Membrane-Based WFI Production: Past, Present, and Future

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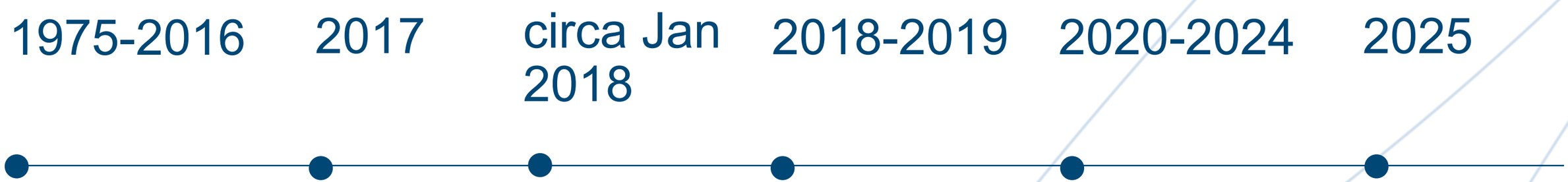
Quick Disclaimer

Opinions and interpretation of current and future market conditions and drivers are mine alone and do not represent those of ISPE. While I believe this information is generally accurate, errors and omissions may exist.

History of Membrane WFI (U.S.)

AT A GLANCE



WFI generated by RO permissible per USP monograph, but only a few installed systems

EP WFI monograph change allows for method of manufacture other than distillation

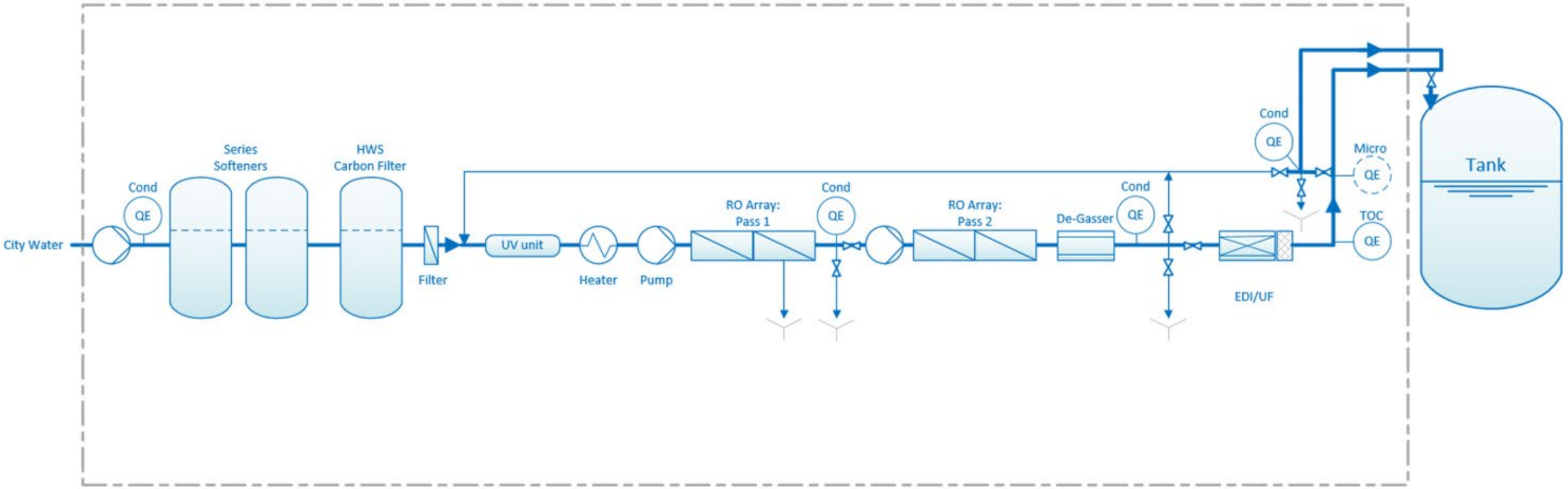
First system validated for membrane (RO/EDI/UF) based WFI

Small number of installed systems, but number is increasing year over year

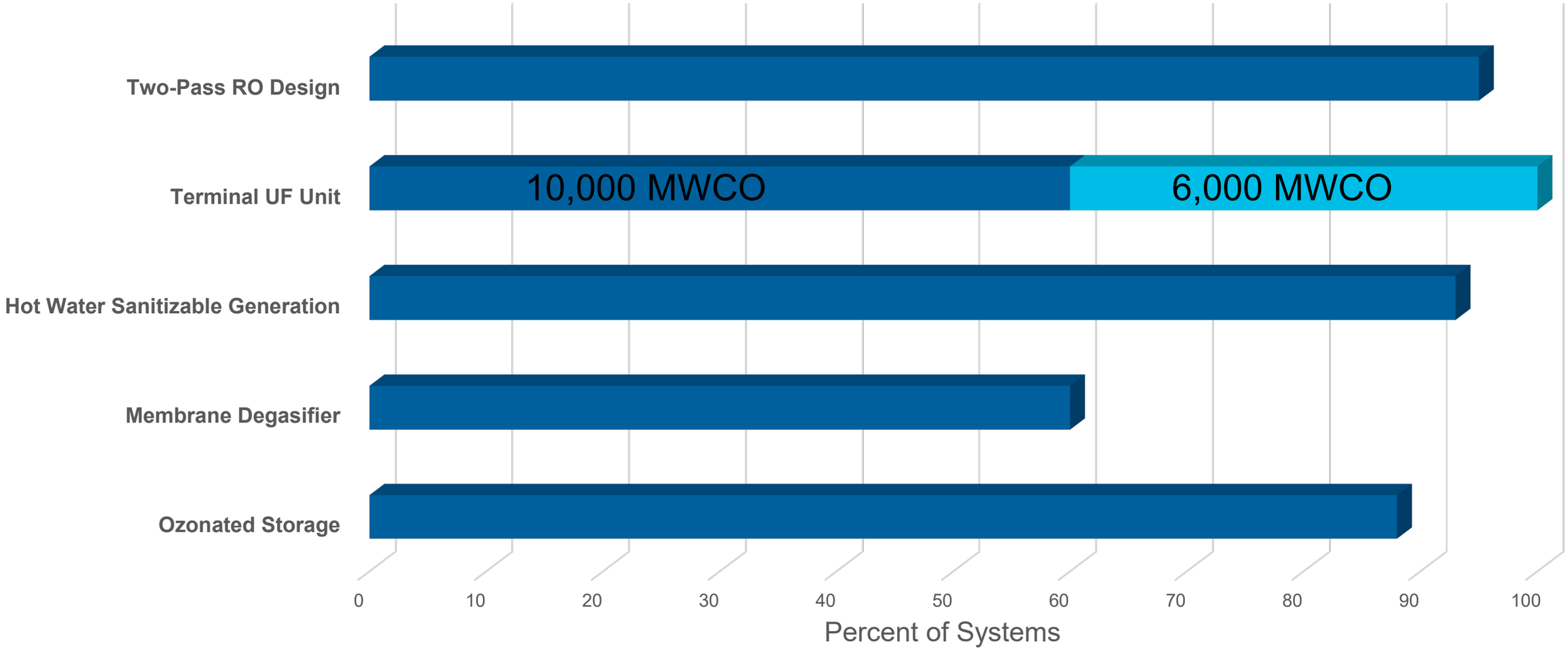
Increase in CGT applications requiring WFI. Most of these new WFI systems are membrane based

Approaching 100 installed systems in the U.S.

Membrane WFI Process



Installed Membrane WFI System Features (U.S.)



Installed Membrane WFI System Features (U.S.)

- No ion-exchange (DI) systems (all EDI)
- No two-pass RO installations without EDI or UF
- Very few chemically sanitized generation systems
- More than 80% are new installations (few conversions)
- Estimated that only half of end-users are integrity testing final UF units (no regulatory guidance)
- Largest capacity system to date:100 GPM
- All manufactured in the U.S.

System Characteristics

Photo Credits: BWT

Majority of systems based on factory integrated technologies

- Single skid designs
- Automated sanitization procedures
- High degree of process monitoring
- All or mostly stainless steel components
- Fully functional wet FATs

Installed Membrane WFI Storage & Distribution System Features (U.S.)

- Most include continuously ozonated tanks
- Distribution loops are sanitized daily (similar frequency to traditional ambient WFI loops)
- Few are heat sanitized
- Some have ability to be sanitized with both ozone and heat
- None are chemically sanitized
- None are steam sterilized
- All are stainless steel construction

Current State of Membrane WFI Market

- Dozens of systems validated and inspected by international regulatory agencies
- For new WFI systems
  - Majority are membrane based
  - More WFI capacity is generated by VC stills
  - Multi-effect distillation market share most impacted
- Fewer conversions of existing distillation systems to membranes. Most installs are new systems
- Most WFI for new CGT applications is produced by membranes
- No known validation failures or unsuccessful applications

Current Barriers to Universal Adoption

- No FDA guidance
- Chinese Pharmacopeia WFI monograph
  - expected to change in 2025
- More monitoring and maintenance required than softened fed VC systems
- No consensus on integrity testing requirement of final UF
- Softened fed VC distillation can be competitive at higher capacities

Future of Membrane Based WFI

Expect widespread adoption in next 5 years

Market Drivers

- Sustainability initiatives
- Reduction in steam availability
- Water & energy savings
- Improved membrane technology
- Increased acceptance of ozone
- Comfort level (ISPE, case studies, successful audits, perception bias)
- Increased process control via on-line monitoring as RMM technologies mature

Thank you for your attention

Further discussions:

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