



# The Future of Water Treatment for Dialysis



By  
Jim Baker  
Vice President  
AmeriWater,  
Inc.





# What is Ultra Pure Water?





# We will cover today.

- Introduction to Water & Water for Dialysis
- What will new regulations do to WT
- New ideas about sodium
- Bacteria and bacterial byproducts
- Ultra-Pure Dialysis fluid and Ultra-Pure Water
- New WT equipment and technologies



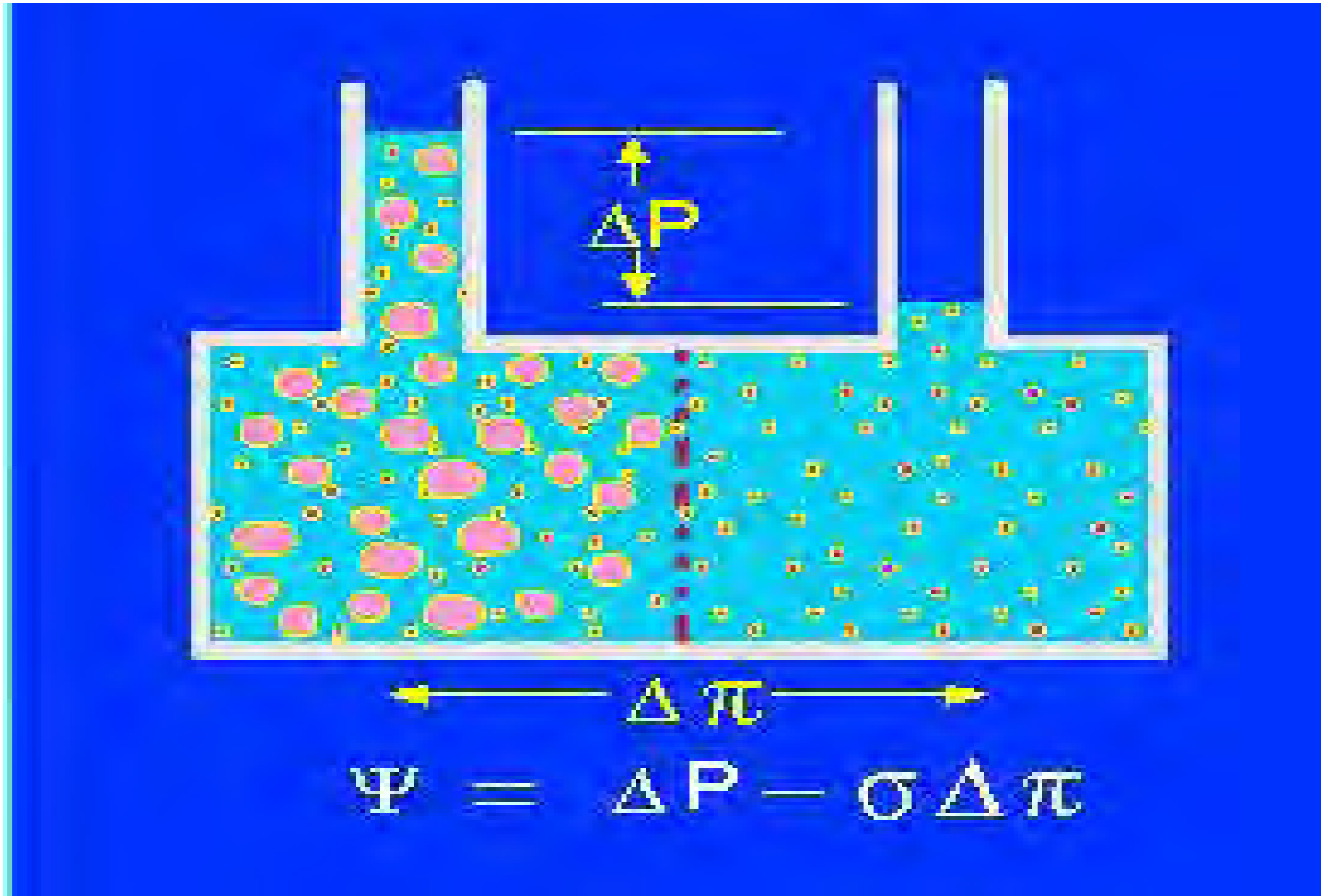
# Introduction to Water

## And

# Water for Dialysis

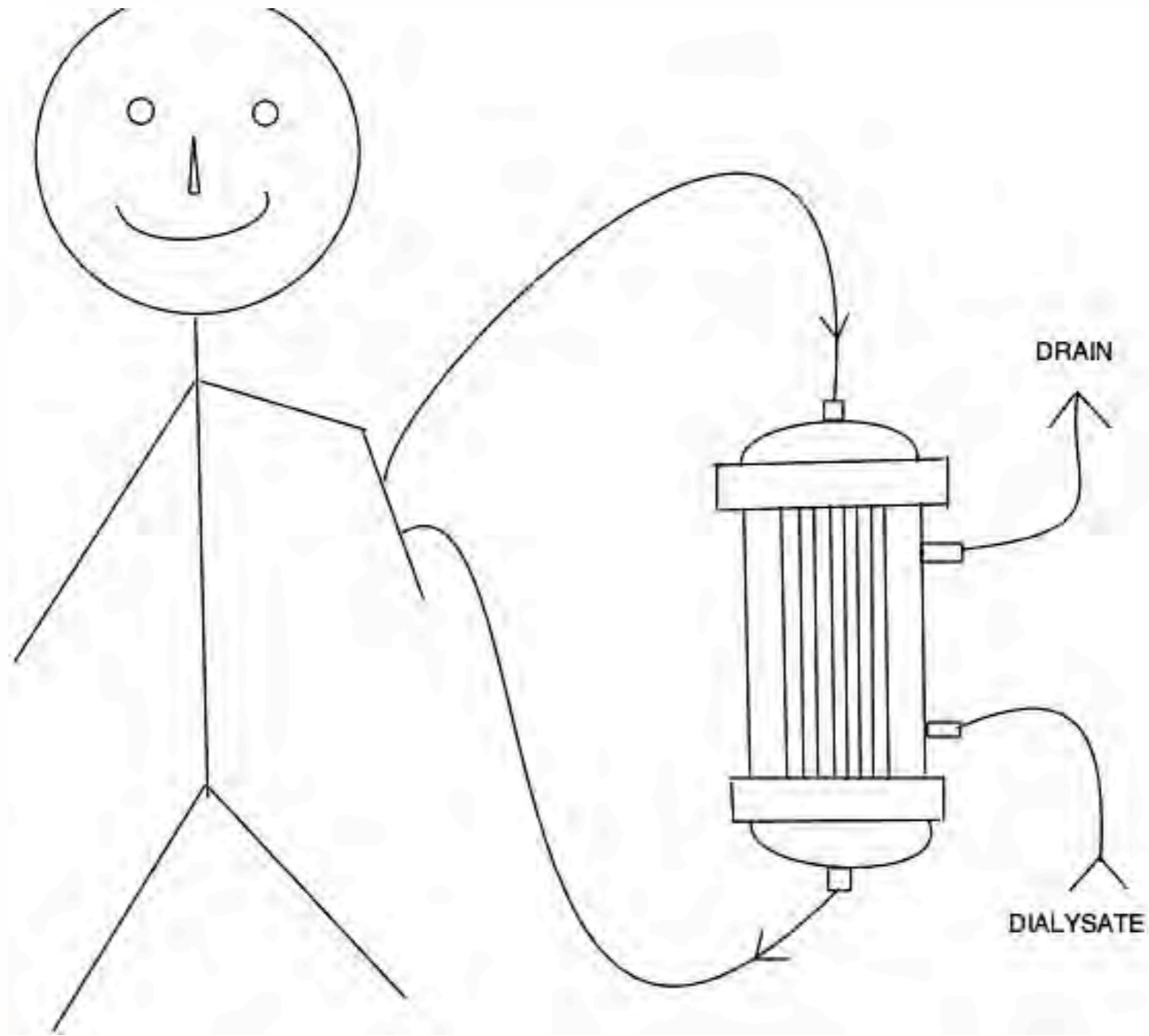


# Osmosis



# Dialysis

## Osmosis and Diffusion





# Patient Water Exposure

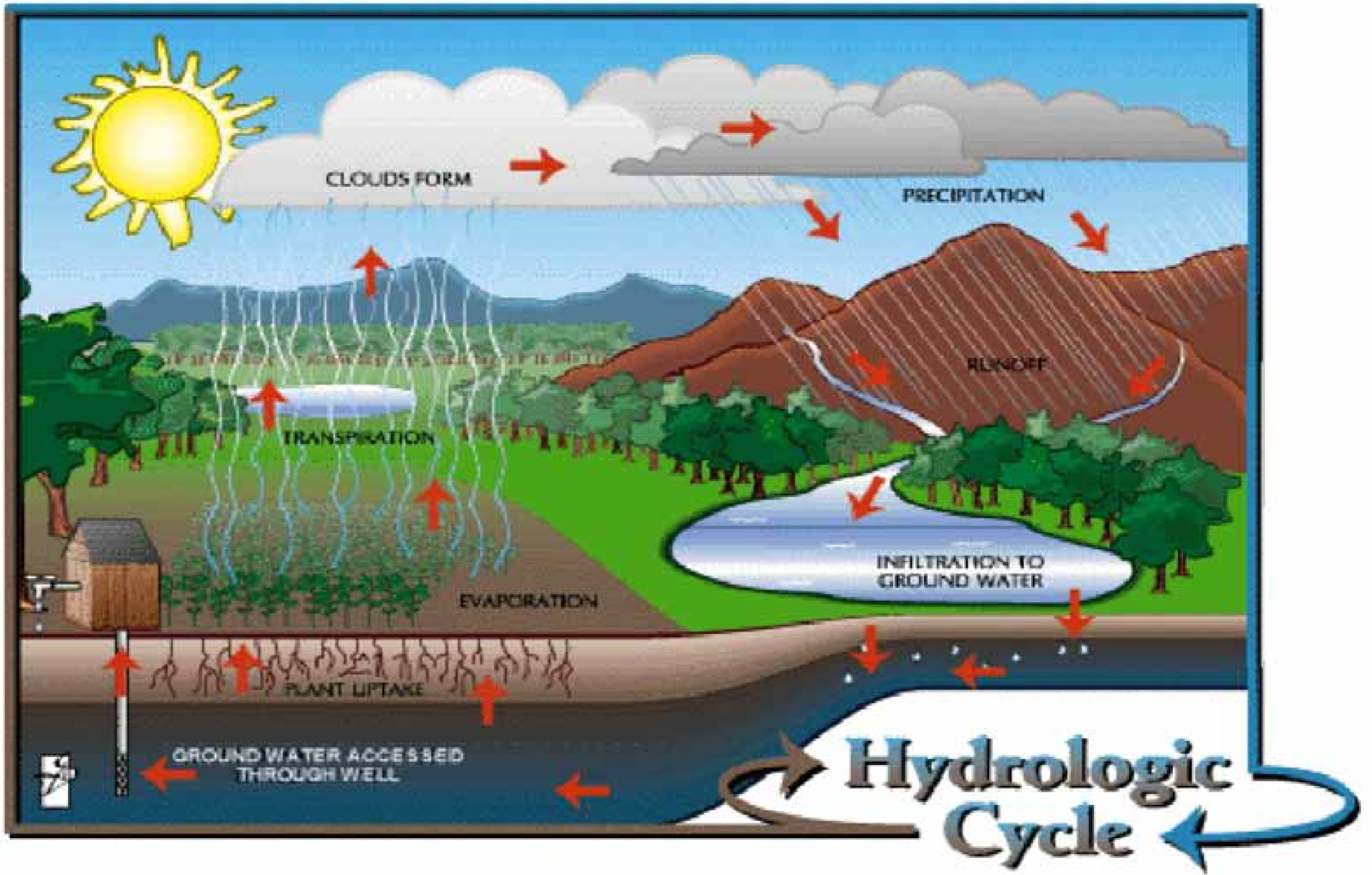
- Normal person
  - 10 to 12 Liters/week
- Dialysis Patient
  - 350 to 400 Liters/week



# Water

- **The universal solvent!**







# Three Types Of Contaminants Of Concern For Dialysis





# Inorganic

Calcium/Magnesium

Aluminum

Sulfate

Copper

Iron

Arsenic

Antimony

Thallium

Sodium/Potassium

Fluoride

Nitrate

Zinc

Lead

Tin

Beryllium



# Sodium

- Are you a 138 dialysis center?
- What is your patient's sodium electrolyte level?
- Should we adjust the dialysate to be closer to the patients sodium level?



# Organic Chemicals

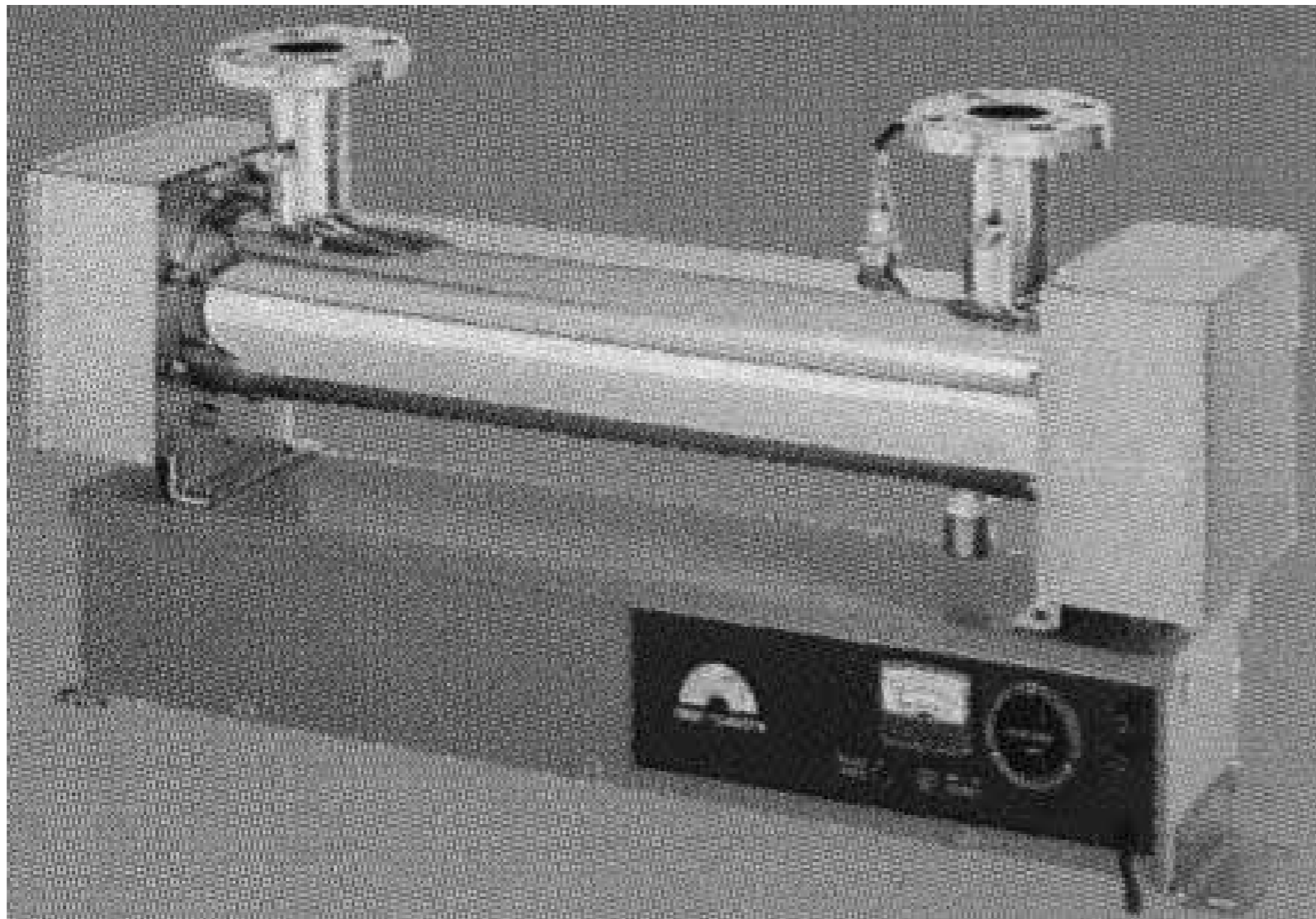
- Chloramine
- Chlorine



# Is Carbon the only way?

- Sodium Metabisulfite and/or 185 UV pretreatment to the RO reduces Chlorine and Chloramine to Chloride which the RO removes easily.

# 185nm Ultra-Violet Unit



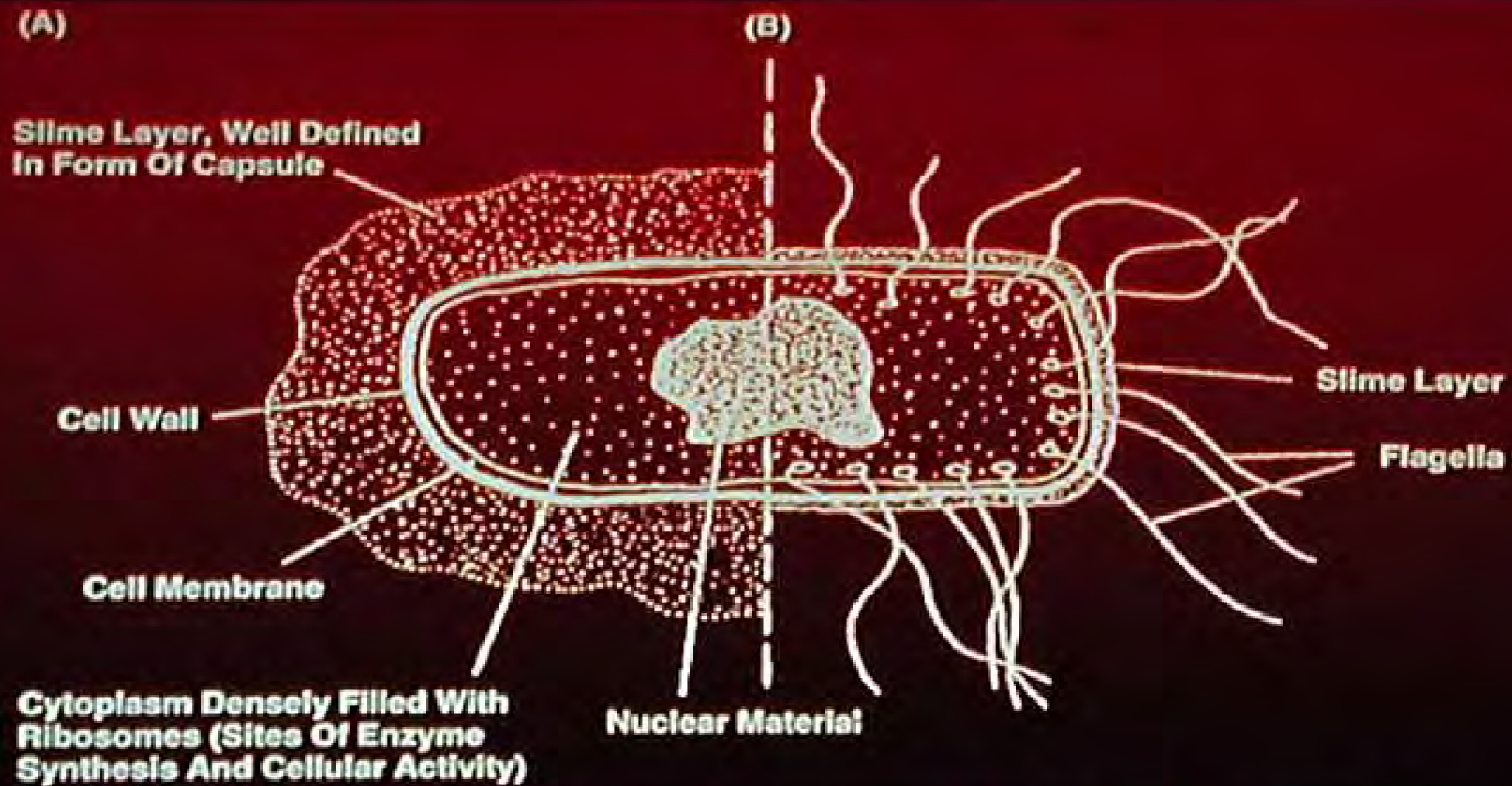


# Microbiological

- **Bacteria**
- **Endotoxin and other bacterial byproducts**



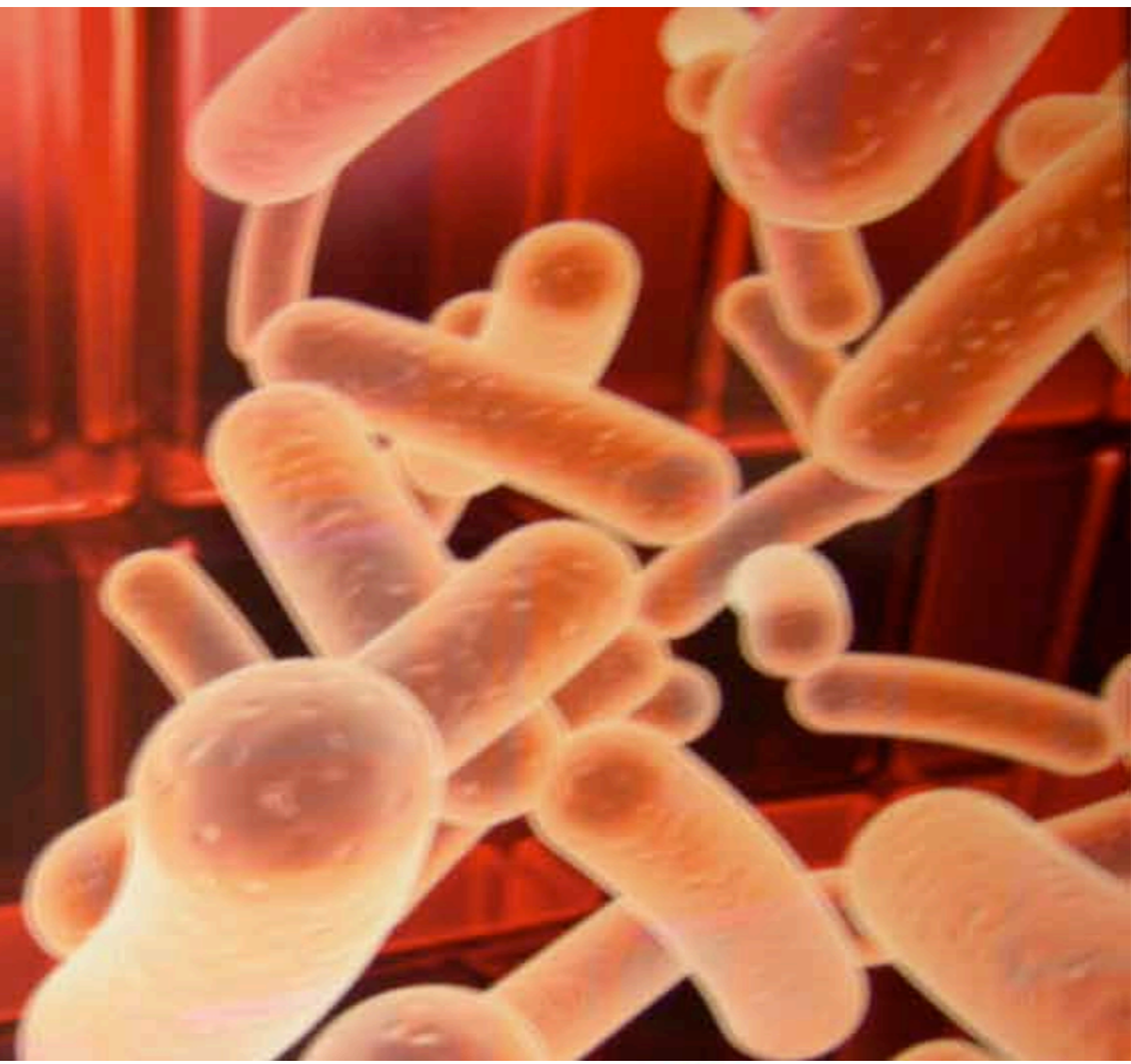
# Bacteria



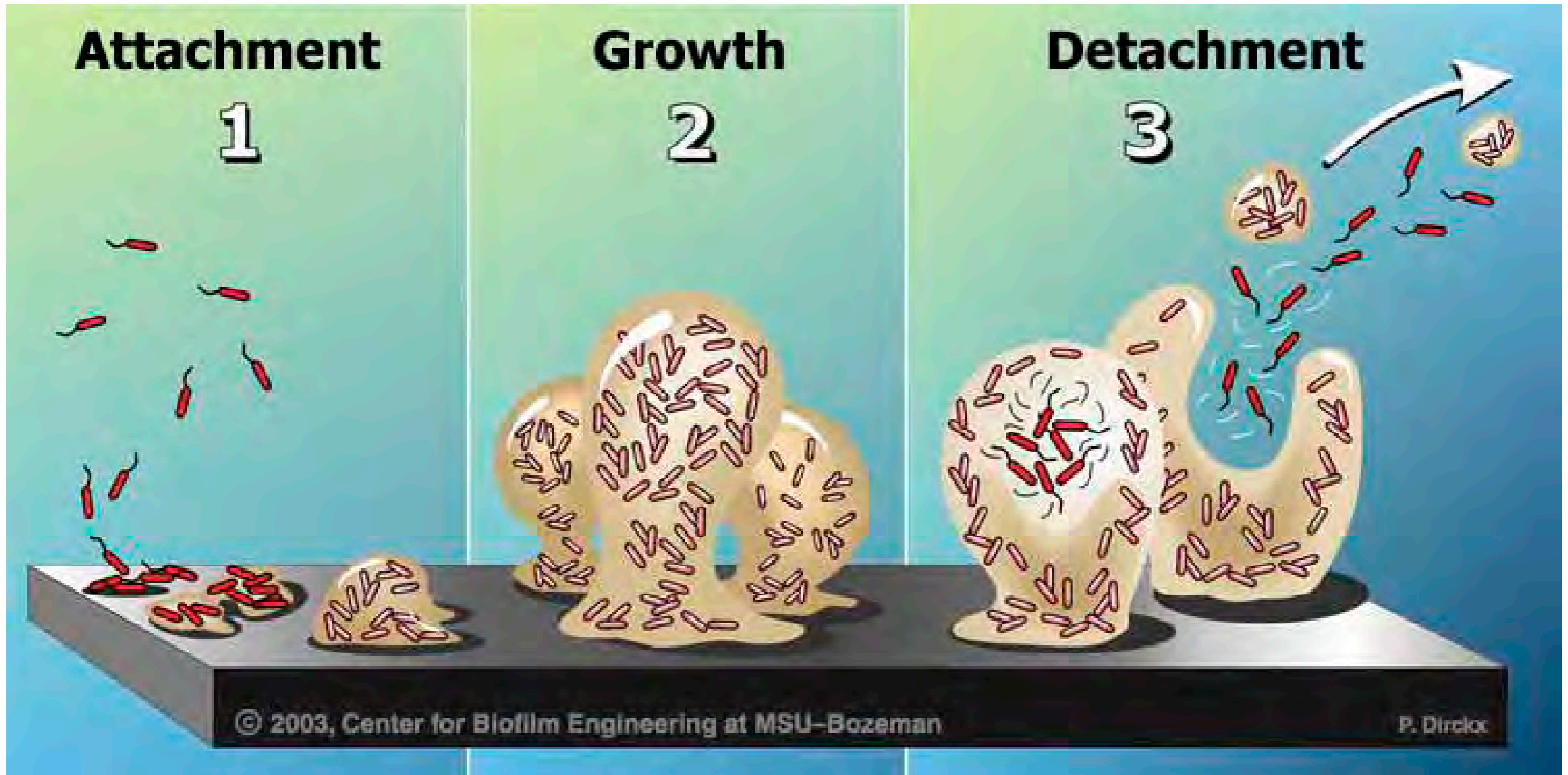
**Fig. 14-1 – (A) Typical Capsulated, Non-Flagellated, Rod-Shaped, Bacterium, And (B) Typical Non-Capsulated, Flagellated, Rod-Shaped Bacterium.**



# Biofilm battle










# Biofilm

- Bacteria creates biofilm.
- We need to disinfect enough to try to control biofilm.
- It will probably require weekly Disinfection
- With monthly cultures and LALs on all water systems and ROs



- **Bacterial byproducts are the problem going forward.**



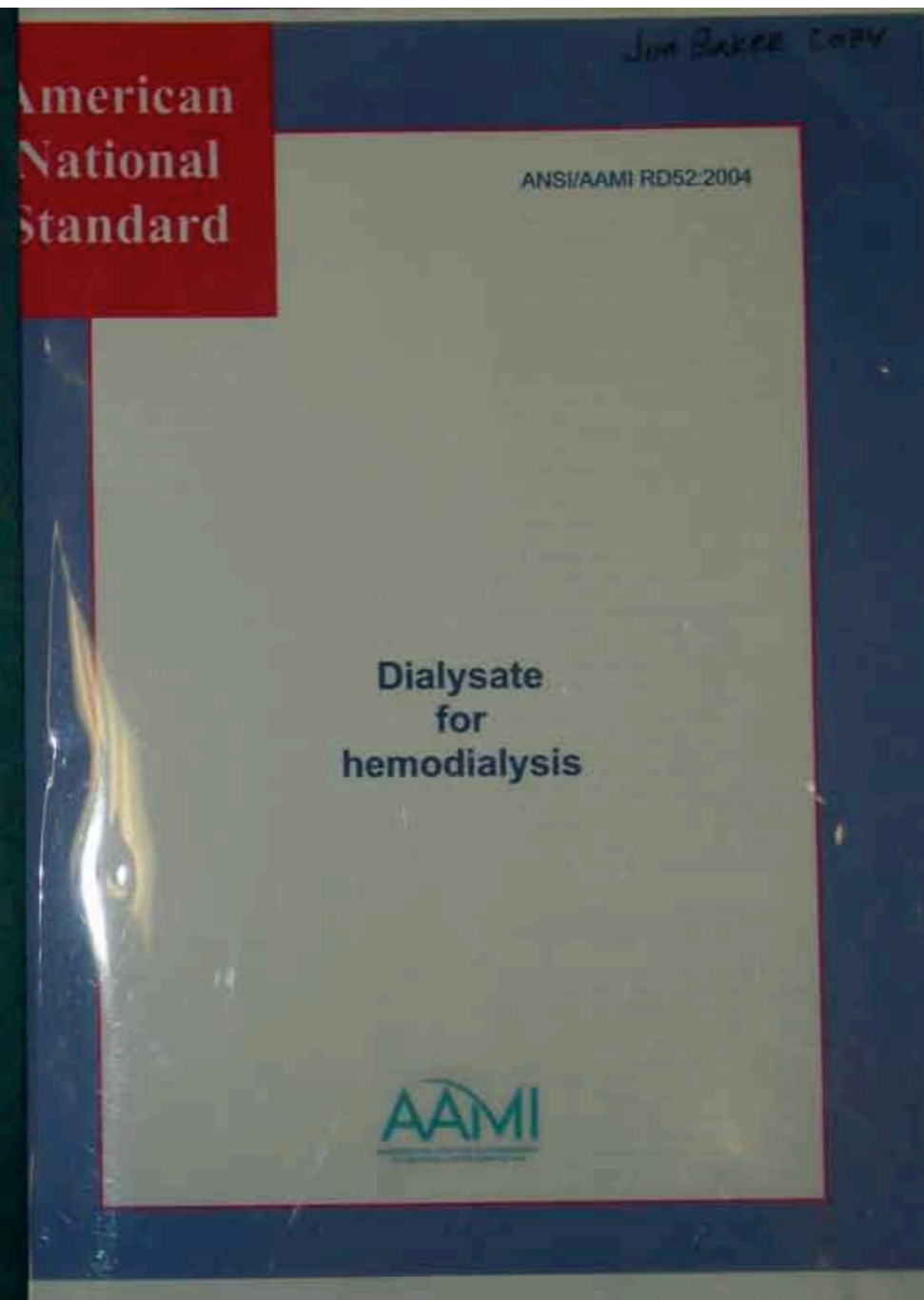
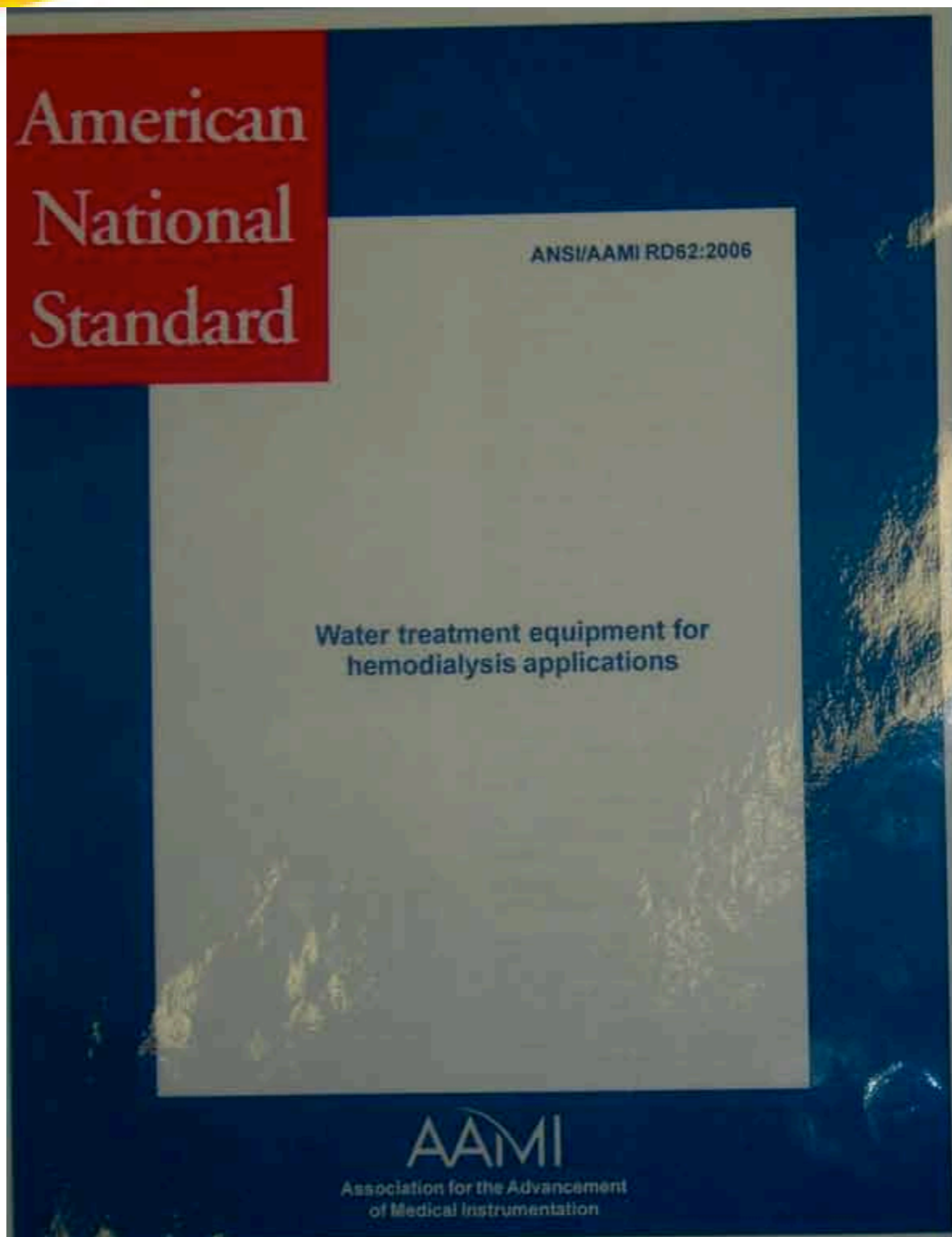
- 
- Every time we dialyze a patient we attack their immune system.

# Dialysis Standards

- AAMI
- CMS
- FDA
- JCAHO
- ISO





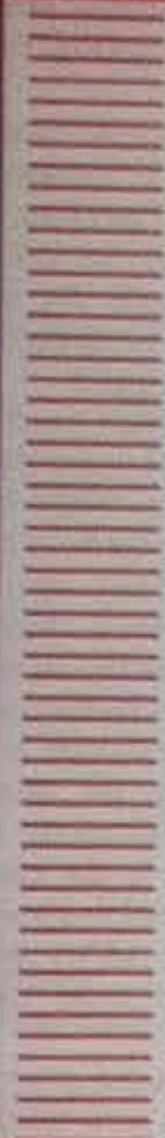






# American National Standard

ANSI/AAMI/ISO 23500:2011



**Guidance for the preparation and  
quality management of fluids  
for hemodialysis and related  
therapies**



# New AAMI/ISO standards

- ISO = International Standards Organization
- AAMI/ISO 23500 replaces AAMI RD52 (CMS has not included in there new rule yet).
- Bacteria < 100 CFU w. 50 CFU Action limit
- Endotoxin
  - Water < 0.25 EU w. 0.125 EU Action limit
  - Dialysate < 0.50 EU w. 0.25 EU Action limit
- Ultra-Pure Dialysate and Water
  - Bacteria < 0.1 CFU/ml
  - Endotoxin < 0.03 EU



# Chronic Central Systems





# Antiscalant Feed

- Chemical is injected before the RO.
- The chemical ties up the calcium and magnesium which prevents the hardness scaling of the membranes and sends it down the drain.
- It can be used instead of a water softener on portable ROs, in installations with floor weight restrictions and where water softeners are not allowed.



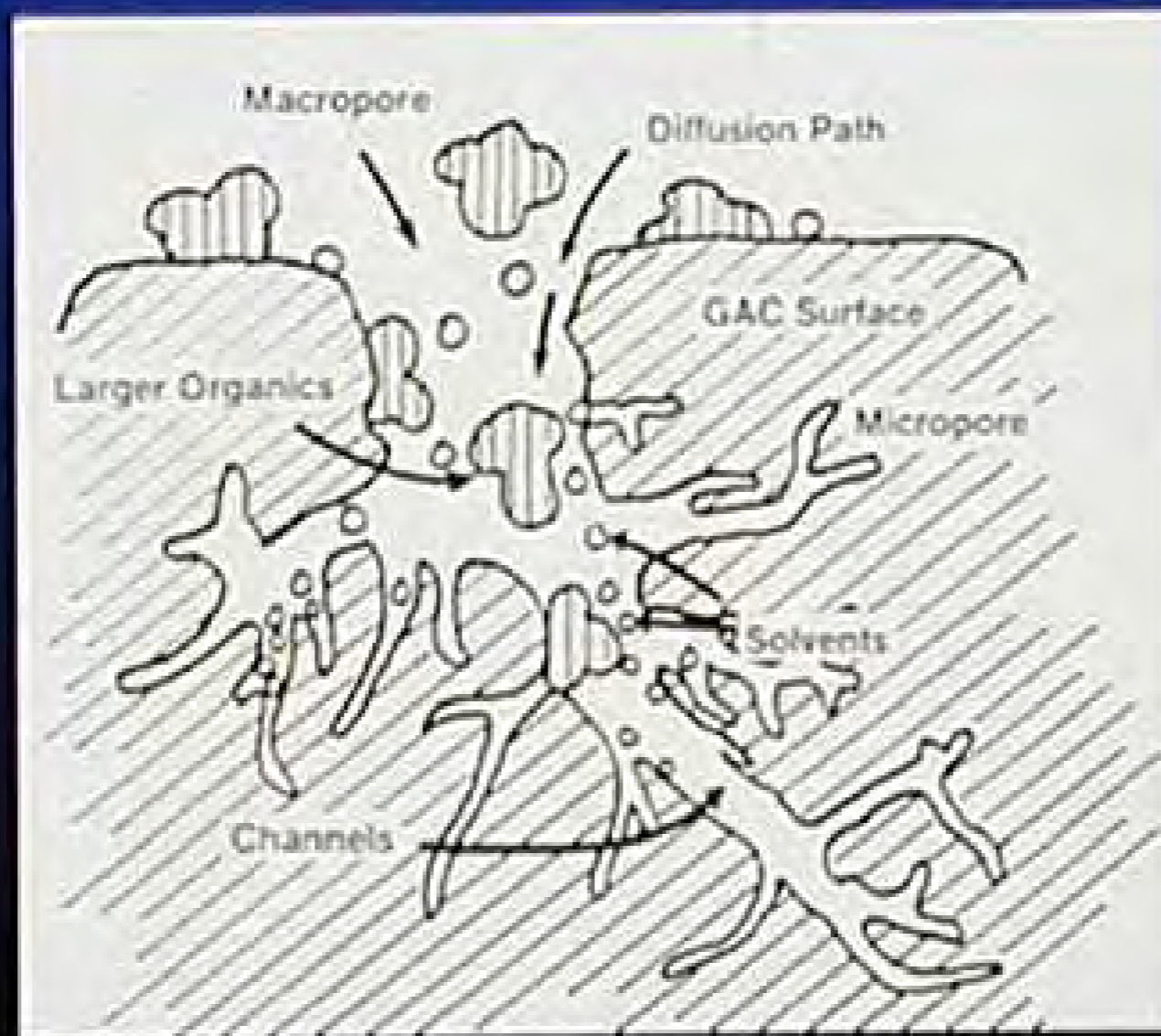
# Portable ROs

## Down Time = Bugs

- Bacteria and endotoxin proliferation (caused by carbon and lack of use)
- If biofilm develops in a portable RO you may have to disinfect it daily for a week or more.



# Inside the Carbon Granule





# Ultra-Filters

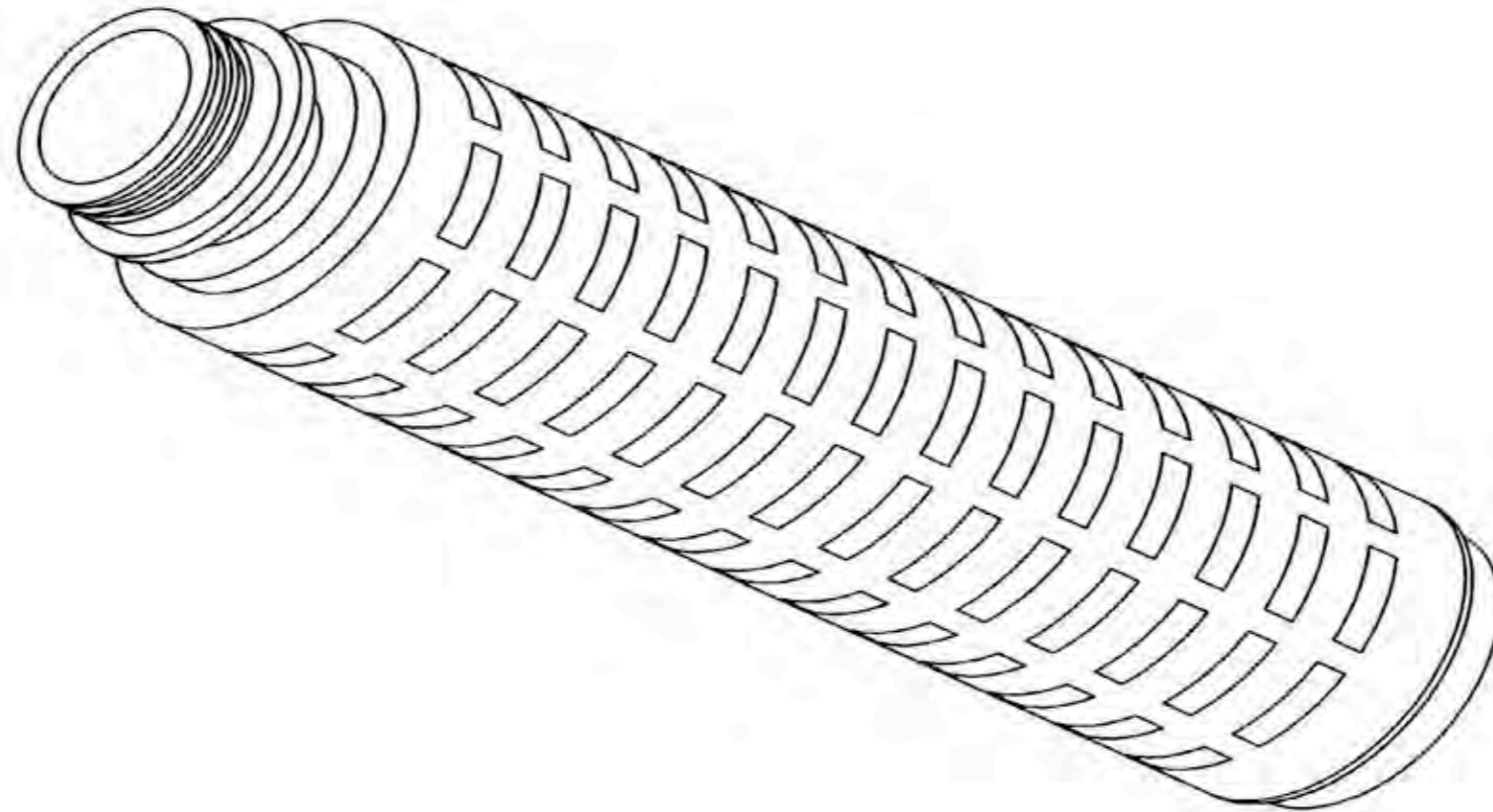




# Endotoxin Retentive Filter

- Now required (sub-micron non endotoxin validated are not acceptable)
- Disinfectant compatibility is critical
- Good design and maintenance practices are very important!

# 222 “O” Ring Endotoxin Filter



# Cartridge Endotoxin Filter

Cartridge endotoxin filters have a charged surface that hold the endotoxin fragments.



## Nephros Dual Stage Ultra-Filter Capsule

Produces biologically pure water which can be utilized in various dialysis applications.

The Nephros DSU has a 0.005 micron filter pore size designed to remove a spectrum of bacteria, viral agents and biological toxins including endotoxin.

This final filter withstands multiple disinfection cycles without degrading the fibers.

- Acts as a firewall for the patient by blocking microbiological contaminants like no other filter of this nature can.
- Provides up to 12 months of performance life in frequent use.
- Proven durability combined with safety and reliability of true redundant ultra-filtration.



**Two Filtering Stages for Built-In Redundancy**



**INLET    Stage 1    Stage 2    OUTLET**

### For use with Portable RO's

Some portable RO's have bacteria build up due to infrequent use. The Nephros DSU provides additional security in an acute setting to ensure the highest quality water for the patient.

### For use with Individual Dialysis Stations

Endotoxin and/or bacteria can colonize in the connection to the RO loop. The Nephros at each wall box is a final safeguard to ensure that the water going to the dialysis machine is ultra-pure.

NEPHROS DUAL STAGE ULTRA-FILTER CAPSULE	
Model	Description

# Ultra Filter in portable RO



# Ultra Filter at Wall Box





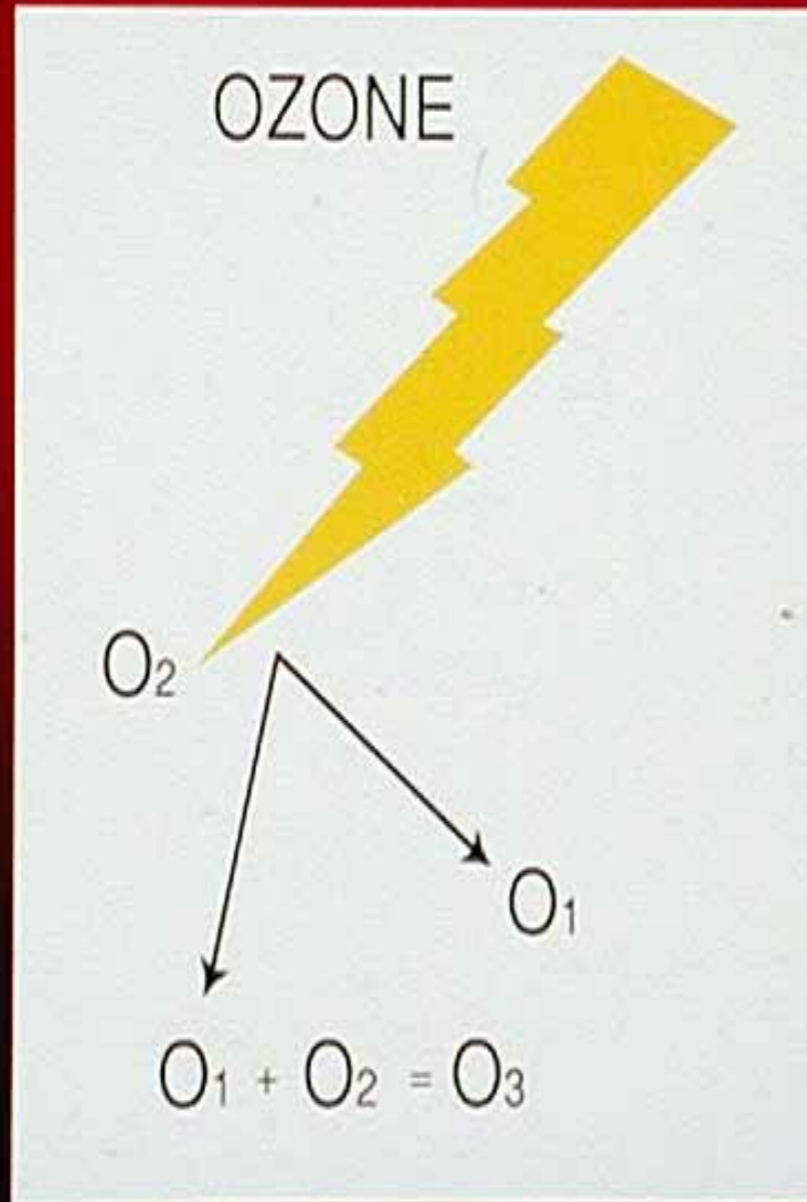
# Disinfectants

- Chlorine (bleach)
- PAA (Peracidin, MinnCare, etc.)
- Ozone
- Heat





# Ozone Disinfection





# Dissolved Ozone

- Best chemical disinfectant
- Dissipates
- Very little rinse needed
- Test strips, ozone meter or test kit to monitor
- Filters and deionizers are not compatible with ozone (like most chemicals)




# AAMI/ISO - Ozone Disinfection

- Ozone concentration levels of 0.5 ppm.
- Exposure time should be at least 10 minutes after the above level is established in the entire system.
- Ambient air in the area of use should be tested or monitored.
- Test for ozone dissipation prior to patient treatment.
- Not for disinfecting the RO, DI, or UF.

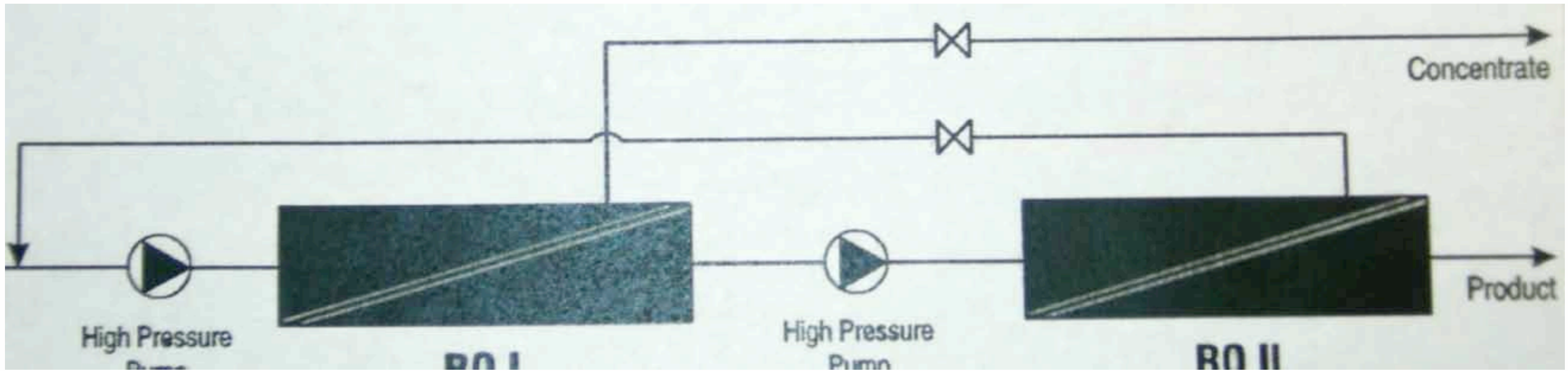
# Heat disinfect loops and ROs





- Double pass RO's  
for Ultra-Pure Water

# Double Pass RO



# Heat Disinfect portable ROs with final ultra-filter





# AAMI/ISO Heat Disinfection

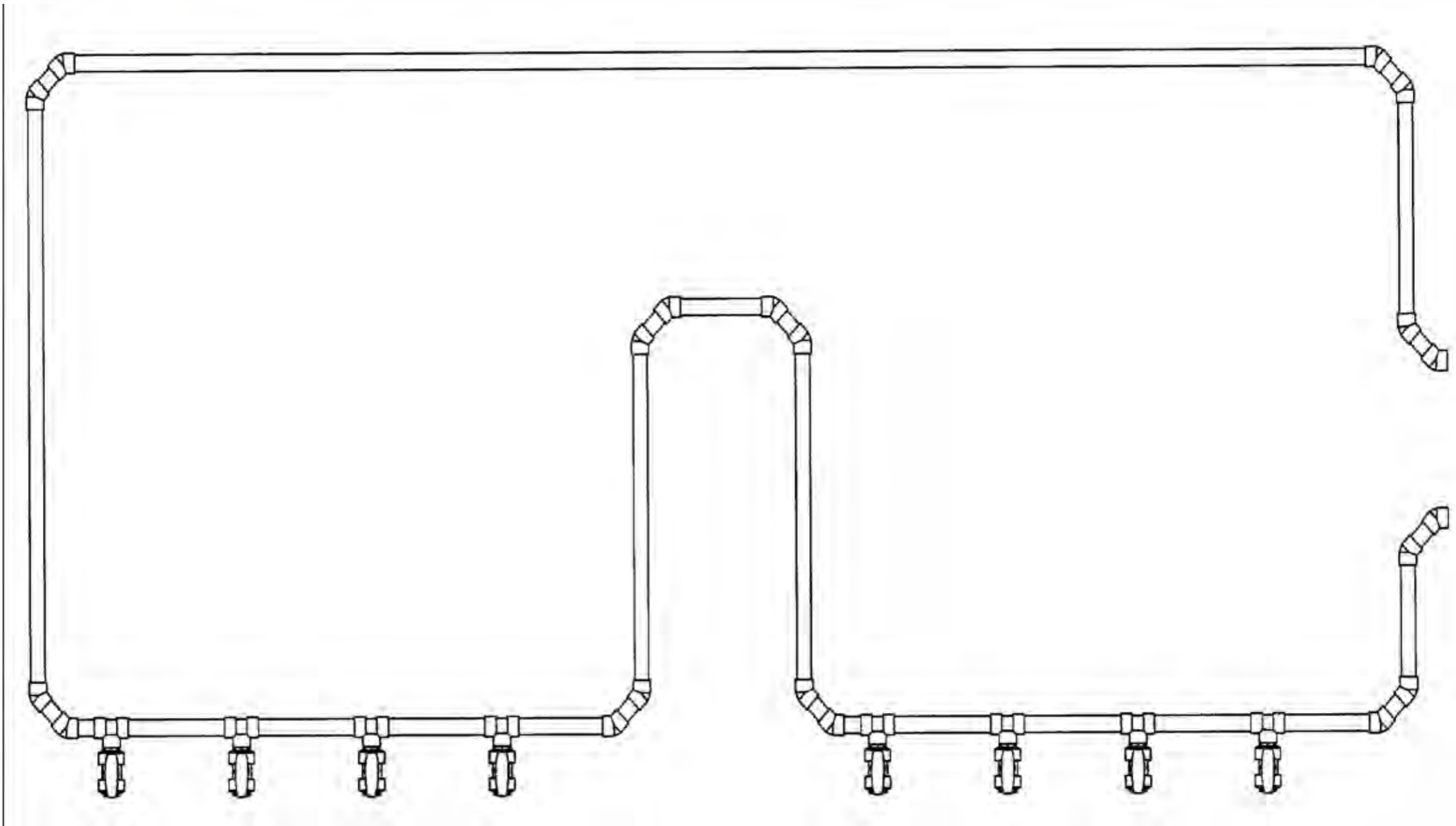
- Determine the temperature of the water in the RO or end of the Distribution Loop.
- Document the temperature and duration.





# Distribution Loop

Dissolved Ozone is ok with PVC





Heat will change the  
loop to PEX, PTFE or  
Stainless Steel



# Design Considerations- Distribution Loops



# Design Considerations- Distribution Loop





# PEX Loop Piping

## PEXa is best for Dialysis

- More fully cross-linked not just on the cover
- Tubing rated for 80 psi at 200 °F
- Uses stainless steel and glass-reinforced polysulfone fittings
- Fittings rated for 150 psi at 210 °F





# Piping Recommendations

- No dead legs (3 x the pipe diameter)
- Flow velocity (recirculation)
  - Minimum direct GPM = 1 1/2 ft./sec.
  - Minimum indirect GPM = 3 ft./sec.
- Good installation practices should be followed



# What does continuous loop flow mean?

- Flow meter at end of loop
- Minimum flow plus treatments
- Example 1" loop indirect feed:
  - Minimum flow = 6 GPM
  - 24 stations @ 0.21 GPM = 5 GPM
  - Total pump flow = 11 GPM



# Microbial Levels

The lower the bacteria and endotoxin level, the healthier the patient.

This is especially true of endotoxin and other bacterial by products, even at low levels.







# Bacteria 7 Day Plate Count

- The new 7 day plate count procedure: Use TGEA or R2A medium at 17 to 23° C for 7 days
- New 4 hour method using RNA

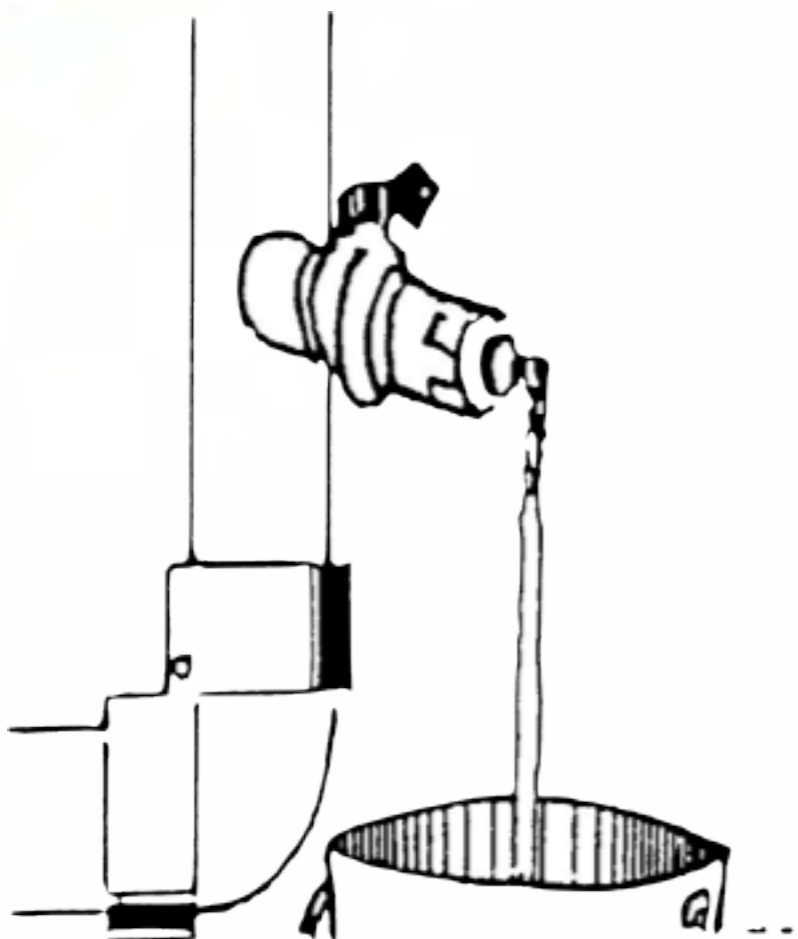


# Rapid Bacteria Detection using ribosomal RNA to detect bacteria.

A component of the ribosome, the enzyme that is the site of protein synthesis.



# Proper Sampling



Flush for  
1 to 2 minutes



Clean  
Catch



# Aseptic Sample Ports



# Electronic Monitoring

- Download records using USB stick
- On line monitoring through an Ethernet
- Notification when specifications are not met through e-mail
- Wi-Fi



# Remote Monitoring





# Thank You!

Any questions ?

