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Guidance Document

Pure Water Systems

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BACKGROUND	"Pure water" is the term generally used to describe water that is free from particulate matters, minerals (soluble ions), bacteria, pyrogens (any substance or agent that tends to cause a rise in body temperature, such as some bacterial toxins.), organic matters, and dissolved gases, which frequently exist in the potable water supply. Pure water systems are usually required in the hospital's pharmacy, central-supply room, laboratories, and laboratory-glassware washing facilities. There are two basic type of pure water available in hospital facilities: bio-pure water (water containing no bugs or other life forms) and high-purity water (pure water that is free from minerals, dissolved gases, and most particulate matters). Water purity is most easily measured as specific resistance (in ohm-centimeter units) or expressed as parts per million (ppm) of an ionized salt. The theoretical maximum specific resistance or pure water is given as 18.3MΩ-cm at 770F (250C). This water purity is difficult to produce, store, and distribute. This water is "starved" for impurities and constantly attempts to absorb contaminants. It is important to note that the specific resistance of the pure water is indicative only of its mineral contents and in no way shows the level of bacterial, pyrogenic, or organic contamination. An independent laboratory analysis should be made, whenever possible.
GOALS OF RULES AND POLICIES	The goal of this guidance document is to protect public health of inpatients within a health care facility by producing pure water through processes of distillation, demineralization, reverse osmosis, filtration, and/or recirculation of the water supply system.
APPLICABLE RULES	Wisconsin Administrative Code: SPS 382.40 and SPS 382.70
METHODS	The five basic methods of producing pure water are as follows: distillation, demineralization, reverse osmosis, filtration, and recirculation. Depending upon the type of pure water required in the facility, one (or more) of these methods will be needed. Under certain conditions, a combination of several methods may be necessary. **Distillation** 1. Produces bio-pure water, which is completely free from particulate matters, minerals, organics, bacteria, pyrogens, and most of dissolved gases. 2. Distilled water a minimum specific resistance of 300,000 Ω. 3. An important consideration in this case is that the water is free from bacteria and pyrogen contamination, which is dangerous to the patients, particularly where intravenous solutions are concerned. **Demineralization** 1. Sometimes called "deionization" produces high-purity water that is completely free from minerals, most particulate matters, and dissolved gases. 2. Depending upon equipment used, it can have a specific resistance ranging from 50,000 Ω to nearly 18 MΩ.

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<td>3. It could be contaminated with bacteria, pyrogens, and organics (these contaminants may be produced inside the demineralizer itself).
4. Demineralized water can be employed in most laboratories, the laboratory’s glass-washing facilities (as a final rinse) and as a pre-treatment for still feedwater. The typical demineralizer apparatus consists of either a two bed deionizing unit or a mixed-bed deionizing unit.

Reverse Osmosis
1. Produces high-purity water that does not have the high resistivity of demineralized water and is not bio-pure.
2. An RO process can be used as pretreatment for demineralization.

Note: Chlorine must be removed from the water, otherwise it will destroy the RO membrane.

Filtration
1. Various types of filtration are currently available to remove particulate matters from water as pre-treatment (Ultra-filtration, Nano-filtration, etc.).

Recirculation.
1. High-purity systems should be provided with a circulation loop.
2. Dead-end legs should be avoided whenever possible or limited to 50 inches.
3. System design velocity should be between 4 and 7 ft/s so as to discourage bacteria accumulation and provide transport back to the ultraviolet sterilizer and filtration for removal.</td>
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<td>MATERIALS</td>
<td>1. General pure-water component requirements include:
a. Inert materials
i. must not leach contamination into the water
b. Clean joining methods
i. avoid solvents, lubricants, and crevices
c. No material erosion
i. must not flake off particles
d. Material should not enhance microorganism growth
e. Material should be smooth, crack and crevice-free, and nonporous
2. Common pure-water component materials include:
a. tin lined
b. stainless steel
c. glass or glass-lined
d. polypropylene
e. PVC
f. PVDF
3. Common pure-water piping materials-Approved Wisconsin
a. Polyethylene (PE) NSF 51; NSF 61
b. Polypropylene (PP) NSF 51; NSF 61
c. Polyvinylidene fluoride (PVDF) NFF 51; NSF 61
d. Polyvinyl chloride (PVC) NSF 51; NSF 61</td>
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<td>INSTALLATIONS AND CONDINTIONS</td>
<td>1. The connection of the potable water supply to the high-purity water system is required to have cross-connection protection.
2. Dead-end legs need to be less than 50 inches.
3. Provisions for future cleaning and disinfection.
4. Tank vent filtration to prevent microbial contaminants from entering water storage
5. Pure water systems are to be identified per Table 382.40-1a as device specific water and labeled for the specific use.
6. Pure water systems are to designed and maintained to achieve the quality intended.</td>
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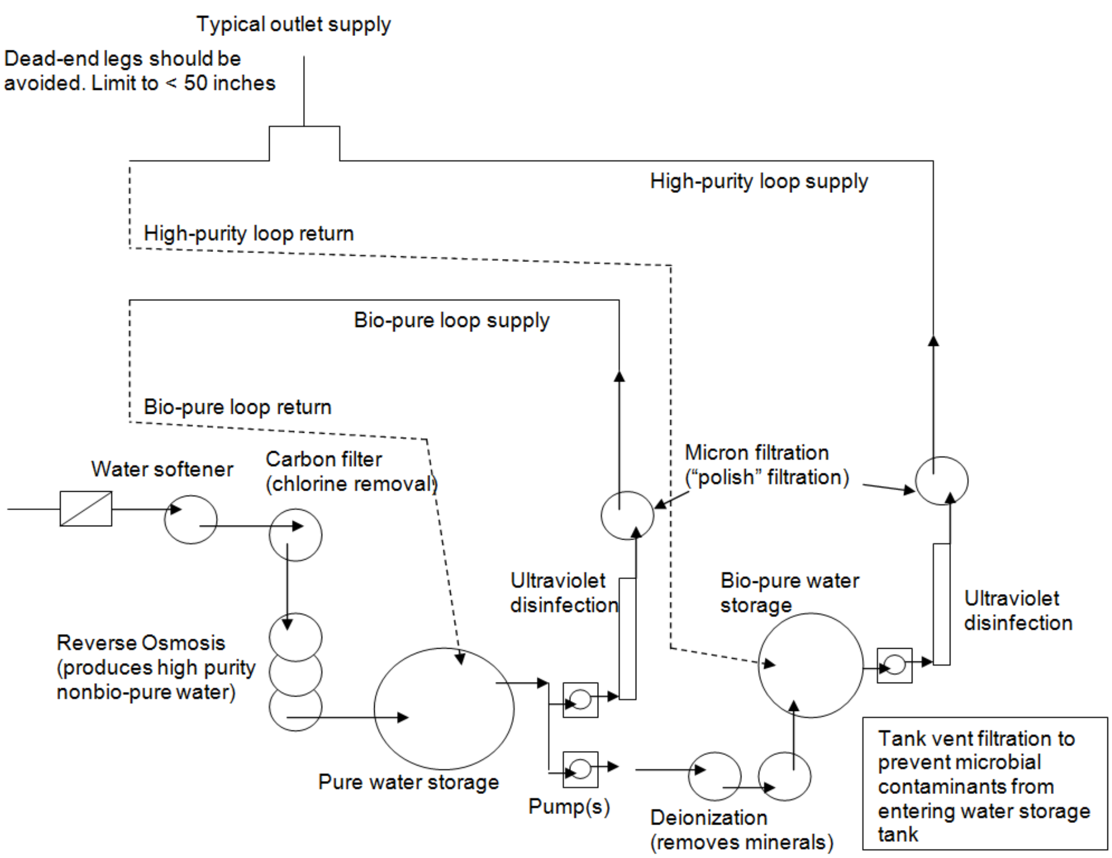
	7. If a serrated nipple is installed on the pure-water faucet, the faucet is to be labeled with signage as to the specific use of the faucet (water) and include verbiage: "If a hose is connected to the faucet, it is to be removed immediately after each use." a. Equipment connected to the pure-water system is to have product approval. b. A cross-connection control device protecting the pure water system shall conform to ASME A112.18.3., NSF 51 and NSF 61. 8. Normal Wisconsin approved backflow protection that incorporates "air vents" have the potential to be contaminated from air-borne microorganisms.
DOCUMENTATION	1. The owner of the facility is responsible for quality of the pure water system. 2. A record shall be kept on dates of cleaning, replacement of components or parts, and when the device was shutdown and the reason for shutdown. 3. Department and Health representatives shall have access to the water treatment system and records on request.
NOTIFICATION	The Department of Health Services is to be cc'd as part of this approval. Email to: David R. Soens, Director, david.soens@dhs.wisconsin.gov
DEPARTMENT TRACKING	The Division of Industry Services reserves the right to amend/revise this document as conditions arise making them necessary for code compliance and/or to protect public health and the waters of the state. For more information contact a Wisconsin Department of Safety and Professional Services Plumbing Consultant at 608-267-9421 or send an e-mail to DspsSbPlbgTech@wisconsin.gov
EXAMPLE SYSTEMS	**Bio-Pure and High-Purity Water Component/Piping Layout** 

High-Purity Water Component/Piping Layout