Energy, Water and Money
and the Design and Operation of High Purity Water Systems

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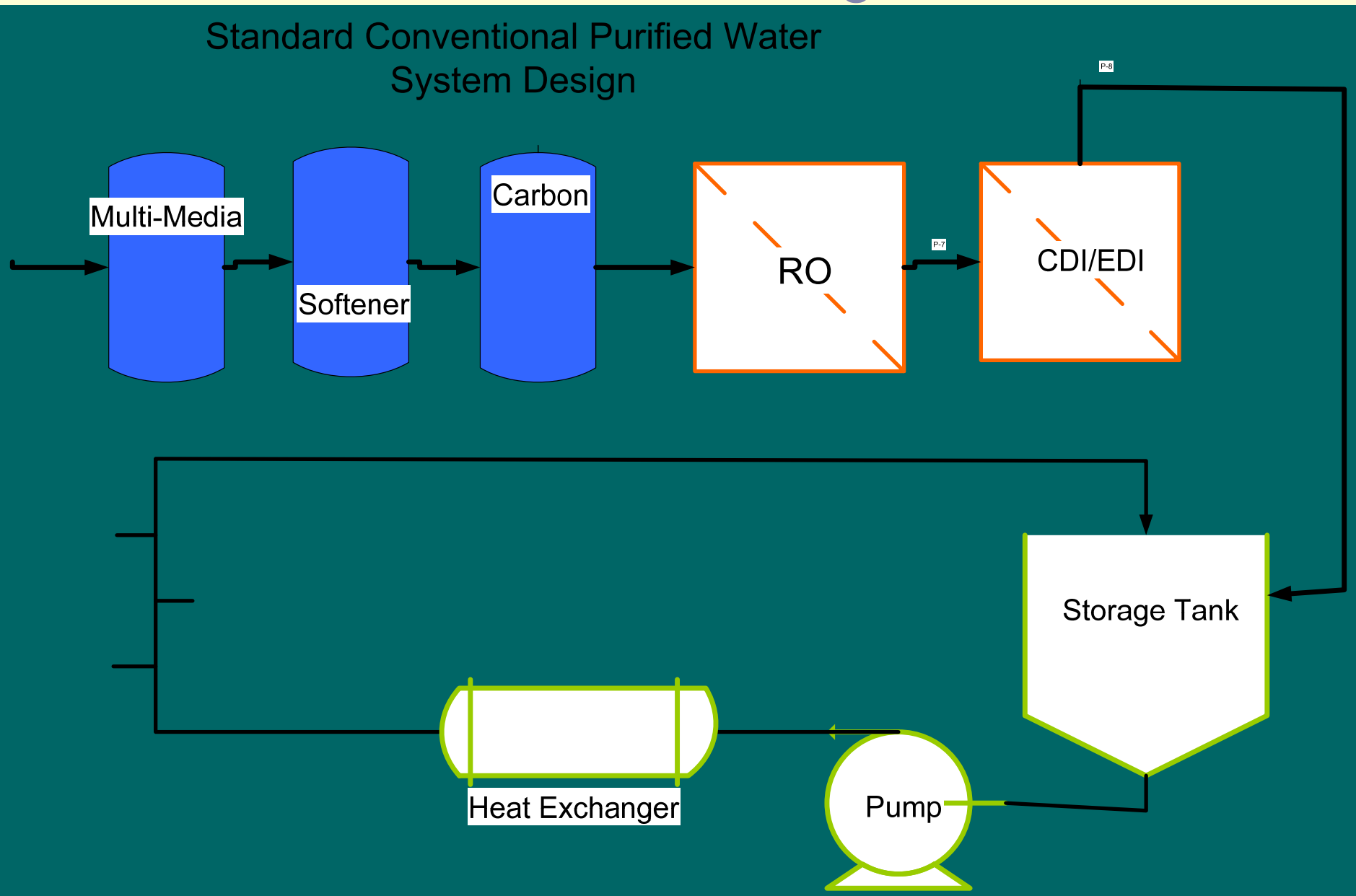
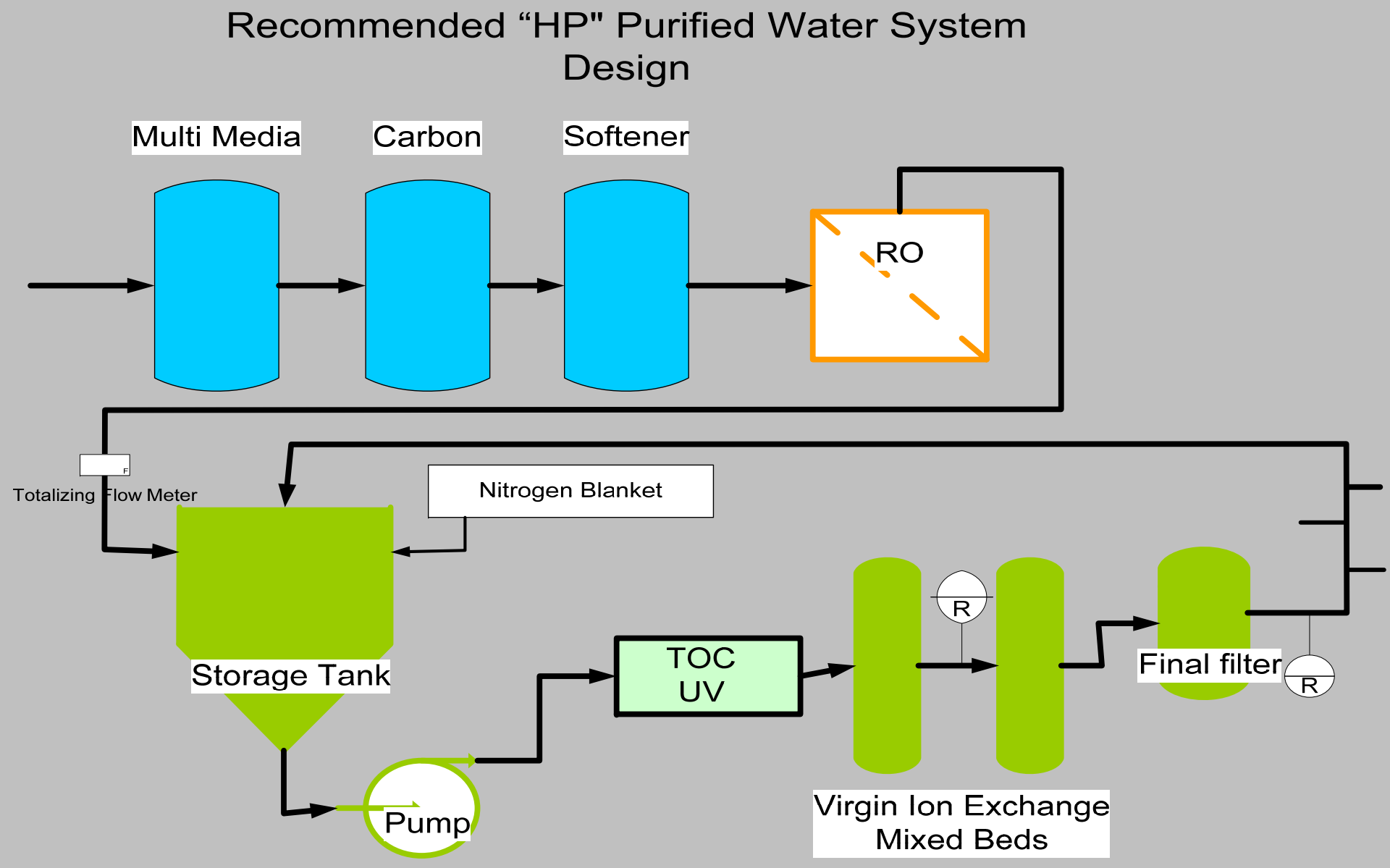
Water System Design Options

- RO/DI (Lab Water, Research)
- USP Purified and HP Purified Water
- WFI Water
  - Vapor Compression Distillation
  - Multi Effect Distillation
  - Alternative Design (HP Purified)

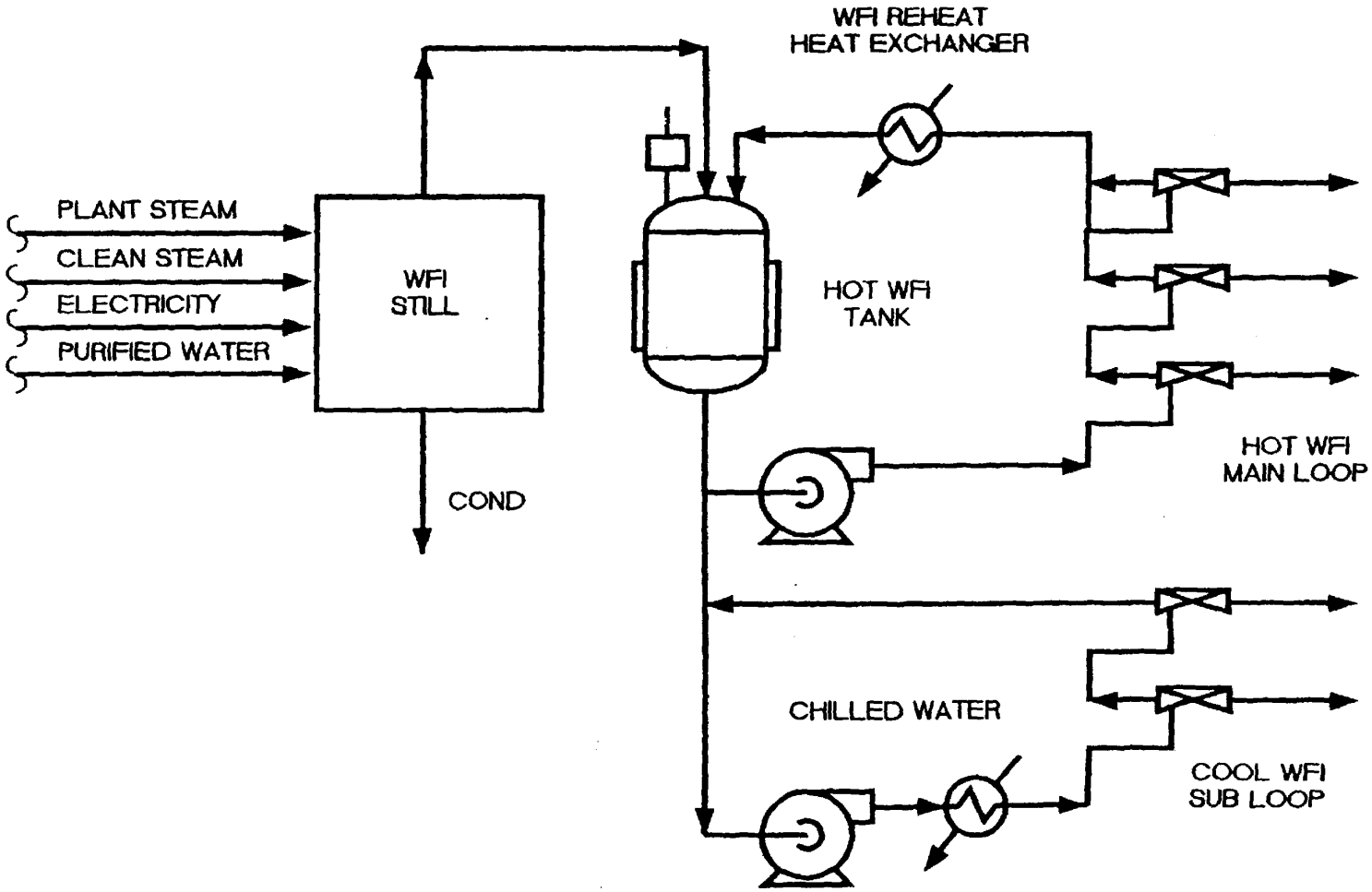
USP Purified Design



RO/ DI Design


Recommended “HP" Purified Water System Design
Multi Media
Carbon
Softener
RO
Totalizing Flow Meter
Nitrogen Blanket
Storage Tank
Pump
TOC
UV
R
Virgin Ion Exchange
Mixed Beds
Final filter
R

WATER FOR INJECTION (WFI)
HOT AND COOL LOOPS



Cost of Systems

600 gph, 1000 gal storage, 2” distribution
(Distribution piping not included)

- RO/DI not validated $ 120,000

Purified (Validated)

- Purified (RO/EDI) $ 140,000
- HP Purified $ 160,000

Stills (WFI)

- Vapor Compression $ 575,000
- Multi effect $ 600,000

Utility Support is where the BTU's are
Where there is heating, there is cooling

- RO/DI no utility support

Purified

- Purified (RO/EDI) utility support ??
- HP Purified utility support ??

Stills (WFI)

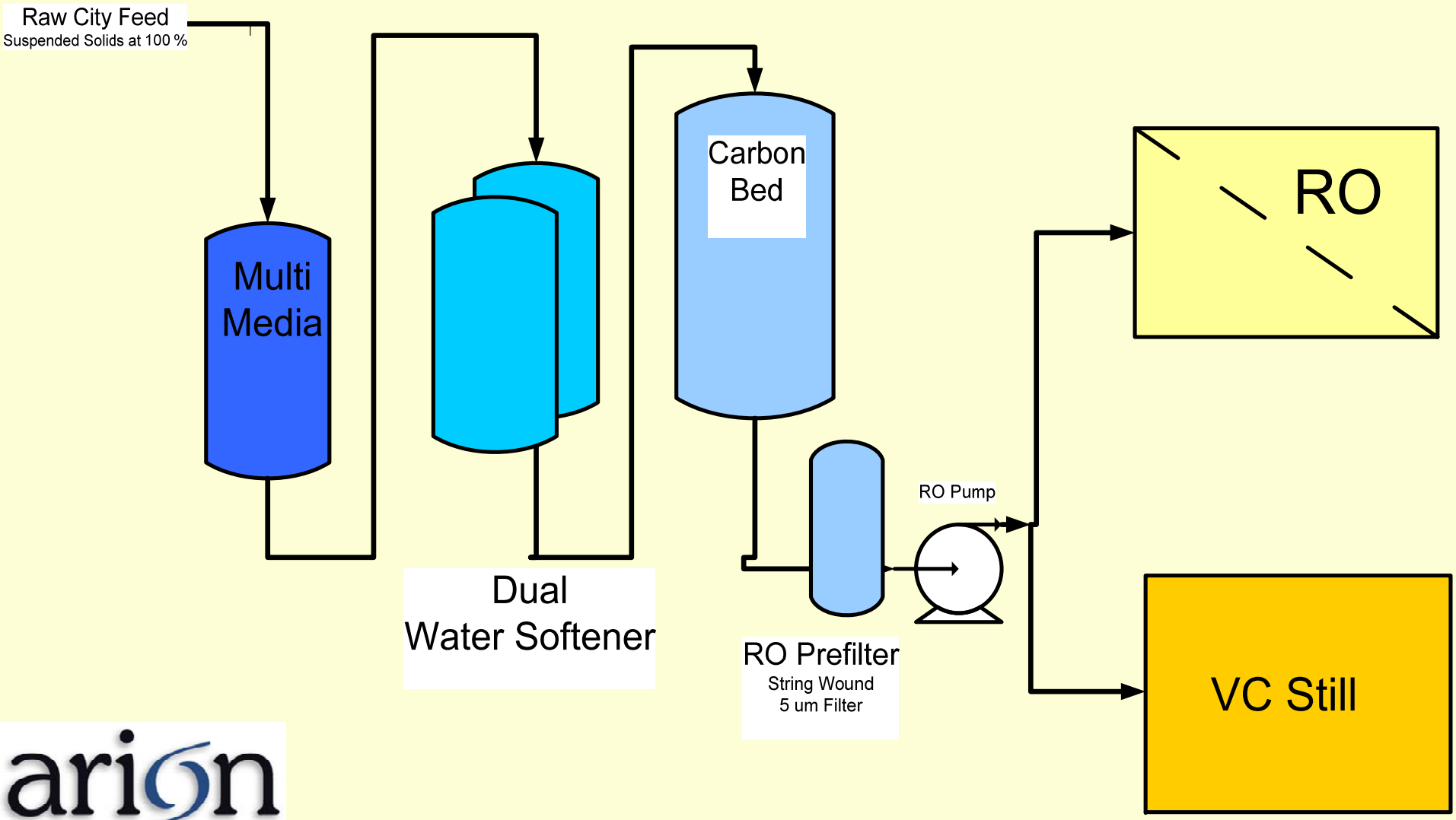
- Vapor Compression utility support
- Multi effect utility support

System Design

3 step classification

- 1) Pretreatment (filtration)
  - Prepare water for RO or distillation
  - Multi media, Softener, Carbon
- 2) Purification (dissolved solids)
  - RO, CDI or EDI, Distillation
- 3) Post Treatment (polishing and distribution)
  - Storage, Pumps , DI beds, UV, Ozone

PRETREATMENT - Keep it SIMPLE



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Avoid Pretreatment Chemical Additions

- Chlorine
- Sodium Bisulfite
- Sequestrant (hardness control)
- Polyelectrolyte (coagulants)

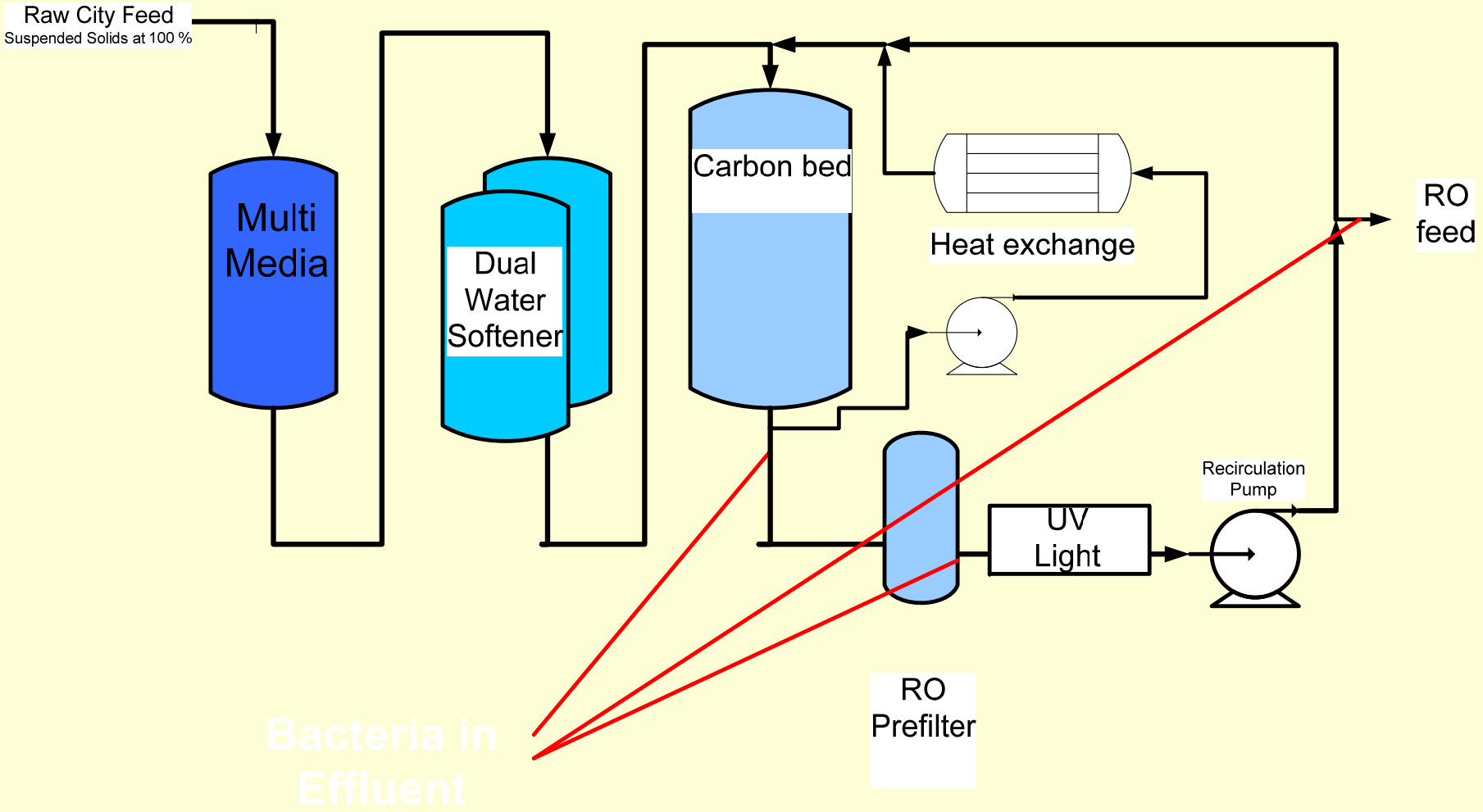
Chemicals are counter productive to the purification process:

they increase the load to be removed and restrict RO REJECT re-use options

Carbon Bed Microbial Control
ENERGY COSTS

- Hot Water Sanitizable Carbon
  - Heating and Cooling requirements
  - Frequency of sanitization
  - Backwash of media?
- Pretreatment UV Units
  - Continuous operation
- Recirculating Pretreatment
  - Continuous operation

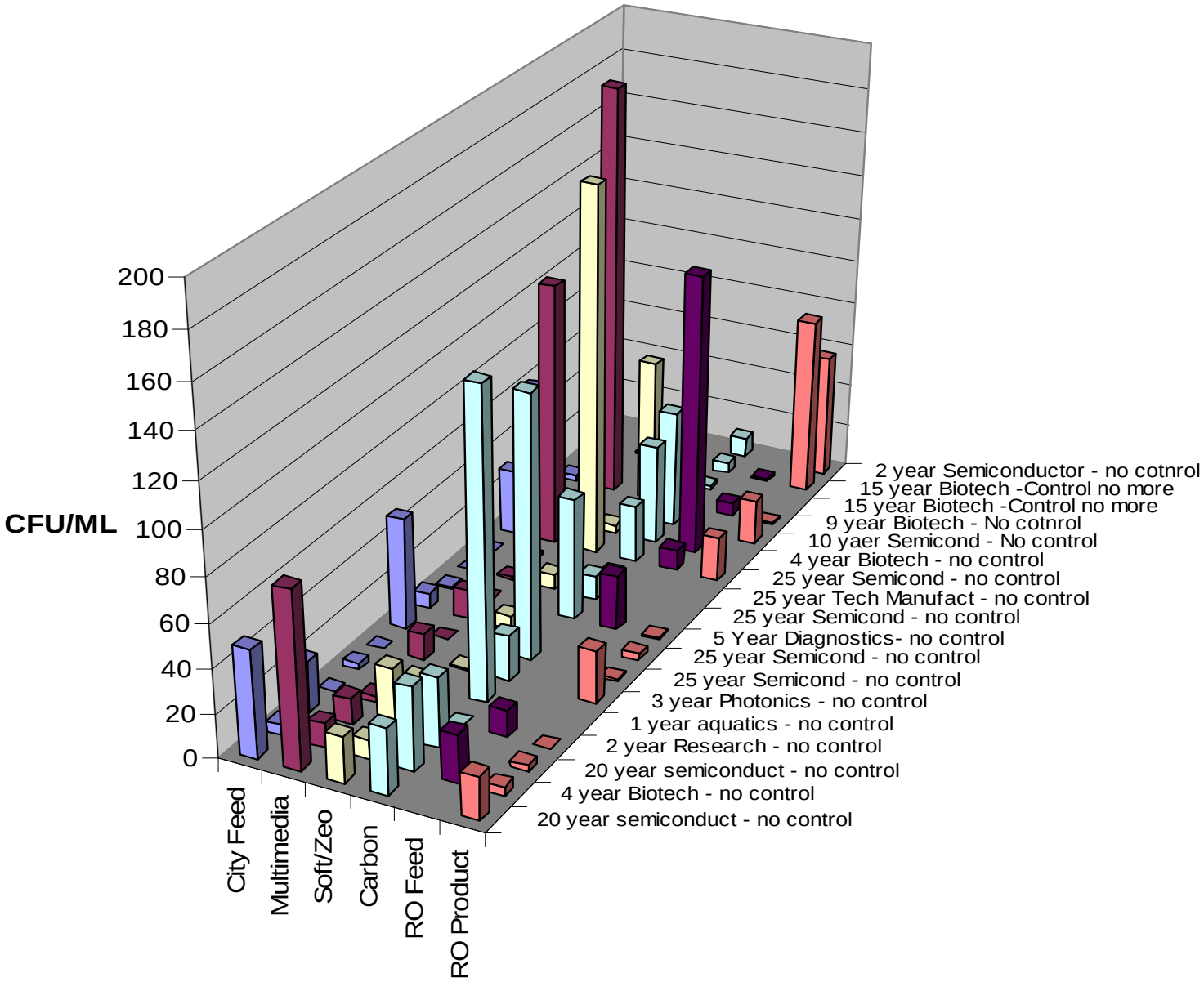
Controlling “bugs” in Carbon Beds?



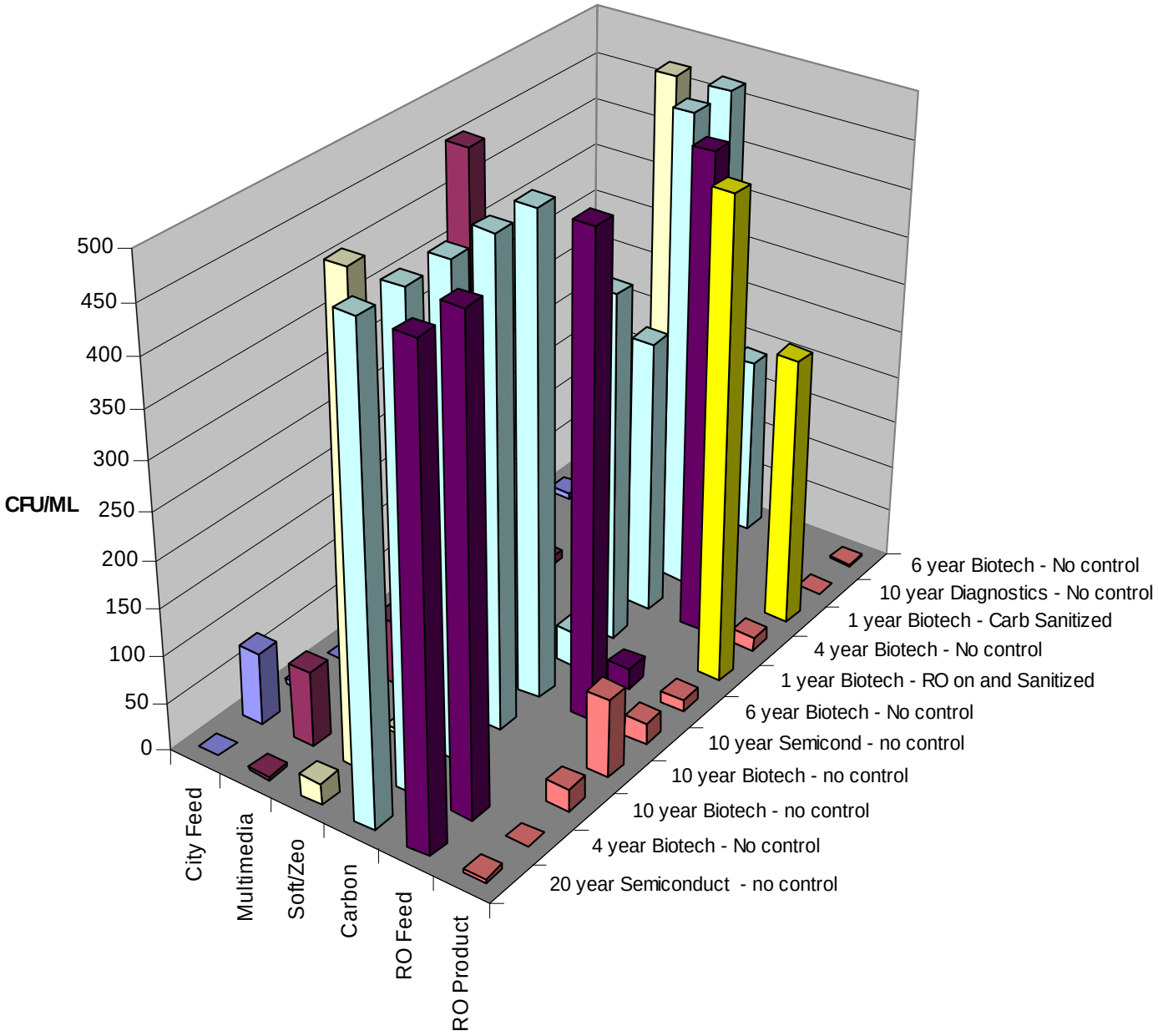
Pretreatment Microbiology

- Microbio activity in pretreatment filtration is not a problem for Purified Water systems
- 1- 100 cfu/ml is common- throughout the pretreatment (Multi-media, softener, carbon)
- The RO unit will reject 99.99% of pretreatment bacteria
- High bacteria in the RO feed will not foul properly operated RO systems

Pretreatment Bugs



High Bacteria in Pretreatment

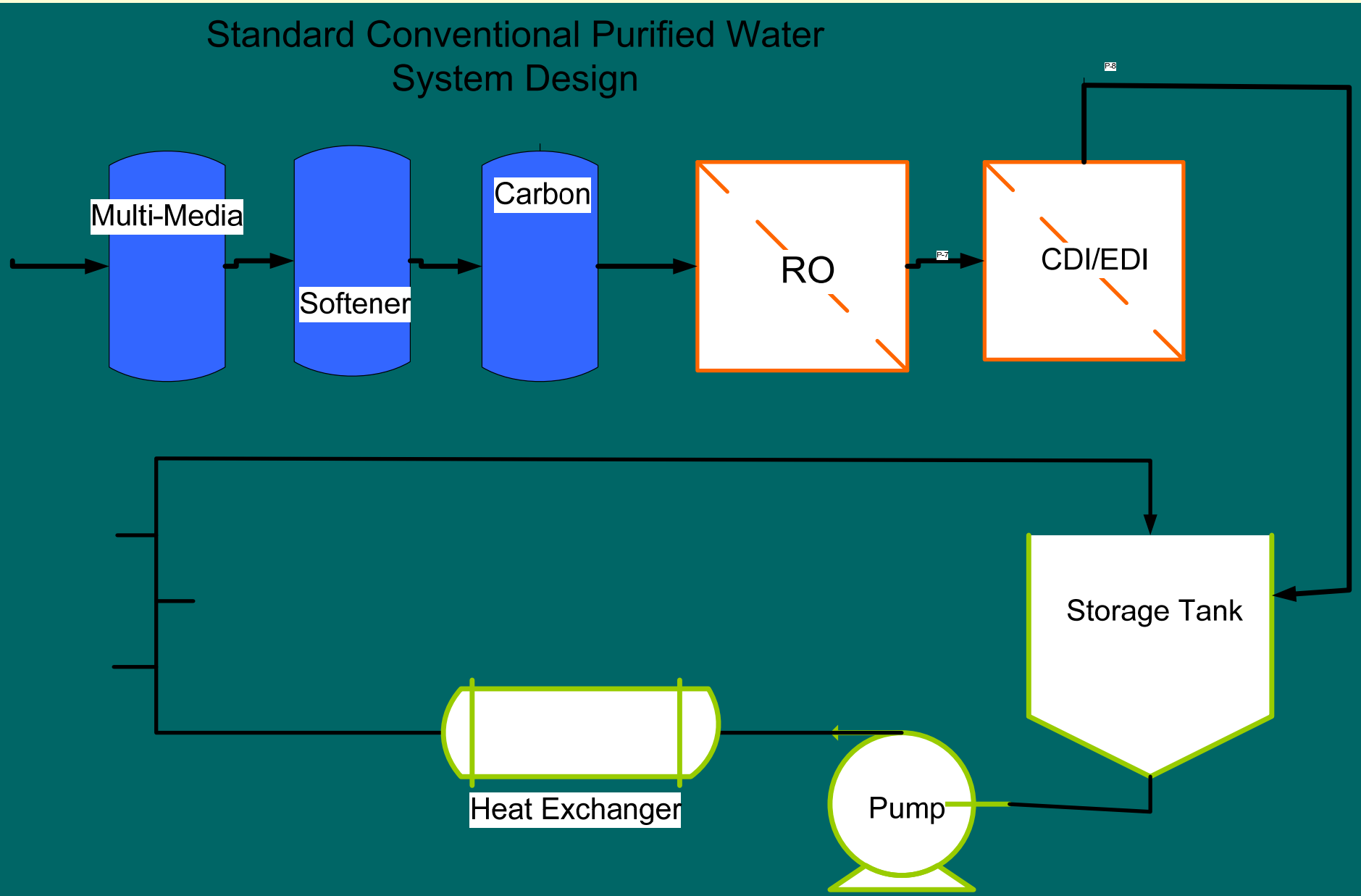


PURIFICATION Opportunities

Saving: Water Energy and Money

- RO
  - On/Off operation
  - Low energy RO membranes
- CDI or EDI
  - Continuous RO/ EDI operation
- Distillation
  - Vapor Compression vs. Multi Effect

PURIFICATION ENERGY SAVINGS



Post Treatment and Distribution

- Single Stage Centrifugal vs. Multi stage pumps
- VFD Pumps
- Heating/cooling requirements

Single Stage Centrifugal pumps VS. Multi stage Centrifugal pumps

- Single Stage Pump is Sanitary Design
- Multi Stage Pump is not Sanitary Design

- **Single Stage Centrifugal Pump uses 2X the Electrical power of a Multi-stage Pump.**
- The extra energy heats the water (often requiring cooling)

Single Stage Centrifugal pumps VS. Multi stage Centrifugal pumps

- Sanitary Design expects 5 ft. sec flow velocity
- The excessive velocities and pump inefficiencies in 80 C hot systems results in pump cavitation
- This is a major source of rouge and pump failure in hot 316 Stainless Steel systems

VFD on Pumps

(Variable Frequency Drive)

- Velocity of water has been shown to have little or no effect on microbiology and biofilm.
- “SOFT START” on large RO units (> 80 Lpm) and 3“ or larger distribution piping is a easy on equipment.
- Lower velocities (~ 1 Ft/Sec) save energy during off hours with little risk

PURIFICATION WATER SAVINGS

(RO CDI/EDI)

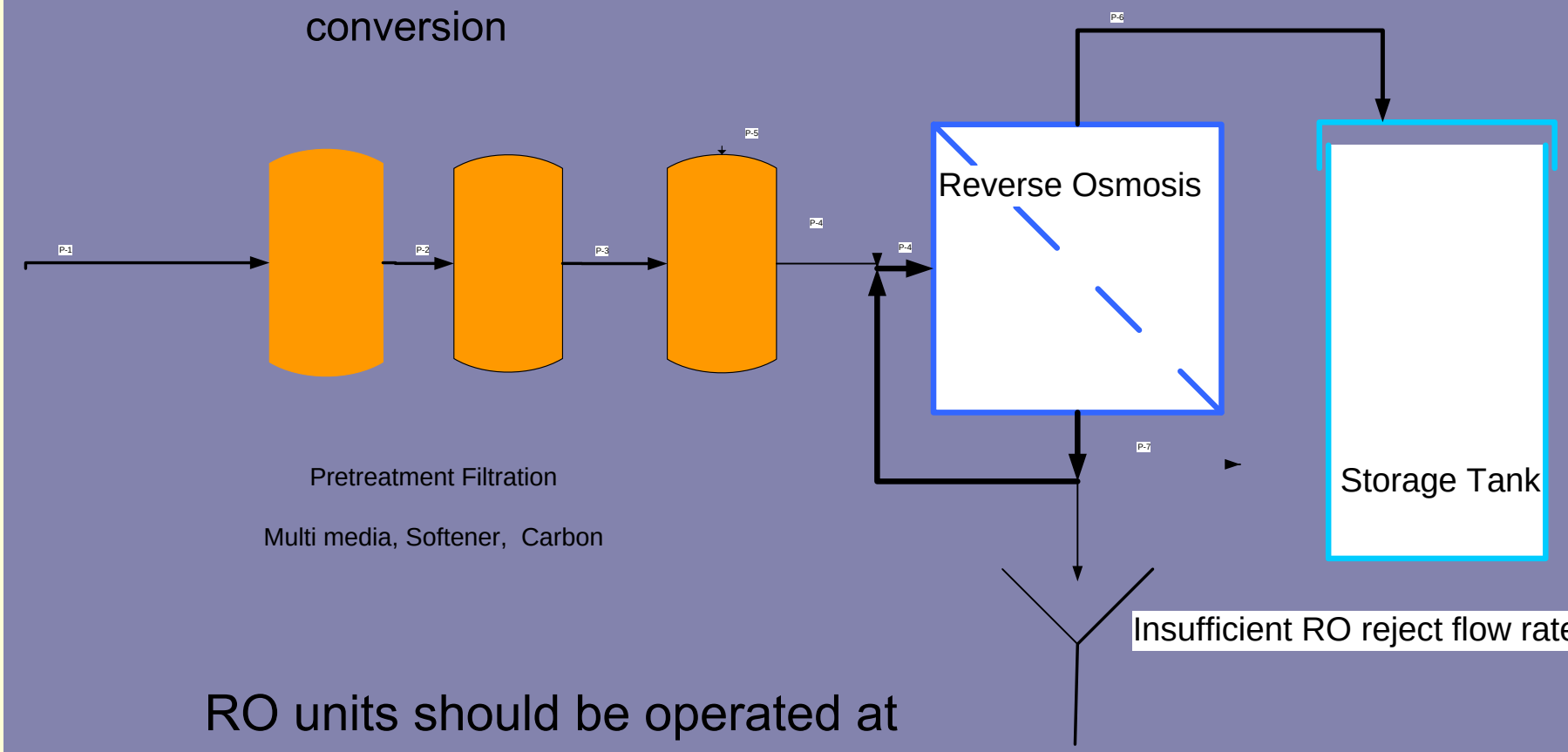
- Process Design Water Wastage
- Continuous RO/CDI operation
- RO reject Water
- HERO (High Efficiency Reverse Osmosis)

RO % Conversion and Maintenance Requirements

- The Ratio of RO product water to reject water is called PERCENT CONVERSION
- RO units are typically operated at excessive conversion rates
- Operating RO units at high conversion rates is the primary problem with most Purified water systems

Excessive RO percent product conversion

Excessive RO product flowrate



Pretreatment Filtration

Multi media, Softener, Carbon

Insufficient RO reject flow rate

RO units should be operated at 60% conversion and then higher only if no problems are encountered.

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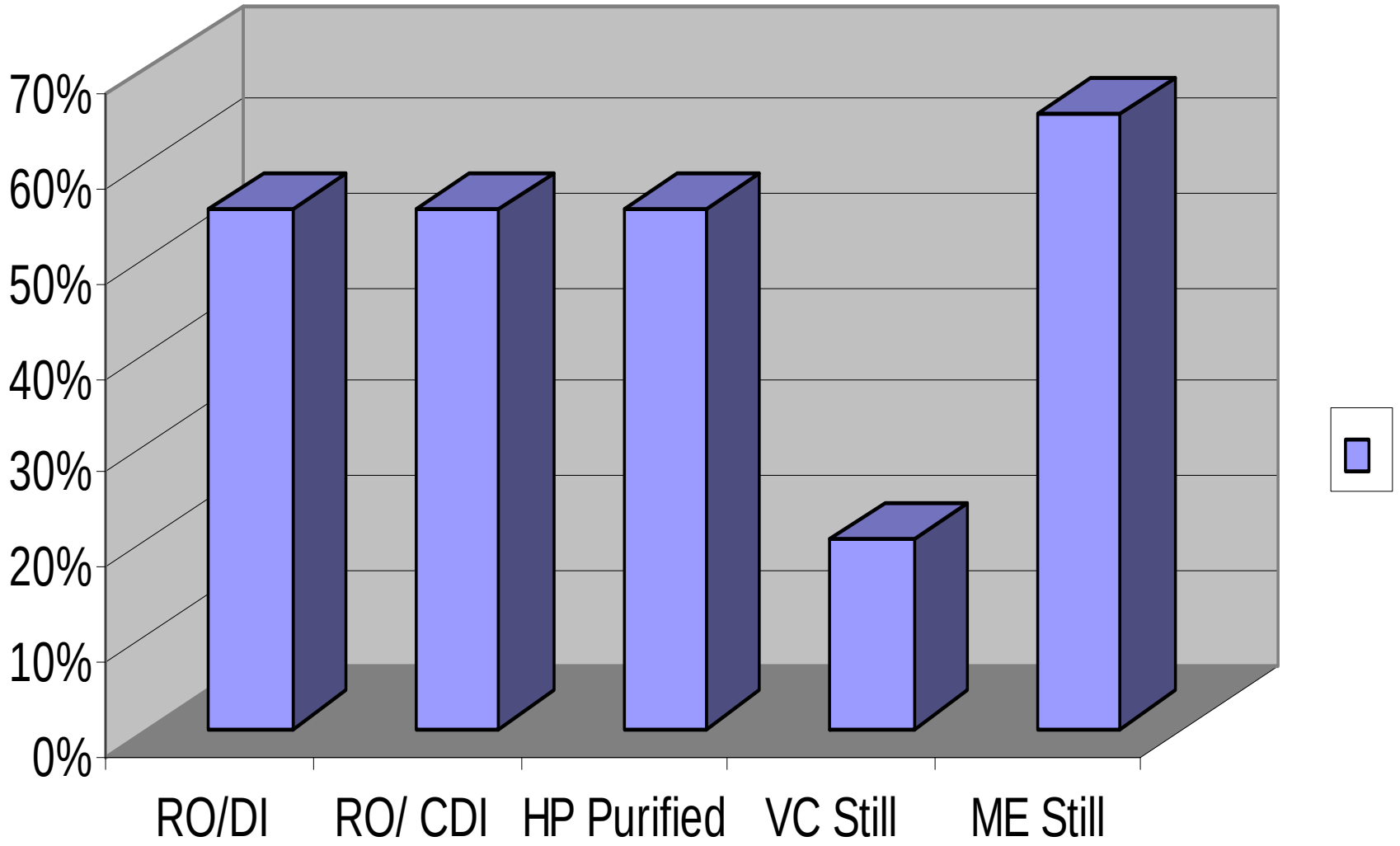
Problems resulting from high RO % Conversion

- Ideal conversion is 50-60%
- Excessive conversion is 70-90%
- High Conversion results in
  - RO Membrane fouling, cleaning and failure
  - Premature ion-x Polisher exhaustion
  - Bacteria problems in product water
  - Reduced RO reject re-utilization options

Water Discharged during Production



Water Discarded

by Design

DESIGN	% DISCHARGE	RE-USE
• RO/DI	55%	YES
• Purified (RO/EDI)	55%-300%+	YES
• HP Purified (RO/DI)	55%	YES
Stills (WFI)		
• Vapor Compression	**20%**	NO
• Multi effect	65% + cooling	YES

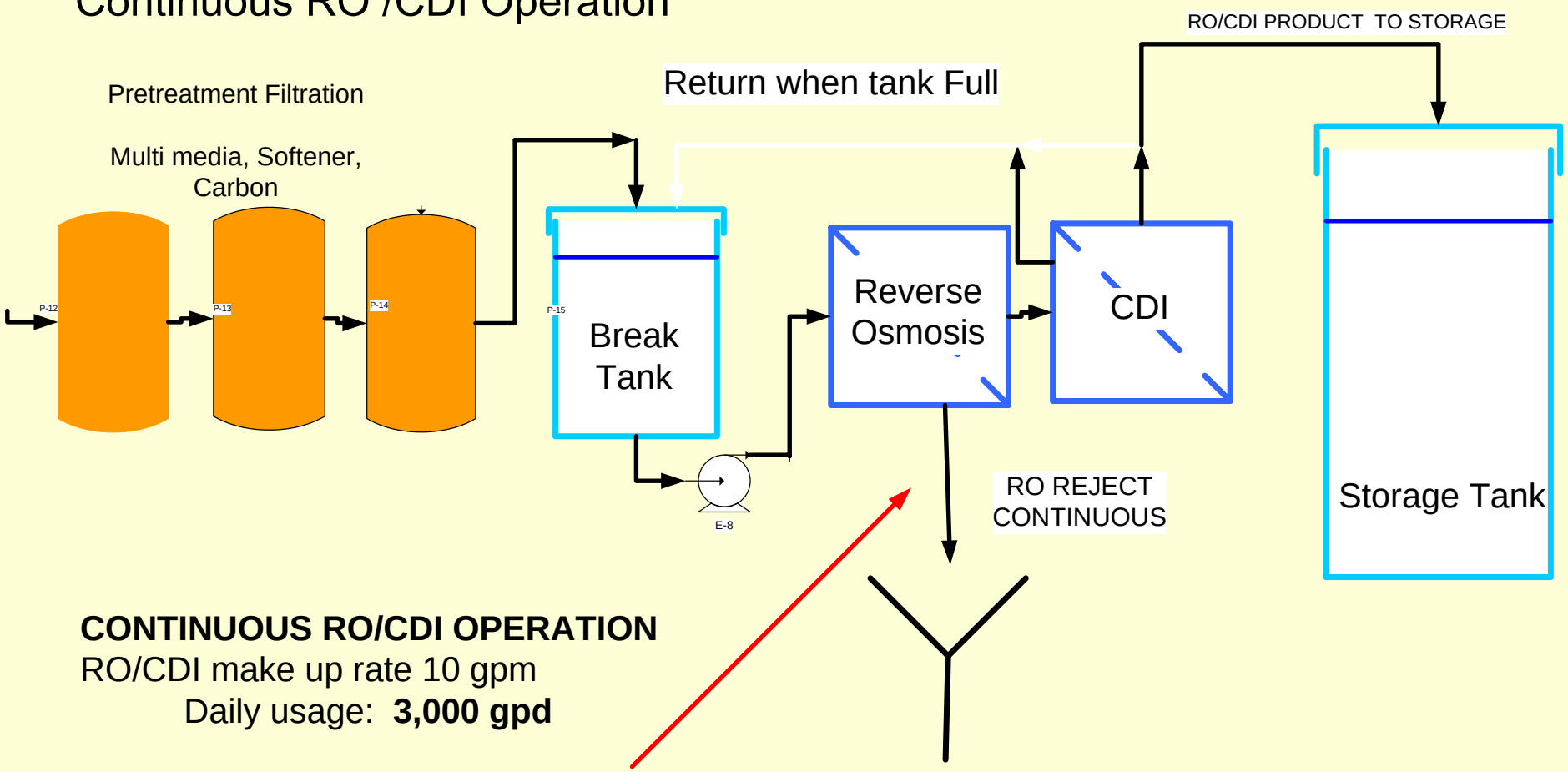
Continuous RO/ EDI operation

- If you have a break tank, you are wasting water !
- The RO does not need to be operated continuously to prevent microbial growth
- The CDI/EDI does not like to be operated in an On/Off Mode

Continuous RO operation

- Wastes 2 to 30 times the amount of water actually USED
- Wastes **water** and **energy**
- Fouls RO membranes and exhausts pretreatment media unnecessarily
- Results in high bacteria from RO system due to avoidable membrane fouling

Continuous RO /CDI Operation



CONTINUOUS RO/CDI OPERATION

RO/CDI make up rate 10 gpm

Daily usage: **3,000 gpd**

Reject water = 3X Daily Usage

= 5X more than ON/OFF

CONTINUOUS RO/CDI OPERATION

- **CONTINUOUS RO/CDI OPERATION**
- RO/CDI make up rate 10 gpm
- Daily usage: **3,000 gpd**
- RO reject flow rate : 5 gpm (tight)
- Reject water to drain
  - Continuous operation: **7,200 gpd**
  - ON/OFF Operation : **1, 500 gpd**

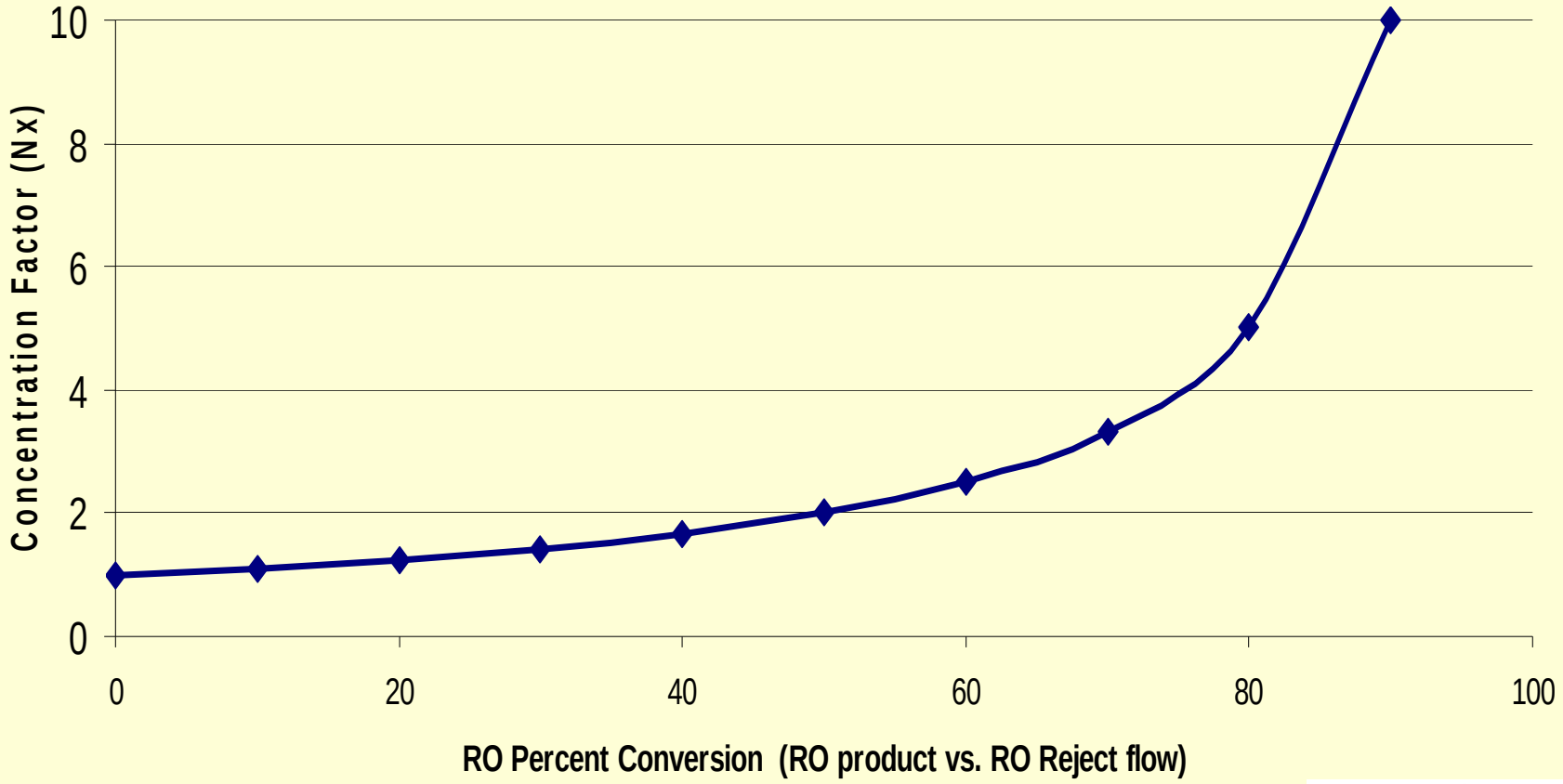
System processes 5X more water than required

Discards = 5X more than ON/OFF

Water Savings
RO REJECT REUSE OPTIONS

- RO reject is FILTERED SOFTENED City Feed (may be better than raw city feed)
- RO Reject has 2X city feed salt TDS
- Uses
  - Cooling towers
  - VC Still Feed
  - Closed Loop Cooling
  - Boiler feed make up

Concentration Factor of both RO Product and RO Reject



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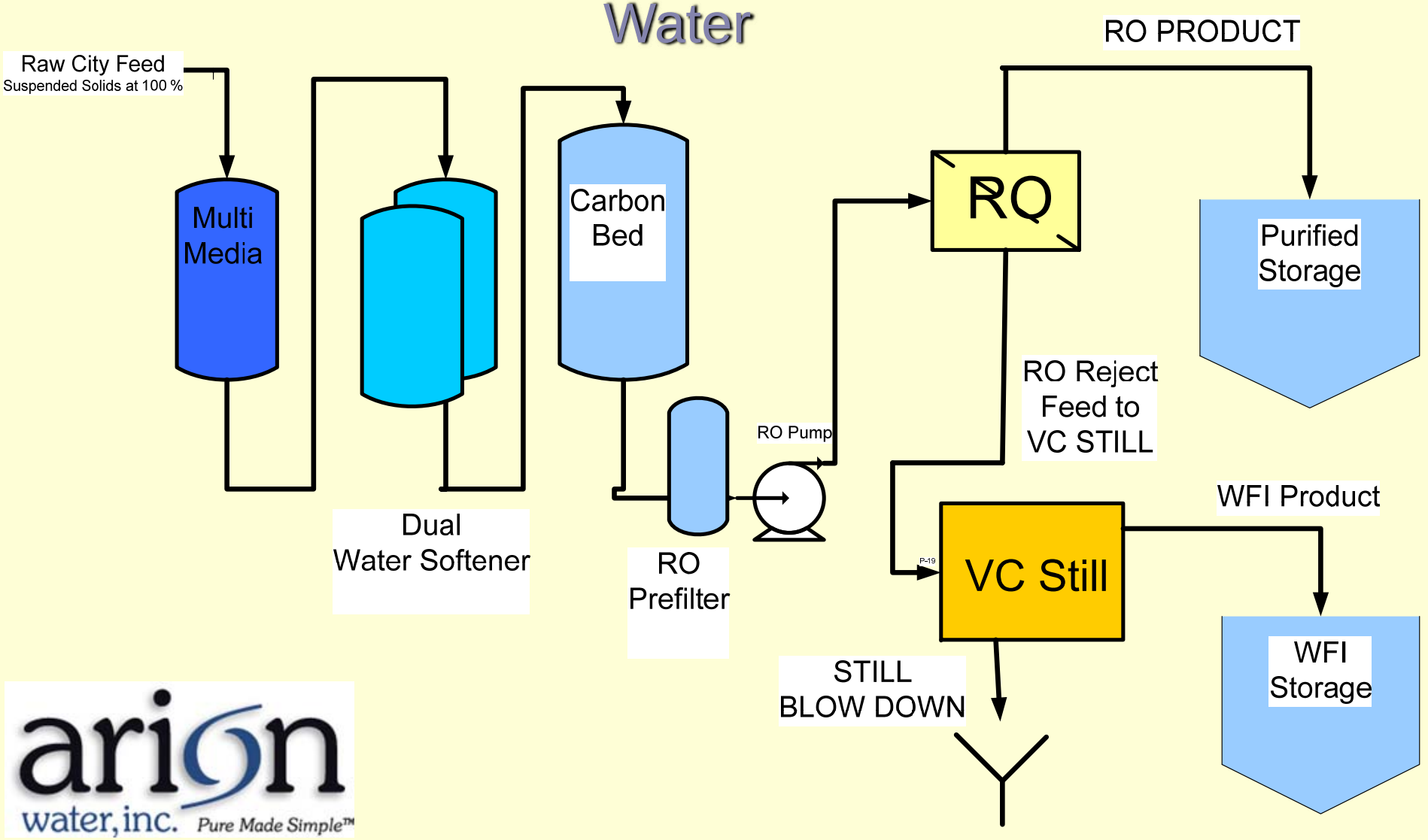
ONLY 25% Reject Water



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Water Savings
Heating/ Cooling dumps

- Water Heating is typically Engineered well
- Water **COOLING** is often poorly engineered or short on capacity
- The time required for heat sanitization often does not include the time required to cool down the Vessel/Loop/RO/CDI.
- Hot water is often *dumped* to get back on line wasting water

RO Membrane Flushing

- Hourly Flushing is not required for TFC membranes and wastes large quantities of water.
  - Flush RO membranes 3 minutes every 12 hours of downtime
  - Use an RO product water divert to drain for larger systems to assure maximum quality upon restart

ENERGY SAVINGS

- Distillation Opportunities
  - Multi Effect vs Vapor Compression

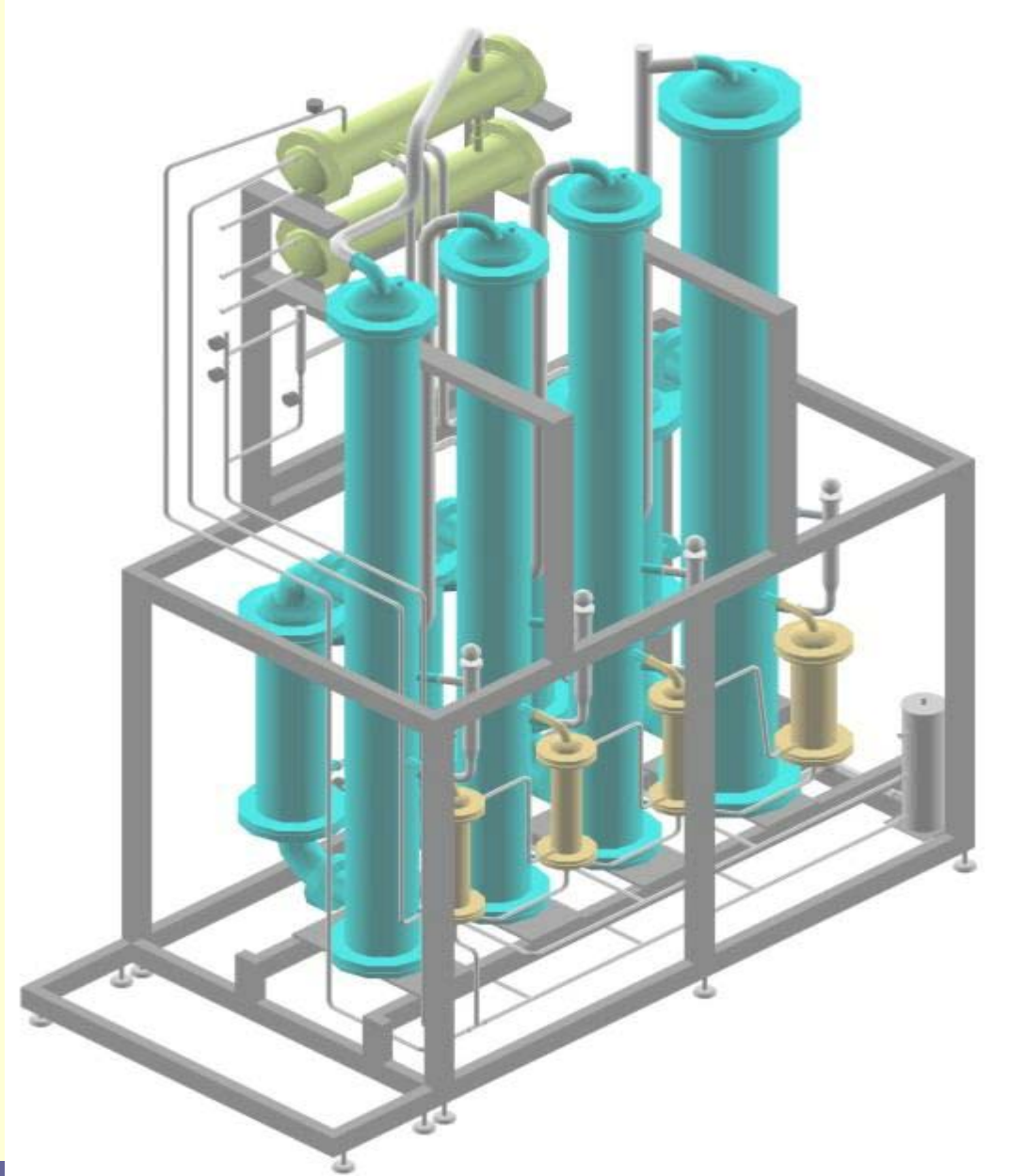
Distillation

MULTI EFFECT (ME) Stills

cannot compete economically with **VAPOR COMPRESSION** (VC) stills

above ~ 50 lph

Multi-Effect Still



Bram

COR

Italy

ME STILL (Multi Effect)

Bram
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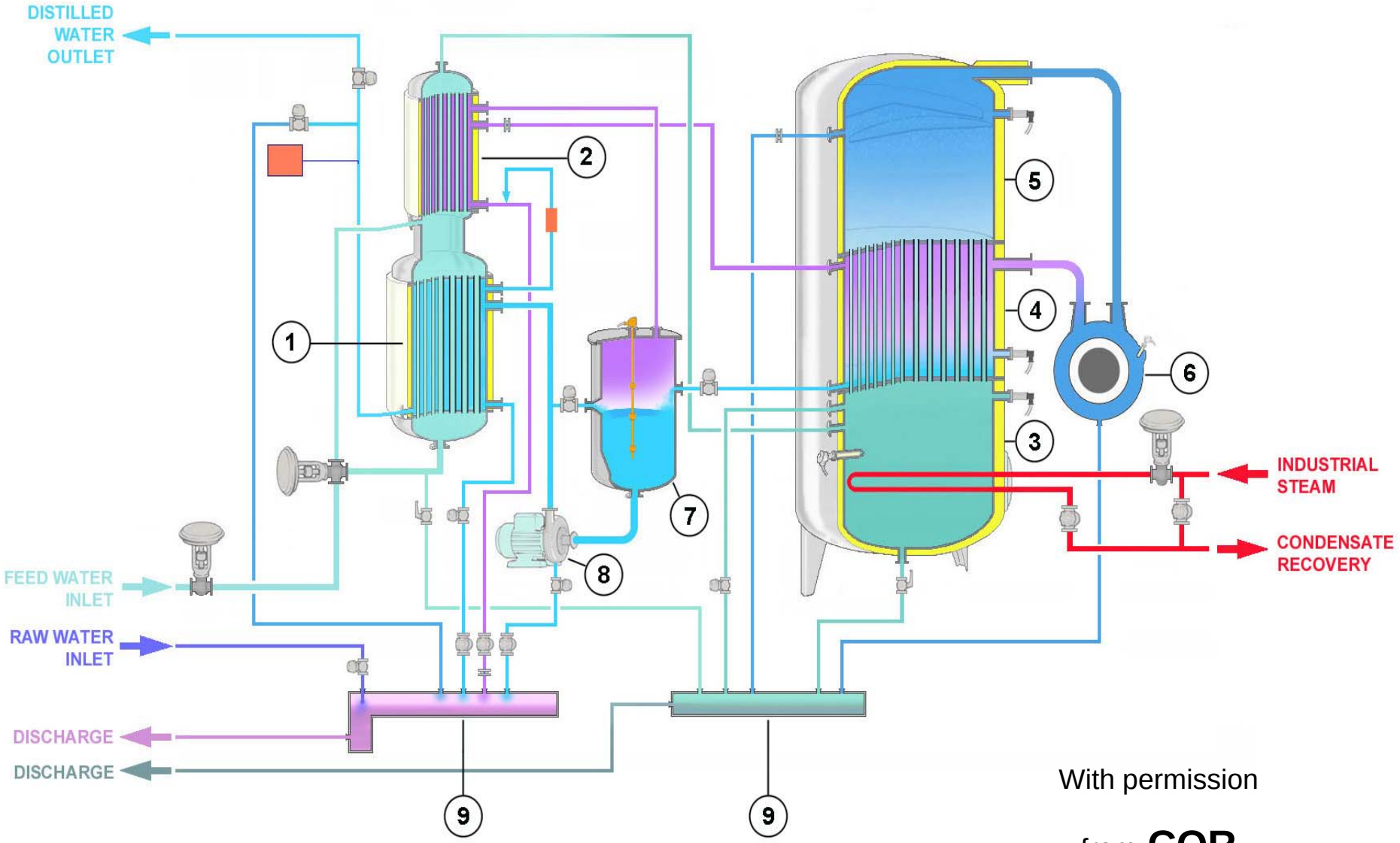
VAPOR COMPRESSION STILL



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from **COR**

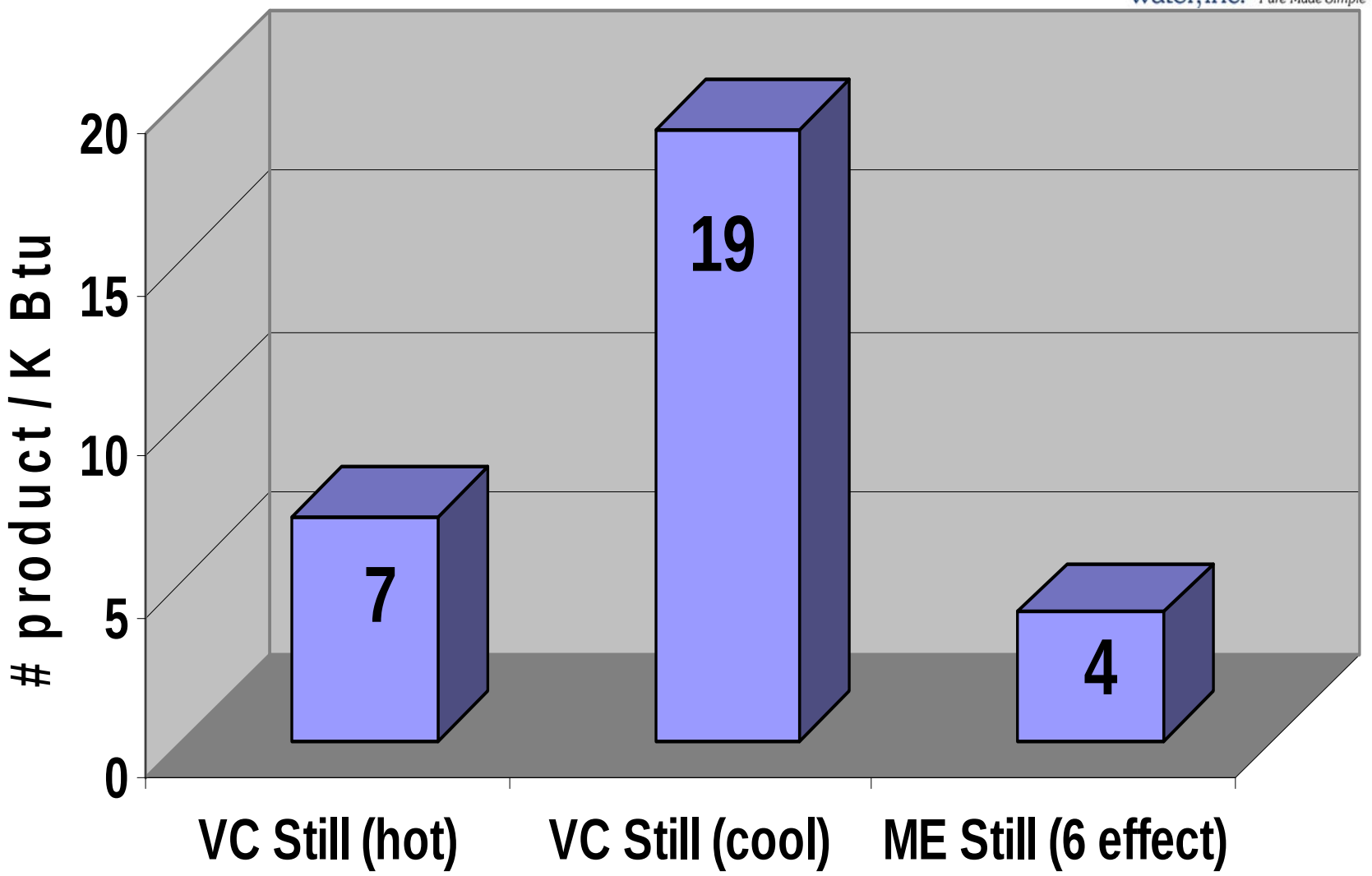

VC
STILL

Distillation
Feed Water Requirements

- **Multi Effect**
  - RO/DI Feed Water required
  - Minimum of 1 MΩ or 1.0 uS
  - LOW Silica in feed

- **Vapor Compression**
  - Softened/Carbon feed only
  - Silica less than 10 ppm
  - NO chloramines

Distillation Output / K Btu



Distillation **OPERATING** Costs
600 gph (2400 lph) 2 shifts

	$/day	$ / yr	$/ gal
ME Still	$2200.	$480K	$0.22

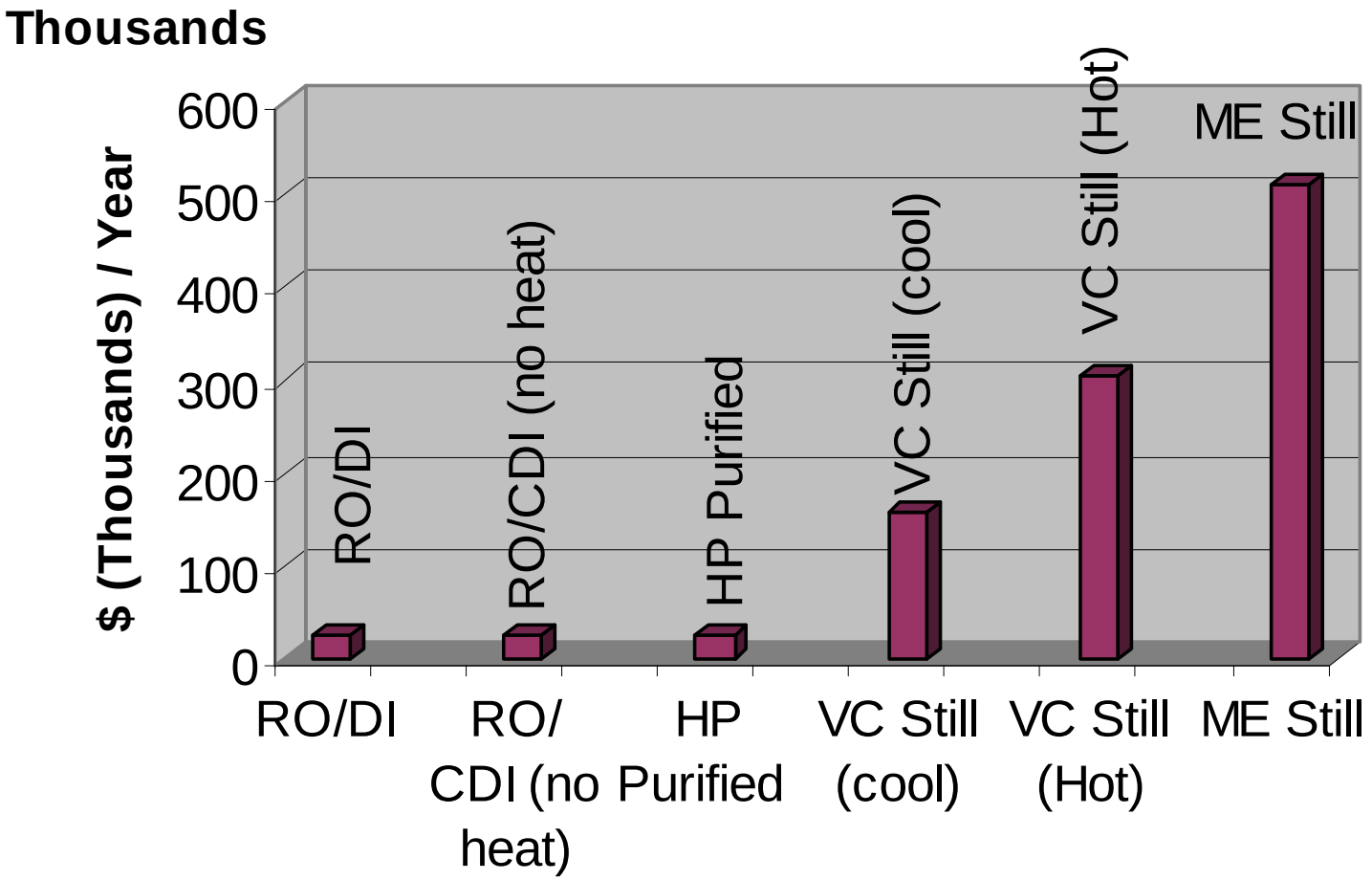
(does not include cost of DI feed and cooling water)

VC Still

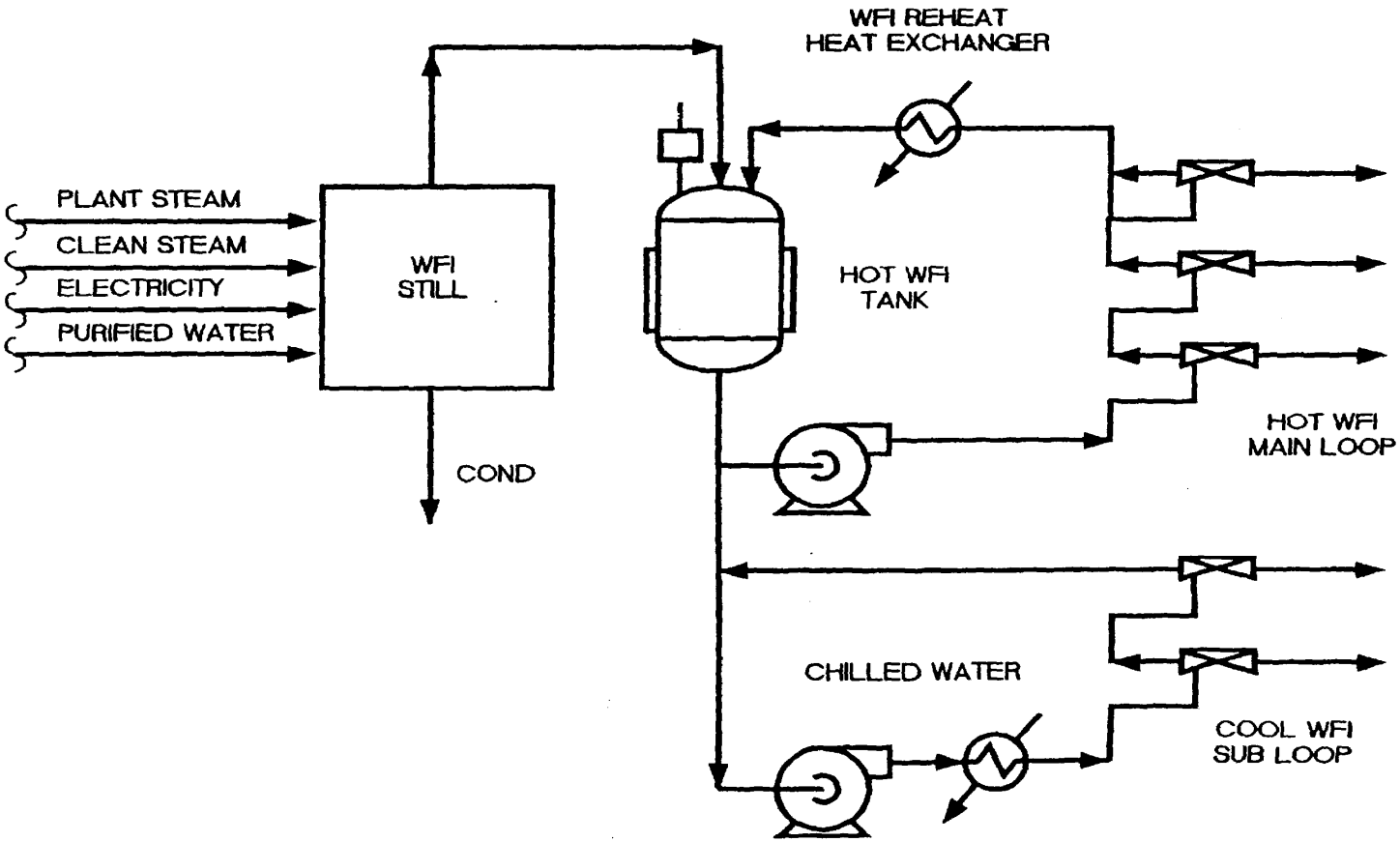
- (90 C prod.) $1,400. $305K $0.14
- (30 C prod.) $ 730. $160K $0.07

HP Water System Operating Costs

6K gpd, 600 gph, 1K gal tank, 2 shifts/day



WATER FOR INJECTION (WFI)
HOT AND COOL LOOPS



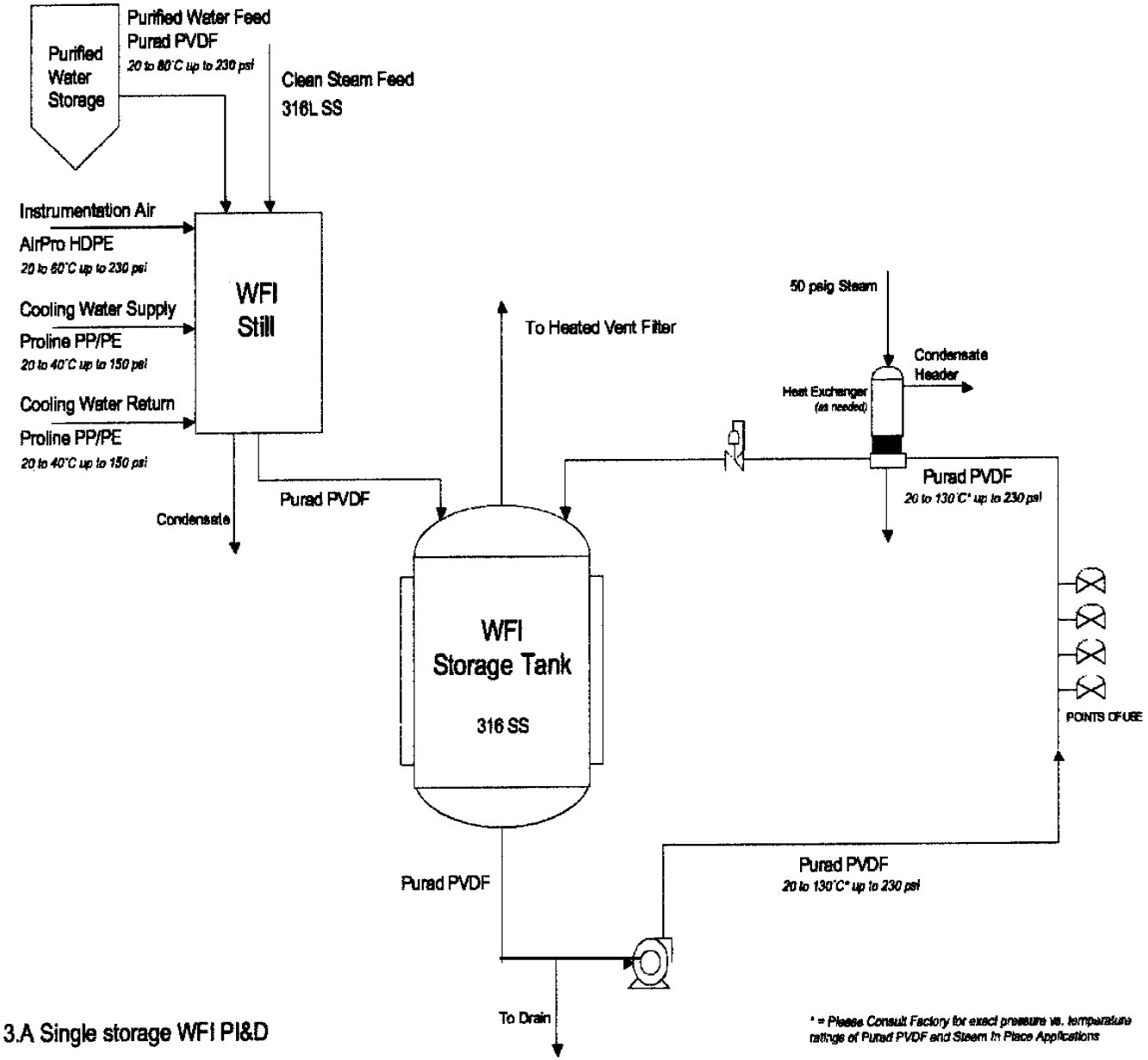


FIGURE 3.A Single storage WFI PI&D

Chemical Savings

Cleaning and passivation of ROUGED WFI systems

The chemicals are an environmental concern, but the production downtime is what is CO$TLY

The most common forms of WFI Rouge

- Uniform Corrosion
  - Caused by the way WFI Water is manufactured and handled
- Pitting Corrosion
  - Caused by the use of Single Stage Centrifugal Pumps (Sanitary Design)
- Both are exacerbated by elevated temperature

Characterizing the need to passivate

- **The tests confirm the need, or lack there of, to clean and repassivate a water system**

Rouge Profile Testing

- **ICP/MS Trace Metals Testing**
- **Rouge SDI Filter Test**
- **Cleaning chemical metals analysis**
- **Visual inspection**

Visual Inspection

- The inspection should include:
  - Tank (Above and Below the water line)
  - Spray ball
  - Pump casing and outlet SPOOL PIECE
  - Diaphragm valves and piping
  - Piping (during gasket replacement)

Heating/cooling

- FDA and EMEA agree temperatures ABOVE 65 C are self sanitizing
- Reduced distribution loop temperatures from 80 C to 70 C should cut “general or Uniform” type Corrosion (rouging) in HALF

Distillation
>65 C vs 80 C Operation
600 gph VC still @ 3k gpd

- Reduced Distribution Operating Temperatures (>65C vs. 80C) save MONEY as follows:
- Q=m*Cp*delta T
- 10 gpm = 5000 lb/hr steam
- Delta T = (176 -158F) 18 F
- Q= 90000 BTU/ hr
- 0.09mmbtu/hr*5hr/day*$20/ mm BTU= **$10/day**

(BIG) HOT Water
>65 C vs 80 C Operation

Dual 4,000 gph VC still @ 100K gpd

- Reduced Distribution Operating Temperatures (>65C vs. 80C) save MONEY as follows:
- Q=m*Cp*delta T
  - 50 gpm = 25,000 lb/hr steam
  - Delta T = (176 -158F) 18 F
  - Q= 450000 BTU/ hr
  - 0..45mmbtu/hr* 15hr/day* (2 stills)*$20/ mm BTU
- **= $270/day ~ $ 100K / yr**

Microbial Control in Vivarium Water

Animal Watering Systems (AWS)

- Flushing
  - (Dead ended systems)
- Chemical Additions
  - Chlorine, Acidulation, Ozone, Antibiotics
- Filtration
- UV

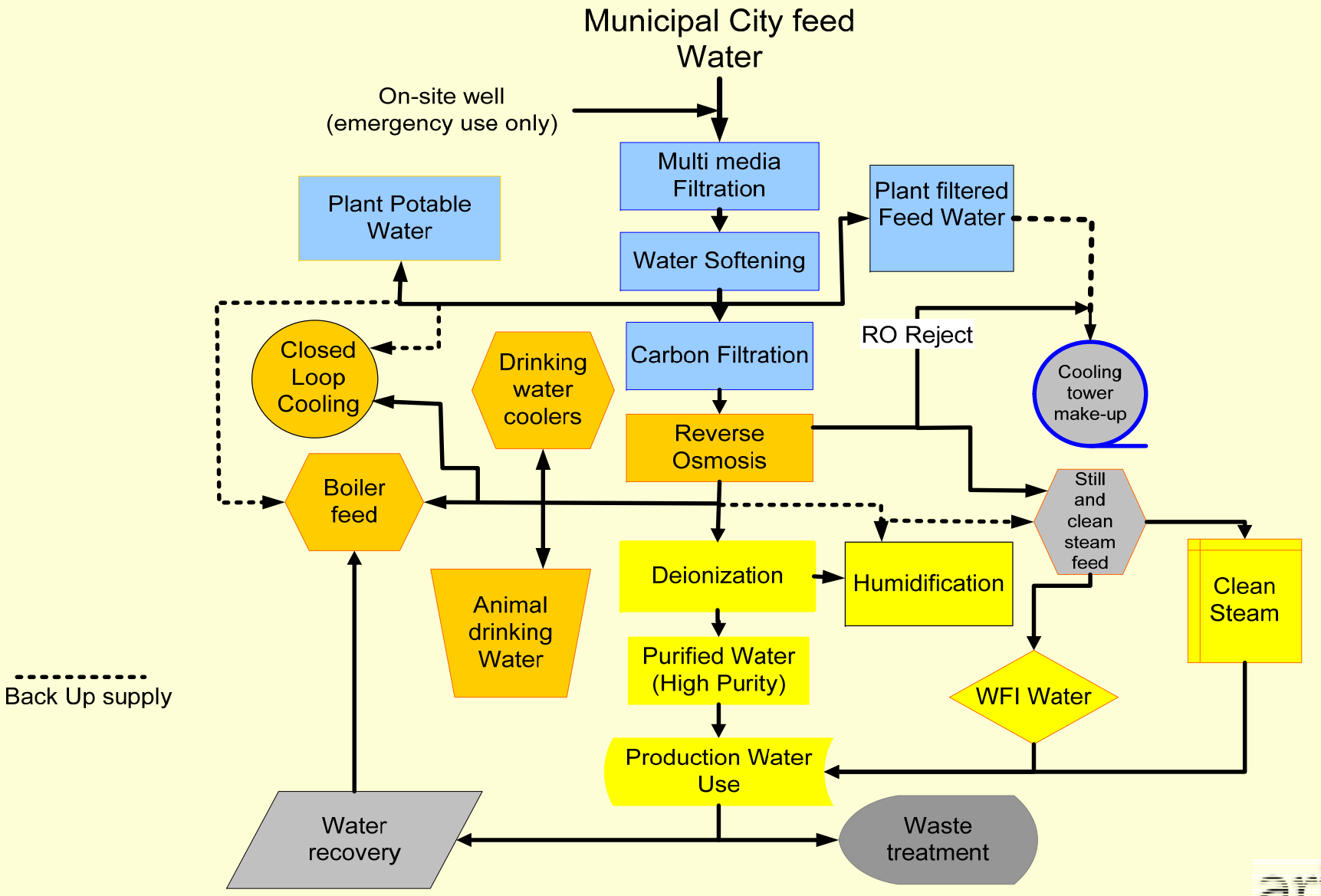
AWS Microbial Control via Chemical Addition

- Chlorine Addition (recirculating systems)
  - Target : 1 – 5 ppm total chlorine
- Acidulation (recirculating systems)
  - Target pH of 4.0
- Ozonation
  - Attractive but untried
- Antibiotics (not recommended)

Flushing is a BIG WATER WASTER

- Flushing is frequently used in Animal Watering Systems to maintain residual Chlorine levels
- Flushing water use is often not monitored.
- Flushing consumes many times the quantity of water drunk.

Facility Water use



Water Recovery and Water Reclaim

- Neither are done in the Pharmaceutical Industry - Yet
- Water Recovery is capturing water that has not been contaminated during use
  - Final Rinse water
- Water Reclaim is treating contaminated water for reuse
  - Water Reclaim is more expensive and risky than Water Recovery

Water Savings
HERO

- High Efficiency Reverse Osmosis
- Invented by Deb Mukhopadhyay
- HERO is a registered trademark of GE Water
- HERO systems are smaller due to recirculation
- 90 % water recovery from low quality feed water !!

Water/Energy Assumptions

- City Water : $12.00/ Kgal ($4.50/ M_3)
- Plant Steam : $18.00 mm BTU
  $20.00/ ton

Cooling Water : $24.00 / mm BTU

Electric : $ 0.18 / Kw

1 MM BTU = **About 133 lbs Carbon Dioxide , which is about 1000 standard cubic feet (volume at 1 atm pressure and 32 deg C)"**

References

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PHARMACEUTICAL GUIDANCE WEB SITES

- www.fda.gov/ora
- www.fda.gov/cder
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Questions ?