**TSEAC**
**July 17 & 18, 2003**

**TOPIC #3**
**Questions for the Panel**

1. What information in the published literature should be viewed as supportive data to establish methods and procedures for reprocessing medical devices potentially contaminated with TSE?

2. Data in the published scientific literature or developed from in-house studies with a specific medical device may not be applicable to other medical devices. For example, differences in device fabrication material, device design, methods for cleaning, or changes in device intended use may alter the effectiveness of a TSE inactivation procedure.

    a. Please discuss which aspects of a medical device and its use should be considered when determining whether a new TSE inactivation study might be needed for a specific device?

    b. Please provide guidance on how these aspects of a medical device should be included in the TSE inactivation study design.

3. What criteria should be considered when analyzing the results of TSE inactivation studies? For example, is log reduction of TSE infectivity, (expressed as), an appropriate endpoint for such studies?

    a. If so, what magnitude of log reduction in LD50 would be considered safe?

    b. Are there other endpoints, such as the presence of PrPres that would be acceptable surrogate markers for infectivity?

4. The extent of TSE inactivation required for any reprocessing procedure depends on the amount of infectious agent present in/on the device.

    a. Considering the scientific literature describing the level of infectious material present in different human tissues, please discuss what amounts of infectious material may be present on contaminated medical devices.

    b. Please provide guidance on how the level of infectious material on a medical device should be considered when designing and interpreting a TSE inactivation study.