
ACIPC 2024
Navigating the Impacts of
Water Quality on CSSD Operations

Declaration of Interest

- **Nil**

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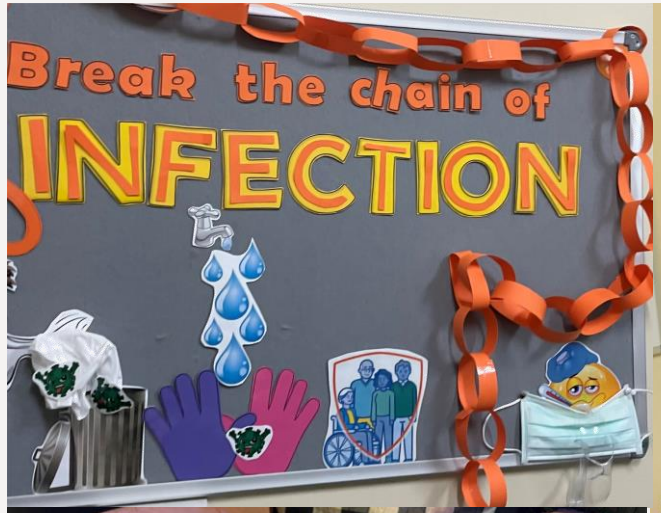
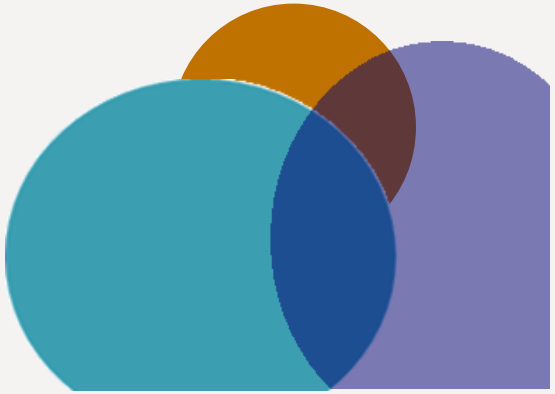
Once upon a time...





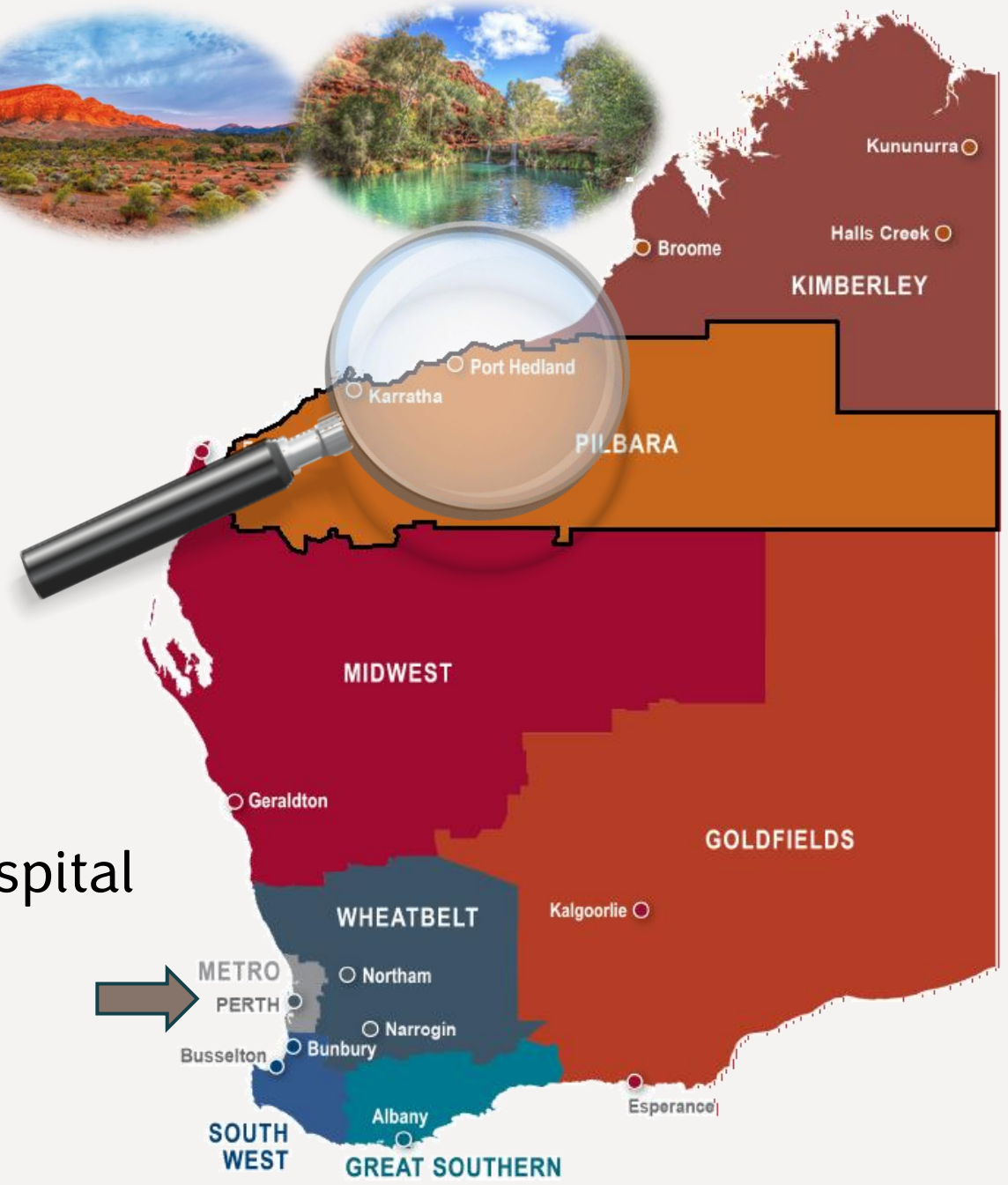
In a land far away

Pilbara Region

- 507, 896 km²
- 62,062 people
- 1,600 km from Perth

Hospitals

- Hedland Health Campus
- Karratha Health Campus
- Roebourne Hospital
- Newman, Tom Price & Paraburdoo Hospital
- Onslow Hospital
- Marble Bar & Nullagine Health Clinics



An evil water problem was brewing

Final Rinse – Washer Disinfector – Reverse Osmosis		
TVC	≤100 CFU / 100mL	2900
Endotoxin	≤0.25 EU/mL	<0.25
pH	5.5 – 8.0	7.0
Conductivity	≤30 uS/cm	15
Total Hardness	≤10 mg CaCO3/L	1.2
Chloride	≤10 mg/L	<1
Iron	≤0.2 mg/L	<0.010
Phosphates	≤0.2 mg/L	0.048
Silicates	≤1.0 mg/L	0.15


ISO

International Standard

ISO 15883-1

Washer-disinfectors —

Part 1:
General requirements, terms and definitions and tests

Laveurs désinfecteurs —
Partie 1: Exigences générales, termes et définitions et essais

Second edition
2024-10

TECHNICAL SPECIFICATION

ISO/TS 5111

First edition
2022-12

Guidance on quality of water for sterilizers, sterilization and washer-disinfectors for health care products

Recommandations relatives à la qualité de l'eau destinée aux stérilisateurs, à la stérilisation et aux laveurs désinfecteurs de produits de santé

ISO

Reference number
ISO/TS 5111:2022(E)

© ISO 2022

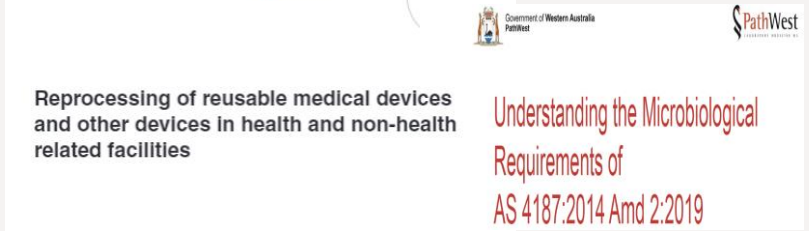

Health Technical Memorandum 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care

Part A: Management and provision


AS 5369:2023

Australian STANDARD

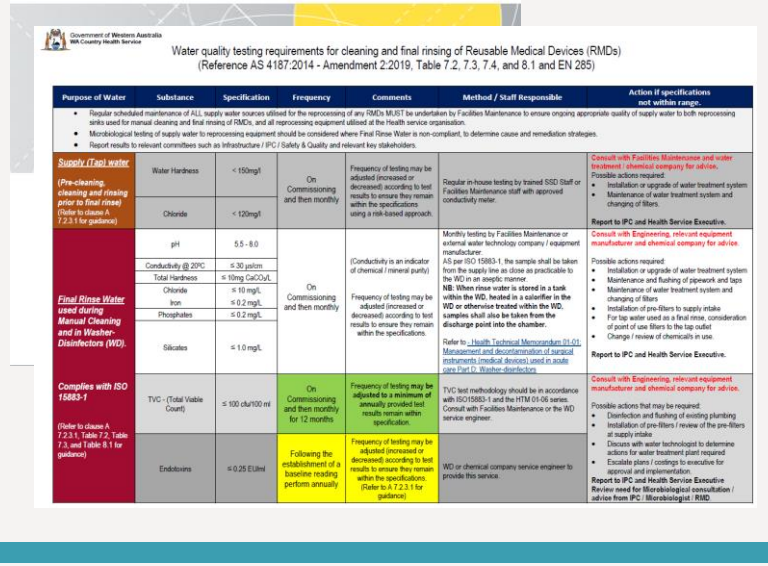
STANDARDS AUSTRALIA


Government of Western Australia PathWest

PathWest

Reprocessing of reusable medical devices and other devices in health and non-health related facilities

Understanding the Microbiological Requirements of AS 4187:2014 Amd 2:2019


Government of Western Australia WA Country Health Service

Water quality testing requirements for cleaning and final rinsing of Reusable Medical Devices (RMDs)
(Reference AS 4187:2014 - Amendment 2:2019, Table 7.2, 7.3, 7.4, and 8.1 and EN 285)

Purpose of Water	Substance	Specification	Frequency	Comments	Method / Staff Responsible	Action if specifications not within range.
• Regular scheduled maintenance of ALL supply water sources utilised for the reprocessing of any RMDs MUST be undertaken by Facilities Maintenance to ensure ongoing appropriate quality of supply water to both reprocessing sinks used for manual cleaning and final rinsing of RMDs, and all reprocessing equipment utilised at the Health service organisation. • Microbiological testing of supply water to reprocessing equipment should be considered where Final Rinse Water is non-compliant, to determine cause and remediation strategies. • Report results to relevant committees such as Infrastructure / IPC / Safety & Quality and relevant key stakeholders.						
Supply (Tap) water (Pre-cleaning, cleaning and rinsing prior to final rinse) (Refer to clause A 7.2.3.1 for guidance)	Water Hardness	< 150mg/l	On Commissioning and then monthly	Frequency of testing may be adjusted (increased or decreased) according to test results to ensure they remain within the specifications using a risk-based approach.	Regular in-house testing by trained SSD Staff or Facilities Maintenance staff with approved conductivity meter.	Consult with Facilities Maintenance and water treatment / chemical company for advice. Possible actions required: • Installation or upgrade of water treatment system • Maintenance of water treatment system and changing of filters. Report to IPC and Health Service Executive.
	Chloride	< 120mg/l				
Final Rinse Water used during Manual Cleaning and in Washer-Disinfectors (WD).	pH	5.5 - 8.0	On Commissioning and then monthly	(Conductivity is an indicator of chemical / mineral purity) Frequency of testing may be adjusted (increased or decreased) according to test results to ensure they remain within the specifications.	Monthly testing by Facilities Maintenance or external water technology company / equipment manufacturer. AS per ISO 15883-1, the sample shall be taken from the supply line as close as practicable to the WD in an aseptic manner. **NB: When rinse water is stored in a tank within the WD, heated in a calorifier in the WD or otherwise treated within the WD, samples shall also be taken from the discharge point into the chamber.** Refer to – Health Technical Memorandum 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care Part D: Washer-disinfectors	Consult with Engineering, relevant equipment manufacturer and chemical company for advice. Possible actions required: • Installation or upgrade of water treatment system • Maintenance and flushing of pipework and taps • Maintenance of water treatment system and changing of filters • Installation of pre-filters to supply intake • For tap water used as a final rinse, consideration of point of use filters to the tap outlet • Change / review of chemicals in use. Report to IPC and Health Service Executive.
	Conductivity @ 20°C	≤ 30 µs/cm				
	Total Hardness	≤ 10mg CaCO3/L				
	Chloride	≤ 10 mg/L				
	Iron	≤ 0.2 mg/L				
	Phosphates	≤ 0.2 mg/L				
	Silicates	≤ 1.0 mg/L				
Complies with ISO 15883-1 (Refer to clause A 7.2.3.1, Table 7.2, Table 7.3, and Table 8.1 for guidance)	TVC - (Total Viable Count)	≤ 100 cfu/100 ml	On Commissioning and then monthly for 12 months	Frequency of testing may be adjusted to a minimum of annually provided test results remain within specification.	TVC test methodology should be in accordance with ISO15883-1 and the HTM 01-06 series. Consult with Facilities Maintenance or the WD service engineer.	Consult with Engineering, relevant equipment manufacturer and chemical company for advice. Possible actions that may be required: • Disinfection and flushing of existing plumbing • Installation of pre-filters / review of the pre-filters at supply intake • Discuss with water technologist to determine actions for water treatment plant required • Escalate plans / costings to executive for approval and implementation. Report to IPC and Health Service Executive Review need for Microbiological consultation / advice from IPC / Microbiologist / RMD.
	Endotoxins	≤ 0.25 EU/ml	Following the establishment of a baseline reading perform annually	Frequency of testing may be adjusted (increased or decreased) according to test results to ensure they remain within the specifications. (Refer to A 7.2.3.1 for guidance)	WD or chemical company service engineer to provide this service.	

Challenges, Learnings & Impacts

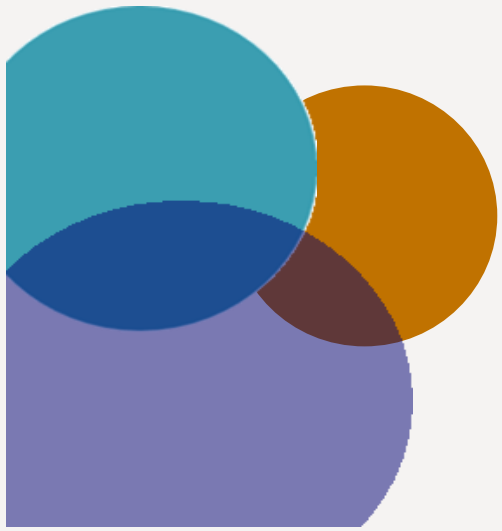
1. Interpreting and understanding the requirements

or was it?

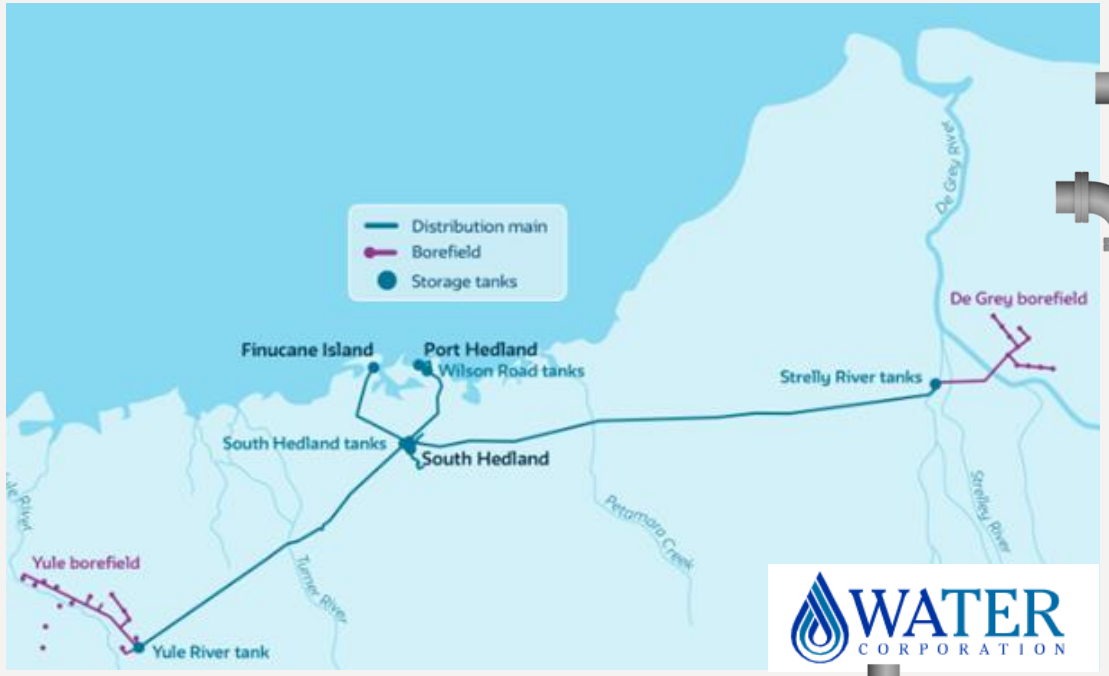
Final Rinse – Washer Disinfector – Reverse Osmosis			
Analyte	Specification		
TVC	≤100 CFU / 100mL	2900	19
Endotoxin	≤0.25 EU/mL	<0.25	0.17

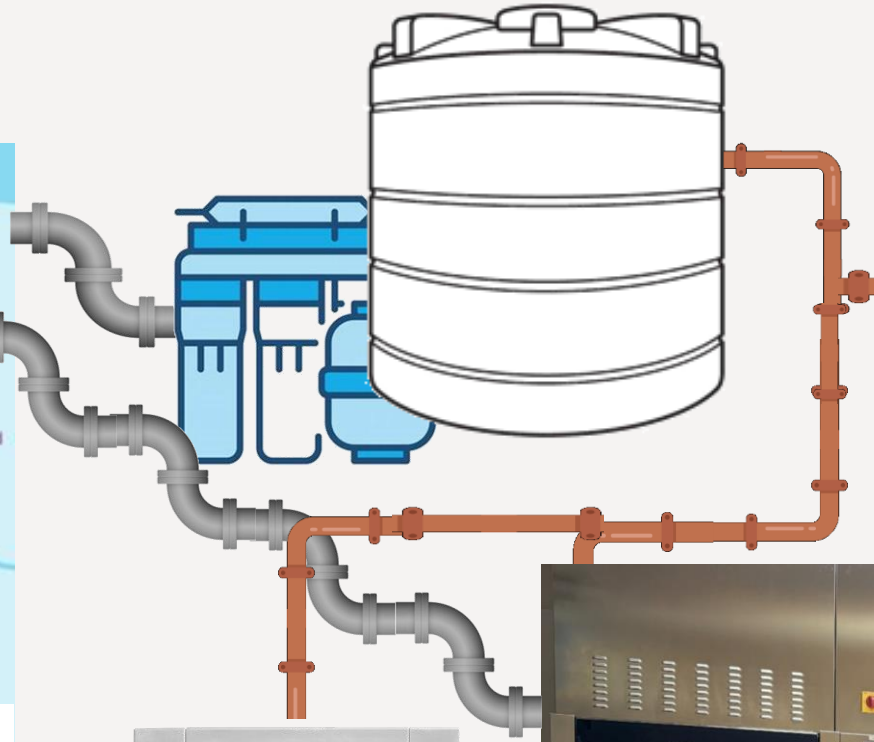
Analytical Results

Analyte
Chloride
Electrical Conductivity (EC)
Calcium - Dissolved
Magnesium - Dissolved
Hardness
Iron (Fe)
Phosphate as P
* Reactive Silica
pH
Total Aerobic Microbial Count
* Endotoxin Determination



Reconnaissance Mission





Challenges, Learnings & Impacts

1. **Interpreting and understanding the requirements**
2. Infrastructure
3. Resource & capability constraints

Reconnaissance Mission

Washer Disinfector – Table 7.2		
Potable Water Cleaning	Hardness Chloride	• Efficacy of process – higher concentrations of detergent potentially required • Damage or deterioration of the equipment
Reverse Osmosis Water Final Rinse	pH Conductivity Total Hardness Chloride Iron Phosphates Silicates	• Spotting, staining and/or corrosion of medical devices and equipment. • Scale build-up.
	TVC Endotoxins	• Contaminate instruments • Biofilm build up

Report Date:	13/03/2023
Page 1 of 3	>4 weeks from received date

COPY TO:

ORIGINAL TO:

Received From:	
Received Date:	09/02/2023

Location of Test: (except where noted)

Analytical Results

Desc. 1: ^ CSSD - RO Is this final finse of Washer Disinfector? Can we include a reference for the specific piece of equipment.

Desc. 2: ^ Date Collected: 08/02/2023

Agreement is conductivity at 20 degrees. What is the significance of temperature variation for this test.

Sample Number: 457671049
Condition Rec'd: NORMAL
Temp Rec'd (°C): 1.6
Date Started: 9/02/2023

Results apply only to the sample as received

Analyte	Result	Units	Method Reference	Result Date	Loc.
Chloride	<1	mg/L	INORG-081	17/02/2023	MPL
Electrical Conductivity (EC)	3.2	µS/ cm	INORG-002	17/02/2023	MPL
Calcium - Dissolved	<0.050	mg/L	METALS-020	17/02/2023	MPL
Magnesium - Dissolved	<0.050	mg/L	METALS-020	17/02/2023	MPL
Hardness	<1.0	mgCaCO3/L	METALS-020	17/02/2023	MPL
Iron (Fe)	0.011	mg/L	Metals-022	17/02/2023	MPL
Phosphate as P	<0.0050	mg/L	INORG -060	17/02/2023	MPL
Reactive Silica	<0.10	mg/L	INORG-120	17/02/2023	MPL
pH	6.4	pH Units	INORG-001	17/02/2023	MPL
Total Aerobic Microbial Count	27	CFU/100mL	M49.3	14/02/2023	
Endotoxin Determination	<0.05	EU/mL	M60.2	14/02/2023	MEL

Calcium & magnesium is not on agreement. Is this part of establishing hardness?

* here for March report, but not Feb

* here for March report, but not Feb

Can we get normal reference ranges included on the report?

Challenges, Learnings & Impacts

1. Interpreting and understanding the requirements
2. Infrastructure
3. Resource & capability constraints
4. Standardised collection and reporting processes

The plot thickens

Analytical Results

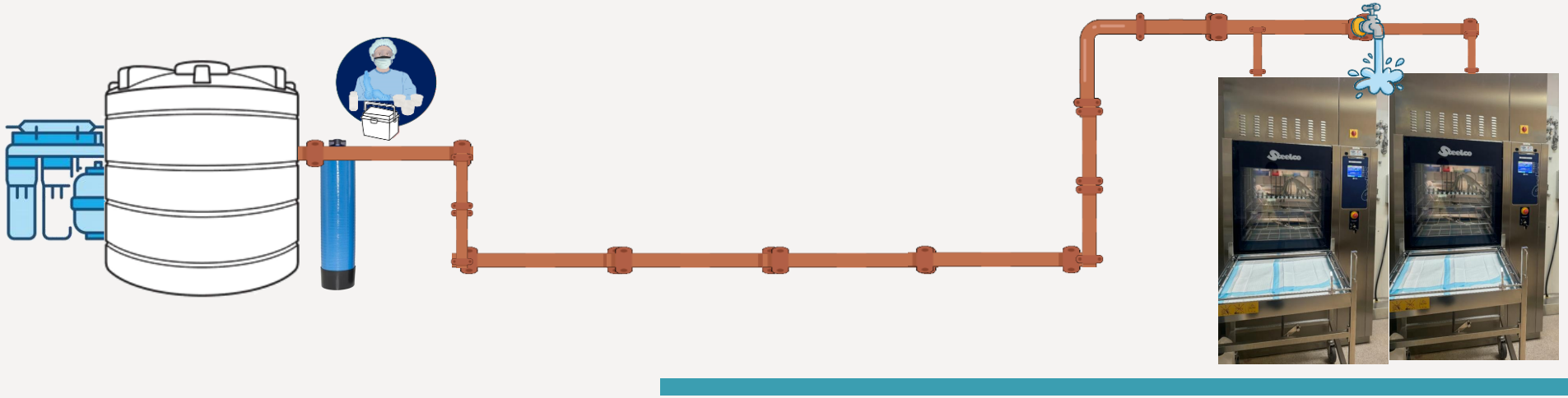
Analyte
Chloride
Electrical Conductivity (EC)
Calcium - Dissolved
Magnesium - Dissolved
Hardness
Iron (Fe)
Phosphate as P
* Reactive Silica
pH
Total Aerobic Microbial Count
* Endotoxin Determination

Final Rinse – Washer Disinfector – Reverse Osmosis				
Analyte	Spec			
TVC	≤100 CFU / 100mL	2900	19	2900
Endotoxin	≤0.25 EU/mL	<0.25	0.17	<0.25
pH	5.5 - 8.0			9.1
Conductivity	≤30 uS/cm			66
Phosphates	≤0.20 EU/mL			2.6
Silicates	≤1.0 EU/mL			4.8

Supply		
Water Hardness	<150 mg/L	range 200 – 240
Chloride	<120 mg/L	range 120 - 200

Investigation

Final Rinse – Washer Disinfector – Reverse Osmosis											
TVC	≤100 CFU / 100mL	2900	19	2900	1 1	690 140	39 8	1500 600	3	930	950
Endotoxin	≤0.25 EU/mL	<0.25	0.17	<0.25	0.07 <0.05	0.1 0.25	<0.05 <0.05	0.164 0.206	0.08	0.129	0.089
pH	5.5 - 8.0			9.1	10.3	6.7					
Conductivity	≤30 uS/cm			66	160	9.5					
Phosphates	≤0.20 EU/mL			2.6	7.5	0.007 4					
Silicates	≤1.0 EU/mL			4.8	14	<0.10					



Challenges, Learnings & Impacts

1. Interpreting and understanding the requirements
2. Infrastructure
3. Resource & capability constraints
4. Investigation complexities
5. Budget & Financial Constraints

Crisis

Analytical Results

Analyte
Chloride
Electrical Conductivity (EC)
Calcium - Dissolved
Magnesium - Dissolved
Hardness
Iron (Fe)
Phosphate as P
* Reactive Silica
pH
Total Aerobic Microbial Count
* Endotoxin Determination

Final Rinse – Washer Disinfector – Reverse Osmosis					
Analyte	Spec	Tap	Tap	Chamber	Tap
TVC	≤100 CFU / 100mL	930	950	110	360
Endotoxin	≤0.25 EU/mL	0.129	0.089	15.9	2.82
pH	5.5 - 8.0			6.9	6.7
Conductivity	≤30 uS/cm			12	13
Phosphates	≤0.20 EU/mL			<0.0075	<0.0050
Silicates	≤1.0 EU/mL			0.39	0.36

Endotoxin

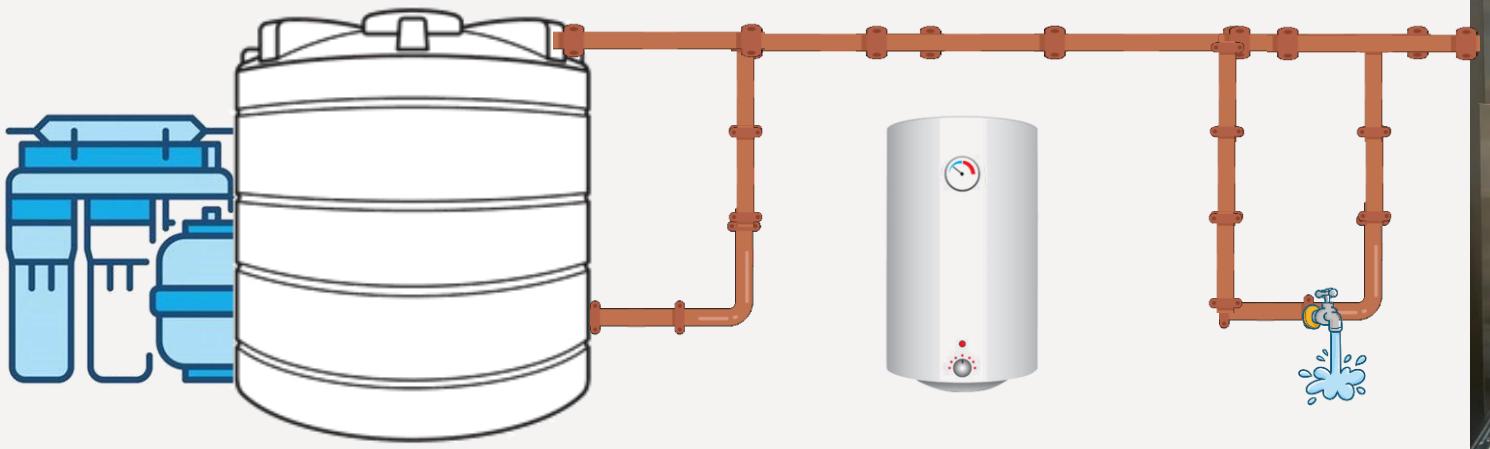
Thermostabile compound capable of withstanding disinfection and sterilisation processes
In humans can cause fever like reaction and other severe adverse events

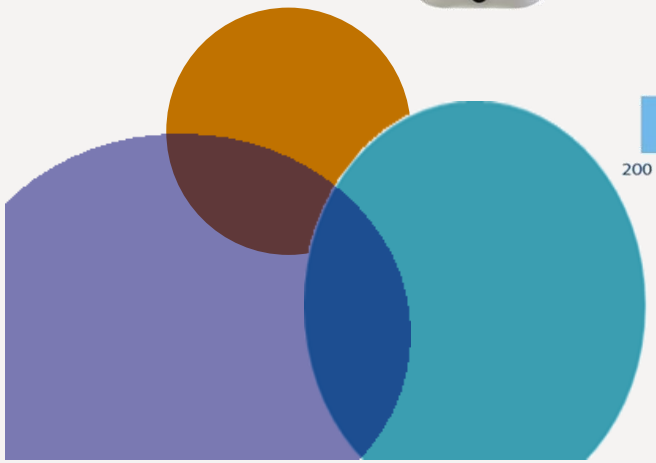
Supply		
Water Hardness	<150 mg/L	range 200 – 240
Chloride	<120 mg/L	range 120 - 200

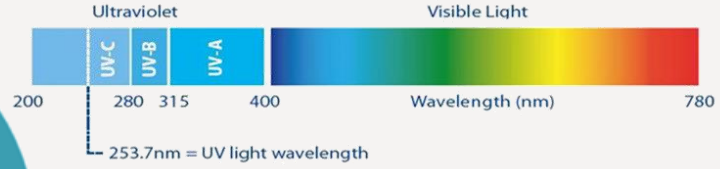
Challenges, Learnings & Impacts

1. Interpreting and understanding the requirements
2. Standardised collection and reporting processes
3. Infrastructure
4. Resource & capability constraints
5. Investigation complexities
6. Quantifying risk and comprehending implications

The hero – a whole system approach







Challenges, Learnings & Impacts

1. Interpreting and understanding the requirements
2. Standardised collection and reporting processes
3. Infrastructure
4. Resource & capability constraints
5. Investigation complexities
6. Quantifying risk and comprehending implications
7. Tyranny of distance

Happily ever after

Final Rinse – Washer Disinfector – Reverse Osmosis				
Analyte	Spec			
TVC	≤100 CFU / 100mL	38	10	45
Endotoxin	≤0.25 EU/mL	0.0050	0.050	0.06
pH	5.5 - 8.0	6.6	6.6	6.5
Conductivity	≤30 uS/cm	5.7	6.8	6.5
Phosphates	≤0.20 EU/mL	<0.0050	<0.0050	0.013
Silicates	≤1.0 EU/mL	0.12	0.37	0.11

Challenges, Learnings & Impacts

1. Interpreting and understanding the requirements
2. Standardisation of collection and reporting processes
3. Infrastructure
4. Resource & capability constraints
5. Investigation complexities
6. Quantifying risk and comprehending implications
7. Tyranny of distance
8. Review systems for improvements / optimisation proactively