1. Quality Monitoring of the Feedwater should be performed according to established procedures and schedules.

2. Clean Steam Sampling Procedures should be established and sampling personnel should be qualified in these procedures.

3. When Operating Continuously, the Clean Steam Generator and Distribution System should be sampled and tested against specifications as follows:

   - Weekly sampling of the generator;
   - Monthly sampling from at least one Critical Use Point (CUP) located outside the Aseptic Processing Area (APA); and
   - Use points sampled on a rotating basis so that all use points are sampled, at least once, every six (6) months.

   Following any shut down, samples from the generator and all use points should be taken and tested before use is authorized to resume.

4. Clean Steam Condensate Samples when required for Bacterial Endotoxin Testing (BET) should be collected in endotoxin free containers using a technique designed to minimize microbial contamination of the samples. BET should be conducted as soon as possible after collection. The time of collection should be recorded.

5. Bacterial Endotoxin Alert and Action Levels for monitoring clean steam condensate should be established based on process capabilities and product requirements or the values below, whichever is smallest:

   - Alert Level -based on product requirements and system performance, but not to exceed 0.125 EU/ml; or
   - Action Level -two successive positive BET results or any result ≥0.25EU/mL.

   Exceeding alert and action levels should initiate an immediate investigation, resample, and retest.

6. Chemical Alert and Action Levels for clean steam should be established based on process capabilities and product requirements. Maximum acceptable chemical levels should meet applicable WFI compendial limits and should be determined by applicable compendial methods.

