8. Anion/Cation Exchange Resins and Continuous Electrodeionization (CEDI) Systems should be monitored by measuring the conductivity of the output water. Resins should be regenerated or replaced based on performance monitoring.

9. Hydrophobic Microbial-Retentive Vent Filters on still condensers and storage tanks should be integrity tested before and after use (see PQS P4104). Vent filters for HPW and WFI systems should be sterilized before use. Vent filters should be maintained condensate free (e.g., heated filter housing) and replaced annually or at intervals indicated by validation or qualification studies, whichever is shorter.

10. In-Line UV Lights can be used to minimize microbial levels in ambient temperature recycle streams (e.g., recirculating water purification and PW distribution systems). UV lights should be monitored for emission wattage and replaced when emissivity reaches 80 percent, or as recommended by vendor technical specifications, and at least once a year.

11. A Water Testing Plan should be established to quantify system performance, including seasonal effects, and should be part of the water system validation. Operational Qualification (OQ) testing is typically performed daily during the first month of validation. During Performance Qualification (PQ), an additional month of daily sampling should be performed followed by less intensive sampling during the remaining months. OQ and PQ should be conducted over a period of one full year to assess the potential effects of seasonal changes on the water system. Data acquired during the year should be summarized and analyzed at least every two months, and should be used to establish alert and action levels based on process capabilities.

    Water data should continue to be recorded, analyzed, and trended as the data are collected by the Site Quality Team.

12. Water Used in API and Drug Product Production should be sampled as required in Table 2. Where the type of water used at a sampling location changes with the manufacturing step for water used in the final steps of an API process, the frequency of sampling may be varied to match the water use.

13. Water Sampling Procedures should be established and sampling personnel should be qualified in these SOPs (see Table 2).

14. All Water Types should be sampled and tested for microorganism counts (TVO). Low Endotoxin Deionized Water, HPW, and WFI samples should also be tested for bacterial endotoxins. Where on-line conductivity and TOC probes are used with established alert and action levels, chemical testing frequency may be less frequent than defined in Table 2 and is based on validated intervals.

15. In the Event the PW, HPW, or WFI Distribution System is monitored continuously by validated in-line controls, sampling and testing for bacterial endotoxins and microorganisms (as applicable) may be suspended for intervals

