



## Quality Tech Services, Inc. News Release

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**For Immediate Release**

**MINNEAPOLIS, MINN.** -- Sopheak Srun (QTS Validation and Sterilization

Specialist) and Brian Nissen (QTS Project Engineer) have co-authored an article

that has been published in the May/June issue of *Biomedical Instrumentation &*

*Technology* (BI&T). This article, which is entitled, "Medical Device SALs and

Surgical Site Infections: A Mathematical Model," presents a mathematical model

that can be used to predict the impact that choosing an alternate sterility

assurance level (SAL) would have on the incidence of surgical site infections.

Using nosocomial infection data published by the Centers for Disease Control

and Prevention, the mathematical model predicts that an industry-wide change

in the SAL requirement from  $10^{-6}$  to  $10^{-5}$  or  $10^{-4}$ , and in some examples even  $10^{-3}$  or

$10^{-2}$ , would not have a statistically detectable impact on the incidence of surgical

site infections. Industry-wide acceptance of an alternate SAL would have

profound impacts on product innovation. Many medical device manufacturers encounter tremendous difficulties in sterilizing special device materials that cannot withstand traditional methods of sterilization. For example, some combination devices containing a drug component cannot withstand a typical gamma radiation sterilization dose of 25 kGy, nor can these devices withstand any exposure to ethylene oxide. Using Method  $VD_{max}$ , a device normally sterilized with a minimum delivered dose of 25 kGy could alternatively be sterilized with a minimum delivered dose of approximately 17 kGy in order to achieve an SAL of  $10^{-3}$ .

The AAMI Sterilization Standards Committee SAL Working Group, of which Sopheak and Brian are members, has discussed the implications of this mathematical model on AAMI ST67 (*Sterilization of health care products – Requirements for products labeled “STERILE”*), which is the standard that provides the requirements and guidance for how to justify an alternate SAL if an SAL of  $10^{-6}$  cannot be used. The committee hopes to use the data presented in this paper towards efforts to harmonize SAL requirements around the world.

Quality Tech Services, established in 2001 by a team of dedicated medical professionals, QTS specializes in Class 7 clean room assembly, packaging, and sterilization services for medical devices. The company is privately-held and headquartered in Bloomington, MN. QTS is ISO 13485 certified, FDA Registered and JPAL Compliant.

For more information please visit [www.qtspackage.com](http://www.qtspackage.com)

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