Storage and Distribution

WFI is either collected in a holding tank or recirculated through facility piping systems (Fig. 15-4). In large operations the holding tanks may have a capacity of several thousand gallons and be a part of a continuously operating system. In such instances the USP requires that the WFI be held at a temperature too high for microbial growth. Normally, this temperature is a constant 80°C. It is possible to use temperatures other than 80°C, but validation of this temperature to maintain water quality will be significantly scrutinized by regulatory authorities.

The USP also permits the WFI to be stored at room temperature but for a maximum of 24 hours. Under such conditions the WFI usually is collected as a batch for a particular use with any unused water being discarded within 24 hours. Such a system requires frequent sanitization to minimize the risk of viable microorganisms being present. The stainless-steel storage tanks in such systems usually are connected to a welded stainless-steel distribution loop supplying the various use sites with a continuously circulating water supply. The tank is provided with a hydrophobic membrane vent filter capable of excluding bacteria and nonviable particulate matter. Such a vent filter is necessary to permit changes in pressure during filling and emptying. The construction material for the tank and connecting lines usually is electropolished 316 L stainless steel with welded pipe. The tanks may also be lined with glass or a coating of pure tin. Such systems are very carefully designed and constructed and often constitute the most costly installation within the plant.

When the water cannot be used at 80°C, heat exchangers must be installed to reduce the temperature at the point of use. Bacterial-retentive filters should not be installed in such systems because of the risk of bacterial buildup on the filters and the consequent release of pyrogenic substances.

The one component of the holding tank that generates the most discussion is the vent filter. It is expected that this filter is integrity tested to assure that it is intact. It is expected, therefore, that the vent filter be located in a position on the holding tank where it is readily accessible.

Typically, filters are now jacketed to prevent condensate or water from blocking the hydrophobic vent filter. If this occurs (the vent filter becomes blocked), either the filter will rupture or the tank will collapse.

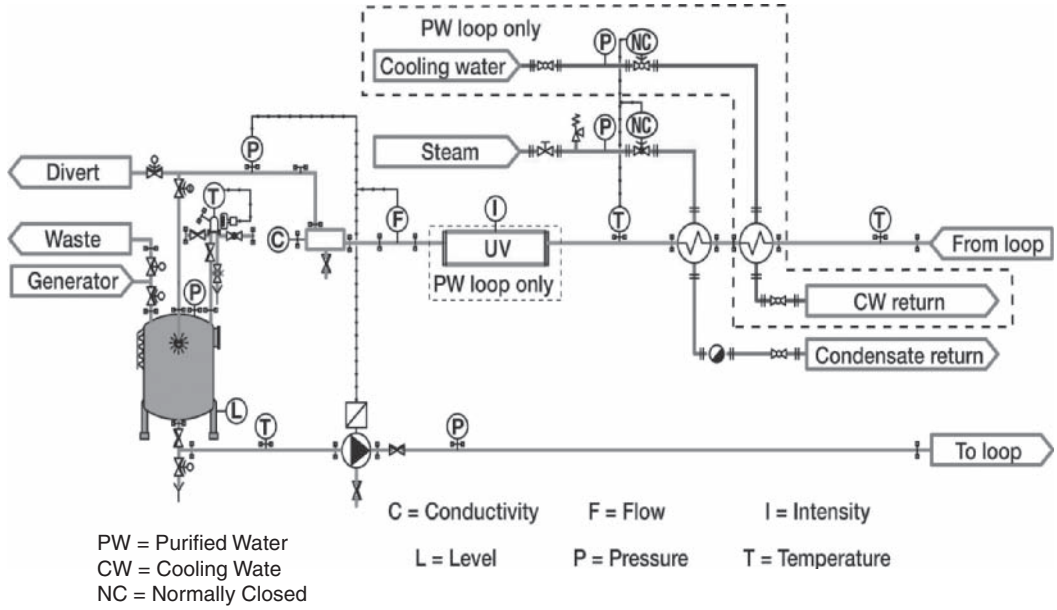

Figure 15-4 Storage and distribution of purified water (PW) and water for injection (WFI). *Source:* Courtesy of Getinge Water Systems. (*Note:* Only difference between PW and WFI is UV system only part of PW loop).