# DISINFECTION, STERILISATION AND INACTIVATION

## Not knowing the difference could cost you a life

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Maintaining the microbial health of water is paramount for the fit for purpose supply of all sorts of products and services including cooling tower management, sterile products and safe work environments. Disinfection, sterilisation and inactivation are all important components in your microbial risk management toolbox. But do you know the difference, and which is the right approach for your situation? Not picking the right risk controls or knowing how to apply them – could cost you a life.

Our White Paper explains the differences, and provides solutions to help you improve your microbial sanitation and hygiene risk management.

# Introduction

Many legal and formal requirements place strict conditions on fitness for purpose. These conditions include product quality, maintaining safe environments at work, provision of services, facility management or patient safety. Maintaining the microbial health of products and services is an important component of fitness for purpose. Designing for and maintaining microbial health, applies to many areas such as cooling tower management, sterile supply management and other products and services critical for the care of patients.

Here we take a look at some of the issues we have observed in managing microbial system health risks. If you are a manager of any of these products and services, here's what you need to know to meet microbial system health obligations.



## Fit for purpose – ignorance is not a defence

There are many cases where environments, processes, services, and products haven't been fit for purpose. Exposure to unfit products and services has significant impacts including acute and chronic illness and, in some cases, death. The advent of molecular typing and other forensic tracing and tracking techniques means it's now becoming easier to establish cause and effect. There is nowhere to hide from shoddy practices. Ignorance is generally not a defence.

Disinfection, sterilisation, and inactivation are all methods for preventing, reducing and/or removing microbes. These methods can be used in isolation or together, depending on the outcome required.

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Do you know the difference between these processes, what to use and when? If not, you could be putting your staff, your patients, your contractors, your visitors, your organisation, and yourself, at risk. Disease and liability risk end points could be in your sights!

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## Why microbes are a problem

Microbes are great at colonising all sorts of environments. It can be from thermal vents at temperatures of over 100°C, to environments as low as 0°C and everything in between. Every microbe is a pathogen (disease-causing organism) or a degrader, waiting for a niche (see Table 1).

Depending on your objectives, microbes can either be spoilage organisms or pathogens. So, to be confident that you are maintaining a microbially safe environment, you need to understand:

- Where they are
- What they can do
- The conditions that can increase the likelihood of their presence
- What you need to monitor.

> It's better to avoid an event, than reacting after the fact – prevention is better than cure.

You may be aware of the usual microbial suspects as seen in Table 1. However, more pathogens, microbial toxins and products, and spoilers are coming at us. Some of these are *Burkholderia pseudomallei*, antibiotic resistance genes, endotoxins, cyanobacterial toxins, Mycobacteria and Pseudomonads.

So, your best line of defence is understanding and mitigating your microbial risk. It's better to avoid an event, than reacting after the fact – prevention is better than cure.

**TABLE 1. EXAMPLES OF PATHOGENS IN DIFFERENT SECTORS.**

| Organism | Type | Sector | Outcome | Exposure Group |
|---|---|---|---|---|
| *Listeria monocytogenes* | Bacterium | Food production e.g. dairy products and soft cheeses in particular | Causative agent of listeriosis, a fatal opportunistic foodborne infection | Predominantly a problem for pregnant women, newborns, the elderly, debilitated patients, immunocompromised patients.[1] |
| *Legionella* spp (particularly pathogenic strains such as L. *pneumophila*) | Bacterium | Any industry which has plumbing systems and cooling towers such as hospitals, residential buildings, shopping centres and hotels. | Causative agent of Legionellosis or Legionnaires Disease. Symptoms range from mild respiratory tract illness to fatal pneumonia. | Predominantly immunocompromised individuals but can also affect healthy individuals.[2] |
| *Naegleria fowleri* | Protozoan | Utility, recreation and plumbing sectors. Mainly a risk in aqueous environments with temperatures routinely above 25°C and free chlorine residuals below 0.5 mg/L. | Causes primary amoebic meningoencephalitis, which is nearly always fatal. | Bathers, recreators, showerers, anyone exposed to an inhalation exposure pathway (exposure is via the nasal cavities and into the brain).[3] |

1 Vázquez-Boland JA, Kuhn M, Berche P, Chakraborty T, Domínguez-Bernal G, Goebel W, González-Zorn B, Wehland J, Kreft J. Listeria pathogenesis and molecular virulence determinants. Clin Microbiol Rev. 2001 Jul;14(3):584-640. doi: 10.1128/CMR.14.3.584-640.2001. PMID: 11432815; PMCID: PMC88991.

2 Wei SH, Chou P, Tseng LR, Lin HC, Wang JH, Sheu JN, Liu MT, Liu FC, Wu HH, Lin MC, Ko CF, Lin HY, Kao PH, Hwang KP, Hsu YL, Kuo TL, Chiang CS. Nosocomial neonatal legionellosis associated with water in infant formula, Taiwan. Emerg Infect Dis. 2014 Nov;20(11):1921-4. doi: 10.3201/eid2011.140542. PMID: 25340315; PMCID: PMC4214307.

3 Ryu, H, Brown, A, Biyela, P, Alum, A, Rittmann, B, and Abbaszadegan, M (2010). Identification of Amoebic Activity and Naegleria fowleriin Arizona Drinking Water Systems. Poster Q-1449. https://wet.asu.edu/wp-content/uploads/2015/06/Q-1449-Identification-of-Amoebic-Activity-and-Naegleria-fowleri-in-Arizona-Drinking-Water-Systems.pdf

## How microbes create hygiene and sanitation risks

Microbes can be planktonic (free-living in fluids) or bound to surfaces in biofilms. Therefore, the type and method of sanitisation you employ, and its efficacy, will depend on the living state of the microbe. Biofilms can shield microbes from chlorine disinfection and particles can reduce the efficiency of sanitising agents. As an example, Ryu et al (2010) found the following factors in *Naegleria fowleri* colonisation of drinking water systems:

- Lack of chlorine
- Higher heterotrophic plate counts
- Stagnation, and
- Lack of flushing

Furthermore, once systems have become seeded with a type of microorganism, it is often difficult to eradicate. At that point, you are at a much higher state of risk of not meeting your objectives of microbial system health. Proactive risk management – rather than risk reaction – is the key.

> There are four essential steps to optimising effective sanitisation that discourages microbial growth: planning, procurement, commissioning and operation.

Sites for microbial attachment and the formation of biofilm communities occur due to chemical changes in the water. These are often created by substandard materials or the degradation of pipework from corrosion or pitting. Asset condition and configuration can affect the effectiveness of sanitising agents and methods. There are four essential steps to optimising effective sanitisation that discourages microbial growth. They are planning, procurement, commissioning, and system operation.

Microbiology is a specialised field. Always seek and follow advice from qualified and experienced professionals.

## Why you need to know your sanitisation terms

There are many sanitisation methods to use, such as disinfection, sterilisation, or inactivation. Each has its own outcomes. The following table (Table 2) sets out each of these terms and describes some of the use contexts for each one.

## TABLE 2. SANITISATION TERMS, METHODS AND OUTCOMES.

| Term | Description | Example | Use | Comments |
|---|---|---|---|---|
| Disinfection | Disinfection is a process of complete elimination of vegetative forms of microorganisms except spore forms, where low levels of viable microorganisms can be present. | • Chemicals such as chlorine, peracetic acid, hydrogen peroxide, ozone etc.<br>• Hot water between 80 and 90°C | • Endoscopy<br>• CSSD<br>• Renal dialysis<br>• Cooling tower<br>• General hospital use | • Effectiveness of a given chemical disinfectant depends on the concentration of disinfectant, contact time, water temperature, turbidity, particulate concentration, the target microorganisms as well as the residual concentration maintained to validate the process.<br>• With thermolabile equipment such as endoscopes, water at > 50°C cannot be used.<br>• If using the A0 principle, a theoretical concept that uses temperature and time at which this temperature is held for inactivation of microorganisms, and A0 value of 3,000 may be required to achieve complete destruction of difficult microorganisms in planktonic state and in biofilm community.<br>If using hot water at < 80°C, a contact time > 500 minutes may be required to achieve effective disinfection.[4]<br>• Depending on the normal operational water temperature, more frequent application may be required for biofilm control. |
| Sterilisation | Sterilisation is a process of complete elimination or destruction of all forms of microbial life (i.e., both vegetative and spore forms) hence viable microorganisms are no longer present. | Steam sterilisation/ autoclaving at > 100°C | CSSD | • With thermolabile equipment such as endoscopes, steam sterilisation cannot be used.<br>• The use of liquid chemical sterilant in endoscope reprocessing is not a sterilisation process due to two key points:<br>1. the requirement for the final rinsing with water. This water itself is not sterile.<br>2. where the reprocessed devices cannot be adequately contained/ wrapped to maintain sterility. |
| Inactivation | Inactivation is a process of eliminating microbial replication without necessarily destroying the entire surface structure of the microorganism.<br>As this is not necessarily a destruction process, viable microorganisms can be present and/or in some cases, DNA can be repaired, enabling the microorganism to become viable again. | Ultraviolet Irradiation | • Endoscopy<br>• CSSD<br>• Renal dialysis<br>• Cooling tower<br>• General hospital use | • Only the planktonic microorganisms can be inactivated but not the surface bound microorganisms.<br>• The effectiveness of UV depends on the turbidity, particulate concentration, contact time, colour, organic content, water temperature, and the susceptibility of specific microorganisms (pathogen group (viruses, bacteria, and protozoa), species and strains).<br>• Any microorganisms which escape the inactivation process can continue to replicate and colonise the downstream plant and equipment. |

4 Gabriel, N, Gaibor, T, Sacaluga, LG, de la Cerda Ojeda, F, Molas Coténc, JR, Salgueira Lazo, M. (2019) Thermal disinfection in hemodialysis using the A0 concept as dispenser. nefrologia. 3 9(5):482–488.

## How to manage your risks

The good news is that you can get ahead. What you need is a sound and implemented risk assessment and management plan. As part of this plan, you should have various controls in place to help prevent and/or manage the risks you have identified.[5]

A fundamental component of managing your liability relates to staff and contractors. They must be aware of the risks and their role in risk management. For instance, at the planning stage, engage contractors who understand the importance of system design. The design must meet requirements for microbial system health. Also, operationally, your system needs to be monitored to ensure it has been maintained to adequate standards.

We have seen many design examples of systems with incorrect sanitisation process trains. These are where the architecture of the system was never going to produce a fit for purpose outcome, and where sampling points or ease of sampling, were not even considered.

Ongoing monitoring is also an essential part of the risk management approach. Monitoring is one of your 'detective' controls. The other controls are preventive, reactive, informative, and supportive[5]. You must have an evidence-based monitoring and sampling plan in place. It should include operational, verification, monitoring, validation, re-validation, and investigation types. A sound plan, and analysis of the results, will give you the confidence your sanitisation and other controls are working. Most importantly, you should have a plan in place for how to react to non-conforming results. An example might be to retest, or if the non-conformance is large enough, to shut down a facility until an investigation has been completed, and confidence is restored.

> You must have an evidence-based monitoring and sampling plan in place.

Most standards/guidelines stipulate compliance monitoring via monthly grab samples. This is for at least the first 12 months - the defect liability period. Relying on these monthly grab samples is not appropriate to prove fitness for purpose though. This is because one compliant grab sample does not mean the system will be compliant over its designated life. There are several areas of uncertainty created with this approach:

- Samples generally only represent the planktonic (or floating) state.
- Microbes in the attached or biofilm state are missed.
- Laboratory analyses often rely on growing up the microbes so they can be identified and counted. Culturing misses those microbes that might still be alive (and capable of doing damage), but not capable of growth on a plate or in a nutrient solution.
- Results are historic i.e. they tell you if something has or has not happened but don't help you head off a risk event.

So, with current approaches, you're left with a black hole on timely identification and mitigation of your microbial risks. Various factors play into this risk such as the system design, operating condition, the method of sanitisation and the frequency of sanitisation. Any unidentified microbial activity and colonisation can create a long term risk.



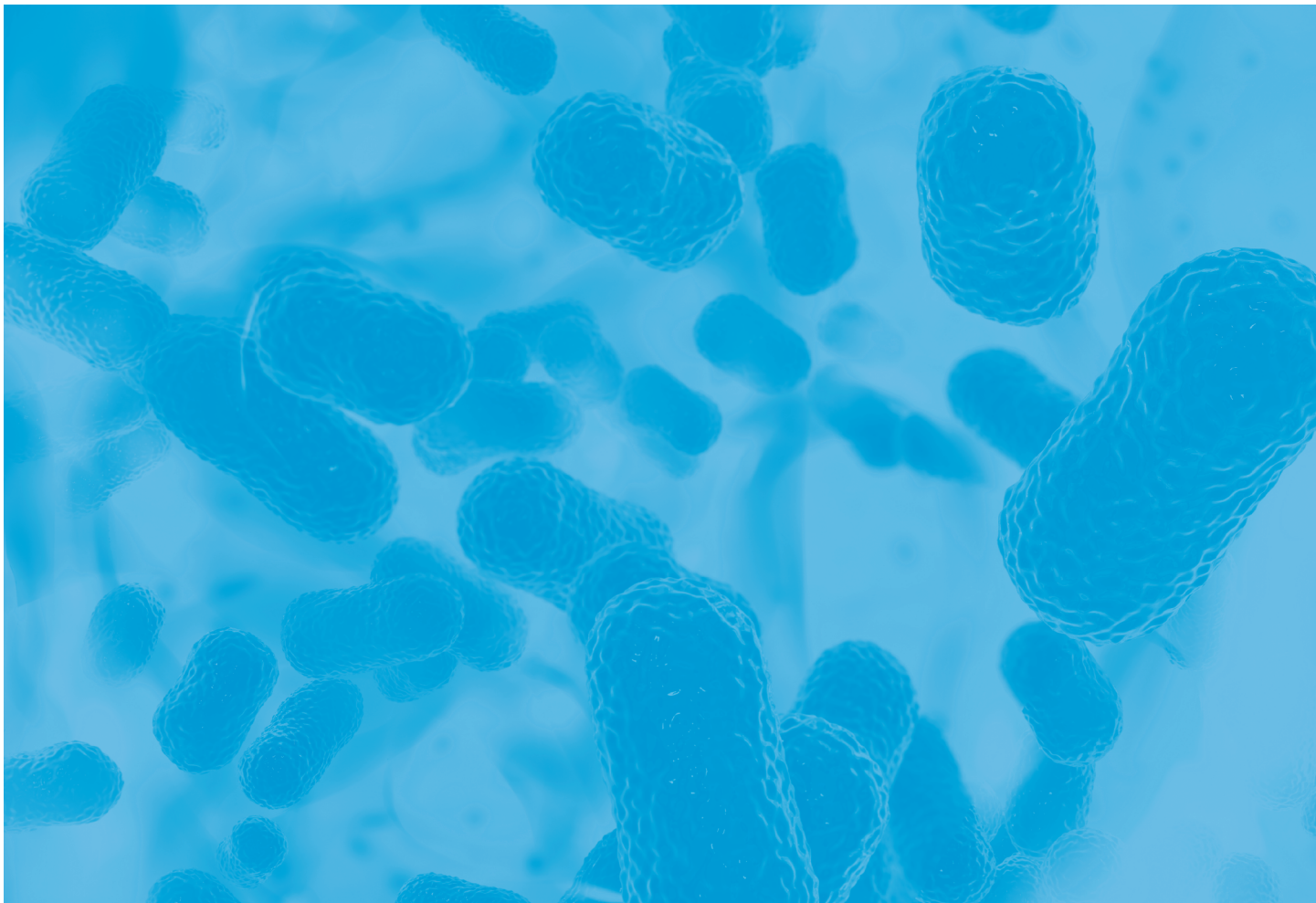
5 Davison, A. (2022) Are you in control? Risk Edge blog. https://www.riskedge.com.au/are-you-in-control/

> Relying on monthly grab samples is not appropriate for proving microbial fitness for purpose.

Monitoring methods and automated knowledge systems have step-changed in recent times. For example, microbial activity and other key system health parameters can now be monitored in near real-time. This gives you a heads up before a situation ever becomes risk critical.

Intelligent aggregate sensors can be used for improved system intelligence. Intelligence such as CT (for disinfection efficacy) or *Legionella* risk potential. This allows you to be proactive in risk management rather than reactive. Reactive management, such as hyper-chlorination, can often be destructive to assets. Asset degradation can lead to the shutdown of departments, operating theatres, and cancellations. Further, chemical use is generally not optimised on microbial system health risk status. This means that more chemical may be used, and more frequently, than needed – impacting your economic objectives.

There are now significant advancements in monitoring and reporting systems. With these advancements, it's possible that your current monitoring and sampling plan could be deficient. Failing to meet compliance and risk objectives could expose you to liability and your customers to illness and death. To avoid exposure, now is a good time to review your microbial system health and risk management measures.



# About the Authors

**Dr Davison (Higher National Diploma, BSc(Hons), MEnvLGovLaw, PhD, GAICD, PMAWA)**

Dr Annette Davison is a sought-after risk and auditing expert, with over 30 year's experience in the water and environment industries. Annette holds a Higher National Diploma and BSc(Hons), both in Applied Biology, a Masters in Environmental and Local Government Law and a PhD in environmental microbiology and biochemistry, as well as being a Graduate of the Australian Institute of Company Directors and Professional Member of the Australian Water Association (AWA).

Annette has served two terms on the board of the AWA, was on the Ozwater 2022 Organising Committee and currently sits on the Strategic Advisory Committee of Water Research Australia. Annette is an expert in the application of the global risk management standard, ISO 31000, to water quality management, having authored and self-published her book on this subject in 2020. Annette is a Water Quality Management System Lead Auditor and an IPART-approved auditor.

Annette has worked with the World Health Organisation including on Legionella risk management, as well as in Water Safety Planning. Annette has won multiple awards for her work including in 2021, Water Professional of the Year, one of the AWA's highest accolades.

**Dr McCaw (BE(Chemical), PhD)**

Dr Surani McCaw is a Chemical Engineer with over 25 years industrial experience, specialising in water treatment in the Healthcare and Pharmaceutical Industries.

Surani holds a Bachelor of Engineering (Chemical) degree and a Doctor of Philosophy degree in water treatment from University of NSW, Kensington, NSW.

Dr McCaw has been involved in the implementation of National Healthcare Standards/Practices for both CSSD and Renal Dialysis since 2008 with the intention of evaluating and implementing risk managed and cost-effective water treatment technologies that are fit for the Australian ecological and demographical environment.

**If you would like a free risk chat or an audit of your facility with Dr Davison or Dr McCaw, contact us on 1800 656 771.**

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