



Ozone in PW & WFI Storage Systems

*PDA Israel
New Developments in Water Systems
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- **5 different main methods for microbial control of PW & WFI system loops:**
 - **“Hot” systems**
 - **“Cold” systems**
 - **“Ambient” systems**
 - **“Hot – Ambient combination” systems**
 - **Ozonated systems**

➤ “Hot” systems

- ❖ **The most effective & reliable method**
- ❖ **Sanitization on a routine basis can be eliminated**
- ❖ **Common practice: 80°C**
- ❖ **Systems at 65°C were validated.
Advantages: energy saving (comparing to 80°C), reduced rouging**
- ❖ **These temperatures will not destroy endotoxins**

➤ **“Cold” systems**

- ❖ **Operate at 4 - 10°C**
- ❖ **Microbial growth rates significantly reduced below 15°C, thus, sanitization frequency may be reduced compared to ambient systems**
- ❖ **Sanitization frequency should be validated on a case by case basis**

➤ **“Ambient” systems**

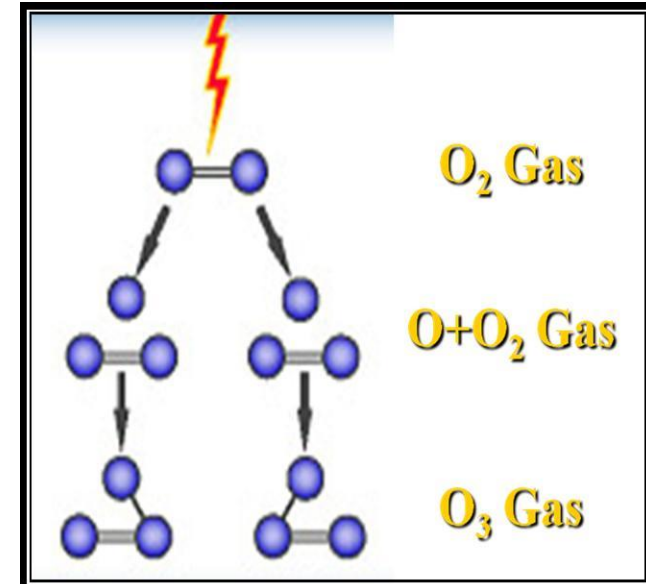
- ❖ **Are common throughout the industry**
- ❖ **Have lower lifecycle costs as well as reduced energy consumption**
- ❖ **However, the frequency of sanitizations must be significantly increased, to prevent formation of biofilm**
- ❖ **Sanitization by heating the water to 80-90°C and circulating for 60-120 min. Hot flush to drain/can be used**

➤ **“Ozonated” systems**

- ❖ **Ozone was discovered in 1840 by C.F. Schonbein, as a by product of the oxygen generated at the anode during electrolysis of sulfuric acid**
- ❖ **It is the second most powerful oxidant and disinfectant, after fluorine, which can be used technically**
- ❖ **It is a gas which is up to 100 times more effective than chlorine**

➤ “Ozonated” systems

- ❖ **Ozone is formed naturally from dioxygen by the action of ultraviolet light (UV) and electrical discharges within the Earth's atmosphere**
- ❖ **It is present in relatively high concentration in the ozone layer of the stratosphere, which absorbs most of the Sun's ultraviolet (UV) radiation**



➤ **“Ozonated” systems**

- ❖ **Ozone is an incredible oxidant and kills microbes, pathogens, endotoxins and organic material in a matter of a few minutes**
- ❖ **Ozone oxidation reduces the organics by 3 log reduction in under two minutes and over 5 log in 5 minutes or less, either in ambient or cold water**
- ❖ **Ozone Kills bacteria 100 times faster than chlorine**

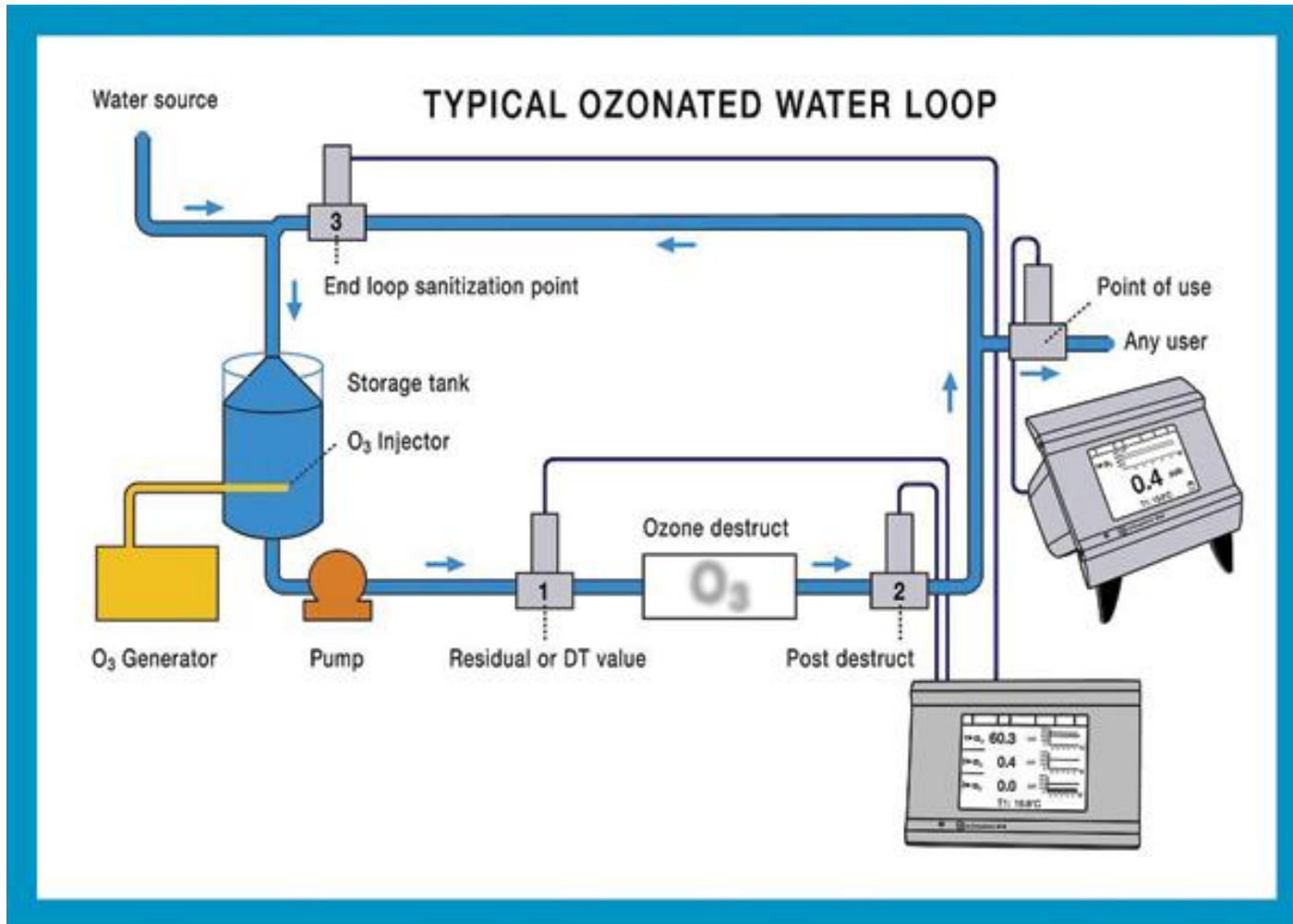
- **“Ozonated” systems**
 - ❖ **Ozone is environmentally benign gas which can be produced, in the required quantities, close to the point of use and quickly breaks down into normal oxygen**
 - ❖ **In contrast to most other oxidants, it generates no undesirable or toxic by-products**
 - ❖ **It decomposes in pure water with a half-life of about 20 min**

- **“Ozonated” systems**
 - ❖ **Ozone is injected, from an ozone generator, either directly to the storage tank, or to the return pipe just before it enters the tank**
 - ❖ **Should be maintained in a concentration of 0.06-0.15 ppm (mg/L) in the storage tank, using ozone electrode for detection**

➤ “Ozonated” systems

- ❖ **Ozone should be removed, at the beginning of the distribution loop, by UV light (254nm): $2\text{O}_3 \xrightarrow{h\nu} 3\text{O}_2$**
- ❖ **For periodic sanitization, the recirculation concentration should be increased to 0.1 - 1 ppm**
- ❖ **The main disadvantages:**
 - ❖ **It is most effective between 10-25°C**
 - ❖ **The lower detection limit of the ozone electrode is 5ppb**

Typical Ozonated water loop



➤ "Ozonated" systems: vent filter and ozone destructor connections

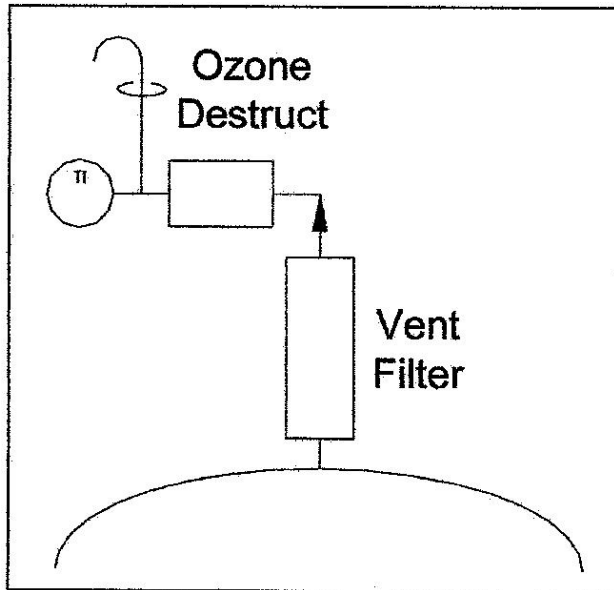


Figure 2. Decomposer mounted after the vent filter in the vent stream.

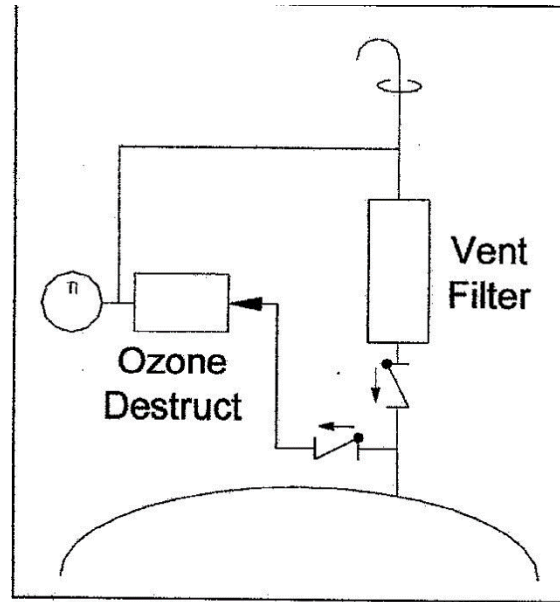


Figure 3. Combined vent filter and decomposer.

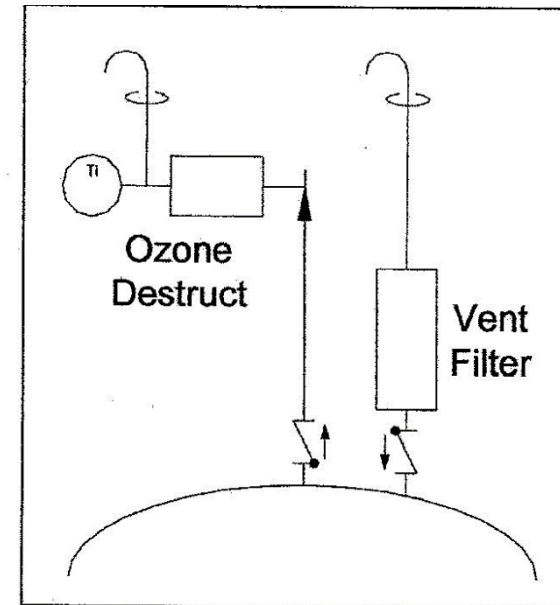


Figure 4. Separated vent filter and decomposer using individual vent lines.

- **Ozonated water storage / distribution loops**
 - ❖ **In the past, FDA perceived both employee safety problems and when drugs are formulated utilizing ozonated water systems. Ozone removal from water, prior to use, must be consistently demonstrated. Trace levels of ozone, below detection limits, can affect product efficacy**
 - ❖ **FDA did not perceive ozonated systems to be robust and forgiving (most effective between 10-25°C)**
 - ❖ **But nowadays, the use of Ozonation in PW & WFI Systems is fast growing**

➤ **Statistics:**

- ❖ **About 65-70% of WFI systems are HOT at 65-85°C, with cooling either by Heat exchangers in the loop or POU coolers. They need little or infrequent sanitization**
- ❖ **About 20-25% are Hot WFI storage with ambient loops - frequent sanitization at least once a week to daily (nightly) sanitization**

➤ **Statistics:**

- ❖ **The other 10% are a combination of exotic combinations and chemical sanitizations, most of them are ozonated systems**
- ❖ **Calculations that were made show that maintaining ozonated systems is 5-7 times cheaper per year than maintaining WFI water at hot temperatures**

Comparison of alternative system designs for microbial control in storage & distribution

Microbial Control methodology	Installed Cost	Operating Cost	Relative Effect./reliability
Ambient system with ozonated tank, periodic ozone in distribution piping	Low	Low	Good
Ambient system with periodic hot water sanitization	Low	Low	Good
Continuous "Cold" system (4-10°C) with periodic hot water sanitization	Medium	High, unless cold water is required for process	Good
Continuous "Hot" system (65-80°C) with multiple Point of Use Coolers	High	Medium	Better



Thank you