requests, we would like to stress our continued efforts in ensuring that our manufacturing operations have minimal impact on the surrounding environment. USS currently utilizes several non-VOC and low-VOC cleaning solvents in our processes and will continue to explore their use in other applications. We would also like to mention that we strictly adhere to good chemical handling work practices to minimize VOC emissions to the extent practicable.

If you have any questions or require any additional information please contact me directly at (203) 492-6254 or by email at [steven.burke@covidien.com](mailto:steven.burke@covidien.com).

Sincerely,



Steven Burke  
Principal Environmental, Health and Safety Engineer