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**STERIS Corporation Comments to
Transmissible Spongiform Encephalopathies Advisory Committee
July 17-18, 2003 Panel Meeting**

Concerns Regarding Current Decontamination Procedures:

In the United States there are currently no approved guidelines for the decontamination of medical devices or high risk manufacturing equipment potentially contaminated with prions, the proposed causative agents of TSEs. Although these diseases are considered rare, iatrogenic transmission of TSEs has been reported both clinically and under experimental laboratory conditions. Further, prions are considered highly resistant to standard high level disinfection or sterilization processes used for medical device reprocessing. In addition to medical device reprocessing, similar concerns exist for high risk manufacturing equipment used to process materials of bovine origin and materials sourced from high risk human tissues.

Although the Center for Disease Control (CDC) has drafted proposed guidelines for disinfection and sterilization that include proposed recommendations for prion decontamination of medical devices, these guidelines have not been finalized. In addition, the CDC draft guidelines are based on the current World Health Organization (WHO) guidelines that were developed based on a review of published literature on prion decontamination technologies and processes. The literature referenced by WHO is based on varying test models and methods that may impact the measured effectiveness of recommended decontamination processes. These issues highlight the need for reproducible and controlled methods for evaluating the effectiveness of WHO recommended decontamination processes and additional technologies that may be effective in reducing or inactivating prions. The evaluation of current and future technologies using standard methodology will facilitate the development of effective guidelines for reprocessing and decontamination in both the medical device and high risk manufacturing settings.

In addition to efficacy considerations, the current WHO recommended methods raise concerns regarding compatibility of recommended processes with medical device and manufacturing surfaces. Several WHO recommended processes have the potential to damage common medical device surfaces and sterilizers used in reprocessing. Current recommendations include the use of 1 N NaOH or Sodium Hypochlorite. These chemicals can damage medical device surfaces and in some cases render the devices unusable. In addition, these chemicals when used in an autoclave can cause damage to the interior of an autoclave. Finally, individuals reprocessing medical devices or equipment surfaces are at greater risk of injury when handling highly corrosive materials such as NaOH. These issues highlight the need for effective reproducible decontamination processes that are compatible with typical medical device surfaces and are practical to use in a clinical setting. As additional scientific information becomes available regarding

the potential for transmission of prions, the development of compatible and effective decontamination procedures may become increasingly important when dealing with temperature sensitive medical devices.

Recommendations:

There is clearly a need for safe, effective and compatible decontamination methods against prion contamination in both medical device reprocessing and high-risk manufacturing. To establish and confirm effective decontamination processes requires the use of a methodology that is consistent and provides an acceptable level of sensitivity to accurately measure performance. This is a key initial step in the development and issuance of guidance documents that provide recommendations on appropriate decontamination procedures in medical device reprocessing and high-risk manufacturing. Based on a review of the published literature for methods used to evaluate decontamination processes, it is clear that *in vitro* methods are not currently sensitive enough for this purpose. At this time, the most viable approach to confirming effective decontamination is the use of *in vivo* infectivity assays. These methods provide appropriate consistency and sensitivity when used in conjunction with adequate internal controls. STERIS Corporation has developed an *in vivo* assay in conjunction with the Commissariat à l'Énergie Atomique (CEA) in France based on the most recent published research in this area to measure infectivity of representative contaminated surfaces. This model represents a worse case, clinically relevant process for evaluating the effectiveness of surface decontamination processes. STERIS will present an overview of this methodology in addition to interim results from the study to provide the committee members with perspective on the potential utilization of this methodology for evaluation, interpretation and validation of decontamination technologies.

In addition, STERIS Corporation fully supports the Advanced proposal to coordinate an international workshop to review, expand and finalize current draft guidelines for TSE decontamination (Rutala & Weber, 2001; CDC HIPAC draft). This working group should include representatives from the medical device industry; infection control/central services personnel, TSE experts, federal regulators, and other interested parties. In reviewing the risks associated with reusable medical devices as a mode of TSE transmission and by critically reviewing existing international guidelines, it is envisaged that this group could advise the FDA on expanding and finalizing current draft guidelines for TSE decontamination; provide recommendations on confirming the effectiveness of proposed decontamination methods; and identify additional areas of research to support these recommendations.

The working group, in recommending the development of decontamination guidelines for medical device reprocessing, would focus on the following:

- Establishment and documentation of facility policy;
- Identification of risks groups (and tissues) and tracking of these cases;
- Use of disposable devices and/or device incineration;

- Decontamination methods for devices (temperature resistant and sensitive) used on at-risk patients.

The working group would also consider the development of decontamination guidelines that may be utilized in high risk manufacturing areas that take into consideration adequate cleaning and decontamination to limit the potential cross contamination of manufacturing equipment.

In addition, the working group would also assess and determine the need for research in prion decontamination, including:

- Development of standard test methodology;
- Confirmation of the effectiveness of currently proposed decontamination processes;
- Evaluation of the compatibility of decontamination methods on medical devices, including reprocessing equipment;
- Development of additional TSE decontamination processes and technologies that are effective and compatible with surfaces to be decontaminated.