Reverse Osmosis and the AS4187 Sterilisation Standard

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Speaker: Sven Denton

12:30 to 12:55 Monday 23rd September

- Principle Consultant and Director - AquaKlar (14 years)
- Water Chemist (30 years)
- M.AIRAH (4 years)
- B.Sc (Hons) Applied Chemistry
- Consulting in Water and Energy Matters
- And we do lots of other stuff !

- Site Audit and water efficiency assessment of water systems for over 300 cooling systems within Australia
- EnHealth Risk Assessments
- Statistical process control evaluation of water treatment analysis and testing
- Generation of Water Treatment Tender Specifications
- Water Treatment Tender Specification Evaluation
- Waste water consultancy : monitoring, design, modifications
- Water Chemistry Assessment and Analysis
- Microbiological Risk Assessment and Consulting for Cooling and Warm Water Systems
- Water Treatment Risk Assessment and Analysis Consultancy
- Boiler System Water and Energy Optimisation Studies
- Corrosion Monitoring and Water Treatment Performance Monitoring
- Steam Boiler and Condensate System Water Treatment Management
- Greening our Hospitals
- Cert 2 trainer for water efficiency
- NGER submission for major Victorian health care networks
- EEO reporting
- EREP reporting
- NPI Reporting
- AIMS reporting
- Water Map reporting
- Compliance Reporting
- Energy and Water auditing
- Risk Management Plans and Reviews
- Chemical and Physical Water Treatment

The AS4187 Standard

- Original AS 4187—1994
- Revision AS 4187—1998
- Revision AS/NZS 4187:2003
- AS 4187:2014 – Introduction of table 7.2

TABLE 7.2

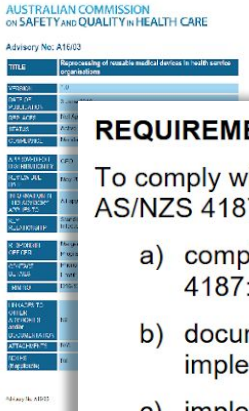
WATER QUALITY USED FOR PROCESSING RMDs

Substance	Maximum concentration levels	
	Cleaning process	Final rinse*
Appearance	Clear, colourless	Clear, colourless
pH	—	5.5–8.0
Conductivity at 25°C	—	30 µS/cm
Total dissolved solids [TDS]	—	40 mg/L
Total hardness [$CaCO_3$]	60 mg/L	50 mg/L
Chloride [Cl]	120 mg/L	10 mg/L
Lead [Pb]	—	10 mg/L
Iron [Fe]	—	2 mg/L
Phosphate [P_2O_5]	—	0.2 mg/L
Silicate [SiO_2]	2 mg/L	0.2 mg/L
Total viable count [cfu/100 mL]	—	10
Endotoxin [EU/mL]	—	0.25

* The term final rinse refers to the final water rinse conducted on the RMD.

Table 7.2 – For Reprocessor Washers 2014

- Aust. Comm on Safety and Quality in Health Care : Advisory No: A16/03 – by 2021
  (published June 2016)



REQUIREMENTS:

To comply with the requirements of Action 3.16.1, where health service organisations apply AS/NZS 4187:2014 health service organisations will need to:

a) complete a gap analysis to determine the current level of compliance with AS/NZS 4187:2014 and document the findings

b) document a detailed implementation plan specifying timeframes to enable full implementation of AS/NZS 4187:2014 over a five year period, from December 2016

c) implement the plan and demonstrate progress toward implementation

- AS4187 Amendment May 2019

  (see next slide)

AquaKlar

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

NSQHS STANDARDS

ADVISORY

TITLE	Reprocessing of reusable medical devices in health service organisations
Advisory number	AS18/07
Version number	2.0
TRIM number	D18-28893
Publication date	August 2019
Replaces	AS18/07 version 1.0 published on October 2018
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c. Demonstrate progress toward implementing the plan, noting health service organisations are permitted to:
   - Return to or maintain pre AS/NZS 4187:2014 water quality input requirements and water quality monitoring requirements
   - Revise or delay implementation plans until the Commission clarifies the minimum requirements to comply with Action 3.14 in November 2019.

AUGUST 2019

The AS4187 Standard - Current

The Key Requirements……..by 2021

TABLE 7.2

FINAL RINSE WATER—MANUAL CLEANING MANUAL DISINFECTION AND WASHER-DISINFECTORS

Substance	Specifications
pH	5.5–8.0
Conductivity at 20°C	≤ 30 µS/cm
Total hardness	≤ 10 mg $CaCO_3$/L
Chloride	≤ 10 mg/L
Iron	≤ 0.2 mg/L
Phosphates (molybdate reactive)	≤ 0.2 mg/L
Silicates (molybdate reactive)	≤ 1.0 mg/L
Total viable count (see Note)	≤ 100 cfu/100 mL
Endotoxin	≤ 0.25 EU/mL

NOTES:

1 Table 7.2 applies to the quality of water used in the types of washer-disinfectors included under the scopes of ISO 15883-1 and ISO 15883-2.

2 ISO 15883-1 is the umbrella (i.e. horizontal) standard that applies to all WDs. Specific or altered requirements are given in each of its subsequent parts (i.e. vertical standards) for different types of WD. See Table 7.3 for specific requirements for WDs used to reprocess thermolabile endoscopes.

3 For TVC, test methodology should be in accordance with ISO 15883-1 and the HTM 01-01 series.

Table 7.2 – For Reprocessor Washers

(a) Water hardness no greater than 150 mg/L.

NOTE: This specification may need to be lower, depending on the RMD being reprocessed, to reduce the risk of deterioration to the RMD.

(b) Chloride no greater than 120 mg/L.

NOTE: This quality of water may be suitable for use in the final rinse of washer-disinfectors within the scopes of ISO 15883-3, ISO 15883-6 and ISO 15883-7.

Supply Water Quality to Reprocessor Washers

TABLE 7.3

FINAL RINSE WATER—WASHER-DISINFECTORS IN ACCORDANCE WITH ISO 15883-4 FOR THERMOLABILE ENDOSCOPES

Substance	Specifications
Total viable count (see Note)	≤ 10 cfu/100 mL
Pseudomonas aeruginosa	Not detected/100 mL
(Atypical) *Mycobacterium sp.*	Not detected/100 mL
Chemical purity	In accordance with WD manufacturer's recommendations
Endotoxin	≤ 30 EU/mL

NOTE: For TVC, test methodology should be in accordance with ISO 15883-1 and the HTM 01-06 series.

Table 7.3 – For Scope Washers

The AS4187 Compliance

Reprocessor Washers Spec

TABLE 7.2

FINAL RINSE WATER—MANUAL CLEANING MANUAL DISINFECTION AND WASHER-DISINFECTORS

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Endotoxin	≤ 0.25 EU/mL

Typical Melbourne Water

Conductivity – 80 to 150 uS/cm

Total Hardness 15 to 30 mg/L

Chloride – 10 to 30 mg/L

Silicates – 4 to 6 mg/L

Total Viable Count (HCC) – Occasionally >100cfu/ml

Endotoxins - >0.25 (2 to 8) EU/mL

What is the Fix : use Reverse Osmosis !

Other options are economically unviable or mechanically unsuitable

Reverse Osmosis

Key Concepts

- Permeate
  (The treated water)
- Concentrate
  (The water left behind)
- Permeate Flow
  (Flow rate of cleaned water)
- Differential Pressure
  (Between inlet and outlet)
- Percent Rejection
  (Ratio of permeate to concentrate flow or concentration)

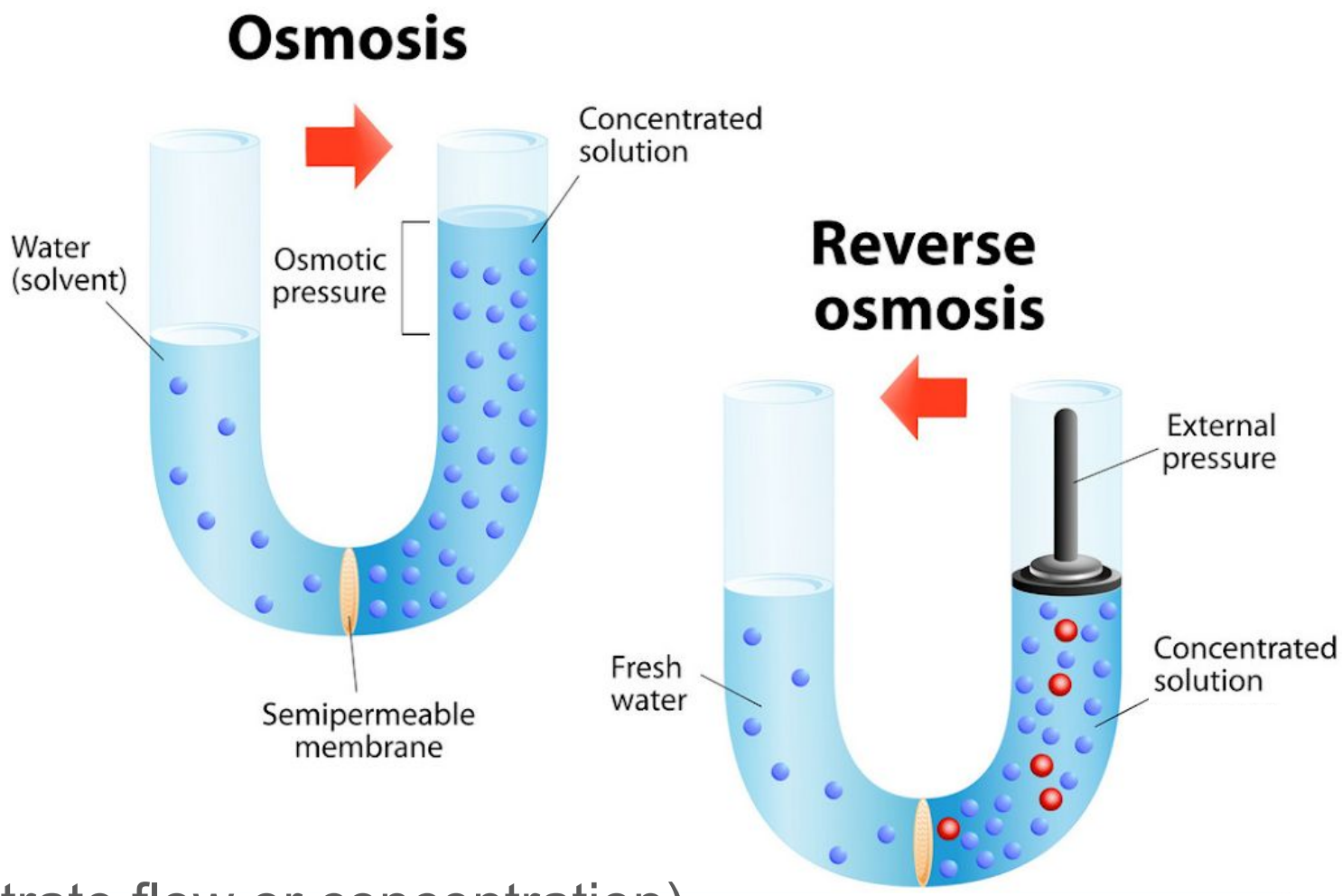
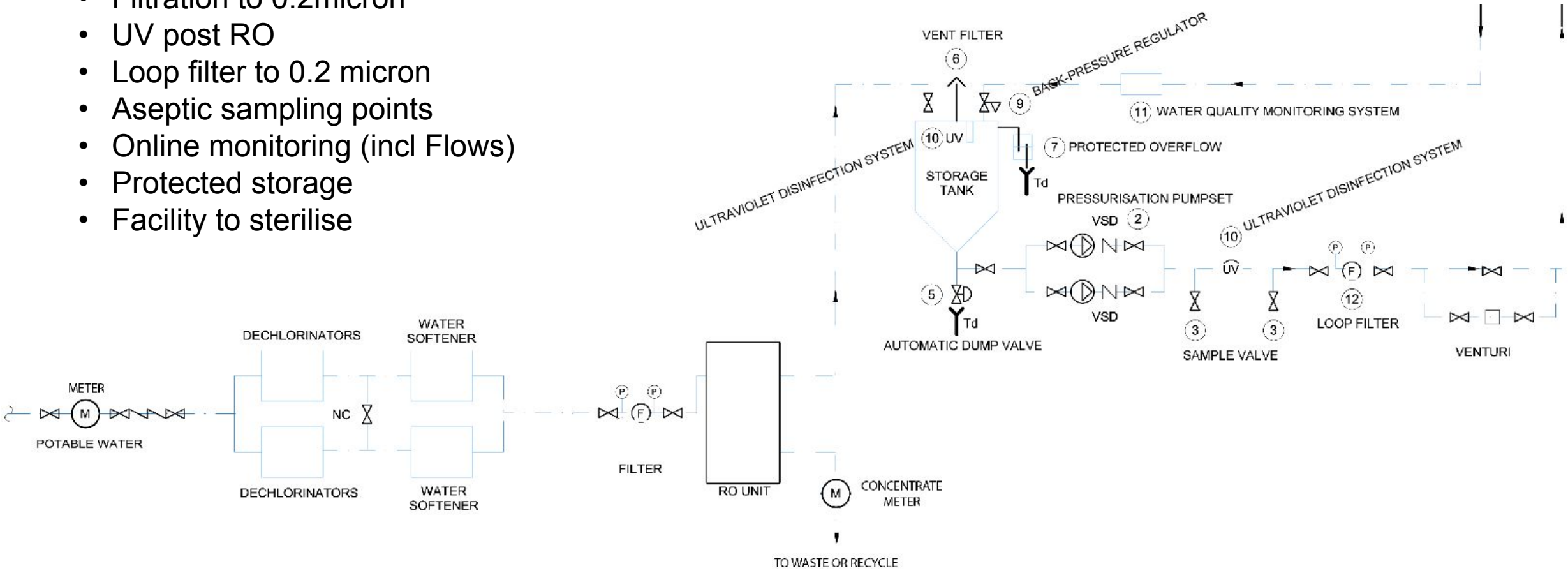


Image: Royalty free

Best Practice Configuration

Typical RO System Setup – Key Elements

- Dechlorination (particularly reqd. with Thin Film Composite (TFC) membranes)
- Softening (particularly when hardness is >100mg/L)
- Filtration to 0.2micron
- UV post RO
- Loop filter to 0.2 micron
- Aseptic sampling points
- Online monitoring (incl Flows)
- Protected storage
- Facility to sterilise



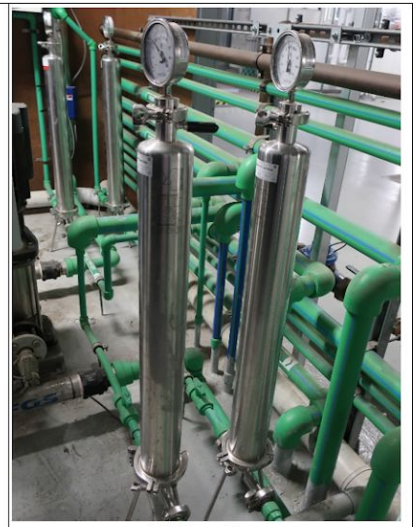
My thanks to Craig Marshall (Focus Energy) for providing schematic

What do they Look Like (A)?

Prefiltration

0.22micron Filter

UV Disinfection



Filtration

Pressurisation Pumps

Washer RO Unit

Laboratory RO Unit

Holding Tank (with Air Filtration)

What do they Look Like (B)?

Prefiltration

Filtration

UV Disinfection

1.0 and 0.35 micron Filtration

Pressurisation Pumps

Washer RO Unit

Holding Tanks

Holding Tank

What do they Service?

Myths, Do’s and Don'ts?

- **Myth :** RO units are just fancy filters.
  Truth: RO units will <u>always</u> have to lose water. Efficiency is optimised by minimising water loss without fouling the RO membrane.
- **Myth** : All RO installations are the same
  Truth : Membranes vary (Thin Film Composite vs Cellulose Acetate). TFC is more flexible but cannot handle chlorine.
  Pretreatment options are important.
- **Do** measure recovery rate (cycles of concentration) and differential pressure – SIMPLE !
- **Do** (try to) measure normalised permeate flow – COMPLICATED !
- **Don’t** use larger micron prefilters if they are plugging too quickly. This is probably a microbial problem.
- **Don’t** use RO on its own. It will <u>always</u> need pre-treatment. Use Ion Exchange when hardness is greater than 100mg/L (not an issue in Victoria)
  Use can even consider chemical scale inhibitor treatment with very challenging water
- Do sample correctly (see AS2031)

Water and Savings

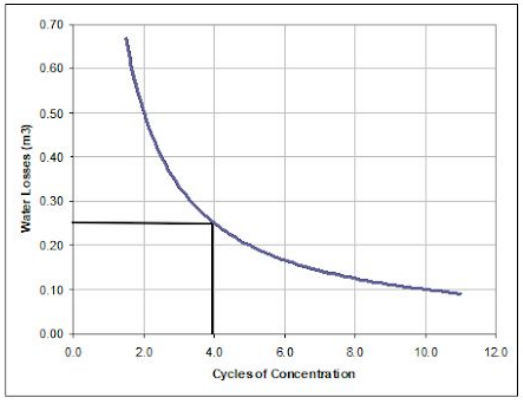
Calculations

$$\text{Cycles (n)} = \frac{\text{Concentrate Conductivity}}{\text{Supply Conductivity}}$$

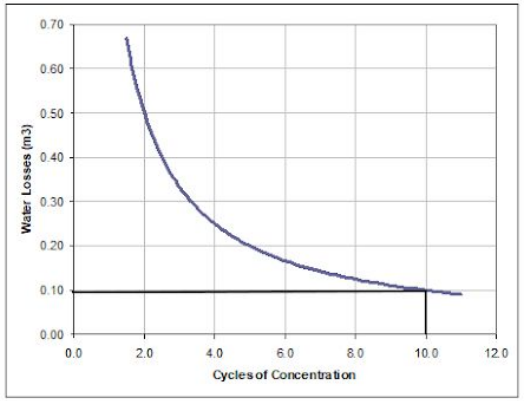
Feed conductivity = 100 uS/cm
Concentrate Conductivity = 400 uS/cm
Cycles of concentration = 400/100 = 4

Cycles of less than 3 are common in RO water systems !

Assume 4 Cycles Currently: (250litres)



Assume 10 Cycles possible: (100litres)



Saving: 150litres for 1m^3 of makeup

Water and Savings

$$\text{Percent Rejection} = \frac{\text{Feed Conductivity} - \text{Permeate Conductivity}}{\text{Feed Conductivity}}$$

Feed conductivity = 100 uS/cm
Permeate Conductivity = 3
Percent rejection = 97/100 = 97%

But this is too good !

In Melbourne it is normally Silicates which govern percent rejection (for AS4187):

Parameter	Units	Typical supply Concentration	AS4187 Spec	Percent Rejection
Conductivity	uS/cm	100	30	70%
Total Hardness	mg/L	20	10	50%
Chloride	mg/L	30	10	67%
Sillicate	mg/L	5	1	80%

Water and Savings

Normalised permeate flow calculation is a bit complicated!

(but it is the most sensitive in telling you membrane is failing)

TCF = exp { K * [1/(273 °K + t) - 1/(273 °K + 25 °K)] }

Where t is degrees Celsius, and K = 2700 °K for composite membrane.

Where

C_p = Permeate concentration, ppm

C_{fb} = Feed-Brine concentration, ppm, which equals the feed concentration, in ppm, multiplied by the log mean average of the recovery, (equation 4)

= $C_f * CF_{lm}$

Equation 1 gives the

$Q_N = Q_t \times (NDP_r/NDP_t) \times$ (6)

Equation 2 gives the formula for Net Driving P

such as psi, kPa, bar.

$NDP = P_f - ½ * \grave{a}P_{fb} - P_{osm}$ - (2)

Where:

P_f = Feed Pressure

$\grave{a}P_{fb}$ = Pressure drop between th

P_{osm} = Osmotic pressure

P_p = Permeate pressure

ssure is further expanded i

$P_{osm} = CF_{lm} * C_f * 11/1000 * K_{p\text{-cond}}$

Where:

CF_{lm} = Log mean concentration factor.

C_f = Feed conductivity (≠S-cm)

$K_{p\text{-cond}}$ = conversion factor, conductivity to press

is a function of the TDS of the sam

The log mean concentration factor ca

Equation 4.

$CF_{lm} = \ln [1/(1-R)] / R$

Where R is recovery, expresse

$R = Q_p/Q_f$, Permeate Flow divided b

Finally, the Temperature Correction Factor is given

Normalized Salt Passage

The salt passage of a system can be normali by the following equation:

$\%SP_n = (EPF_a/EPF_n) * (STCF_n/STC$ (3)

(7)

Where:

$\%SP_n$ = Percent Salt Passage normalized to standard conditions

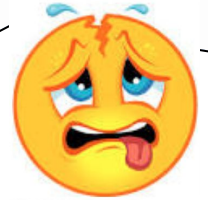
$\%SP_a$ = Percent Salt Passage at actual conditions

EPF_n = Element Permeate Flow rate at standard conditions

EPF_a = Element Permeate Flow rate at actual conditions

$STCF_n$ = Salt Transport Temperature Correction Factor at standard conditions

$STCF_a$ = Salt Transport Temperature Correction Factor at actual conditions



Performance - Sampling

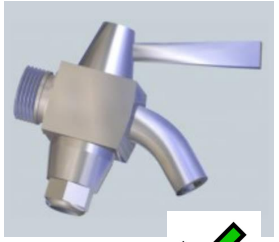
- Water sampling has been desirable since 2014 – Introduction of Table 7.2
- Sampling should be Monthly
- Sampling as per AS2031:2012 or as per manufacturers recommendations (if exceeds AS)
- We recommend following Table 1, row (a).

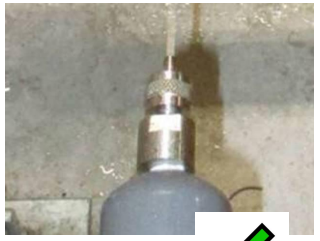
Table 1 — Sampling at a tap for different purposes

Purpose (see above)	Water type	Remove attached devices and inserts	Disinfect	Flush
a)	In the distribution main	Yes	Yes	Yes
b)	As it is delivered to the tap	Yes	Yes	No [a] (minimal)
c)	As it is consumed	No	No	No

[a] Flush briefly only to overcome influence of disinfection of the tap.

- Disinfection by alcohol or flame (preferred) – from an aseptic sampling point





Performance – Real Data (A)

CURRENT SPEC:	Chloride 10.0	Conductivity @ 25°C 30.0	Endotoxin <0.25	Total Viable Count <100	Metals <0.2	pH 5.5 to 8.0	Phosphate <0.2	Silicate <1	Total Hardness <10
POOR RO EXAMPLE									
2017									
<13/06/2017	2.1	14.0	High	22,000	0.0	6.7	0.1	0.1	1
2018									
Qtr2	1.5	14.0	High	440	0.0	7.0	0.0	0.1	1
Qtr3	2.9	20.0	High	25,000	0.0	7.0	0.1	0.1	10
Qtr4	4.0	24.0	High	25,000	0.0	7.0	0.0	0.1	3
2019									
Qtr1	1.6	13.0	High	9,500	0.0	7.4	0.0	0.1	2
Qtr2	86.0	428.0	High	6,600	0.0	6.8	0.0	2.4	120
Qtr3	1.7	10.4	High	5,600	0.0	6.7	0.0	0.1	0
GOOD RO EXAMPLE									
2017									
Qtr2	1.0	3.9	None	1	0.0	7.0	0.0	0.1	0
Qtr3	1.0	3.1	None	3	0.0	6.7	0.0	0.5	0
Qtr4	1.0	3.9	None	1	0.0	6.9	0.0	0.1	0
2018									
Qtr1	1.0	3.9	None	1	0.0	7.0	0.0	0.1	0
Qtr2	1.0	3.5	None	1	0.0	7.0	0.0	0.1	0
Qtr3	1.0	4.5	None	1	0.0	7.0	0.0	0.1	1
Qtr4	1.0	8.0	None	1	0.0	6.7	0.0	0.1	1
2019									
Qtr1	1.0	5.7	None	1	0.0	6.9	0.0	0.1	0
Qtr2	1.0	3.4	None	1	0.0	6.9	0.0	0.1	0
Qtr3	1.0	3.3	None	1	0.0	6.4	0.0	0.1	0
MODERATE RO EXAMPLE									
2019									
Qtr3	1.0	4.8	None	150	0.0	6.2	0.0	0.2	0

Performance – Real Data (B)

Observations

- **Sample points are typically poor**
- **Routine (none AS4187) performance analysis is uncommon**
  - (Water rejections as high as 90% have been recorded when data is captured).
- **AS4187 Analysis:**
  - Mineral removal efficiency is typically “too good”
  - None compliance is typically microbial (not mineral)
  - Once a system is infected it is very challenging to disinfect effectively

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THE END

Thank you for Listening!
Any Questions ?