Draft guidelines for validating treatment processes for pathogen reduction

Supporting Class A water recycling schemes in Victoria

Draft for consultation

3 September 2010

Department of Health Victoria

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Foreword

In progress

Acknowledgements

In progress

This document has been developed by the Department of Health with support from Water Futures Pty Ltd and the Smart Water Fund. We acknowledge the significant contribution from national and international peer reviewers.

Glossary of terms and abbreviations

AGWR	*Australian guidelines for water recycling: Managing health and environmental risks (Phase 1)[1]*
AS/NZS	Australian and New Zealand Standard
ASTM	American Society for Testing of Materials International
bacteriophage	Viruses that infect bacterial host cells. They typically consist of a nucleic acid genome surrounded by a protein coat.
biological treatment	Activated sludge, biological nutrient removal (BNR) and biofiltration.
bubble point test	Pressure applied to a fully wetted membrane module, with the pressure gradually increased. The pressure at which water is first evacuated from the pores represents the bubble point of the membrane associated with a particular module[2]
BOD	Biochemical oxygen demand
CEB	Chemically enhanced backwash
cm	Centimetre
challenge test	An empirical study to determine the reduction efficiency, measured as the $\log_{10}$ reduction value (LRV).
CFD	Computational fluid dynamic
CFU	Colony forming unit
chloramination	Use of monochloramine (compound formed by the reaction of hypochlorous acid or the hypochlorite ion depending upon pH, or aqueous chlorine with ammonia) as a means of disinfection.
chlorination	Use of uncombined chlorine as a means of disinfection.
chlorine demand	The difference between the amount of chlorine added to water and the amount of residual chlorine (or monochloramine) remaining after a given contact time. Chlorine demand may change with the disinfectant dose, temperature, time of contact, pH, and the type and amount of naturally occurring substances (such as dissolved or suspended organic matter and inorganic reductants).
chlorine dioxide	A chemical compound with the formula ClO_2. It disinfects by oxidation.
CIP	Clean in place
coagulation	The term coagulation as used in this document includes all of the reactions and mechanisms involved in the chemical destabilisation of particles and in the formation of larger particles through perikinetic flocculation (aggregation of particles in the size range from 0.01 to 1 µm).

composite sample	Formation of a single sample from selective grab samples that then represents water quality over a sequence of time.
CCP	Critical control point: A point, step or procedure at which control can be applied and that is essential for preventing or eliminating a hazard, or reducing it to an acceptable level.[1]
COD	Chemical oxygen demand
Critical limit	A prescribed tolerance that must be met to ensure that a CCP effectively controls a potential health hazard; a criterion that separates acceptability from unacceptability.[1]
CT	Disinfection residual concentration (C, in mg/L), multiplied by contact time (T, in minutes) at the point of residual measurement; a measure of disinfection effectiveness.[3]
DIT	Direct integrity test: A physical test applied to a membrane unit to identify and isolate integrity breaches.[4]
disinfectant	An oxidising agent (such as chlorine, chlorine dioxide, chloramines or ozone) that is added to water and is intended to inactivate pathogenic (disease-causing) microorganisms.
disinfectant residual	The amount of free and/or available disinfectant remaining after a given contact time under specified conditions.
disinfection	The process designed to inactivate or destroy microorganisms in water. Disinfection processes include ultraviolet disinfection, chlorination, chlormaination, chlorine dioxide disinfection and ozonation.
DO	Dissolved oxygen
DOC	Dissolved organic carbon
DVGW	Deutscher Verein des Gas- und Wasserfaches e.V. - Technisch-wissenschaftlicher Verein (German Technical and Scientific Association for Gas and Water)
EC	Electrical conductivity
E. coli	*Escherichia coli*
EPA Victoria	Environment Protection Authority Victoria
flocculation	Process in which small particles are agglomerated into larger particles through gentle stirring by hydraulic or mechanical means.
floc strength	The resistance of the generated flocs to shearing forces, an important characteristic since particulate matter in flocs with a low floc strength will move relatively rapidly through the filter due to the shearing forces on any deposited flocs.
flux	Flow per unit of membrane area[4]
F/M ratio	Food/microorganism ratio

FRNA	FRNA bacteriophage. Also known as F-specific RNA bacteriophage.
grab sample	Single sample collected at a particular time and place that represents the composition of water only at that time and place.
greywater	Wastewater from a hand basin, shower, bath, spa bath, washing machine, laundry tub, kitchen sink and dishwasher.
HACCP	Hazard analysis and critical control point: A systematic methodology to control safety hazards in a process by applying a two-part technique: first, an analysis that identifies hazards and their severity and likelihood of occurrence; and second, identification of CCPs and their monitoring criteria to establish controls that will reduce, prevent, or eliminate the identified hazards.[1]
HAZOP	Hazard analysis and operability study
hr	hour
HRT	Hydraulic retention time
independent third-party oversight	An independent third party is a person who has no real or apparent conflict of interest regarding the recycled water scheme or the ultimate use of the treatment process unit being tested.
indicator	A parameter (biological, chemical or physical) or a combination of parameters that can be used to: • assess the quality of water, a specific contaminant, group of contaminants or constituent that signals the presence of something else, or • measure the integrity or efficacy of a treatment process unit.
integrity breach	One or more leaks (in a membrane system) that could result in contamination of the filtrate.[4]
indirect integrity monitoring	Monitoring some aspect of the filtrate water quality that is indicative of the removal of particulate matter.
ISO	International Organization for Standardization
kPa	Kilopascal
L	Litre
LRV	Log_{10} reduction value: Used in reference to physical-chemical treatment of water to remove or inactivate microorganisms such as bacteria, protozoa and viruses (1-log_{10} = 90 per cent or 10-fold reduction, 3- log_{10} = 99.9 per cent or 1,000-fold reduction and so on). *For inactivation processes:* LRV = log_{10} (N_0) – log_{10} (N), where N_o = concentration of infectious microorganisms before exposure to disinfectant or UV light and N = concentration of infectious microorganisms after exposure to disinfectant or UV light. *For removal processes:* LRV = log_{10} (C_f) – log_{10} (C_p), where C_f = feed concentration during validation study and C_p = filtrate concentration during validation study.

$LRV_{C\text{-}test}$	The overall pathogen removal demonstrated during challenge testing.
LRV_{DIT}	Direct integrity test sensitivity in terms of LRV
LT2ESWTR	Long-term 2 enhanced surface water treatment rule
MBR	Membrane bioreactor
MCRT	Mean cell retention time
media filtration	Process in which particulate matter in water is removed by passage through porous media (typically sand or anthracite).
membrane filtration	The process of passing water through porous membranes in the form of sheets or tubes to remove suspended solids and particulate material.
min	Minute
mg	Milligram
mJ	Millijoule
mL	Millilitre
MLSS	Mixed liquor suspended solids
module	The smallest element of a membrane unit that has a specific surface area.[4]
MPN	Most probable number
MS2	MS2 bacteriophage. Also known as male-specific bacteriophage-2.
MWCO	Molecular weight cut off
NATA	National Association of Testing Authorities
NF	Nanofiltration
NSF	United States National Science Foundation
NTU	Nephelometric turbidity unit
NWRI	National Water Research Institute
ONORM	Österreichisches Normungsinstitut (Austrian Standards Institute)
operational monitoring	The sequence of measurements and observations used to assess and confirm that individual barriers and preventive strategies for controlling hazards are functioning properly and effectively.
ORP	Oxidation reduction potential
ozonation	The process by which ozone is produced when oxygen (O_2) molecules are dissociated by an energy source into oxygen atoms and subsequently collide with

	an oxygen molecule to form an unstable gas, ozone (O_3), which is used to disinfect water. The mechanisms of disinfection using ozone include: direct oxidation/destruction of the cell wall; with leakage of cellular constituents outside of the cell; reactions with radical by-products of ozone decomposition; and damage to the constituents of the nucleic acids.[5]
PDR	Pressure decay rate
PFU	Plaque forming unit
Q_{breach}	Flow of water through the critical breach during filtration
QCRV	Quality control release value: Used in membrane filtration. A minimum quality standard for a non-destructive performance test established by the manufacturer for membrane module production that ensures the module will attain the targeted LRV during challenge testing.[4]
QMRA	Quantitative microbial risk assessment
QPCR	Quantitative polymerase chain reaction
raw water	Water in its natural state, before any treatment; or the water entering the first treatment process of a treatment plant.
Re	Reynolds number. A dimensionless number in fluid dynamics. Reynolds number is the ratio of inertial forces to viscous forces and is used to determine whether a flow will be laminar or turbulent.
recovery	Ratio of filtrate volume produced to feedwater applied to a membrane over a continuous operating cycle.[4]
RED	Reduction equivalent dose
resolution	Smallest integrity breach (leak) that generates a response from a direct integrity test.[4]
recycled water	Water generated from sewage or greywater and treated to a standard that is appropriate for its intended use.
RWQMP	Recycled water quality management plan: A plan that covers the production of Class A recycled water at a treatment plant. The validation (body of evidence) supporting the capability of the treatment plant to achieve the specified water quality objectives must be contained within this plan.
R-WT	Rhodamine WT
representative sample	A portion of material or water that is as nearly identical in content and consistency as possible to that in the larger body of material or water being sampled.
RO	Reverse osmosis: 1) the reverse of the natural osmosis process, that is, the passage of a solvent (such as water) through a semi-permeable membrane from a solution of higher concentration to a solution of lower concentration against the concentration

	gradient, achieved by applying pressure greater than the osmotic pressure to the more concentration solution; also: 2) the pressure-driven membrane separation process that employs the principles of reverse osmosis to remove dissolved contaminants from water.[4]
sensitivity	The maximum LRV that can be reliably verified by the direct integrity test.[4]
sewage	Wastewater collected in sewerage systems from blackwater municipal services including human excrement and trade waste.
SS	Suspended solids
SOPs	Standard operating procedures
SRT	Sludge retention time
surrogate	A challenge organism (such as bacteriophage), particulate or chemical (such as rhodamine) that is a substitute for the target microorganism of interest. For a surrogate to be suitable it must be either: • reduced (removed or inactivated) by the treatment process unit to an equivalent or lesser extent than the target pathogen, or • possible to demonstrate a reproducible correlation from literature, laboratory or field trials between reduction of the surrogate and the target pathogen.
T_{10}	Contact time
target pathogen	The pathogen that has been demonstrated to be the most resistant to the specific treatment process unit in question and therefore is the subject of the validation study for the specific treatment process unit.
TDS	Total dissolved solids
TDT	Theoretical detention time
TOC	Total organic carbon
TOD	Transferred ozone dose
TMP	Trans membrane pressure
TPU	Treatment process unit
treatment process train	The overall treatment process (comprising several treatment process units) for a given project (such as activated sludge + membrane filtration + UV disinfection + chlorination).
treatment process unit	A specific treatment process step (membrane filtration) that combines with other processes to constitute a treatment process train.
UCL	Upper control limit
UF	Ultrafiltration

US EPA	United States Environmental Protection Agency
UV disinfection	Ultraviolet disinfection
UVDGM	United States Environmental Protection Agency: *Ultraviolet disinfection guidance manual*[6]
UVT	Ultraviolet transmittance: a measure of the fraction of incident light transmitted through a material.
validation	The substantiation by scientific evidence (investigative or experimental studies) of existing or new processes and the operational criteria that demonstrates the pathogen reduction capability of the process to effectively control hazards.[1]
verification	An assessment of the overall performance of the treatment system and the ultimate quality of recycled water being supplied to customers.

1 Introduction

Recycled water derived from sewage or greywater is a valuable resource that is increasingly being used for a variety of purposes.

As the sources of recycled water can contain significant concentrations of human hazards, such as pathogenic microorganisms, it is essential that recycled water is treated before it is used to reduce these hazards to safe levels. The levels that are considered safe will depend on the proposed use of the recycled water. In Victoria, 'Class A' recycled water schemes require the highest level of treatment because these schemes involve uses of recycled water that carry a high risk of direct human exposure to or incidental ingestion of the water.

The regulatory and approval requirements for Victorian Class A water recycling schemes are described in the Environment Protection Authority (EPA) Victoria's *Guidelines for environmental management: Use of reclaimed water* (EPA Victoria publication 464.2)[7] and *Guidelines for environmental management: Dual pipe water recycling – health and environmental risk management* (EPA Victoria publication 1015)[8]. The Department of Health (the department) endorses Class A schemes to ensure treatment plants can reliably produce recycled water of an appropriate microbial quality.

The approval process for Class A recycled water schemes is illustrated in Appendix 1.

These guidelines have been developed to supplement the EPA guidelines and assist Class A scheme proponents in the validation process.

These guidelines describe:

- guiding principles for validating Class A recycled water schemes (section 2)
- the treatment validation steps (section 3)
- the validation requirements for specific treatment process units (sections 4–9).

These guidelines also support the implementation of the validation requirements in the *Australian guidelines for water recycling (AGWR): Managing health and environmental risks, Phase 1.*

1.1 What is validation?

Treatment validation is the process of demonstrating that:

- a treatment system can produce water of the required microbial quality under a defined range of operating conditions
- the system can be monitored in real time to provide assurance that the water quality objectives are being continuously met.

The process of treatment validation correlates the direct evidence of a treatment process' capability (for example, through one-off challenge tests) with the everyday operational monitoring tools that are used (for example, through disinfectant residual or a membrane integrity test). The operational monitoring parameters can then be routinely used to provide confidence that the system is performing reliably and that events that may lead to system failure will be rapidly detected. This allows for immediate corrective action to prevent the supply of substandard water.

In the context of these guidelines, the term 'validation' links to the terms 'validation monitoring' and 'operational monitoring' from the AGWR (see Box 1).

Treatment validation is an exercise undertaken before a treatment process is endorsed to supply recycled water. Typically, treatment validation is undertaken once, unless the system or its operating conditions are modified.

During treatment validation, each unit within the process is investigated to:

- quantify its capability to remove or inactivate pathogens from the key groups of bacteria, viruses and protozoan parasites – this is usually expressed in terms of '$\log_{10}$ reduction values' or LRVs, where a one $\log_{10}$ reduction equates to a 90 per cent reduction of a pathogen group, two $\log_{10}$ reduction to a 99 per cent reduction, three $\log_{10}$ reduction to a 99.9 per cent reduction and so on.
- characterise operational monitoring parameters (for example, disinfectant residual and flow) that can be measured continuously and will correlate with the reduction of the pathogen groups.

As a result of this treatment validation, the LRVs for each unit can be added together to provide a total LRV for the whole treatment process train and each unit can be tightly monitored and controlled to ensure it is always providing its required LRV.

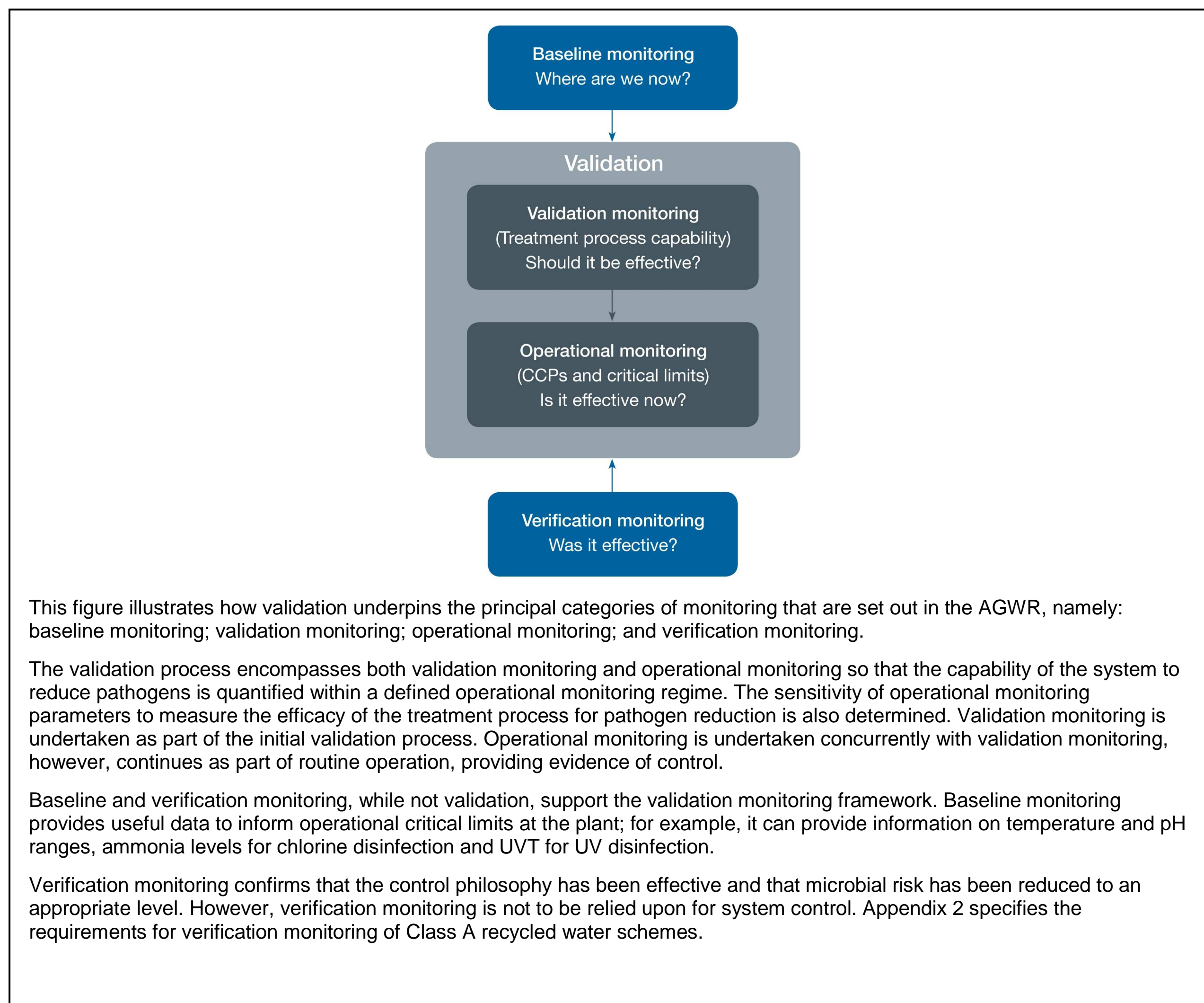
Historically, end-point water quality monitoring (or 'verification' – see Box 1) was used to indicate treatment efficacy. Such monitoring typically relied upon measurement of *E. coli* or faecal coliforms. Up-front treatment validation and the

subsequent reliance on operational monitoring parameters to indicate treatment efficacy has replaced this historical approach, and is considered far more protective of public health because it:

- provides results in a timeframe that allows rapid response (reliance on verification monitoring may have placed people at risk for days before a problem was detected)
- demonstrates how effectively more resistant and significant pathogens, such as viruses and protozoa, are removed by the treatment process (bacteria such as *E. coli* are far more susceptible to most types of treatment)
- defines the inherent capability of the treatment process to reduce pathogens, and defines the range of operating conditions under which the system will perform reliably.

While it should not be relied upon for operation and control of recycled water treatment processes, periodic verification monitoring is still recommended in the AGWR to complete the monitoring feedback loop (see Box 1). Verification requirements for Victorian Class A schemes are described in Appendix 2.

Box 1: Types of monitoring described in the *Australian guidelines for water recycling*



This figure illustrates how validation underpins the principal categories of monitoring that are set out in the AGWR, namely: baseline monitoring; validation monitoring; operational monitoring; and verification monitoring.

The validation process encompasses both validation monitoring and operational monitoring so that the capability of the system to reduce pathogens is quantified within a defined operational monitoring regime. The sensitivity of operational monitoring parameters to measure the efficacy of the treatment process for pathogen reduction is also determined. Validation monitoring is undertaken as part of the initial validation process. Operational monitoring is undertaken concurrently with validation monitoring, however, continues as part of routine operation, providing evidence of control.

Baseline and verification monitoring, while not validation, support the validation monitoring framework. Baseline monitoring provides useful data to inform operational critical limits at the plant; for example, it can provide information on temperature and pH ranges, ammonia levels for chlorine disinfection and UVT for UV disinfection.

Verification monitoring confirms that the control philosophy has been effective and that microbial risk has been reduced to an appropriate level. However, verification monitoring is not to be relied upon for system control. Appendix 2 specifies the requirements for verification monitoring of Class A recycled water schemes.

1.2 Victorian regulatory framework

The EPA Victoria *Guidelines for environmental management: Use of reclaimed water* (EPA Victoria publication 464.2) and *Guidelines for environmental management: Dual pipe water recycling – health and environmental risk management* (EPA Victoria publication 1015) specify the requirements for recycled water. Under these guidelines, proponents of Class A recycled water schemes are required to submit a *Recycled water quality management plan* (RWQMP) to the Department of Health for endorsement, prior to submission to EPA Victoria for approval (refer to Figure 1). The

department's endorsement focuses on the capability of the recycled water treatment system to achieve its water quality objectives. The endorsement process for Class A recycled water schemes is illustrated in Appendix 1.

The department has prepared the *Guide for the completion of a recycled water quality management plan for Class A water recycling schemes*[9] to assist Class A recycled water scheme proponents complete their RWQMP. The validation of treatment processes to produce Class A recycled water quality is a key component of the RWQMP.

In Victoria, Class A recycled water is a health-based microbiological standard required for high-exposure uses including those in residential developments (such as 'dual pipe' systems for toilet flushing and garden use), the irrigation of public open spaces where access is unrestricted, and the irrigation of crops that are consumed raw or unprocessed.

Figure 1 Validation in the context of Class A recycled water schemes in Victoria

1.3 Scope and application of these guidelines

1.3.1 Class A recycled water schemes

These guidelines apply to the design and operation of both new and existing Class A recycled water schemes.

In the case of existing Class A recycled water schemes, these guidelines provide a benchmark against which scheme managers can assess existing facilities and identify improvements. The adoption of these guidelines by a scheme manager is implicit in the obligation to exercise their duty of care.

Scheme managers of existing Class A recycled water schemes are expected to undertake a gap analysis against these guidelines within eight months of their publication date and provide a written report for the department's consideration. This report must identify deviations from the requirements of these guidelines and a proposed work program to ensure consistency with these guidelines. The proposed work program, including timeframes, should be scheme specific and appropriately address the deviation from these guidelines. Where a scheme manager undertakes major upgrades to an existing plant (for example, a change to the operation of a treatment process) or proposes changes to operational conditions (critical limits), this plant should also be validated in accordance with these guidelines.

1.3.2 Microbial water quality objectives

These guidelines focus on managing the acute health risks posed by pathogens in recycled water, and therefore only address the validation of treatment processes to meet microbial water quality objectives. Chemical parameters are not addressed; however, the same principles and approach to validation could be applied.

Victorian Class A schemes must meet microbial water quality objectives that are determined using quantitative microbial risk assessment (QMRA), consistent with the AGWR. QMRA uses quantitative data to mathematically assess the public's exposure to pathogens and the resulting health risk. The required level of treatment and the associated water quality objectives vary depending upon the nature of the end use for the recycled water scheme. Therefore, the required level of treatment increases with the risk associated with particular end uses.

Microbial water quality objectives are developed for each of the pathogen groups of bacteria, viruses and protozoan parasites rather than individual organisms, due to the wide array of pathogens that may be present in sewage. These microbial water quality objectives are expressed in terms of LRVs.

Treatment processes employed to achieve these microbial water quality objectives must be validated. Typically only a few to a dozen pathogens have had their sensitivity to any one type of treatment process evaluated. Therefore, the target pathogen(s) that is the subject of the validation study are those that have been demonstrated to be the most resistant to the specific treatment process unit.

These guidelines do not cover helminth reduction, which is covered by the AGWR. Research is required to facilitate the development of a validation approach for helminth reduction via alternative treatment processes such as media filtration systems and biological processes. In general, helminth reduction is most relevant to agricultural irrigation schemes that are typically of a class lower than Class A and so outside the intended scope of these guidelines. In general the Chief Veterinary Officer within the Department of Primary Industries should be consulted in relation to helminth risks.

1.3.3 Class A recycled water treatment processes

In accordance with the AGWR, these guidelines focus on direct pathogen reduction rather than treatment process criteria. This approach enables a high level of innovation and flexibility in the treatment processes that can be used by allowing the water quality monitoring criteria to be customised to the treatment process. This approach, however, does require a greater emphasis on validation for individual treatment processes.

These guidelines describe the validation approach for some typical treatment process units:

- biological treatment, media filtration and membrane bioreactors
- membrane filtration (microfiltration, ultrafiltration, reverse osmosis)
- disinfection processes (ultraviolet disinfection, ozonation, chlorination, chloramination, chlorine dioxide).

The discussion on the validation of specific treatment processes is not intended to influence the selection of treatment process. Where alternative treatment technologies are proposed, scheme proponents should develop a draft validation program consistent with the guiding principles and validation steps described in the following sections.

Scheme proponents need to determine the most appropriate treatment process based on catchment and feedwater characteristics, intended uses of the treated water and scheme scale. This non-prescriptive approach recognises that sewerage and other catchments are different and in some cases specific treatment processes may not be appropriate due to the inherent quality of feedwater. Furthermore, the chemical and physical specifications of water quality for a defined end use will typically influence the treatment process.

1.4 Approach to developing these guidelines

1.4.1 Adoption of authoritative and evidence-based approaches

The philosophy behind the development of these guidelines is to adopt, where appropriate, existing validation approaches that are authoritative and evidence based.

Where authoritative guidance is not available, the approach has been based on best available science. Knowledge gaps and areas of uncertainty have been explicitly acknowledged. In these circumstances, a conservative approach to validation has been adopted. Transparency and acknowledgement of these knowledge gaps are fundamental to assuring water safety and indicate the need for further research.

The department will provide ongoing review of these guidelines to ensure they remain current and, where appropriate, reflect advances in research. These guidelines will be reviewed at a frequency no less than five years. The review process will include national and international expert peer review and consultation with the water industry.

1.4.2 Review of existing validation guidelines and literature and benchmarking

At the time of publication, no similar validation guidance document existed, either in Australia or overseas. Existing validation guidelines tend to only refer to specific technologies and are often tailored to drinking water applications. Notwithstanding this, review of existing validation guidelines and scientific literature has been undertaken in developing these guidelines. This included:

- guidance for specific treatment processes
- first principles and scientific theory on the validation of treatment processes to identify:
  - which theoretical approach to adopt in process validation
  - which target microorganisms to select as the focus of the validation for each pathogen class
  - which microorganisms or surrogates to use for any microbial testing
  - what depth of analysis is required, (for example, desktop validation, indigenous microorganism analysis or challenge testing).

Furthermore, in developing these guidelines knowledge gaps, particularly in relation to appropriate operational surrogates for system integrity monitoring, were identified. To assist in addressing these knowledge gaps, an international benchmarking study tour was undertaken to collate information on approaches to treatment validation and research specifically in the area of surrogates and indicators for monitoring treatment efficacy.

1.4.3 Consultation and peer review

A small focus group workshop was held to discuss validation requirements with key informants selected to be broadly representative of the Victorian water industry.

These draft guidelines have been subject to national and international peer review by researchers, regulators and recognised independent experts in treatment validation.

These draft guidelines are now subject to consultation by the regulators, researchers and the water industry including manufacturers of treatment processes, water authorities and consultants.

1.4.4 Knowledge management and implementation

While the science pertaining to the behaviour of viruses and protozoan parasites has progressed in water recycling in recent years, more research is needed to better understand the mechanisms of pathogen reduction via some treatment processes typically used in the water recycling industry. These guidelines will assist in directing research needs to inform evidence-based decisions and facilitate the development of water recycling schemes.

Furthermore, learnings and research outcomes from existing schemes should and will be considered in future reviews of these guidelines.

2 Guiding principles

These guidelines are underpinned by the following guiding principles.

Safety is paramount: While recycled water can be a valuable resource, it is derived from a high-risk water source – sewage. Using recycled water is a potentially high-risk activity and must be carried out with safety as the foremost requirement.

Preventive risk management: The preventive risk management framework in the *Australian guidelines for water recycling* (AGWR) must be adopted. The AGWR defines preventive risk management as the systematic evaluation of the recycled water supply system (including catchment inputs and treatment), the identification of hazards and hazardous events, the assessment of risks, and the implementation of preventive strategies to manage the risks.

Evidence-based approach: Evidence used in validation must be: scientifically defensible and verifiable; traceable; transparent; and statistically valid.

Protozoan parasites and viruses are most significant: Although bacteria may be more abundant in raw sewage, protozoan parasites and viruses are more significant in recycled water schemes due to their relative infectivity and resistance to most treatment processes. Therefore, viruses and protozoan parasites represent the target pathogen groups for validation.

Multiple barrier approach: Consistent with the AGWR, the use of more than one preventive measure as a barrier against a specific pathogen group should be adopted. In this context, the multiple barrier approach does not necessarily provide redundant single-process capacity, but rather the intent is to minimise the consequences of faults in the control system and uncertainty associated with the specific treatment process unit and its ability to reduce pathogens.

Each treatment process unit must be validated: A treatment process train as a total entity cannot be validated from influent to effluent. This method of testing does not provide information on how the specific treatment performance varies under different operating conditions. Furthermore, 'end-of-pipe' type testing is not validation and could potentially overestimate the performance of the system. For instance, if the influent to the treatment process unit contains a low pathogen concentration during the testing period, then the end-of-pipe type of testing will not indicate how a treatment process will perform under higher pathogen concentrations.

Therefore, each individual treatment process unit must be individually validated. Validation requires an understanding of the mechanisms of pathogen reduction, the factors that affect the efficacy of the treatment process unit and therefore the relevant operational monitoring parameters (indicators of treatment efficacy). Validation must:

- establish the pathogen LRV for the specific treatment process unit within a defined design and operational specification
- establish the correlation between operational monitoring parameters and pathogen reduction
- establish the sensitivity of the operational monitoring parameter (the maximum LRV that can be reliably verified).

Use of most resistant pathogen in each group: For each of the three pathogen groups (bacteria, viruses and protozoa), the most resistant pathogen must be used as the basis for attributing $\log_{10}$ reductions for each treatment process unit. There is a wide array of pathogens in sewage and typically only a few to a dozen pathogens have had their sensitivity to any one type of treatment process evaluated. While rotavirus and *Cryptosporidium* were used as reference organisms for the quantitative microbial risk assessment in the AGWR, other viruses and protozoa may exhibit similar infectivity but be more resistant to treatment. Therefore, the target pathogen that is the subject of the validation study is the pathogen that has been demonstrated to be the most resistant to the specific treatment process unit being validated.

Limiting reliance on one treatment type: The maximum LRV that can be attributed to any one treatment type, regardless of its capability, is 4 $\log_{10}$. This approach reflects a risk-based philosophy and supports the adoption of the multiple-barrier approach. It is noted that published design criteria for disinfection processes is typically limited to demonstrating 4 $\log_{10}$. Important considerations that support this approach include:

- limited understanding of tailing attributed to resistant sub-populations of microorganisms and the presence of particulate-associated and clumped microorganisms (particularly as it relates to disinfection processes)
- limitations in the sensitivity and dependability of operational monitoring techniques
- the uncertainty of measurement in analytical techniques and instrumentation.

The intended outcome is that, for recycled water schemes requiring greater than 4 log_{10} pathogen reduction, there are at least two validated treatment process types for the specific pathogen group whereby:

- the predominant mechanisms of pathogen reduction and principles of operation are dissimilar (such as a activated sludge plant, ultrafiltration, reverse osmosis, chlorination and UV disinfection)
- the failure modes and hazardous events that lead to failure are different and significantly independent (such as an increase in chlorine demand versus object rupturing membrane surfaces)
- the operational monitoring techniques are dissimilar and thereby the limitations and measurement of uncertainty are different (such as turbidity versus free chlorine residual)
- the associated instrumentation and control loops (although linked to the same programmable logic controller) are independent.

For Class A recycled water schemes that require 4 log_{10} or less pathogen reduction (such as treated greywater for toilet flushing), while it may be acceptable to attribute this to only one treatment process unit through validation, it is expected that the multiple-barrier approach would be adopted.

Given the above reasoning, the use of multiple processes of the same type in series cannot be used to gain more than 4 log_{10} reduction for that process type. For instance, running two chlorination systems in series, each capable of achieving a 4 log_{10} reduction in their own right, will not provide an 8 log_{10} reduction because the same process type is used in each case. The limit for the chlorination process type in this example would still be 4 log_{10}.

Statistical bounds: The statistical methods used to derive the LRV must be conservative and assigned LRVs must be associated with the conservative end of the uncertainty interval. Typically this is the fifth percentile or the lower 95 per cent confidence limit of the mean.

Safety and reliability in design and operation: A safe design basis, with a formal safety management system that includes practices, procedures and training, is critical for ensuring the recycled water treatment plant functions effectively.

During its specified operating life, the recycled water treatment plant (including hardware, software, procedures and operators) must reliably deliver the specified microbial water quality objectives within the validated critical limits, and cease the delivery of recycled water in the event of a breach of the critical limits (such as free chlorine residual or flow rate), or system or component failure (such as chlorine analyser fault). The components of the recycled water treatment plant must be operated, maintained, calibrated, tested and replaced as per the manufacturer's requirements.

Refer to Appendix 3 for further guidance on safety in design and operation including specific requirements for risk assessment and management, design and functionality, commissioning, operation and maintenance, operational personnel and quality assurance.

Quality management system framework: A quality management system such as ISO 9001 Quality Management Systems should underpin validation, the production of 'fit for purpose' recycled water, design and operation, and quality control throughout the product chain. A quality management system framework promotes sound manufacturing processes, from primary supplier, through manufacturing, to site delivery, installation, commissioning and long-term operation.

Independent third-party oversight: In this context, an independent third party is a person or persons with no real or apparent conflict of interest regarding the recycled water scheme or the ultimate use of the treatment process unit being tested.

Independent third-party oversight by a person or persons experienced in testing and evaluating the treatment process unit in question and in the microbial aspects of treatment validation is required to ensure that either:
- the validation study is conducted in a technically sound and unbiased manner, and is consistent with the requirements of these guidelines (including other relevant guidance as specified), or
- data for a specific treatment process unit from a previous validation study is acceptable for the recycled water scheme in question based on the requirements of these guidelines (including other relevant guidance as specified).

Independent third-party oversight by a person or persons experienced in process control and instrumentation is required to ensure that:

- the treatment process unit is physically configured according to validated plans and specifications and is operated within the operating envelope demonstrated during the validation study
- the control system, including critical limit alarms and corrective actions, have been tested and verified.

The scheme proponent must provide written confirmation from the independent third party confirming the above requirements. This written confirmation should be appended to the RWQMP.

3 The validation approach

This section describes the validation approach that underpins subsequent sections on validation for specific treatment process types. For treatment processes that are not covered in these guidelines, the validation approach described in this section should be used to devise a validation program for consideration by the Department of Health. The proposed validation program should be supported by a comprehensive scientific literature review.

It is necessary to validate each individual treatment process unit that contributes to the required microbial water quality objectives (expressed as LRV).

For each treatment process unit, validation comprises:

1. **identification of target pathogens** that are the subject of the validation study for the specific treatment process unit

2. **specification of $\log_{10}$ reduction requirements** for the actual treatment process unit, taking into consideration the QMRA for the recycled water scheme and the treatment system as a whole

3. **identification of mechanisms** responsible for pathogen reduction by the treatment process unit

4. **identification of influencing factors** that affect the efficacy of the treatment process to reduce the target pathogen

5. **identification of operational monitoring parameters** that can be measured continually and that will correlate with the reduction of the target pathogen

6. **identification of validation methodology** to demonstrate the capability of the treatment process unit

7. **data collection and analysis** to formulate evidence-based conclusions

8. **determination of critical limits** as well as an operational monitoring and control strategy

9. **determination of LRV** for each pathogen class (protozoa or virus) in each specific treatment process unit performing within defined critical limits

10. **re-validation or additional onsite validation** where proposed modifications are inconsistent with the previous validation test conditions.

3.1 Identification of target pathogens

Typically only a small number of pathogens have had their sensitivity to any one type of treatment process evaluated. Therefore, the target pathogen that is the subject of the validation study is the pathogen that has been demonstrated to be the most resistant to the specific treatment process unit being validated. It is considered potentially unsafe to use anything other than the most resistant of those that have been evaluated.

The protozoan pathogen that is most resistant to treatment processes is often *Cryptosporidium spp.* oocysts, and therefore is typically the target pathogen for validation purposes.

For viruses, the most resistant virus for one specific process is not necessarily the most resistant to other treatment processes. Therefore, the target virus for validation purposes will vary depending on the specific treatment process unit.

The target pathogens provided in Table 1 should be adopted for validation purposes. Where the target pathogen is unknown, the onus is on the scheme proponent or manufacturer to conduct research to establish the target pathogen. Potential surrogates for the purposes of validation testing should be identified where possible. Where a suitable surrogate cannot be identified, the target pathogen must be used as the challenge particulate. The availability of reliable analytical methods for the target pathogen is an important consideration in designing a validation study. Some methods have poor recoveries and wide ranges of variability, and therefore impact on the ability to establish LRVs. The use of surrogates, where appropriate, may overcome these limitations in some circumstances.

For further discussion on surrogates refer to section 3.6.3.

Table 1: Summary of target pathogens for common treatment processes and potential surrogates (refer to the specific sections on each process for further details)

Process type	Protozoa	Viruses	Bacteria	Potential surrogate for validation testing (refer to sections 4–9)
Activated sludge	*Cryptosporidium* – smallest, least adherent and most resistant	Enteroviruses – smallest of the cultivable viruses	*E. coli* – representative of common bacterial pathogens	Protozoa: Inactivated seeded or indigenous *Cryptosporidium* oocysts. The literature is inconclusive on the use of *Clostridium perfringens.* Viruses: The literature is inconclusive on the use of bacteriophage. Therefore, site-specific studies must be undertaken to demonstrate that these surrogates do not overestimate pathogen reduction. Refer to section 4.
Media filtration	*Cryptosporidium* – smallest and least adherent	Enteroviruses – smallest of the cultivable viruses	*E. coli* – representative of common bacterial pathogens	Protozoa: Inactivated seeded *Cryptosporidium* oocysts. The literature is inconclusive on the use of *Clostridium perfringens,* yeast and dyed microspheres as surrogates for protozoa. Therefore, site-specific studies must be undertaken to demonstrate that these surrogates do not overestimate pathogen reduction. Viruses: The literature is inconclusive on the use of bacteriophage. Therefore, site-specific studies must be undertaken to demonstrate that these surrogates do not overestimate pathogen reduction. Refer to section 5.
Ultrafiltration	*Cryptosporidium* – smallest and least adherent	Enteroviruses – smallest of the cultivable viruses	*E. coli* – representative of common bacterial pathogens	As per US EPA (2005)[4] for both viruses and protozoa.
Microfiltration with coagulation	*Cryptosporidium* – smallest and least adherent	Enteroviruses – smallest of the cultivable viruses	*E. coli* – representative of common bacterial pathogens	As per US EPA (2005)[4] for protozoa. For viruses: The literature is inconclusive on the use of bacteriophage because the selection of a suitable surrogate may be coagulant dependent. Therefore, site-specific studies must be undertaken to demonstrate that the surrogate does not overestimate pathogen reduction. Refer to section 6.
Reverse osmosis	*Cryptosporidium* – smallest and least adherent	Enteroviruses – smallest of the cultivable viruses	*E. coli* – representative of common bacterial pathogens	As per US EPA (2005)[4] for both viruses and protozoa noting the potential to use dyes. Refer to section 6.
Membrane bioreactors	*Cryptosporidium* – smallest, least adherent and most resistant	Enteroviruses – smallest of the cultivable viruses	*E. coli* – representative of common bacterial pathogens	Protozoan parasites: Inactivated seeded or indigenous *Cryptosporidium* oocysts. The literature is inconclusive on the use of indigenous *Clostridium perfringens*. Therefore, site-specific studies must be undertaken to demonstrate that this surrogate does not overestimate pathogen reduction. Viruses: The literature is inconclusive on the use of bacteriophage. Therefore, site-specific studies must be undertaken to demonstrate that these surrogates do not overestimate pathogen reduction. Refer to section 7.
Free chlorine (HOCl) disinfection	*Cryptosporidium* – most resistant	*Coxsackie B5* – most resistant	*E. coli* – representative of common bacterial pathogens	All pathogens: Adopt established CT values if applicable to operational conditions. Refer to section 8.
Chloramine (NH_2Cl) disinfection	*Cryptosporidium* – most resistant	Adenovirus serotype 2 – most resistant	*E. coli* – representative of common bacterial pathogens	All pathogens: Adopt established the CT values if applicable to operational conditions. Refer to section 8.
Ozone disinfection	*Cryptosporidium* – most resistant	Not yet established for recycled water	*E. coli* – representative of	Transferred ozone dose (TOD) and CT (ozone residual).

Process type	Protozoa	Viruses	Bacteria	Potential surrogate for validation testing (refer to sections 4–9)
		Poliovirus serotype 2, hepatitis A virus and echovirus serotype 1 are potential candidates	common bacterial pathogens	Protozoa: *Clostridium perfringens* Viruses: *Clostridium perfringens*. Some types of bacteria and bacteriophage may be conservative for pathogens but this would need to be proven on a site-specific basis. Commonly used bacteriophage, such as MS2, are not at all conservative and are not suitable as surrogates. Note: *Clostridium perfringens* appears to be a highly conservative surrogate for all of the important pathogens, albeit potentially too conservative for practical use. Refer to section 8.
UV disinfection	*Cryptosporidium* – most resistant protozoan parasite	Adenovirus serotype 40 – most resistant	*E. coli* – representative of common bacterial pathogens	As per US EPA 2006[6]: All pathogens: MS2 or *Bacillus subtilis* endospores are used to estimate UV system reduction equivalent dose (RED), which is then translated into pathogen log_{10} reductions. Refer to section 9.

3.2 Specification of log_{10} reduction requirements

When designing a Class A recycled water scheme, the end uses for the recycled water must be determined. Once the uses are defined, the log_{10} reduction target for the water recycling scheme can be derived from the AGWR. The AGWR use QMRA to determine health-based water quality objectives for recycled water.

Once the scheme's total log_{10} reduction target has been determined, proposed individual LRVs can be assigned to components of the treatment train (refer to Table 2).

Table 2: Example breakdown of a scheme's log_{10} reduction target

Pathogen	Target LRV	Treatment process units (TPU)		
		TPU1	TPU2	TPU3
Virus	$A=a+b+c$	$\geq a$	$\geq b$	$\geq c$
Protozoa	$B=x+y+z$	$\geq x$	$\geq y$	$\geq z$

Note: Maximum LRV attributed to any one TPU is 4 log_{10}.

3.3 Identification of mechanisms

Successful validation of a treatment process unit relies upon identifying which mechanisms apply to the process, and characterising how they specifically affect the target pathogen.

Mechanisms of reduction may include inactivation or physical removal via straining, adsorption, coagulation, flocculation, sedimentation or predation. A single treatment process may integrate multiple pathogen reduction mechanisms (such as a membrane bioreactor, which deploys an activated sludge microbial phase, combined with filtration). The characterisation of the mechanisms that lead to pathogen reduction assists in the selection of the target pathogens, the identification of the factors that affect the efficacy of the treatment process in reducing the target pathogens, and in identifying appropriate operational monitoring parameters.

3.4 Identification of influencing factors

Identifying the factors that influence treatment efficacy relies on a detailed understanding of the mechanisms that are responsible for pathogen reduction. Any factor that is deemed to have a significant effect on treatment efficacy needs to be monitored because the ultimate control of the system will rely on ensuring these factors are within their validated range. Essentially, a validation study will only be applicable to treatment process units that operate within the validated operational envelope.

Influencing factors may include, but are not limited to, feedwater characteristics (biological and physicochemical), hydraulic loads and surges, integrity failure or deterioration of treatment process components (such as manufacturing defects, pinholes in membranes, ageing or fouled UV lamps).

A risk assessment tool, such as the hazard analysis and critical control point (HACCP) system, must be used to identify factors that affect treatment efficacy and the associated operational monitoring that should be undertaken to indicate when these factors are within an acceptable range. The AGWR (and, specifically, element 2 of the *Preventive risk management framework*) should be referred to when conducting an assessment of the recycled water system.

The risk assessment should consider the methodology for ensuring quality control (ISO 9001) in the manufacturing process (including failure analysis of system components), commissioning and ongoing reliable operation.

3.5 Identification of operational monitoring parameters

Operational monitoring parameters are parameters used to measure the performance of the treatment process, and relate to the reduction performance of the target pathogen (treatment efficacy). Continuous monitoring of operational parameters provides assurance that the system is under control and alerts operators and control systems when treatment efficacy is reduced to an unacceptable level. This would trigger corrective actions to prevent unsafe recycled water being delivered to the end user.

In theory, every factor that may affect the efficacy of the treatment process would have an operational monitoring parameter. In practice, it is often possible to select a few key operational monitoring parameters that effectively demonstrate efficacy.

3.6 Identification of validation methodology

The objective of identifying the validation methodology is to demonstrate the pathogen log reduction capability of the treatment process.

For some treatment processes, the validation study merely involves accessing data from existing process performance tables. In other cases, a testing program is required that involves quantifying the reduction of indigenous or challenge-spiked organisms or particulates, while concurrently monitoring the operational parameters to confirm that the system is within some defined specification (operational envelope).

As discussed in section 2, independent third-party oversight is required to ensure that the validation study is conducted in a technically sound and unbiased manner, and is consistent with the requirements of these guidelines (including other relevant guidance as specified).

Key concepts in designing a validation study are discussed below.

3.6.1 Validation test program

Validation testing must be conducted at full-scale and be site specific.

- **For membrane filtration:** challenge testing must be conducted according to the US EPA *Membrane filtration guidance manual* (MFGM)[4] on a full-scale membrane module identical in material and construction to the membrane modules proposed for use in-situ. A module is defined as the smallest component of a membrane unit in which a specific membrane surface area is housed in a device with a filtrate outlet structure. The term ‘module’ refers to all types of membrane configurations including terms such as ’element’ or ‘cartridge’ that are commonly used in the membrane treatment industry.

  Pre-validated membrane modules can be used provided the validation testing conditions, including design configuration, operating conditions (validated range or limits) and control philosophy, are representative of in-situ conditions.

- **For UV disinfection systems:** validation testing must involve full-scale testing of a reactor (including open and closed channels), according to the US EPA *UV disinfection guidance manual* (UVDGM) for the long-term 2 enhanced surface water treatment rule (LT2ESWTR)[4].

  Pre-validated UV disinfection reactors can be used provided the validation testing conditions, including design configuration, UV-dose response curve, operating conditions, and dose-monitoring strategy, are representative of in-situ conditions.

- **For chlorination, chloramination, chlorine dioxide and ozonation:** CT values established from bench-scale experimental studies can be adopted where appropriate (further guidance on CT values is provided). Where tracer studies are used to establish the minimum contact time, these studies must be conducted at full-scale.

  Computational fluid dynamic (CFD) models must not be used in lieu of validation studies. CFD is a useful design tool for establishing theoretical equations for modelling the hydraulics through a chamber or reactor and informing the full-scale design; however, treatment systems must use empirical data or models established through validation testing.

- **For biologically influenced treatment processes** such as activated sludge, membrane bioreactors and media filtration (due to variability in wastewater catchments, flora of the biological media and seasonality): validation testing must be undertaken on the treatment process unit as a whole and in-situ. A pilot study may be undertaken to evaluate the relationship between the target pathogen and surrogate and therefore establish the surrogate's suitability for the validation study. A pilot study must not be used, however, to establish the LRV for the treatment process unit. For membrane bioreactor (MBR) systems where the LRV is attributed solely to the membrane component (excludes mixed liquor component and cake layer), refer to the above discussion on membrane filtration.

Where pre-validated treatment process units or benchtop experimental studies are adopted, it is important to ensure that validation data:

- is not extrapolated (for example, dose–response relationships cannot be extrapolated beyond the validated range)
- is critically reviewed to ensure it is directly applicable to the treatment process unit to be installed and the operational conditions at the site
- does not overestimate the ability of the treatment process unit to reduce the target pathogen. Overestimation may occur in laboratory-based studies due to controlled experimental conditions versus variations in physicochemical parameters in the 'real' environment (such as feedwater quality impacting on coagulation) and the relative susceptibility of laboratory-based strain and indigenous organisms due to environmental factors (for example, protection mechanisms such as particle association for indigenous microorganisms).

Refer to sections 5–10 for specific considerations for individual treatment process units.

3.6.2 Laboratory grown strain versus indigenous microorganisms

If there is a consistent sufficient concentration of a suitable indigenous microorganism in the feedwater to the unit process, it may be possible to simply measure the upstream and downstream concentrations of that microorganism directly in the wastewater being treated. In most circumstances, however, suitable indigenous microorganisms are either too depleted or too variable in concentration to be of use for validation studies. To demonstrate high magnitude $\log_{10}$ reduction requirements, it is not always possible to use indigenous microorganisms – it may only be possible to demonstrate a $\log_{10}$ reduction that is equal to or less than the difference between the upstream indigenous microorganism concentration and the limit of reliable quantification of the assay.

Where there are insufficient indigenous microorganisms in the wastewater, it becomes necessary to conduct spiked-challenge tests with a surrogate (either a laboratory grown strain, particulate or molecular marker), a process described as challenge testing.

The challenge test dose must not result in artificially high LRVs due to excessive over-seeding. It is equally important not to underestimate the required challenge test dose since it is only possible to demonstrate a $\log_{10}$ reduction that is equal to or less than the difference between the upstream challenge surrogate concentration and the limit of reliable quantification of the assay.

3.6.3 Surrogates for validation testing

Surrogates may be used in place of infectious pathogens during validation studies because they may be:

- easier to cultivate and use in seeding studies
- cheaper or quicker to assay
- safer to handle.

In this context, a surrogate is a challenge organism, particulate or chemical that is a substitute for the target microorganism of interest. For a surrogate to be suitable it must be reduced (removed or inactivated) by the treatment

process unit to an equivalent or lesser extent than the target pathogen. If this cannot be achieved, it must be possible to demonstrate a reproducible correlation from scientific literature, laboratory or field trials between the surrogate and the target pathogen (over the $\log_{10}$ reduction range being applied).

Refer to Table 1 for potential surrogates that may be used for validation testing.

3.6.4 Test operating conditions, monitoring and sampling

The validation testing program needs to demonstrate the $\log_{10}$ reduction of the target pathogen or surrogate provided by the treatment process unit. Therefore, samples need to be taken from both the influent and treated water, that is, at completely mixed points prior to, and post treatment.

The validation testing program must be conducted under the expected field operating conditions for the scheme.

The expected operating conditions are generally informed by historical baseline monitoring and should be underpinned by a HACCP analysis. Some examples include:

- ammonia profiling to inform disinfection operation mode
- pH, temperature and turbidity to inform the required CT for disinfection processes such as chlorination
- UVT to define the lower bound of validation for UV disinfection systems
- flow rate or flux for all treatment systems.

The test operating conditions will generally define the critical limits for ongoing operational monitoring for which the scheme can deliver recycled water. It is therefore critical that this step is planned and documented. The operational monitoring parameters identified as important (in section 3.5) must be monitored concurrently with the target pathogen or surrogate, so that the operating conditions at the plant during the validation period can be accurately characterised.

The validation testing program should specifically include:

- type of samples (composite or grab)
- number of feed and treated water samples to be collected – if a range of operational conditions (such as flow rates and temperatures) are to be tested, then at least three samples of the challenge particulate should be collected for each operating condition
- sample volumes
- collection of samples under steady-state conditions
- sample locations
- sampling duration
- sampling intervals – where processes are influenced by seasonal factors, the monitoring program should be spread over a reasonable period of time to allow for those influences to be reflected in the dataset
- estimate of time required to collect each sample
- sampling equipment required
- operational monitoring requirements, including what parameters to monitor, how often to monitor, and the range of acceptable results.

The *Australian guidelines for water quality monitoring and reporting*[10], published under the auspices of the *National water quality management strategy*, provides a framework for designing a monitoring study, data analysis and interpretation approaches.

3.6.5 Quality assurance and quality control

The validation monitoring program must be supported by a quality assurance (QA) and quality control (QC) framework.

The QA framework must ensure the QC framework is implemented and is effective in producing scientifically credible results. The *Standard methods for the examination of water and wastewater*[11], provides guidance on producing measurement-based information that is technically valid, defensible and of a known quality, and provides further guidance on how to address measurement uncertainty.

The QC framework should comprise activities designed to ensure:

- data integrity (consistency and accuracy)
- use of standardised procedures for sampling, analysis and data interpretation
- identification of errors or omissions, and estimation of uncertainties
- calibration of equipment
- credible results that relate to the data and analysis.

3.7 Data collection and analysis

The data collected during the validation testing program must be representative and reliable. To ensure that quality data is collected:

- appropriate sampling methods and techniques must be consistent with the *Standard methods for the examination of water and wastewater*
- National Association of Testing Authorities (NATA) accredited methods must be used where available; where NATA accredited methods are not available, the laboratory must:
  - demonstrate that the methodology employed is consistent with a standard method
  - document the methodology used to perform the analysis
  - retain documentation and appropriate quality assurance data
  - engage independent expert(s) to peer review and endorse the methodology
- field and laboratory equipment must be maintained and calibrated
- limits of detection and characteristics should be appropriately measured
- all procedures should be performed by qualified personnel and be subject to quality assurance/quality control procedures.

The monitoring program designed for the validation study must ensure that the data collected is relevant and sufficient to undertake a statistically valid analysis. These guidelines, where appropriate, describe the analysis that should be used to calculate the LRV.

The raw data and its analysis should be appended to the validation report. If data is excluded from the analysis the rationale must be provided.

The statistical analysis performed on the raw data must be transparent and consistent with the data analysis guidance provided for specific treatment process units described in sections 5–10. Statistical methods that yield conservative results should be used.

In analysing data, it is necessary to account for validation uncertainty including biases and error in measurements, laboratory equipment, experimental design and analytical techniques. The degree of uncertainty needs to be considered in determining and attributing an LRV to the treatment process unit.

Under the ISO Standard to which NATA accredits laboratories, *ISO/IEC 17025-2005 – General requirements for the competence of testing and calibration laboratories*[12], accredited laboratories are required to estimate the uncertainty associated with the results they produce (known as the measurement of uncertainty). Measurement of uncertainty data must be provided as part of the reporting of analytical results. This information will enable an appreciation of the variability in the analytical data and will assist in formulating evidence-based conclusions.

Furthermore, during validation testing, all equipment should be carefully selected and calibrated to minimise uncertainty. Measurements should be traceable to an independent standard where this is available.

Increasing sample sizes and using more accurate and precise measuring devices will typically reduce the gap between the conservative estimate that will provide the pathogen $\log_{10}$ reduction value and the best estimate.

In some circumstances, such as experimental studies, all data must be statistically valid and meaningful.

3.8 Determination of critical limits

A critical limit is a prescribed tolerance that must be met to ensure that a critical control point (CCP) effectively controls a potential hazard; it is a limit that separates acceptability from unacceptability.

Determining critical limits is essential to demonstrate that the system can be controlled to meet the required pathogen $\log_{10}$ reduction. Critical limits need to be established for operational monitoring parameters. They will be confined to the test operating conditions during the validation testing program. Therefore, the test operating conditions in the validation study should align with the expected field operating conditions for the scheme.

The critical limits will correspond to the point at which the treatment process is considered to be performing inadequately. The validated LRV will apply to the point at which the treatment process is operating within its critical limits.

All operational monitoring, critical limit alarms and corrective actions must be tested and verified by an independent third party.

Real-time monitoring, linked to an appropriate alarm-monitoring system and automatic shutdown, is required for all critical limits and must be available at all times. Any delay associated with critical limits, before shutdown, must be kept to a minimum, justified and specified in the plans and specifications.

3.9 Determination of $\log_{10}$ reduction value

The LRV that may be attributed to a treatment process unit is the lowest value of either:

- the lower bound validated LRV demonstrated during challenge testing, or
- the maximum LRV that can be verified by the operational monitoring technique specifically used to measure the efficacy of the treatment process unit to reduce the target pathogen (the sensitivity of the operational monitoring technique).

The LRV should be no more than 4.0 $\log_{10}$ for any unit process or process type, as indicated in section 2.

In most cases, the LRV attributed to a treatment process unit will be limited by the sensitivity of the operational monitoring technique.

3.10 Re-validation or additional onsite validation testing

Validation included in the RWQMP applies to the treatment process unit specified at commissioning. Re-validation or additional onsite validation testing may be required if there are design modifications to the validated treatment process unit (including critical system components such as UV lamps and membrane modules), control philosophy and operational monitoring parameters (including critical limits) that are inconsistent with documented validation test conditions.

Scheme proponents should discuss such modifications with the department to confirm the degree of re-validation required and the program for re-validation or additional onsite validation testing. Proposed modifications must be submitted to the department for endorsement.

4 Activated sludge processes

Data on pathogen reduction across activated sludge plants, both internationally and within Australia, is limited and it is therefore difficult to make any conclusive statements. However, observations from published and unpublished data include:

- Activated sludge processes differ markedly between plants and there is a wide range of designs.
- There is no consistent correlation between operational monitoring parameters and pathogen reduction between different plants [13].
- The log_{10} reduction data for pathogens is not consistently normally distributed from plant to plant and therefore it is difficult to draw reliable conclusions from a small sample size[13].
- The significance of seasonal variation is not well understood but can be marked in some plants[13].
- *Cryptosporidium* is typically removed less than *Giardia*. The data available suggests that typically a 0.5 log_{10} reduction can be achieved (lower fifth percentile value)[13-18].
- Virus studies are limited and where available focus typically on enteroviruses, although there is more recent data on adenoviruses. The data available suggests that a 0.5 log_{10} reduction can be achieved (lower fifth percentile value)[13]. The literature, although limited, shows that mean removals of greater than 1 log may be achieved [16, 17, 19-21].
- There is no ideal surrogate yet proven for viruses or protozoan parasites for all of the various types of activated sludge plants that are found[13, 16, 17, 21, 22].

Conditional evidence-based, rounded default pathogen LRVs for well-designed, managed and operated plants may be adopted. These default pathogen LRVs are:

- bacteria 1.0 log_{10}
- viruses 0.5 log_{10}
- protozoa 0.5 log_{10}.

In applying these default LRVs, while validation monitoring is not required, a risk analysis is still required to establish the CCPs and limits for the activated sludge plant based on optimal plant performance such as steady state biochemical oxygen demand (BOD), suspended solids (SS), dissolved oxygen (DO), ammonia and sludge age for the given temperature or season, sludge blanket levels and average dry weather flow (wet weather flows are considered outside the operating envelope for these default values). The monitoring of these parameters is consistent with a well-operated plant. Refer to section 4.3.

Request for information

Do you have site-specific pathogen data from activated sludge plants that either supports or contradicts the application of these default LRVs?

4.1 Pre-validation preparation

The performance of individual activated sludge plants for pathogen reduction is highly variable and therefore direct validation of performance should be undertaken if LRVs greater than the default values are sought.

Key mechanisms of pathogen reduction in activated sludge processes include adsorption of pathogenic microorganisms to suspended solids, removal of solids (with adsorbed pathogens) and predation. There is uncertainty on which process variables influence pathogen reduction and to what extent they achieve this. In the absence of scientific certainty these guidelines identify several characteristics that may influence pathogen reduction and therefore should be included in the validation test program. The approach may be refined in time as more data becomes available.

It is important to understand pathogen reduction under poor plant operating conditions and include such events that give rise to these conditions within the risk management framework (such as HACCP). At a minimum, the key events that should be addressed through the framework are identified in Table 3. The framework should confirm the validation test program and subsequently underpin the operational monitoring parameters for the scheme. It is important that these operational monitoring parameters are tracked concurrently with the microbial sampling program, so that the operating conditions at the plant during the validation period can be determined.

Table 3: Factors that may influence the efficacy of pathogen reduction*

Factors that may influence the efficacy of pathogen reduction	Indicative operational conditions for the validation test program (expected worst-case limit) Subject to confirmation by risk management framework
Loss of mixed liquor in activated sludge reactor – reduced pathogen-solids adsorption leading to reduced removal rates and loss of predation	• mixed liquor suspended solids (MLSS) concentration in reactor – low • Sludge age – low
Loss of aeration in activated sludge reactor – reduced pathogen-solids adsorption and poor sludge settling as well as impact on nitrification	• Dissolved oxygen concentration – low • Ammonia concentration – high
Mixed liquor settling characteristics	• Sludge volume index (or equivalent) – low
Sludge bulking (mixed liquor does not compact or settle well, and floc particles are discharged in the clarifier effluent)	• Sludge blanket level – high • Suspended solids concentration – high
Sludge rising in clarifier caused by denitrification, resulting in pathogen carryover	• Sludge blanket level – high • Suspended solids concentration – high
Sludge foaming caused by filamentous organisms, resulting in pathogen carryover	• Suspended solids concentration – high
Peak flow events – loss of mixed liquor from reactor and clarification failure (not relevant if recycled water is bypassed)	• Flow (or hydraulic retention time) – high flow or low HRT • MLSS concentration in reactor – low • Sludge age – low • Suspended solids concentration – high
Seasonal variation and sewerage catchment characteristics including trade waste inputs impacting on biomass and adsorption capacity	• MLSS concentration in reactor – low • Temperature – low and high • Salinity – high • pH – low and high
Enhanced adsorption via coagulant dosing	• Coagulant dose rate (failure or suboptimal)

*These factors are based on the literature. For further information refer to [23-31].

4.2 Validation monitoring

4.2.1 Microbial surrogates and indicators

Microorganisms or surrogates that must be monitored for site-specific validation are provided in Table 4.

Table 4: Microorganisms or surrogates for validation monitoring of the activated sludge process

Pathogen group	Target microorganism	Minimum samples[1]
Viruses	Enteroviruses and adenovirus (unless it can be demonstrated that one virus is less removed than another) by cell culture or quantitative polymerase chain reaction (QPCR)	20 evenly time-spaced paired grab samples over a 12-month period or intensive monitoring during worst-case seasonal/diurnal period (if known, must be based on evidence). Triplicates samples are recommended to avoid 'negative' $\log_{10}$ reductions.
Protozoan parasites	*Cryptosporidium*	
Bacteria	Pathogenic *E. coli*	

Note 1: 20 samples have been adopted as the default minimum to define the fifth percentile value.

4.2.2 Monitoring program

Samples should be collected for the activated sludge treatment step only; therefore, the samples are collected from influent to the activated sludge plant and its effluent. Grab samples should be collected. In pairing samples, the effluent sample should, wherever possible, be taken from the same body of water from which the influent sample was taken. This requires an understanding of the hydraulic retention time (HRT) in the activated sludge system. It is important that the paired samples reflect the performance of the system at a point in time: it would be inappropriate to pair samples that were taken under differing operational conditions or diurnal conditions.

For each sampling event, triplicate sampling is required to achieve statistical robustness and to assess standard deviations. Sampling events should occur across summer and winter months because seasonal variations to parameters such as temperature (which may affect biological activity), nitrification and MLSS may impact on the reduction of pathogens. Sampling should be conducted within the proposed operating envelope where recycled water will be supplied, that is, not for bypass conditions if recycled water is not supplied during this time. Sampling events should also be conducted across the range of sludge ages that the plant operates under, which may also represent summer and winter regimes.

The validation monitoring program must provide details on all monitoring parameters (including microbial surrogates and indicators, and operational parameters), where they will be sampled, at what frequency, which analytical methods will be used and what quality assurance procedures will be applied.

The operational monitoring parameters identified by the risk assessment framework must be monitored concurrently with the microbiological sampling program.

4.2.3 Data analysis

The LRV must be calculated as the fifth percentile of the paired $\log_{10}$ reductions based on the average of triplicate samples. The fifth percentile is adopted since there is limited data to establish a correlation between operational monitoring and pathogen reduction and the effects of season and plant performance are unlikely to result in a normal distribution of LRVs.

4.3 Operational monitoring

Operational monitoring should be in line with the operating envelope to which the LRV has been attributed. Consistent with what already occurs at well-managed activated sludge plants, ongoing monitoring of performance and management (as identified in the risk management framework) is expected for:

- online measures of activated sludge and clarifier performance such as turbidity, flow and dissolved oxygen
- regular observations of clarifier performance such as sludge settling supplemented with SVI quantification (or equivalent)
- regular quantification of activated sludge properties such as MLSS concentrations.

Critical limits need to be set on key parameters identified by the risk assessment, such as DO, turbidity, sludge blanket depth, flow, ammonia and sludge age.

Unlike discharge licences, performance would need to be continuous since pathogens present an acute risk – this means 100 percentile plant performance targets rather than median or 90 percentile values.

5 Media filtration

The data on pathogen removal by granular-multimedia filtration is highly variable. It is very difficult to accurately predict pathogen removal by media filtration based on design specifications or extrapolations or interpolations from the literature. Furthermore, performance cannot be assessed with confidence based purely on turbidity and particle counts. Media filtration types differ markedly in terms of the media and coagulants used, the process configuration and the operational conditions applied. Most data on performance of media filtration comes from drinking water studies yielding very low filtered effluent turbidity levels that are not typically achieved in wastewater filtration.

Studies on relationships between surrogates and pathogens are limited, although observations from the literature indicate:

- the relationship between phage and enteric virus removal is inconsistent [16, 17, 32, 33]
- while microspheres and some bacteria show potential as surrogates of parasite removal, they are not conservative surrogates in all situations[34-40]
- relationships can be highly dependent on coagulation regime, how the system is operated and system configuration[32, 34, 36, 41, 42]
- there is a need to first confirm the adequacy of surrogates for the specific filtration system and coagulant regime before using those surrogates for the validation study[34, 38-40]
- particle counts and turbidity do not aid in quantitatively assessing pathogen removal, however, together with a combination of other tools, may serve as useful indicators of filter performance[16, 33, 39, 43-45]

5.1 Pre-validation preparation

Media filtration may comprise the following.

- Chemical coagulation followed by flocculation, sedimentation, granular-media filtration. Under this approach the flocculation and sedimentation process provides significant removal of particles prior to the actual filtration. Filtration then provides additional polishing and particle removal but may not be the key removal step.
- Direct filtration where a low dose of coagulant (such as alum with anionic polymer for assisting flocculation) is injected into the filter feed line just ahead of the filter, coupled to a static in-line mixer. Under this approach particle removal occurs within the filter bed, resulting from the gradual increase in size of micro-flocs as they travel into the bed. Provided large flocculated particles are not formed before reaching the filter bed (causing rapid headloss), the progressive size growth process of the flocculated particles assists removal without premature particle breakthrough.

The mechanisms for removal of particles within a granular-media filtration are relatively complex and will vary depending on the characteristics of the particles and the filtration. Mechanisms may include:

Straining – particles larger than the water passages through the filter media are filtered out of the flow streams. Straining is believed to become significant when the ratio of particle size to media size is greater than 0.2 and straining can be the dominant mechanism for particle sizes above 100 µm.

- Adsorption – particles smaller than the water passages in the filter are removed by adsorption processes, either on the filter media or already absorbed particles. Attachment depends on the particles colloidal stability and the attachment forces (effective particle destabilisation through coagulation). Under most conditions, transport is not considered rate limiting and therefore attachment determines removal efficiency.
- Sedimentation – particles deviate from fluid streamlines and settle out in the localised spaces in the filter bed. This mechanism is particularly important for particles with a density significantly greater than water.
- Impingement/impaction – particles impinge on the surfaces of the media through inertial force.
- Coagulation/flocculation – particles modified by the added coagulant and flocculant coagulate with the filter media or form larger flocculated particles and are removed from the flow streams.
- Interception – a transport process defined as those particles that remain in fluid streamlines but pass within a distance of the filter media of half the particulate diameter. The significance of interception for filtration increases as particle size increases.

- Diffusion – Brownian motion resulting in deviation from fluid streamlines.

Principal influencing factors and failure modes that prevent or inhibit treatment performance may include:

- changes in hydraulic flow rate – large changes in flow rate can cause deterioration of filtered water quality by the detachment of previously retained particles
- suboptimal chemical pre-treatment during coagulation and flocculation (due to variation in feedwater, coagulant quality and dose, compromised floc formation and transfer onto media)
- breakthrough due to filter head loss (breakthrough of several $\log_{10}$ units have been reported in the early stages of filter head loss) [36, 42]
- deterioration of pathogen removal during vulnerable periods of operation such as end-of-run filtration
- placing filters offline and online without backwashing
- in addition to particle size and particle size distributions, important influent particle characteristics that influence filter performance include floc strength and suspended solids concentrations. This is largely influenced by the mean cell residence times in the biological process[46]. If the floc strength is weak, there is a stronger tendency for the floc particles to be sheared and carried through the filters.

A HACCP analysis should support the selection of operational monitoring parameters for factors that affect the efficacy of the media filtration process. These operational monitoring parameters must be monitored concurrently with the microbial monitoring program. The limits experienced during validation monitoring will define the operating envelope.

The HACCP analysis should also consider chemical risks from trade waste inputs that may affect process performance, and how these events will be identified and controlled.

5.2 Validation monitoring

Validation of media filtration should be undertaken on a full-scale unit. Pilot scale may only be used to establish a correlation between pathogens and potential surrogates.

Direct performance testing should occur under conditions representative of filter performance. Factors such as flow rates and chemical pre-treatment should be included in performance evaluation, while consideration should also be given to filter ripening, steady state operation, end-of-run cycle and breakthrough. The management plans for Class A plants involving granular-media filtration should consider the following, within the HACCP framework:

- control over chemical dosing to ensure optimal conditions (based on direct testing such as jar tests and online instrumentation rather than theoretical predictions)
- the operating conditions for the upstream treatment processes that may influence filter performance (such as mean cell residence time for activated sludge plants)
- wasting of filtrate during ripening, if necessary (taking into account likely substantial differences in $\log_{10}$ reductions between ripening and stable operation)
- an ongoing direct testing/verification program to ensure estimated removals continue to be achieved.

The validation study must demonstrate that the filtration process can be tightly controlled.

5.2.1 Microbial surrogates and indicators

Microorganisms and surrogates that must be monitored for site-specific validation are provided in Table 5.

Table 5: Microorganisms and surrogates for validation monitoring of media filtration

Pathogen group	Target microorganism	Microbial indicators
Protozoan parasites	*Cryptosporidium*	Indigenous or seeded *Cryptosporidium* oocysts. Indigenous or seeded *Clostridium perfringens* or yeasts may be used as a surrogate. It must be demonstrated, however, that *Clostridium* spores or yeasts do not overestimate oocyst removal. This relationship may be demonstrated at the pilot scale. Seeded formalin-inactivated oocysts may be used as a surrogate for *Cryptosporidium* in spiked-challenge studies provided differences in oocyst zeta potential prior to coagulation do not impact on overall coagulation chemistry.
Viruses	Enteroviruses (encompassing polioviruses, coxsackieviruses, echoviruses, enteroviruses) It should be noted that very few viruses have been investigated	Indigenous or seeded enteroviruses and somatic or FRNA bacteriophage. Indigenous somatic or FRNA bacteriophage, or seeded MS2 bacteriophage, may be used as a surrogate. However, it must be demonstrated that phage do not overestimate viral pathogen removal. This relationship may be demonstrated at the pilot scale.
Bacteria	Pathogenic *E. coli*	Indigenous or seeded *E. coli*

5.2.2 Monitoring program

The monitoring program should characterise the performance of the media filtration system during all stages of the filter cycle including during vulnerable periods of operation such as suboptimal coagulation (poor floc formation), end-of-run filtration and late breakthrough.

The recycling of untreated backwash water may constitute a significant source of pathogens[47, 48]. Where recycling of untreated backwash water occurs (such as when returned to the head of works), the additional pathogen load needs to be accounted for in the treatment process train.

Samples should be collected, representing the coagulation and media filtration step; therefore, at a minimum, samples are collected from the influent to the coagulation dosing unit and media effluent stream. Samples should also be taken from the backwash water. Additional samples after a coagulation/flocculation/sedimentation process step could inform the significance of the pre-treatment step versus filtration process for pathogen removal and therefore tighten management controls and operational monitoring.

The validation monitoring program must provide details on all monitoring parameters (including microbial surrogates and indicators, and operational parameters), where they will be sampled, how frequently, which analytical methods will be used and what quality assurance procedures will be applied. Operating parameters must also be monitored concurrently and recorded to show the operating envelope within which the LRV can be attributed. These operating parameters must characterise the performance of the coagulation/flocculation system and media filter. The operating parameters include, but are not limited to:

- coagulant type, dose rate, jar testing (to optimise the dosing regime), floc strength, zeta-potential (or equivalent), mixing speed and hydraulics of the coagulant dosing system
- temperature, organic content, pH, alkalinity and ammonia levels
- filtration rates and run times, head loss and backwash rate
- suspended solids, turbidity and particle size and distribution (influent and effluent).

The sampling program for indigenous organisms is provided in Table 6. Where spiked-challenge tests are conducted, the sampling protocol must be designed to ensure that spiking does not overestimate the $\log_{10}$ reduction demonstrated.

Table 6: Sampling program for microorganisms removed during media filtration[1]

Period	Sampling event[2]	Filter cycle				
		Ripening[4]	Stable	End of run	Early breakthrough[4]	Backwash[3]
Over extreme seasonal periods (winter and summer) or intensive monitoring for worst-case seasonal/diurnal period (if known, must be based on evidence).	Number of paired samples per filter cycle (total for triplicates as recommended to avoid 'negative' $\log_{10}$ reductions).	3 (18)	3 (18)	3 (18)	3 (18)	1(3)
	Number of filter cycles (non-consecutive days)	6	6	6	6	6

Notes:
1. Concurrently monitor operational parameters.
2. Grab samples rather than composite to avoid impact of interfering factors.
3. Monitoring backwash to demonstrate that backwash operation is effective at removing microorganisms from the filter media.
4. Number of paired samples per filter cycle may be reduced to one sample if it can be demonstrated that controls for filter to waste are reliable during the ripening period and that a conservative approach to early breakthrough is adopted (such as filter to waste prior to turbidity levels increasing).

5.2.3 Data analysis

If the validation monitoring program demonstrates that the coagulation and media filtration system is robustly controlled, then the LRV may be calculated as the lower fifth percentile of the paired $\log_{10}$ reductions.

5.3 Operational monitoring

As there is no one ideal surrogate or indicator of pathogen reduction and filtration performance, it is necessary to use a combination of tools to monitor the performance of the coagulation/flocculation and filtration process.

The management controls and operational monitoring should be in line with the operating envelope to which the LRV can be attributed. These should comprise the following.

- A robust monitoring strategy of the coagulation process to provide continuous assurance that optimal coagulation is achieved. For example, floc formation using jar testing, an online zeta-potential meter or streaming current detector (or equivalent), mixer speed (if appropriate), hydraulics, pH, daily ammonia, temperature, alkalinity, and organic content[49]. Refer to the *Practical guide to the optimisation of chemical dosing, coagulation, flocculation and clarification*[50].
- Establishment of filter run profiles to determine the extent of ripening periods when pathogen removal is compromised, filter run times, filter breakthrough and terminal headloss. Establishment of adequate backwash protocols based on clarity of the backwash water and adequate expansion of the fluidisation of the media. Appropriate management of backwash process and monitoring for determining backwash sequence.
- Adequate filter-to-waste times.
- Monitoring of suspended solids, turbidity and particle size and distribution (influent and effluent).

The operational monitoring program should be supported by a verification monitoring program that includes weekly monitoring of phage and *E. coli* of the filter effluent. The concentrations measured during the validation monitoring program may form the basis for setting investigation trigger levels for operational monitoring.

6 Membrane filtration

Membrane filtration processes include microfiltration (MF), ultrafiltration (UF), nanofiltration (NF) and reverse osmosis (RO). Membrane module configurations include:

- hollow-fibre modules to accommodate MF or UF membranes
- spiral-wound modules to accommodate NF and RO membranes
- tubular modules for porous (MF/UF), semi-permeable (NF/RO) membranes and ceramic MF/UF systems
- plate-and-frame configurations containing a series of flat sheets.

The most authoritative guidance on membrane filtration is the US EPA's *Membrane filtration guidance manual* (MFGM)[4]. The validation of membrane filtration systems must be consistent with the approach described in the MFGM. This chapter describes key components of the MFGM and must be read in conjunction with the MFGM.

Membrane validation involves three complementary approaches. These approaches are used in combination as they each have inherent limitations and therefore, in isolation, they do not provide effective performance monitoring. The three approaches are:

- **Challenge testing:** required to demonstrate the capability of the membrane to reduce the target pathogen concentration. Challenge testing provides the most meaningful measure of pathogen removal performance but is not suited to frequent testing and therefore does not provide timely detection of integrity failures.
- **Direct integrity testing:** can provide a sensitive, direct measure of membrane integrity when undertaken on a daily basis. The most common example is the pressure hold test. Direct testing can be highly sensitive for detecting membrane integrity failures, but while it can be undertaken relatively regularly, it does require the relevant membrane modules to be taken out of service during testing. It therefore does not provide a 'real-time' measure of integrity.
- **Continuous indirect integrity testing:** must be available to provide a real-time measure of integrity. For membrane filtration the indirect approaches traditionally use surrogate parameters such as particle counts or turbidity. The weakness of indirect methods is that they are not typically as sensitive as direct integrity testing or challenge testing. They therefore provide a relatively crude measure of performance and may only detect gross failures of integrity.

The maximum reduction value that a membrane filtration system may receive is the lower of the:

- maximum LRV demonstrated during challenge testing, or
- maximum LRV that can be verified by an integrity test under normal plant operation.

Pre-validated membrane modules are acceptable provided the validation testing conditions are representative of in-situ conditions (refer to section 6.2).

The validation report must include:

- specifications on the membrane module
- challenge test protocol consistent with the MFGM approach
- challenge test results for intact membrane modules.

Section 3.13.3 of the MFGM provides an outline for a challenge test report.

Critical limits for the direct integrity test and continuous indirect integrity monitoring must be validated. These critical limits represent a threshold response which, if exceeded, indicates a potential integrity problem. Corrective actions must be initiated if the critical limits are breached. Validation includes demonstration of the resolution and sensitivity of the direct integrity test, and evidence showing the correlation between continuous indirect integrity monitoring with membrane integrity.

6.1 Pre-validation preparation

Prior to undertaking challenge testing, a HACCP analysis should be undertaken to identify parameters and operational controls that influence or indicate process effectiveness (and pathogen reduction). It is important that these operational controls and parameters are monitored concurrently with the sampling program, so that the operating conditions at the

plant during the validation period can be accurately characterised. Factors that influence the efficacy of the membrane filtration process to reduce pathogens may include:

- chemical or physical processes (such as coagulation and flocculation)
- feedwater quality characteristics (clean water versus secondary effluent)
- filtration cycle – membrane ripening, fouling, backwash and chemical cleaning procedures
- membrane module, hydraulic configuration and mode of operation
- integrity of the membrane filtration unit as a whole, including membrane media and structure, glue lines, interconnectors/end-cap O-rings, pipework flanges, valves and instrument seals
- operational constraints (such as flux, transmembrane pressure and temperature).

The HACCP analysis should also identify the risks from chemical inputs to the source water that may affect process performance.

Table 7: Failure modes, management controls and research needs

Failure mode	Potential causes	Issues	Management controls
Deterioration of membrane material	Influent water quality Chemical attack Abrasion Enlargement of pores Lack of quality assurance during manufacturing process Inappropriate storage practices Off-specification pre-treatment chemicals	The effect of membrane deterioration on virus removal has not been studied. Evidence is needed on the performance of membranes for virus removal over the operational life of a membrane system that is treating wastewater and subjected to frequent backwashing and chemical cleaning.	Install oxidation-reduction potential (ORP) meters online. The ORP meters will be able to detect chemicals exceeding the design threshold and allow corrective actions to divert water and minimise deterioration of the membrane. Perform routine monitoring (weekly) of the membrane filtrate stream for FRNA bacteriophage. Implement quality assurance procedures for manufacturing, chemical handling and storage of membranes.
Membrane integrity failure such as pinholes, broken fibres, cracked/twisted/leaking O-rings, mechanical seals, glue lines or de-lamination	Lack of quality assurance during manufacturing, transport, commissioning and storage Membrane type and configuration (glue-lines, internal fibre diameter thickness, mode of operation) Influent water quality Surge loadings	Evidence is needed on the frequency of integrity failures in membrane filtration systems used in wastewater treatment.	Perform direct integrity test (DIT). Perform routine monitoring (weekly) of the membrane filtrate stream for FRNA bacteriophage. Undertake periodic microbial virus challenge studies (annually). Ensure design and operation complies with manufacturer's specifications. Prevent de-lamination of RO and NF membranes through good design and operation to minimise backpressure during start-up and shutdown and minimise concentration polarisation.

Request for information and research:

Research to identify a reliable and practical direct integrity monitoring technique for virus reduction in membrane filtration processes is needed.

Manufacturer guarantees underpinned by fault analysis using site-specific data on membrane filtration performance in wastewater.

6.2 Validation monitoring

6.2.1 Microbial surrogates and indicators

Surrogates and indicators used for the challenge study must be consistent with those identified in section 3.9 of the MFGM.

6.2.2 Monitoring program – challenge testing

Challenge testing is required to demonstrate the ability of the treatment process to reduce the target pathogens. Challenge testing must be consistent with chapter 3 of the MFGM. The core requirements for challenge testing are summarised in section 3.2 of the MFGM. If virus $\log_{10}$ reduction is sought, additional challenge testing is required on impaired membrane modules (refer to section 6.4).

Challenge testing must be undertaken at maximum operating flux and recovery and under representative hydraulic conditions (refer to section 3.11.2 of the MFGM).

In some instances it may be necessary to re-validate membrane modules. For instance, if a validated membrane module has been modified, resulting in changes to the fundamental characteristics of the module, the removal efficiency and/or the DIT results and the associated quality control release value (QCRV) (refer to section 3.14 of the MFGM).

For the purposes of challenge testing, the number and the particular modules should be selected on a scientifically defensible basis, taking into consideration the manufacturing variability in the product line and quality control and assurances procedures in place. Two common approaches to module selection discussed in the section 3.7 of the MFGM are:

- selection of modules based on previously collected QCRV for the product line
- random sampling of membrane modules from several manufactured lots according to a statistical sample design.

Previous challenge testing studies have demonstrated that variability does exist between membrane modules. Therefore, notwithstanding the above, at least five membrane modules from different manufactured lots must be evaluated during a challenge test.

The sampling protocol for each module (under worst-case operating conditions) should comprise the following process:

- take three samples (of the influent and permeate) immediately after clean in place (CIP), at mid-filter run and at the end of the filter run (five minutes, 20 minutes, 30 minutes after CIP) – refer to Table 8 .
- take a blank sample of the feed and permeate
- spike a sample of the feed and permeate (any die-off of surrogates in these samples would indicate the presence of an oxidant residual).

Prior to undertaking the challenge test, each module must be subject to a DIT. Furthermore, the modules must be flushed and sampled to ensure that no disinfectant residual is present.

Table 8: Sampling program for membrane filtration module

Sampling event	Immediately after clean in place (CIP)	Mid-filter run	End of filter run
Number of paired samples in–out of each module	3	3	3

6.2.3 Data analysis

A single LRV is calculated for each module tested. The overall removal efficiency demonstrated during challenge testing is called $LRV_{C\text{-}test}$. The approach to determining the LRV results is as follows:

- If fewer than 20 modules are tested, then the lowest of all representative LRVs is assigned as $LRV_{C\text{-}test}$.
- If more than 20 modules are tested, then the $LRV_{C\text{-}test}$ is assigned a value equal to the 10th percentile of the representative LRVs.

6.3 Operational monitoring

To provide an effective barrier against particulate and microbial contaminants, the membrane filtration system must be free of defects and leaks that could result in an integrity breach. If membrane integrity breaches occur, it is essential that operators have the ability to demonstrate the integrity of the barrier on an ongoing basis.

The minimum requirements for operational monitoring include:

- direct integrity test on each membrane filtration unit (given that Class A recycled water applications result in potentially high exposures to public health, the required test frequency is daily)
- diagnostic testing
- online indirect testing (such as turbidity or particle counting) of the filtrate from each membrane unit must be undertaken at a minimum frequency of 15 minutes (refer to section 5.5 of the MFGM)
- monitoring of operational parameters as per the validated operating conditions (such as flux, transmembrane pressure and temperature).

6.3.1 Direct integrity tests

Direct integrity testing is a critical component of membrane performance monitoring because it represents the most reliable and accurate means of demonstrating the integrity of an operational membrane filtration system.

Detailed guidance for establishing direct integrity tests is given in chapter 4 of the MFGM.

The guidance requires that direct integrity tests meet the following specified criteria.

- Resolution: Resolution is the smallest integrity breach (leak or breakage) that generates a measurable response from a direct integrity test. The resolution criterion is based on the size of the target organism, which in the case of the US EPA LT2ESWTR[51], is based on 3 µm, the lower size range of *Cryptosporidium* oocysts.
- Sensitivity: The maximum LRV that can be verified by the direct integrity test. A test control limit is established for the membrane that reflects the target $\log_{10}$ removal. Should the results of the direct integrity test exceed the control limit, the affected membrane unit would need to be shut down for diagnostic testing and repair.

A more detailed discussion of these criteria follows below, focusing primarily on pressure-based testing. The resolution and sensitivity are site- and system-specific and therefore cannot be accurately quantified until the full-scale system is commissioned. The calculations for test resolution (required test pressure), test sensitivity (LRV_{DIT}) and corresponding upper control limit (UCL) must be worked through and included in the RWQMP.

It is important to ensure that the membrane unit is engineered and fabricated to high tolerances, particularly with respect to air leakages. Valves, flanges and other gland seals need to be airtight in order to ensure the air-pressure-based integrity test has sufficient sensitivity.

Test resolution

The minimum applied test pressure necessary to achieve a resolution of 3 µm is given by equation 4.1 in the MFGM.

To calculate the minimum test pressure, conservative default values for the pore shape correction factor (κ=1) and the liquid-membrane contact angle ($\theta=0^{o}$) are provided in the MFGM. The use of a value other than the default values provided in the MFGM should be scientifically justified, for example, through independent third-party testing using a method accepted by the scientific community and demonstrating statistically significant data.

In relation to the liquid-membrane contact angle, a value other than the default value must be supported by data demonstrating that the contact angle is maintained throughout the life of the membrane. The data must be specific to the membrane module under consideration and be representative of in-situ operating conditions (such as CEB and backwash regimes and feedwater characteristics).

The surface tension at the lowest anticipated water temperature should be used to calculate a conservative value for the minimum required test pressure.

The maximum backpressure on the system during the test must be accounted for in equation 4.1.

Test sensitivity

The test sensitivity must be determined on a case-by-case basis using the information provided by the membrane manufacturer and the equations in the MFGM.

The MFGM describes a general procedure for experimentally determining the threshold response of a pressure-based direct integrity test if this information is not available from the manufacturer. This procedure requires intentionally compromising system integrity in small, discrete and quantifiable steps, and monitoring the corresponding integrity test responses. Compromises include generating a hole in the membrane using a pin of a known diameter or cutting a hollow fibre at a predetermined location. Fibre breakages at the filter–pot interface will typically provide the most conservative case for calculating Q_{breach} because it provides the shortest flow path for feed to enter the filtrate.

Control limits

A key step in the practical application of integrity testing is the establishment of control limits that indicate a potential integrity issue and trigger appropriate actions (refer to section 4.5 of the MFGM). A mandated control limit is called an upper control limit (UCL). If the direct integrity test result exceeds the UCL, this will trigger a membrane unit being taken offline for diagnostic testing and repair.

The supervisory control and data acquisition (SCADA) system should be programmed to calculate the LRV based upon the results of the most recent integrity test results and current operating conditions. These parameters should be displayed and trended to track system performance.

6.3.2 Diagnostic testing

The MFGM provides a summary of the diagnostic tests that can be utilised to physically identify and isolate integrity breaches. Standard operating procedures (SOPs) for identifying and isolating integrity breaches must be implemented. Following any repairs to membrane modules, SOPs should include initiation of a DIT prior to bringing membrane modules back online.

6.3.3 Indirect integrity testing

Continuous indirect integrity testing uses water quality parameters such as particle counting and turbidity as a surrogate measure of membrane integrity. Control limits must be established for the indirect integrity parameters. These control limits are used as a general indication of the presence of an integrity breach to the system, rather than a definitive measure of performance. A DIT must be initiated if the performance-based control limits for the indirect integrity test are breached.

The critical limit established for the indirect integrity testing should be verified during the commissioning process. Notwithstanding this, the critical limit established for turbidity must not exceed the default control limit of 0.15 nephelometric turbidity unit (NTU) established in the MFGM under the LT2ESWTR. The basis for the 0.15 NTU limit is that integral membrane plants consistently achieve less than this value.

6.4 Application of membrane filtration for virus removal

This discussion applies to ultrafiltration and microfiltration systems and is limited to hollow fibre configurations. Where microfiltration systems are aided by coagulation, additional requirements for validation monitoring apply as per section 6.4.1.

The most significant factor limiting the virus LRV that may be attributed to a membrane relates to the fact that there is no direct integrity monitoring technique able to detect a virus-sized integrity breach during operation. These virus-sized integrity breaches, while not as common as broken fibres, may occur as the membrane ages or as a result of degradation due to exposure to incompatible treatment chemicals. The inherent feedwater characteristics of wastewater and the need for more frequent and rigorous cleaning regimes may increase the potential for virus-sized integrity breaches.

The application of membrane filtration for virus removal needs to be holistic, taking into consideration: quality assurance in manufacturing, installation and operation; preventive maintenance schedules; challenge studies on intact and impaired modules; utilising existing integrity monitoring techniques; and ongoing challenge studies. Table 7 identifies management controls and research needs to establish confidence in the capability of membranes to reduce virus concentrations.

The approach developed for attributing virus LRVs to a membrane is described below.

- *Step 1: Conduct challenge testing on intact and impaired membrane modules.*

  Challenge tests using MS2 bacteriophage must be conducted on both intact and compromised membrane modules in the manner described above and in the MFGM. The impaired membrane integrity studies should reflect 'worst-case' defects that would result in significant virus breakthrough.

  For instance, most impaired integrity challenge studies are based on fibre breaks at the filter–pot interface. This is considered the most conservative case because it provides the shortest flow path for contaminated feed to enter the filtrate.

  It is acknowledged that this approach has limitations in that it only considers modes of failures such as broken fibres and not the gradual deterioration of the membrane surface itself.

  Step 2: Compare the results of the challenge test for the intact membrane modules with the fibre's pore size distribution.

  The membrane module supplier is required to provide a pore size distribution for the membrane fibre so that the virus removal determined by the intact module challenge testing is consistent with expectations based on comparison of whether MS2 bacteriophage particle size falls relative to the distribution (maximum of 2 per cent of pores are greater in size than MS2).

- *Step 3: Correlate the sensitivity of the DIT (the LRV_{DIT}) to the challenge test results for the impaired membrane modules.*

  If the resulting bypass flow of air or water from the compromised membrane module exceeds the UCL, then the minimum virus LRV demonstrated during the impaired membrane challenge test may be attributed to the membrane module.

  The following example is provided by way of illustration. A challenge test using MS2 bacteriophage on a membrane module with one broken fibre resulted in a minimum LRV of 2.5. The challenge test conditions were consistent with the operating conditions of the scheme under consideration. The bypass flow of air resulting from the impaired membrane is 500 L/hr. The UCL for the membrane system comprising 50 modules was calculated as being 250 L/hr. Since the UCL established for the 50 module system is less than the resulting bypass airflow through the impaired membrane, the membrane filtration system is attributed with a virus LRV of 2.5.

- *Step 4: Establish the integrity of modules in a product line that are not subject to challenge testing.*

  For membrane modules not subject to challenge testing, the MFGM recommends that a destructive performance test, such as a scanning electron microscopy analysis of the membrane media to confirm the pore size distribution, must be conducted on a statistically significant number of modules in each production lot.

- *Step 5: Conduct challenge testing annually.*

  Annual challenge testing is required using either seeded MS2 bacteriophage or indigenous FRNA bacteriophage to confirm ongoing virus reduction by the membrane.

  This requirement is in recognition of the limitations of current membrane integrity test methods in detecting minute breaches of membranes (for example, deterioration of the membrane surface over time through chemical cleaning and backwashing) that may allow virus particles to pass through the membrane.

  The annual challenge testing can be conducted on the 'worst-case' modules, if that is more expedient or cost effective than undertaking bacteriophage testing on the full membrane system. The 'worst-case' module selected for the challenge study must have the worst-case record of integrity during the prior 12 months and have been subjected to the most backwashes, chemically enhanced backwashes and clean in place.

  The challenge test must be conducted according to the MFGM and be undertaken under the most conservative operating conditions experienced during full-scale operation, such as low turbidity feedwater, maximum flux and recovery, and immediately after a CIP. The protocol for the annual challenge testing should be included in the RWQMP.

  Furthermore, the pore size distribution of a fibre from those modules selected for the annual challenge testing should be compared with the results from step 2 to determine if the pore size distribution changes with operation.

- *Step 6: Routinely monitor the membrane filtrate.*

  FRNA bacteriophage testing of the membrane filtrate must be undertaken weekly. An increase in bacteriophage concentrations in excess of background levels (such as > 1 FRNA bacteriophage/L) for an intact membrane filtration unit would suggest that the target LRV is not being achieved. Where the background concentration is exceeded, immediate retesting of filtrate and influent levels should be undertaken. Should the results indicate the target virus LRV is not being achieved the unit should be immediately taken offline.

Table 9 provides an example of how control limits are incorporated into an operating procedure for a membrane filtration process.

Table 9: *Example* of operational monitoring procedure for membrane filtration*

Critical control point **Ultrafiltration unit**					
Process inputs	Ultrafiltration membrane units are designed to reduce effluent suspended solids, effluent turbidity and effluent pathogens. Inputs include wastewater and chemicals for treatment				
Hazards and hazardous events	Microbiological (pathogens) breakthrough due to deterioration of membrane surface or integrity failures, for example, broken fibres, twisted or cracked O-rings, incorrect installation or bypass through valves Microbiological recontamination due to maintenance works or incorrect operation of the UF process				
Control measures	Quality assurance test procedures during manufacturing, transport, installation, commissioning, operation and maintenance; this includes checking that algorithms in the programmable logic controller are configured correctly, set points and limits are correct and corrective actions and interlocks work Pre-treatment, for example, pre-filtration and coagulation upstream of the UF membranes to facilitate the removal of particles Compliance with the manufacturer's specifications for cleaning and backwashing Quality assurance procedures for chemicals used in the treatment process HAZOP and quality assurance procedures to ensure instrumentation is configured correctly at all times and, specifically, post maintenance. Ensure up-to-date as-built drawings Robust process control Regular calibration of instrumentation Regular testing of corrective actions Standard operating procedures for diagnostics and corrective actions Use of sanitary practices and QA procedures during maintenance				
Operational monitoring	Indirect integrity monitoring – filter turbidity and/or particle counting DIT – pressure-based test and MS2 challenge studies Oxidation reduction potential (ORP) meters on influent stream to detect chemicals that may lead to the deterioration of the membranes Design operational parameters – flux, transmembrane pressure				
	Filtrate turbidity	DIT (at 110 kPa test pressure for two minutes)	MS2 challenge test on pilot-sized test unit	ORP	Flux and trans membrane pressure (TMP)
Alert limits	> 0.015 NTU	< 4.0 LRV (equates to PDR > 8 kPa/min)	< LRV demonstrated by challenge study for intact system	-	-
Critical limits	Two consecutive readings >0.15 NTU	< 3.5 LRV (equates to PDR > 10 kPa/min)	< LRV attributed to the membrane system	As per validated condition and manufacturer's specifications	
Frequency	Continuous online (at a minimum frequency of once every 15 minutes) Each UF unit permeate	Daily on each duty unit or in response to elevated turbidity or particle counts Integrity test undertaken on standby unit before bringing into duty mode Each UF unit	Annually Select module from membrane unit showing the worst record of integrity during the prior 12 months and the most backwashes, chemically enhanced backwashes and clean in place	Continuous online	

Corrective action/s	Immediately initiate DIT	Alert: Isolate membrane modules; membrane diagnostic testing and repair as per preventive maintenance schedule Critical: Immediate shutdown of unit for membrane diagnostic and repair Conduct DIT prior to retuning online	Isolate unit and challenge remaining units. Notify the Department of Health	Conduct mini-challenge test to ensure the integrity of the membrane surface	Initiate plant shutdown
Verification and validation records	Ensure quality assurance processes are available for the entire product chain Identify all procedures relevant to this CCP including SOPs, calibration procedures and HACCP plan Maintain records providing evidence that all elements of the control plan are being implemented and that elements of the control plan are effective Monthly internal audit of records by management Annual independent third-party audit of the control plan				

* The numbers in this table are for illustration purposes only. These numbers have not been validated and would be site specific.

6.4.1 Additional requirements for microfiltration with coagulation for virus reduction

The MFGM notes that while microfiltration membranes can remove viruses, removal is generally attributed to cake formation or fouling on the membrane. The literature shows that removal rates can vary from 0 to 0.5 $\log_{10}$ with a clean membrane, through to 3.0 $\log_{10}$ with coagulation. This cake layer is removed during backwashing and therefore it is not a removal process consistent with the MFGM, which focuses on removal efficiency specifically of the membrane.

Notwithstanding this, microfiltration with controlled coagulation can be an effective barrier for viruses. Validation studies have demonstrated that robust design and control of the coagulation system is critical. Studies on microfiltration systems have shown that with suboptimal coagulation and poor hydraulic design the $\log_{10}$ reduction of viruses can be substantially reduced from 3.0 to 0.5 $\log_{10}$.

The validation program and operational monitoring for microfiltration with coagulation must consider the following.

- The coagulation process must be optimised in order to effectively produce stable flocs that will assist the combined filtration process to remove virus and protozoa. The optimisation of the coagulation process involves site-specific experiments that will identify the appropriate coagulation conditions (choice of coagulant, pH, alkalinity, flow rates, turbidity, mix time and intensity, dosing point)[50].
- Once the appropriate coagulant has been determined by completing site-specific experiments and the coagulation procedure has been optimised, an appropriate surrogate must be found for the challenge test. Independent expert advice is required when selecting an appropriate surrogate for challenge testing; the scientific literature suggests that there is no ideal surrogate for the coagulation-assisted microfiltration process.
- Validation monitoring must be conducted using worst-case operating conditions, taking into consideration seasonal variations and operational variations. Changes such as dissolved iron, ammonia levels, pre-chlorination, temperature, pH, alkalinity and dissolved organic content will all have an impact on the efficacy of the coagulation process.
- The sampling protocol for the challenge test should (refer to Table 10):
  - be conducted at full-scale
  - comprise three sample events in triplicate on each day of sampling.

  For each sample event, feed and product samples should be taken immediately after CIP and backwash, at mid-filter run and at the end of the filter run (five minutes, 20 minutes, 30 minutes after backwash and CIP).

Table 10: Example sampling program for coagulation-microfiltration validation

Operating conditions	Sampling event	Low fouling (after CIP)	Medium fouling	High fouling (before CIP)
Worst-case operating conditions (site specific)	Number of paired samples in–out	9	9	9
	Number of experimental days	Three days at operational limits (worst case) as informed by risk analysis (HACCP)	Three days at operational limits (worst case) as informed by risk analysis (HACCP)	Three days at operational limits (worst case) as informed by risk analysis (HACCP)

- The calculation of removal efficiency should be consistent with section 3.13.1 of the MFGM.
- Prior to undertaking the challenge test, each module must be subject to a direct integrity test. Furthermore, the modules must be flushed and sampled to ensure there is no disinfectant residual. Duplicate blank samples should be taken from the feed and permeate.
- Given the coagulation dependence of microfiltration to attain virus log_{10} removals, it is necessary to establish a robust monitoring strategy of the coagulation process to provide continuous assurance that optimal coagulation is achieved. Current management practices adopt the use of multiple approaches to coagulation control, thereby avoiding reliance on a single technique and providing protection against possible failures of one monitoring method. Management practices should comprise: online monitoring for pH; turbidity or particle counting of influent and filtrate; coagulant dose rates or levels; mixer speed; streaming current detectors or zeta potential meters; routine monitoring of ammonia, alkalinity, dissolved organics, jar testing and visual inspection of floc formation; and chemical quality assurances.

Research gap:

With regard to filtration processes assisted by coagulation, it has been suggested that the effect of coagulation differs for various viruses and that it may be unwise to extrapolate the data on viruses to other untested viruses.

Further research is required to better understand the relationship between viruses, surrogates and coagulation regimes.

A methodology to assist in the identification of an ideal surrogate based on site specific conditions is needed.

6.5 Reverse osmosis

Reverse osmosis (RO) technology is not an absolute barrier for pathogen removal and there are no currently available online direct integrity tests.

Integrity methods for full-scale high-pressure membrane systems (RO and nanofiltration) have been limited to electrical conductivity (EC) and total organic carbon (TOC) monitoring – approaches that can generally only assess pathogen removal up to 2 log_{10} (99 per cent). Therefore, ≤2 log_{10} is generally attributed to RO systems.

The validation of RO systems must be consistent with the US EPA MFGM.

Virus reduction by RO membranes does vary significantly. Important considerations include:

- mass transfer – diffusive contributions, solute transport and rejection and partitioning/adsorption
- properties of the pathogen – weight, size, structure, isoelectric point and hydrophobicity
- membrane properties – surface charge (zeta-potential) and hydrophobicity (contact angle)
- operational conditions (such as pressure, flux and recovery)
- feedwater composition (such as pH, temperature and DOC).

Pathogens could be recovered in the permeate of the spiral-wound RO membranes as a result of one or more of the following:

- defective interconnector/endcaps O-rings that isolate the feed from the permeate channel
- imperfections in the glue lines attaching membrane sheets or delamination of membrane sheets during operation
- the RO membrane structure.

A study by Lozier et al[52] showed good correlation between MS2 bacteriophage and the two non-biologic viral indicators, namely, Rhodamine WT (R-WT) and fluorescent microspheres, when used to indicate loss of integrity in spiral-wound, high-pressure membrane systems. The study concluded the following.

- The R-WT can be considered a practical surrogate for detecting imperfections in RO membranes relative to virus removal, however, is limited to a sensitivity of 4 $\log_{10}$.
- Fluorescent microspheres demonstrated very good correlation to MS2 bacteriophage with respect to both intact and compromised membranes and, as such, represent a more ideal surrogate than R-WT. However, more work is necessary to reduce the cost of production and analysis of fluorescent microspheres.
- Conductivity and/or TDS rejection cannot be used as an accurate predictor of viral passage. Intrinsic imperfections are not distinguishable using normal manufacturer's quality assurance/quality control 'wet testing', which simply measures per cent rejection of a salt solution.

6.5.1 Challenge testing

A challenge test on each skid using a molecular marker or MS2 bacteriophage is to be conducted at full scale because this will identify imperfections upon commissioning, as well as establishing the LRV. The challenge test procedure must be consistent with the MFGM and must consider the previous discussion in this section. The R-WT challenge test should be undertaken in accordance with the American Society for Testing of Materials International (ASTM) method D 6908-03[2].

The molecular marker (in this case R-WT) should have a negligible adsorption affinity for the membrane and other materials in use. A mass balance must be conducted on the feed, filtrate and concentrate streams to assess the potential for adsorption or other loss of the molecular marker.

The challenge test protocol must be submitted to the department for approval.

6.5.2 Operational monitoring

A direct integrity test method would ideally be a vacuum decay test or molecular-based marker; however these methods are not currently practical to implement during routine operation. These can be conducted at commissioning to ensure the integrity of the installed system.

Conductivity profiling is a common practice associated with RO systems to identify leaks in modules, O-rings and seals. Integrity breaches are identified by significant changes in conductivity. The limitations with conductivity profiling include:

- increased salt passage over time as a function of either an uncontrolled increase in membrane solute transport or a planned increase in system recovery or flow, parameters unrelated to the physical integrity of the membranes and their ability to serve as a barrier to particulate matter
- permeate conductivity (and other dissolved constituents) may vary with water quality parameters such as pH and temperature, factors that are likewise unrelated to membrane integrity
- change in the ion ratio – an increase in fraction of monovalent:divalent ions will increase conductivity because of the high rate of passage of monovalent ions.

Notwithstanding the above, given the absence of sensitive integrity test methods for RO membranes, EC (with daily normalised salt rejection) and TOC will be accepted as means of indirect integrity monitoring. However, the LRV attributed to the RO membrane system for pathogen removal will be limited to the sensitivity of the EC or TOC monitoring.

The control philosophy for integrity monitoring of the RO membrane needs to be justified. Assurance is needed that the normal variation in the relationship between TDS and EC at a treatment plant, under its specified operating conditions, will not be significant. This above relationship is obviously dependent upon several design and operating factors

including temperature, flux, permeability and system recovery. These parameters must be included in the operational control system (SCADA) at the plant.

At a minimum, online EC monitoring of the feed and permeate from a skid should be normalised daily. Furthermore, EC monitoring of the permeate from each pressure vessel should be conducted at least fortnightly.

6.5.3 EC profiling

EC profiling should be conducted when either:

- membrane modules are removed for inspection or are replaced with new modules, or
- the critical limit for the ORP meter has been exceeded.

6.5.4 Mini-challenge study

A ‘mini-challenge’ study using R-WT or indigenous or spiked MS2 bacteriophage should be conducted when either:

- the critical limit for EC (normalised salt passage) or TOC LRV is not met and the cause cannot be detected, or
- at least annually.

The R-WT challenge test would confirm the LRV capability of the system, and the integrity of individual elements. The results from these challenge studies would assist in the development of future guidance and confirm the adequacy of the control philosophy based on EC or TOC monitoring.

There are several ASTM methods relevant to the operation of RO systems. In addition to the ASTM methods mentioned above, scheme proponents should also refer to ASTM D3923 – 08 *Standard practices for detecting leaks in reverse osmosis and nanofiltration devices*[53].

7 Membrane bioreactors

Membrane bioreactors (MBRs) are essentially a combination of a biological treatment system (such as activated sludge) and a membrane filtration system. Therefore, there are many factors that contribute to pathogen removal or inactivation. To date these have not been well characterised but broadly include: predation and die-off within the mixed liquor; adsorption to particulate matter; membrane fouling and cake layer formation; removal through the backwash and wasting processes; and membrane-based size exclusion.

To attribute an LRV based on membrane-based size exclusion, refer to section 6. The LRV attributed must be based on a clean water study where there is no cake layer on the membrane.

In practical terms the sensitivity of the membrane DIT, for protozoan parasites and the methodology described in section 6.4 for attributing a virus LRV to membranes, will surpass the sensitivity of the online indirect monitoring parameter for the MBR systems. Therefore, it would be reasonable to expect that MBR configurations that can be subjected to a direct integrity test (pressure test) would be attributed higher pathogen LRVs compared with MBR configurations that cannot be pressure tested.

To determine a validated LRV based on all mechanisms that occur within an MBR process (including biological aspects) specific validation is required. There is insufficient evidence from which to make a more definitive estimate of the LRV applicable to an MBR at this time. The guiding principle of conservatism in the face of uncertainty is applied for MBRs.

Research needs include:

- Validation data for protozoa and viruses (and surrogates) for various MBRs associated with a prescribed operating envelope, and for various configurations.
- Studies that consider the concentration effects of MBRs on pathogens
- Collation of literature, desktop and manufacturers' data to inform the LRV that might be attributed as a minimum to MBRs (as has been applied to activated sludge plants).
- Identification of appropriate monitoring approaches to determine and verify the LRV for membrane configurations where a DIT is not available or cannot be applied (flat sheet), linked to an operating envelope.
- Critical failure analysis and evidence-based data on failure modes, their timelines and impact on pathogen reduction is needed.
- Quantifying and understanding concentration factors associated with the failure modes above, and the impact on observing and controlling a change in pathogen reduction.
- Quantifying and understanding the LRV at different points of the MBR over time – from commissioning, to biofilm development and ripening, to chemical and physical clean.
- Transparent evidence of good manufacturing practices in accordance with ISO 22000 and quality control principles in ISO 9001.

7.1 Pre-validation preparation

As described in the guiding principles, quality assurance must be evident in the product chain. This commences with the manufacturer of the membrane material or cassette, its incorporation into the treatment cell, to storage, site installation, commissioning then long-term operations. This is described in more detail in the US EPA MFGM. If sufficient evidence of quality control and good manufacturing process can be established, this can be provided as evidence that the LRV attributed is claimable through the manufacturing process, and may allow less site-specific validation to occur.

Consideration should be given to the size exclusion LRV that can be attributed to the membrane being used, as well as the mode of operation of the MBR, such as anoxic, aerobic or anaerobic. Possible changes in MBR LRV performance over time from start-up through ripening to CIP should also be considered as the ecology of the microbial community, including the free-mixed liquor and the fixed biofilms, will vary over this time. This is likely to impact the $\log_{10}$ reduction of pathogens. The most conservative point of this 'curve' should be considered as the attributed LRV for the MBR.

Factors that influence process effectiveness may include:

- MBR configuration:
  - external membrane
  - submerged membrane (directly submerged or integrated into the bioreactor) and either suction filtration or gravitational filtration
- membrane characteristics – material, molecular weight cut off (MWCO), flux, permeability, filtration resistance, transmembrane pressure and cross-flow velocity
- membrane integrity
- chemical or physical processes, predatory biota and adsorption/detachment processes that affect pathogen removal or inactivation, denitrification/nitrification
- filtration cycle – backwash type and frequency
- chemical cleaning (in situ and ex situ) including type and frequency
- control of membrane biofilm (including thickness, attachment and detachment)
- bioreactor characteristics – volume, solids residence time (SRT), HRT, mixed-liquor suspended solids (MLSS) concentration, food/microorganism (F/M) ratio and waste cycle
- feedwater characteristics – temperature, pH, ammonia, salinity, oxygen and COD concentration
- mechanics of aeration and cycle
- trade waste and toxic chemicals that impact on mixed liquor and membrane fouling and integrity.

The HACCP analysis should consider risks from chemical inputs to the source water that may affect process performance, and how these events will be identified and controlled. This is a particular issue for small-scale systems, for example, within an apartment building. The HACCP should focus on those known compounds that can impact the activated sludge as well as membrane integrity, as stipulated by the manufacturer.

The concentration factor within MBRs may be a critical factor if an integrity breach or other failure mode occurs, and is not detectable by the operational monitoring approach. Therefore, this must be considered an area to be validated as part of the design of equipment and possibly supported by research outcomes.

Because pressure-based membrane integrity tests cannot be performed online on all MBR configurations (gravity-feed systems), the LRV attributed to the system will be limited by the sensitivity of indirect operational monitoring parameters (such as turbidity, particle counts or other suitable parameters).

7.2 Validation monitoring

7.2.1 Microbial surrogates and indicators

Microorganisms or surrogates that must be monitored during the validation program are provided in Table 11.

Table 11: Microorganisms or surrogates for validation monitoring of MBRs

Pathogen group	Target microorganism	Microbial indicators
Viruses	Enteroviruses	Indigenous cultivable enteroviruses Indigenous or seeded coliphage, such as somatic or FRNA coliphage, may be used as a surrogate. It must, however, be demonstrated that phage do not overestimate viral pathogen removal. This relationship may be demonstrated at the pilot scale.
Protozoan parasites	*Cryptosporidium*	Indigenous *Cryptosporidium* Indigenous or seeded *Clostridium perfringens* may be used as a surrogate; however, it must be demonstrated that *Clostridium* spores do not overestimate oocyst removal. This relationship may be demonstrated at the pilot scale.
Bacteria	Pathogenic *E. coli*	Indigenous *E. coli*.

7.2.2 Validation monitoring program

Samples should be collected representing the MBR step only; therefore, the samples should be collected from primary effluent entering the MBR, and from the MBR permeate, leaving the MBR process. Grab samples should be collected because there is evidence that composite sampling from biologically active wastewater can lead to variations in the concentrations of entities within the composite sampling devices, which causes biased results. For each sampling event, triplicate sampling is required to achieve statistical robustness and to assess standard deviations.

Sampling events should occur across summer and winter months because temperature affects biological activity, nitrification, MLSS characteristics and therefore the $\log_{10}$ reduction of pathogens attributed to the biological inactivation mechanism. Sampling should be conducted within the proposed operating envelope of providing recycled water, that is, not for bypass conditions if recycled water is not supplied during this time or during activities such as backwash. Sampling events should also be conducted across the range of membrane-ripening periods, which may take some weeks to months and may need to roll into verification-monitoring periods.

If a series of modules of MBR are deployed, refer to the membrane-filtration section to determine the number of modules to be tested.

The validation monitoring program must provide details on all monitoring parameters (including microbial surrogates and indicators, and operational parameters), where they will be sampled, at what frequency, which analytical methods will be used and what quality assurance procedures will be applied. Operating parameters must also be monitored and recorded to show the operating envelope within which the LRV can be attributed. These operating parameters should include, but are not limited to:

- F/M ratio, SRT and HRT
- pH, ammonia permeate, dissolved oxygen of MBR zone, temperature
- suspended solids permeate and turbidity permeate
- MLSS concentration
- membrane flux, permeability, filtration resistance, transmembrane pressure and cross-flow velocity
- membrane integrity (direct or indirect integrity test).

Controls must be in place to ensure process stabilisation prior to process validation.

At a minimum, six sampling events should be conducted for low-, medium- and high-fouling conditions over extreme seasonal periods (such as winter and summer) or intensive monitoring for worst-case seasonal/diurnal period (if known, it must be based on evidence).

In addition to this, events that may impact on the optimal efficacy of the MBR system will need to be incorporated into the monitoring program as determined by the HACCP plan. Such events may include peak washing machine use and

reduced industrial inputs on weekends, and toilet cleaning after hours in office buildings. Additional pathogen monitoring will be required to determine the duration of time for the system to re-stabilise after a CIP.

The concentration of pathogens in the MBR is considered to be significant. Unpublished work suggests that the concentration of pathogens in the MBR may be up to 50 times greater compared with the influent concentration. The concentration factor must be quantified such that the consequences of integrity breaches can be better understood. Samples must be taken from the MBR to establish pathogen levels in the mixed liquor.

To determine the pathogen concentration factor in the bioreactor, one triplicate sample of the target microorganisms or indicators in the MBR should be taken for each filter cycle. Given the limited number of samples, to conservatively estimate the concentration factor the ratio of the maximum pathogen concentration in the MBR and the average pathogen concentration in the influent should be used.

For each sampling event, the above operational monitoring parameters should be monitored concurrently to define the validated operational monitoring conditions.

An example sampling program for MBR validation is provided in Table 12.

Table 12: Example sampling program for MBR validation (to be conducted for the summer and winter period)

Period	Sampling event	Low fouling (after CIP)	Medium fouling	High fouling (before CIP)
During extreme seasonal periods (winter and summer) or intensive monitoring for worst-case seasonal/diurnal period (if known, must be based on evidence)	Number of paired samples in–out (total for triplicates)	3 (18)	3 (18)	3 (18)
	Number of filter cycles (non-consecutive days)	6 during peak usage and 6 during off-peak	6 during peak usage and 6 during off-peak	6 during peak usage and 6 during off-peak

7.2.3 Online monitoring technique and correlation with pathogen reduction

Where it is not practical to undertake direct integrity testing, such as a pressure-based test (as described in section 6.3), it becomes necessary to correlate the resolution and sensitivity of the indirect integrity monitoring to the pathogen reduction.

An experimental approach, such as the approach described below, can be undertaken to determine the resolution and sensitivity of the online measurement (for example, turbidity and particle counts) in monitoring MBR performance.

Request for evidence-based information:

The following approach is based on the assumption that the MLSS concentration in the permeate provides an indication of the pathogen concentration in the permeate. We seek your feedback on this assumption.

Is this approach scientifically valid?

We request studies that correlate pathogen reduction with online monitoring techniques such as turbidity.

We request studies that correlate MLSS concentration in the permeate with pathogen concentrations.

Step 1: Establish the relationship between the online monitoring technique and suspended solids concentration and microorganisms in the permeate. For this relationship to be valid, the equation of best fit should result in a regression coefficient of greater than 0.9.

The objective of this step is to identify the limit where a reliable and measurable change is detected by the online monitoring technique. Baseline data for the online monitoring technique should be collected and the online monitoring results during impaired membrane integrity studies should be profiled.

The impaired membrane integrity studies should be conducted:

- during worst-case operational conditions whereby the greatest breakthrough of pathogens through the membrane would be expected
- in a manner whereby the membrane is progressively impaired until there is a measurable and reliable change in the online instrument reading. Triplicate samples of suspended solids concentration should be taken at each impaired membrane integrity test point.

Step 2: Measure the pathogen concentration factor in the MBR.

Take triplicate samples of the microorganisms and surrogates in Table 12 from the MBR to establish the concentration factor in the bioreactor. The worst-case concentration factor for each target pathogen should be adopted.

Step 3: Calculate the pathogen concentration in the permeate at the limit where a reliable and measurable change is detected by the online monitoring technique.

Using the equation in step 1 and applying the concentration factor from step 2, calculate the pathogen concentration in the suspended solids at the limit where a reliable and measurable change is detected by the online monitoring technique, as established in step 1.

Step 4: Calculate the pathogen LRV at the measurable change detected by the online monitoring technique.

Calculate the LRV taking the concentration of the pathogen in the permeate and influent to the MBR.

7.2.4 Data analysis

The maximum pathogen LRV that may be attributed to the MBR is the lower value of either:

- the lowest value validated LRV demonstrated during challenge testing (section 7.2.2)

  The LRV derived from the challenge test should be calculated as the lowest of the paired $\log_{10}$ reductions based on the average of triplicate samples. The most conservative LRV attributed under the tested operating envelopes is then adopted. For example, during winter where nitrification can be challenged, or during summer when temperature can impact the membrane operating pressure – which ever is the least, or
- the maximum $\log_{10}$ reduction that can be demonstrated by the online operational monitoring technique (section 7.2.3).

7.3 Operational monitoring

The ongoing operational monitoring including critical limits should be informed by the validated operating envelope within which the LRV can be attributed. In many cases, these may be best served by online analysers (pH, DO, temperature, SS, turbidity) or grab samples over the operating period (for example, three samples in 24 hours for ammonia to confirm nitrification).

Routine (weekly) monitoring of bacteriophage concentrations in the MBR permeate is required.

Where maintenance is being undertaken, the MBR must be re-stabilised prior to delivering recycled water. Re-stabilisation must be verified with monitoring bacteriophage concentrations in the MBR permeate and physicochemical monitoring parameters discussed above. Where membranes are being replaced, new membranes should be subject to a direct integrity test prior to operation. Where a direct integrity test is not practical, the validation monitoring sampling program should be implemented for at least three filter cycles.

8 Oxidant disinfectants

This section covers oxidant disinfectants and their validation requirements. The oxidants considered in this section are chlorine, chloramine, ozone and chlorine dioxide.

8.1 Pre-validation preparation

Most oxidant disinfectants are of limited use against *Cryptosporidium* oocysts. For practical purposes, chlorine and chloramine are ineffective at controlling *Cryptosporidium* oocysts. However ozone and chlorine dioxide can be effective at controlling *Cryptosporidium* oocysts if quite large doses are applied.

Most oxidant disinfectants are effective against both bacteria and viruses; however, chloramine is of limited effectiveness at controlling viruses unless quite large doses are applied.

The major interfering factors that need to be considered in validating oxidant disinfectants are particles, disinfectant demand and short-circuiting. Each has very different implications for validation. Other physicochemical parameters that affect the efficacy of the oxidants include pH, temperature and alkalinity.

8.1.1 Particles

Particles are the more problematic of the two major interfering factors since it is very difficult to objectively measure their interfering effect. Published CT values (such as those given by the US EPA) for oxidant disinfectants can only be applied to treated wastewater that has been subjected to effective filtration (such as coagulation-media or membrane filters). Effective and properly operated filtration systems should produce a filtrate with turbidity less than 0.15 NTU. The efficacy of the upstream filtration processes must be validated.

Particles from wastewater treatment processes can include small floc particles (often termed ‘pin-flocs’), oily suspensions (often termed ‘fat balls’) and pathogen aggregates. Such particles will incorporate pathogens within their mass, making it difficult for disinfectants to penetrate and inactivate the pathogens – an effect often described as ‘shielding’. Experimentally it is extremely difficult to assess whether or not shielding is taking place. Almost all oxidant inactivation experiments and CT values are based on freely suspended mono-disperse seeded pathogens. Therefore, applying the broad body of evidence to the case of indigenous pathogens in wastewater has some limitations.

Validation experiments that involve seeding surrogates, such as phage, into the effluent generally do not capture shielding because by design the seeded surrogates are freely suspended within the bulk liquid phase of the wastewater after pre-treatment and are not entrapped within particles.

Microbial enumeration methods that measure CFU, MPN or PFU do not accurately enumerate the true pathogen concentration in the water being treated if large particles are present. For instance, a single pin-floc might contain an average of 10^4 *E. coli* and pin-flocs might be present at a concentration of one per 100 mL: this would give a true *E. coli* concentration 10^4 organisms per 100 mL. However, upon enumeration using a modern MPN-based assay, each pin-floc would only be entrapped in a single assay tube or single tray well, leading to an estimated concentration of just 1 MPN per 100 mL – an underestimation of 4 $\log_{10}$. Although this is a purely hypothetical and possibly extreme example, it illustrates the problem.

Wastewater treatment processes that operate optimally are unlikely to shed excessive quantities of particles over the clarifiers and, in principle, well-clarified effluent would be expected to be relatively unaffected by shielding upon disinfection. However, the hydraulic residence time in conventional clarification processes may be too short to settle small particles through passive sedimentation. To be effective, the mechanism of clarification relies upon enmeshment of particles within very large flocs as part of the sludge blanket. However, shedding and carryover of pin-flocs and fat balls large enough to interfere with disinfection efficacy can theoretically occur without being detected through turbidity or sludge blanket depth measurements. A treatment plant validated during one set of conditions might subsequently shed particles and might underperform under alternative conditions in ways that might not be readily detectable under routine operation.

8.1.2 Disinfectant demand

Disinfectant demand is a relatively manageable interfering factor, although a number of conservative assumptions need to be applied when taking the effects into consideration.

In the absence of variability in disinfectant demand, it would be possible to dose known quantities of disinfectant and rely on the measured disinfectant dose as an operational monitoring parameter against which critical limits could be set. However, in practice, oxidant demand cannot be empirically measured since the demand results from a variety of chemical and physical characteristics of the wastewater. Therefore, the first implication of the effect of disinfectant demand is that operational monitoring of oxidant disinfectants requires the direct measurement of the oxidant disinfectant (or a suitable indicator parameter) to demonstrate the concentration of oxidant disinfectant freely available at the end of the disinfection period.

Since disinfectant demand results from a variety of different characteristics, disinfectant decay rates are not linear in wastewater. Typically there is a rapid initial disinfectant demand followed by a slower inactivation period. In theory it would be possible to measure the full inactivation profile and take this biphasic or multiphasic inactivation profile into consideration when estimating the effective disinfection dose. However, in practice, the instrumentation costs and complications of such an approach mean that a simpler and more conservative monitoring strategy is usually adopted. Therefore, the disinfectant concentration must be measured at the end of the nominated contact time, such as at the exit of the contact tank. The CT is then assumed to be the multiple of the validated contact time and the disinfectant concentration still present at the end of that contact time.

8.1.3 Short-circuiting

The US EPA has adopted 'T_{10}' in calculations for the required contact time. In tracer studies T_{10} is a time where 10 per cent of the injected tracer has passed through the contact tank. Using this time in oxidant contact time calculations ensures that 90 per cent of the water passing through the contact tank is exposed to an oxidant.

Where disinfection takes place in a long pipe, plug flow can be assumed and therefore it is relatively straightforward to confidently estimate the contact time achieved. In this case T_{10} can be assumed to be approximately equal to the theoretical detention time (TDT). It has been shown that it is necessary to reach a length-to-width ratio of at least 40:1 to achieve maximum plug flow performance[54].

Where more complex storage and mixing arrangements take place, such as in storage tanks, ideal plug flow conditions will not be achieved. It is possible that some short-circuiting will occur and there may also be areas of dead space reducing the effective space. Short-circuiting occurs where water follows a short flow pathway through the storage tank and in such cases T_{10} will be much shorter than the TDT. The purpose of baffling is to maximise the basin volume, increase plug flow and minimise short-circuiting.

The US EPA used the studies conducted by Marske and Boyle[54] to determine 'rule of thumb' fractions called baffle factors (T_{10}/TDT) to be applied based on simple baffling descriptions and tank geometry. These were intended to be used for determination of T_{10} where conducting tracer studies was not practical; however, US EPA points out that these give only rough estimates of the actual T_{10} and are recommended to be used only on a limited basis.

However, from a review of the referenced study by Marske and Boyle[54] it is not clear why the use of baffle factors is justified. In fact the authors concluded that the use of certain factors (such as T_{50}/TDT) was not reliable at describing the hydraulic performance of a contact tank. Furthermore, there is no justification of how or why a baffle factor derived from a contact tank with certain geometry and baffling configuration can be applied to a tank that may not match the size or geometry and is simply based on a generic baffling description.

Without undertaking empirical residence time assessments, or using validated modelling, it is therefore not possible to reliably estimate the true T_{10} within a storage tank by using default baffle factors.

If the contact tank and/or pipe configuration is identical (with respect to dimensional ratios, inlet and outlet configurations, relative flow rates and velocity profiles) to a previously validated arrangement for which T_{10} have been established, it is possible to use the results of the previous studies to assign contact times to the new design. It is also possible to construct physical models of much smaller dimensions using Froude number scaling to derive contact times; however, it is critical to choose scale ratios based on the principles of similitude (that is, there is geometric, kinematic and dynamic similarity for the flows in the model and prototype). In a review of previous studies, it has been demonstrated that large Reynolds numbers (Re >2000) are required in order to apply T_{10}/TDT from the smaller model to the larger one[55].

If the contact tank and/or pipe configuration is not identical to a previously validated arrangement, an empirical contact time study is required. An acceptable method for deriving contact times in reactors has been given by the US EPA[3] and the proposed protocol should be submitted to the department for review.

As T_{10} is inversely proportional to the flow rate tracer, studies conducted at only one flow rate should use the highest flow rate to give a conservative T_{10} value. To give more operational flexibility, tracer studies can be carried out at various flow rates (minimum of three) to derive a relationship between T_{10} and flow.

In addition to flow conditions, detention times determined by tracer studies are dependent on the water level in the contact basin. Tracer studies should be conducted with the water level in the contact tank at or slightly below (but not above) the normal minimum operating level. If the contact tank levels normally vary between high and low, tracer studies should be conducted during a period when the water is falling.

Other factors such as temperature and density must also be taken into consideration during method design.

8.2 Validation monitoring

8.2.1 Validation monitoring conditions

The LRV assigned to the disinfection step must be validated under the worst-case conditions that will be experienced by the system under which it will be authorised to supply recycled water. The following conditions must be met simultaneously for the disinfection conditions under which the CT would apply:

- most adverse pH
- maximum instantaneous flow rate through the contact tank
- lowest water temperature
- minimum contact tank hydraulic volume/level
- lowest dosed oxidant concentration
- lowest oxidant concentration at the end of the contact time
- highest turbidity
- highest suspended solids concentration
- worst upstream particle removal process performance.

In most cases, where oxidant disinfectants are used on adequately filtered water, the validation study will consist of the desktop application of standard CT values from CT tables to the specific validated case site.

In some cases, a desktop study will be sufficient to determine contact times, as outlined above. However, in most cases a minimum contact time will need to be demonstrated through a tracer study.

Critical limits need to be set for the following parameters:

- dosed oxidant concentration
- oxidant concentration measured at or downstream of the point at which the contact time is achieved
- maximum pH for chlorine and chloramine, minimum pH for chlorine dioxide, less important within the normal wastewater pH range (for example, 7.0 to 8.0) for ozone
- maximum instantaneous flow rate
- minimum tank hydraulic volume/level
- minimum water temperature
- maximum turbidity exiting pre-filtration (such as maximum 0.15 NTU for membrane filtration)
- maximum suspended solids concentration.

The LRVs would be assigned for the three pathogen groups (viruses, protozoa and bacteria) separately, based on the most resistant of the tested pathogens for each group.

8.2.2 LRV attributed for bacteria and protozoa

Oxidant disinfectants

For bacteria, due to similarities in disinfection resistance, *E. coli* would be the target microorganism for which $\log_{10}$ reduction credits would be assigned for all oxidant disinfectants. However, in practice, processes are unlikely to ever be limited by bacterial inactivation and viral and protozoan inactivation will dominate. For practical purposes, the $\log_{10}$ reduction credits assigned to bacteria can simply be set at the greater of the $\log_{10}$ reduction credits assigned for protozoa or viruses.

Chlorine dioxide

For protozoa, *Cryptosporidium* provides the pathogen for which $\log_{10}$ reduction credits should be assigned for protozoa for all oxidant disinfectants. The CT tables and equations provided by the US EPA[51] for chorine dioxide are considered appropriate to derive $\log_{10}$ reduction credits for protozoa in filtered wastewater (since chlorine dioxide does not react with ammonia). These CTs are provided in Table 13.

Table 13: CT values for *Cryptosporidium* inactivation by chlorine dioxide[51]

$\log_{10}$ credit	Water temperature, ℃										
	≤0.5	**1**	**2**	**3**	**5**	**7**	**10**	**15**	**20**	**25**	**30**
0.25	159	153	140	128	107	90	69	45	29	19	12
0.5	319	305	279	256	214	180	138	89	58	38	24
1.0	637	610	558	511	429	360	277	179	116	75	49
1.5	956	915	838	767	643	539	415	268	174	113	73
2.0	1275	1220	1117	1023	858	719	553	357	232	150	98
2.5	1594	1525	1396	1278	1072	899	691	447	289	188	122
3.0	1912	1830	1675	1534	1286	1079	830	536	347	226	147

Chlorine

For practical purposes *Cryptosporidium* is not inactivated by chlorine or chloramine at achievable doses, therefore protozoan $\log_{10}$ credits would not apply to these oxidants.

Ozone

There is insufficient evidence to set CT or equivalent values for *Cryptosporidium* oocysts in wastewater. It is noted that ozonation behaves quite differently in wastewater as compared with drinking water and that ozonation CT values are dependent on the initial dose. Therefore, the US EPA[51] drinking water criteria are considered unsuitable for wastewater applications. Further research is required to derive a relationship between CT (including transferred ozone dose) and *Cryptosporidium* inactivation.

8.2.3 LRV attributed for viruses

For viruses, the choice of target virus would vary according to the disinfectant under consideration.

Free chlorine

Coxsackie virus B5 is the pathogen for which $\log_{10}$ reduction credits would be assigned for viruses for free chlorine according to the CT relationship described by Black et al.[56] and summarised in Table 14. The more recent data is considered to supersede the US EPA (1991)[57] CT values that have previously been in widespread use. It is noted that a number of studies have revealed even higher CT requirements than those of Black et al.[56]; however, it is considered that many of these earlier studies were subject to problems of viral aggregation so that the most recent comprehensive study, that is, Black et al.[56], has been selected here.

Chloramines

For chloramines, the CT values given by the US EPA in 1991[57] and then reproduced in 1999[3] are explicitly not applicable to wastewater because wastewater typically has a high chlorine demand. The US EPA guidance specifically states that *'[these] CT values … should not be used for estimating the adequacy of disinfection in systems applying preformed chloramines or ammonia ahead of chlorine …*'(page 332)[57]. In wastewater, the situation is equivalent to the addition of ammonia ahead of chlorine.

The adenovirus serotype 2 preformed monochloramine study of Sirikanchana et al.[58] – see Table 14 – is adopted here as the primary reference study in preference to the SA11 simian rotavirus preformed monochloramine study of Berman and Hoff[59]. Applying the Berman and Hoff[59] study in this case would require CT values for preformed monochloramine

of approximately 5,000 mg•min/L to achieve 2 log_{10} inactivation at pH ≤ 8 and temperature ≥ 5˚C. There is evidence that human rotavirus is more resistant to oxidant disinfectants (chlorine, chlorine dioxide, ozone and peracetic acid) than SA11 simian rotavirus[60]. However, a comparative assessment between preformed monochloramine inactivation of human rotavirus versus SA11 simian rotavirus was not identified during this review. It would have been possible within these guidelines to base the preformed chloramine CT values on the Berman and Hoff[59] study; however, this study targeted an animal rather than a human virus, and, furthermore, the importance of rotavirus from a public health perspective in developed countries is likely to be greatly diminished as routine vaccination of infants is now practiced.

The US EPA (1991)[57] chose not to use the Berman and Hoff[59] study in setting its CT values for monochloramine, but for different reasons. It is recommended that the resistance of human rotavirus to monochloramine be investigated as a priority to resolve this question. Should human rotavirus be shown to be more resistant to monochloramine than adenovirus serotype 2, the guideline may need to be updated accordingly. Norovirus is arguably the most significant waterborne enteric virus in developed countries from a public health perspective. Adenovirus serotype 2 appeared to be more resistant than the conservatively estimated resistance of the human norovirus[61] for which a 2 log_{10} inactivation at pH 8 and temperature 5˚C was estimated to be achieved with a CT of 775 mg•min/L using preformed monochloramine[56] – refer to Table 14.

Table 14: Viral log_{10} reduction criteria for oxidant disinfectants

Oxidant	pH critical limit	Temperature critical limit	CT critical limit (mg•min/L)*	Log_{10} reduction credit**	Evidence base
Free chlorine	Must be ≤ 7.5	Must be ≥ 5˚C	Must be ≥ 5.4	2	Black et al.[56]
			Must be ≥ 8.4	3	
			Must be ≥ 11.5	4	
	Must be ≤ 9.0		Must be ≥ 14.0	2	
			Must be ≥ 18.7	3	
			Must be ≥ 22.9	4	
Monochloramine	Must be ≤ 8.0	Must be ≥ 10˚C	Must be ≥ 1500	2	Sirikanchana et al.[58]
			Must be ≥ 2200	3	
			Must be ≥ 2900	4	
		Must be ≥ 20˚C	Must be ≥ 600	2	
			Must be ≥ 900	3	
			Must be ≥ 1200	4	
	Must be ≤ 10.0	Must be ≥ 10˚C	Must be ≥ 6800	2	
			Must be ≥ 9000	3	
			Must be ≥ 11200	4	
		Must be ≥ 20˚C	Must be ≥ 2900	2	
			Must be ≥ 3900	3	
			Must be ≥ 4800	4	
Chlorine dioxide	Must be between 6 and 9	Must be ≥ 5˚C	Must be ≥ 5.6	2	US EPA (1991 and 1999a)[3, 57]
			Must be ≥ 17.1	3	
			Must be ≥ 33.4	4	
		Must be ≥ 10˚C	Must be ≥ 4.2	2	
			Must be ≥ 12.8	3	
			Must be ≥ 25.1	4	
		Must be ≥ 15˚C	Must be ≥ 2.8	2	
			Must be ≥ 8.6	3	
			Must be ≥ 16.7	4	
		Must be ≥ 20˚C	Must be ≥ 2.1	2	
			Must be ≥ 6.4	3	
			Must be ≥ 12.5	4	

*C: Minimum oxidant concentration critical limit at end of contact time, T.

*T: Contact time under worst-case conditions of maximum instantaneous flow critical limit combined with minimum tank volume critical limit and expressed either as minimum hydraulic contact time or T_{10}.

**Log_{10} reduction credits only apply to wastewater treated to remove particles that may cause shielding and pathogen aggregates. Suitable treatment would involve filtration via coagulation-media systems or membrane systems.

Ozone

Site-specific studies must be undertaken to determine the required CT value. The efficacy of ozonation must be demonstrated operationally through transferred ozone dose (TOD) and ozone residual monitoring.

An ozonation study on wastewater was used to provide an indication of virus inactivation, although this would need to be validated for any specific applications[62]. Unlike the chlorine-based disinfectants, ozone does not maintain a prolonged residual in wastewater, making it very difficult to measure ozone doses in practice. Although the measurement of a residual is critical for the demonstration of adequate ozonation, it is the TOD that forms the principal critical limit parameter for ozone control. In addition, complex side reactions may occur in wastewater that may have different effects on different types of pathogens and indicators in wastewater that may change the rank of sensitivity to ozone as compared with that observed in drinking water. To date, many of the viruses that were most resistant to ozone in drinking water conditions have not been adequately tested under wastewater ozonation conditions. Furthermore, the dose–response relationships for ozone are related to the initial dose such that experiments undertaken at low doses are unlikely to be directly applicable to high dose wastewater situations. Based on Xu et al.[62] the estimated viral LRV likely to be achieved by ozonation would be 3 log_{10} for a TOD that was just above the immediate ozone demand of the wastewater. However, further research is required to provide an evidence base to provide a broad virus log_{10} reduction credit for wastewater, in particular focusing on more resistant viruses. A summary of studies on ozonation in wastewater is provided in Appendix 4.

8.3 Operational monitoring

In general, the most important operational monitoring parameter is oxidant disinfectant concentration measured at a point representing the end of the contact period. The critical limit for the oxidant must be based on the T_{10} for the maximum peak hourly flow rate and the target CT.

Both the dosed and the residual oxidant concentration should be measured online. Residual oxidant can be measured directly using a residual analyser. In the case of chlorination, free chlorine residual meters must be installed to verify CT as part of the suite of operational monitoring parameters required for chlorination. ORP cannot be used to measure disinfection effectiveness for chlorination. Studies have demonstrated that chlorination effectiveness is not well predicted with ORP measurements and that ORP does not vary in direct proportion to chlorine residual. Furthermore, calculation of residual concentration from measured millivolts can result in large errors of ±30 per cent.

In addition, pH, instantaneous flow rate, water temperature and tank hydraulic volume/level should be controlled and measured either on line or at an appropriate frequency commensurate with their inherent rate of change.

In the case of chloramination, the ratio of chlorine to ammonia is an important consideration. Hypochlorous acid (HOCl) reacts readily with ammonia (NH_3) to form three types of chloramines, namely monochloramine (NH_2Cl), dichloramine ($NHCl_2$) and nitrogen trichloride (NCl_3). These reactions are dependent on pH, temperature and contact time and on the ratio of chlorine to ammonia. According to Metcalf and Eddy[63] monochloramine and dichloramine are the two species that dominate in most cases. Based on White[64], all free chlorine will be converted to monochloramine at pH 7–8 when the ratio of chorine to ammonia is equimolar (5:1 by weight) or less, that is, 4:1, 3:1 and so on. Dichloramine will be formed between pH 7 and 8 when the ratio of chlorine to ammonia is 10:1 by weight. Given that monochloramine is the effective disinfectant, it is crucial that the online instrumentation demonstrates that the monochloramine concentration is greater than that required for the log_{10} reduction of viruses being sought. Most analysers used in chloramination mode disinfection systems measure total chlorine. The concentration of chloride ions measured by these analysers must be attributed to monochloramine and not dichloramine, for example. In systems operating in chloramination mode the ammonia-to-chlorine ratio must be monitored online to provide ongoing assurance that the required monochloramine CT is achieved.

It is necessary to measure the performance of the upstream process to ensure that sufficient particle removal has been achieved prior to disinfection. The measurement of the disinfectant residual will permit disinfectant demand to be taken into consideration but will not account for the shielding effects of particulates. Turbidity and suspended solids should be assessed for all processes and should be sufficient for processes treated by filtration upstream of disinfection. In addition, for processes treated by lagoon sedimentation upstream of disinfection, it is necessary to operationally monitor the hydraulic flow rate to ensure adequate sedimentation. Furthermore, it is necessary to operationally monitor the effect of stratification and seasonal variability on particle re-suspension.

For processes that do not employ effective filtration or prolonged sedimentation upstream of disinfection it is not possible to apply conventional CT values with confidence since there is no practicable means of quantifying the pathogen density

being carried over in the effluent. For high exposure Class A and dual reticulation schemes, the process design must ensure the removal of particles that are too large to be readily disinfected.

Note:

AWQC with support from Smart Water Fund is undertaking a research project on chlorine disinfection of human pathogenic viruses in recycled water. The outcomes of this research project will be considered for inclusion in future revisions of these guidelines.

9 Ultraviolet disinfection

This section covers ultraviolet (UV) disinfection and the validation requirements for recycled water schemes. Advanced oxidation with UV and ozone or hydrogen peroxide is briefly discussed under this section. This section of the guidelines is relatively concise since the UV disinfection guidance provided by the US EPA *Ultraviolet disinfection guidance manual for the final long term 2 enhanced surface water treatment rule*[6] (hereon referred to as the UVDGM is considered the appropriate guideline to adopt for validation of UV reactors. The UVDGM is considered to have superseded the DVGW[65-67], NSF[68], ONORM[69, 70] and NWRI[71] guidelines. The DVGW, NSF and ONORM guidelines only provide validation to a set point dose of 40 mJ/cm^2. Unlike UVDGM, these guidelines do not deal comprehensively with concepts such as uncertainty and bias between challenge test microorganisms and target pathogens.

Importantly, some details are provided in this guideline on the application of the UVDGM to wastewater since the UVDGM is in fact designed to be applied only to drinking water and some modification is required. Other than these important differences, the UVDGM can be applied directly.

9.1 Pre-validation preparation

UV disinfection is typically highly effective against both bacteria and protozoa; however, relatively high doses are required to inactivate viruses. Many commercially available pre-packaged UV disinfection systems provide a dose of only 40 mJ/cm^2 or less, which will provide only minimal viral inactivation.

The major interfering factors that need to be considered in validating UV disinfectants are particles, absorbance and short-circuiting. Each has very different implications for validation.

9.1.1 Particles

Particles are the more problematic of the interfering factors since it is very difficult to objectively measure their interfering effect.

The UV doses specified in UVDGM are restricted to water with turbidity values less than or equal to 1 NTU, due to the potential interference of particles in water. Therefore, published UV dose–response values can only be applied to treated wastewater that has been subjected to effective filtration (such as coagulation-media or membrane filters). Effective and properly operated membrane filtration systems should achieve turbidities less than 0.15 NTU.

For UV disinfection systems not preceded by effective filtration, site-specific experimental studies will be required to derive UV dose requirements for the target pathogens.

Particles from wastewater treatment processes can include small floc particles (often termed ‘pin-flocs’), oily suspensions (often termed ‘fat balls’) and pathogen aggregates. Such particles will incorporate pathogens within their mass making it difficult for UV to penetrate and inactivate the pathogens – an effect often described as ‘shielding’. Experimentally it is extremely difficult to assess whether or not shielding is taking place. Almost all UV inactivation experiments and dose–response datasets are based on freely suspended mono-disperse seeded pathogens. Therefore, applying the broad body of evidence to the case of indigenous pathogens in wastewater has some limitations.

Validation experiments that involve seeding surrogates, such as phage, into the effluent do not capture shielding because by design the seeded surrogates are freely suspended within the bulk liquid phase of the wastewater and are not entrapped within particles.

Microbial enumeration methods that measure CFU, MPN or PFU do not accurately enumerate the true pathogen concentration in the water being treated if large particles are present. For instance, a single pin-floc might contain an average of 10^4 *E. coli* and pin-flocs might be present at a concentration of one per 100 mL: a true *E. coli* concentration of 10^4 organisms per 100 mL. However, upon enumeration using modern MPN-based assay, each pin-floc would only be entrapped in a single assay tube or single tray well leading to an estimated concentration of just 1 MPN per 100 mL – an underestimation of 4 log_{10}. Although this is a purely hypothetical example, it correctly illustrates the problem.

Wastewater treatment processes that operate optimally are unlikely to shed excessive quantities of particles over the clarifiers and, in principle, well-clarified effluent would be expected to be relatively unaffected by shielding upon disinfection. However, the hydraulic residence time in conventional clarification processes is too short to sediment small particles through passive sedimentation. To be effective, the mechanism of clarification relies upon enmeshment of particles within very large flocs as part of the sludge blanket. However, shedding and carryover of pin-flocs and fat balls

large enough to interfere with disinfection efficacy can theoretically occur without being detected through turbidity or sludge blanket depth measurements. A treatment plant validated during one set of conditions might subsequently shed particles and might underperform under alternative conditions in ways that might not be readily detectable under routine operation.

9.1.2 UV absorbance

UV absorbance is a relatively manageable interfering factor although a number of conservative assumptions need to be applied when taking the effects into consideration.

In the absence of variability in UV demand, it would be possible to provide a known level of UV irradiation and rely on the measured lamp output as an operational monitoring parameter against which critical limits could be set. However, in practice, UV absorbance varies with a variety of chemical and physical characteristics of the wastewater. It is possible to measure the UV absorbance of the wastewater directly, but some UV is absorbed by fouling on lamps and sleeves, as well as by the water. Measuring the UV absorbance of the wastewater alone will not capture this additional absorbance. Therefore, the first implication of the effect of UV absorbance is that operational monitoring of UV disinfection requires the direct measurement of the UV intensity after it has passed through both lamps and sleeves and the water being disinfected, in order to demonstrate the intensity of light that would actually reach the microorganisms. Note that this means that it is essential to measure UV intensity as an operational parameter in UV disinfection systems, as required under the UVDGM. The NWRI guidelines are, therefore, now considered to have been superseded by the UVDGM. A second implication of varying UV absorbance is that the response of microorganisms in UV reactors of varying UV absorbance is not always linearly correlated. For instance, the relationship between varying UV absorbance and viral inactivation may not be the same as that for protozoan inactivation. Dose–response curves are not necessarily linear so that it is necessary to apply some kind of correction in using data gathered from a validation experiment with one type of microorganism to predict what might happen to another. This 'bias' is considered under the UVDGM but not the NWRI guidelines.

9.1.3 Short-circuiting

The dose of UV irradiation experienced by microorganisms passing through most UV reactors is not even. Some microorganisms will pass through shorter flow paths than others. Furthermore, some microorganisms will pass through flow paths that are further away from the UV lamps than others. The result is that the single UV 'dose' claimed is actually a simple approximation for what is in fact a dose distribution with some microorganisms experiencing both higher and lower doses than the claimed dose. The dose claimed is termed the 'reduction equivalent dose' or RED.

Changing flow rates has a marked effect on both the amount of time spent within the UV reactor and the flow pathways that microorganisms follow. The latter means that it is not appropriate for most UV reactor designs to assume a linear relationship between flow rate and RED. As flow pathways change with flow rate, the dose distribution that is experienced by microorganisms may vary in a way that leads to significant differences from a linear relationship between RED and flow rate. Therefore, it is not possible to reliably extrapolate outside of the validated range of flow rates. Interpolation between tested flow rates is acceptable. However, as noted above, the concept of 'bias' needs to be taken into consideration if experiments are undertaken on one type of microorganism and applied to another. As noted above, this 'bias' is considered under the UVDGM but not the NWRI guidelines.

9.2 Validation monitoring

Pre-validated reactor designs, or units built to simulate designs validated elsewhere, can be accepted without a requirement to repeat the validation for the specific reactor.

The LRV assigned to the disinfection step must be validated under the worst-case conditions that will be experienced by the system under which it will be authorised to supply recycled water. The following conditions must be met simultaneously for the disinfection conditions under which the validated dose would apply:

- worst upstream particle removal process performance
- highest turbidity
- highest suspended solids concentration
- maximum instantaneous flow rate through the reactor
- lowest lamp power

- most aged lamps
- highest level of lamp fouling
- highest UV absorbance.

In most cases, where UV is dosed, the above conditions would represent the worst case, but it may be possible to adjust flow rates to higher levels, and lamp power to lower levels, under better conditions. Therefore, it is common to test a range of conditions, sometimes more than 30, to provide a validated operating envelope that allows lamp power and flow rate to be varied to help reduce power usage and increase water supply rates.

9.2.1 Data analysis for UV validation

The data analysis and validation experimental set-up for a UV disinfection system is complex and specialised. Typically, reactor designs that have previously been validated can be installed provided the operating conditions will remain within the validated range. For new reactor designs, it is necessary to analyse data in accordance with the UVDGM.

One departure from UVDGM is wastewater with low UV transmissivity (UVT) (high UV absorbance – UVA). The UVDGM does not provide RED bias figures for UVT levels below 65 per cent. For wastewater that accepts trade waste containing high levels of UV absorbing substances and/or that does not employ extensive pre-treatment prior to UV disinfection, UVT can be lower than 65 per cent. It is acceptable to undertake a linear extrapolation of the RED bias values for UVT levels below 65 per cent. The method to be used in undertaking the linear extrapolation involves taking the published values given in Appendix G of the UVDGM for the selected LRV and UV sensitivity and fitting a linear relationship to the two values corresponding to the lowest UVT levels taken from one row of the tables and then using the relationship to predict the RED bias for lower UVT levels. This approach is illustrated in Figure 2.

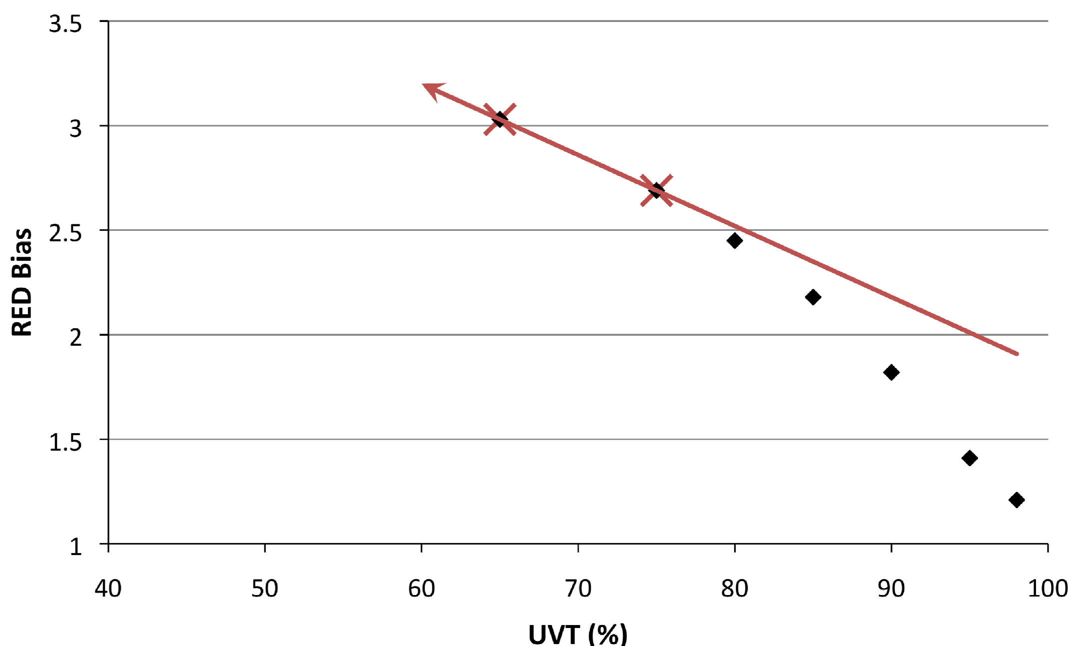


Figure 2: Illustration of the principle of extrapolation of *Cryptosporidium* RED bias to UVT levels below 65 per cent

The ‘diamond’ symbols illustrate the values taken from UVDGM 2006 Appendix G.3 for a specific example challenge microorganism UV sensitivity level (22–24 mJ/cm^2/log$_{10}$ I) and a specific example *Cryptosporidium* LRV (3 log$_{10}$). Note that these values will differ for other UV sensitivities and LRVs. The ‘X’ symbols illustrate the two values that correspond to the lowest UVT levels given in the UVDGM (65 per cent and 75 per cent). To estimate RED bias values for UVT levels below 65 per cent, the trend for the two values that correspond to the lowest UVT levels (65 per cent and 75 per cent) should be used, as illustrated in this case by the trend line shown. Note that this approach is thought to be moderately conservative.

Critical limits needs to be set such that when all process steps are running simultaneously just on their critical limit values, sufficient log$_{10}$ reduction is achieved. Critical limits need to be set for the following parameters:

- minimum UV intensity
- maximum lamp age
- minimum UV transmissivity

- minimum number of lamps that must be on within a lamp bank
- minimum lamp power
- maximum instantaneous flow rate
- maximum turbidity exiting pre-filtration
- maximum suspended solids concentration.

Under the UVDGM, it is acceptable to supply up to 5 per cent of the water when one or more of the critical limit parameters is outside of the validated range. Since wastewater typically starts with a highly contaminated source, such a tolerance is not acceptable under this guideline for wastewater disinfection. Other than tolerable deviations from critical limits to allow for instrumentation errors and system corrections to bring the system back into the validated range, the UV disinfection system should be operating within the validated range at all times when recycled water is being supplied for its intended use. Any time delay associated with process limits (to account for instantaneous spikes and feedback loops) must be kept to a minimum, justified and specified in the RWQMP.

The LRV would be assigned for the two pathogen groups (viruses and protozoa) separately based on the most resistant of the tested pathogens for each group.

For protozoa, *Cryptosporidium* provides the target pathogen for which $\log_{10}$ reduction credits should be assigned for UV for both low and medium pressure systems. Table 1.4 of UVDGM is considered appropriate to derive $\log_{10}$ reduction credits for protozoa in wastewater.

For viruses, adenovirus provides the target pathogen for which $\log_{10}$ reduction credits should be assigned for UV for both low and medium pressure systems. Table 1.4 of UVDGM is considered appropriate to derive $\log_{10}$ reduction credits for viruses in wastewater.

In theory it is possible to validate reactors for multiple virus types, such as ‘adenoviruses’ separately from ‘all other enteric viruses’; however, this approach is not endorsed in these guidelines. It is true that adenoviruses appear to be exceptionally resistant to UV light and that many other types of virus are much more susceptible. Taking the next most resistant virus after adenovirus could provide an approach whereby viral LRVs could be assigned separately to ‘adenovirus’ and ‘other enteric viruses’. Such an approach would allow adenoviruses to again be considered separately at upstream and downstream processes, thereby getting around the limitations of UV for inactivating adenoviruses at relatively low doses. However, such an approach is only valid if virtually all other viral enteric pathogens had been tested and shown to be much more sensitive to UV than to the next-most resistant viral pathogen. To date, only a limited number of enteric viral pathogens have been tested for their UV susceptibility and there are hundreds of different types of enteric viral pathogens. Therefore, the most resistant serotype of adenovirus tested to date remains that pathogen that must be used for deriving UV disinfection LRVs.

9.3 Operational monitoring

In general, the most important operational monitoring parameter is UV intensity measured at a point after which UV light has passed through water that is being treated. In addition, the flow rate must be measured to ensure that the process is operating within its validated flow range.

For units with multiple lamps, one limitation with measuring UV intensity is that the UV sensor is only receiving light from one or a proportion of the lamps. There could be lamps elsewhere in the reactor that are off, aged or fouled, leading to lower intensity regions within the reactor. Therefore, it is important to ensure that the power applied to all lamps is measured and to ensure that the oldest and most fouled lamps are those that are illuminating the UV intensity sensor viewing area.

References

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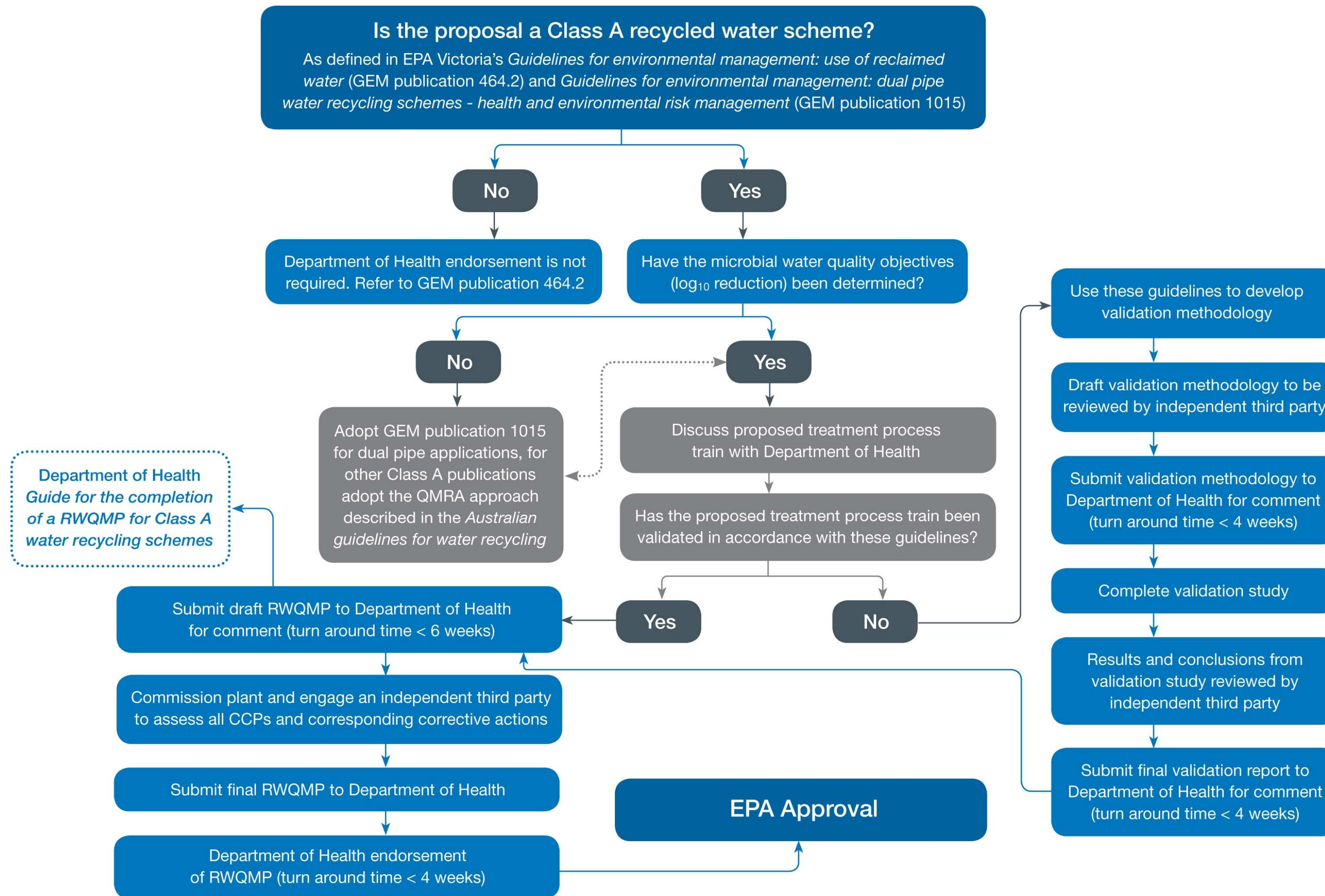
Appendix 1: RWQMP endorsement process



Appendix 2: Verification monitoring

Verification monitoring is endpoint monitoring and is undertaken routinely to indicate that the treatment plant and control philosophy for the plant has worked. Therefore verification monitoring is not to be relied upon for system control. The requirements specified for verification monitoring of Class A recycled water are consistent with the requirements of the AGWR. Treatment process trains employed to deliver Class A recycled water should not result in the detection of the microorganisms specified in the table below.

Detection is likely to indicate system failure or contamination. In the event that an organism is detected in the Class A recycled water, the scheme proponent must notify the department immediately, investigate the cause, and implement corrective actions as necessary.

Table 15 Verification monitoring for Class A recycled water^

Organism	Frequency	Water quality objective	Limit of detection
E. coli	Weekly	No detection	1 cfu per 100 mL
Somatic or FRNA bacteriophage	Weekly	No detection	1 pfu per 100 mL
Cryptosporidium oocysts	Quarterly	No detection	1 oocyst per 1 L

^ The analysis must be undertaken by a laboratory that is accredited by the National Association of Testing Authorities (NATA) to conduct analysis for the specific organism. Where there is no NATA accredited method, the *Standard methods for the examination of water and wastewater*[11] should be adopted.

Appendix 3: Safety in design and operation

A safe design basis, with a formal safety management system that includes practices, procedures and training, is critical for ensuring the recycled water treatment plant functions effectively.

System failures in recycled water treatment processes have occurred due to:

- incorrect plant configuration
- incorrect algorithms and inputs into the programmable logic controller
- failure of the control system logic and key control signals including corrective actions
- instrumentation error and failure.

These can result from plant malfunction, inadequate procedures or operator error.

A systematic, risk-based approach to safety design can help eliminate hazards that pose intolerable risk and mitigate the potential consequences of hazards.

A3.1 Risk assessment and management

A site-specific risk assessment covering all aspects of safety associated with the design and operation of the treatment process must be undertaken and documented.

Where risks are identified, appropriate control measures (based on the hierarchy of controls) must be implemented. Hazards should be eliminated wherever possible, followed by use of engineering controls.

The risk assessment for the treatment process and the effectiveness of implemented control measures should be reviewed on a regular basis. Initial design risk control measures must not be degraded through subsequent modifications of the treatment process. Any proposed modifications that impact on CCPs must be submitted to the department for consideration.

A3.1.1 Risk-based systems

Risk-based systems include ISO 9001, ISO 14001, ISO 22000, ISO 31000 and local standards such as the Australian and New Zealand Risk Management Standard (AS/NZS 4360). A risk-based system must be used to systematically address and manage risks associated with the treatment process prior to commissioning.

A3.1.2 Hazard and operability studies

A hazard and operability (HAZOP) study in accordance with *Australian Standard Hazard and Operability studies (HAZOP studies) – Application guide (AS 61882—2003)[72]* must be conducted. The HAZOP must involve the application of a formal systematic critical examination to the process and engineering intentions of the treatment process to assess the hazard potential of mal-operation or malfunction of individual items of equipment and their consequential effects on the treatment process as a whole.

The actions arising from the HAZOP study must be incorporated into the design and/or operation of the treatment process.

A3.1.3 Recycled water quality management plan

The treatment process must be managed in accordance with the RWQMP. Management encompasses operation, monitoring, maintenance, inspection, training, documentation, reporting and auditing.

Implementation of the RWQMP maximises the ongoing safe production and delivery of recycled water. The validation supporting the capability of the treatment plant to achieve the specified water quality objectives must be contained within the RWQMP.

Any significant modifications to the treatment process that impact on CCPs must be submitted to the department for consideration.

The preventive risk management approach as described in the AGWR must underpin the RWQMP.

The RWQMP should be integrated into a quality assurance system framework, such as outlined in ISO 9001: Quality Management System.

A3.2 Design and functionality

The design of the recycled water treatment plant must:

- be consistent with the RWQMP
- ensure CCPs and associated control limits are effective
- not allow off-specification water into the supply.

The design of the plant must also allow operational personnel to monitor and control the process reliably, accurately and in a timely manner.

All critical equipment is required to operate in a safe, reliable and precise manner. The scheme proponent must ensure that the equipment and associated controls have safety measures against failure through human error or operational malfunctions and that the equipment is safe to operate and maintain.

All key components of the treatment process must be interlocked in the control system to ensure total system shutdown on the failure of any individual equipment item. The recycled water treatment process must alarm and respond to the critical control limits as specified in the RWQMP. All critical systems must be configured so they are ‘fail safe’; that is, failure of a critical component automatically leads to cessation of supply and generation of an alarm.

The operation of shutdown systems must be fully tested at commissioning and at least annually (unless otherwise specified) and the outcome of these tests recorded.

Real-time monitoring linked to an appropriate alarm monitoring system and automatic shutdown is required for all CCPs and must be available at all times. Any delay associated with critical control limits and corrective actions must be kept to a minimum, justified and specified in the RWQMP.

The plant must be fully automated and operated by treatment-plant-based control (by programmable logic controller). The plant must ensure dependable automatic operation with reliable stopping and starting of the system during plant shutdown and start-up. Where the treatment process is shut down due to system failure, the plant must not restart automatically without manual onsite intervention. It is essential that diagnostic testing is conducted to identify the cause of the failure prior to restart.

Operational control loops should be validated and tested considering the critical limits and equipment-monitoring performance specifications.

A3.3 Commissioning

A commissioning plan describing the manner in which the plant and equipment will be tested and the acceptability criteria must be developed.

At the completion of plant construction and commissioning, the scheme proponent must maintain as-built drawings and functional description, maintenance and calibration schedules, as well as commissioning records verifying that the recycled water plant installation and the control system is in accordance with the RWQMP.

The scheme proponent must provide written confirmation in the RWQMP that:

- the treatment process has been installed in accordance with the final plans and specifications
- the control system, including operational monitoring, critical limit alarms and corrective actions within the RWQMP, has been tested and verified by an independent third party.

The scheme proponent must not introduce recycled water into the supply system until endorsement by the Department of Health and approval from EPA Victoria has been provided in writing.

A3.4 Operation and maintenance

The scheme proponent must only use plant and equipment as specified in the RWQMP, and must ensure that this plant and equipment is maintained.

The operational monitoring must be consistent with the RWQMP.

All monitoring equipment associated with CCPs must be maintained and calibrated against a reference instrument or standard at regular intervals to verify that they are within specification. The frequency must be in accordance with the supplier recommendations as a minimum, and be underpinned by a risk assessment. A more frequent regime may be required when:

- the tolerance range and the critical limit boundaries are close
- there is uncertainty of measurement of the instrument, possibly due to interfering factors or sensitivity
- there is high drift of the instrument
- the detection limit is close to the critical limit.

Calibration requires sign-off by the person conducting the calibration and should be formally documented and auditable. Calibration schedules should be reviewed at least annually and should consider manufacturers' specifications, previous data, trends and cross-equipment checks using the same equipment on same sites. Wherever possible, cross-site checks (using the same equipment on several sites) and cross-operator checks (two different people do the same calibration at the same equipment and same site) should be conducted.

A log of reference standards or reference items used must be maintained and documented. This should include date of receipt of reference, date of open, shelf life and date of disposal.

A3.5 Operational personnel

Operational personnel (employees or contractors) must be appropriately skilled and trained in the management and operation of the treatment process. Operational personnel must have an adequate knowledge of the principles of recycled water treatment, the type of plant or equipment and its operation and maintenance.

Operational personnel must have a sound knowledge base from which to make effective operational decisions. This requires training in the methods and skills required to perform their tasks efficiently and competently. Operational personnel must be aware of the potential consequences of system failures, and of how their decisions can affect the safety of the scheme and product water quality.

All operators must be competent in implementing standard operating procedures. The scheme manager must have competent personnel (employees and contractors) to supervise and operate the treatment process.

A3.6 Quality assurance

The quality assurance system must adequately monitor and maintain the treatment process such that any discrepancy, equipment reliability issue or unacceptable variability in the recycled water quality is readily identified and effectively rectified.
A quality assurance and quality control framework must be implemented to verify the accuracy of the results, and the corrective actions and process by which operators are informed of process failure. Furthermore, the operation manual must be a controlled document with defined procedures/processes for amendment.

Appendix 4: Background information on ozone

Table 16 Summary of limitations of existing studies on ozonation in wastewater

Observation	Implication	References	Impact on this guideline
The US EPA SWTR CT values for drinking water were found to be based on very limited data for a study undertaken at 5ºC in ozone-demand-free water on a virus that the same study found not to be the most resistant of those tested	These values cannot be relied upon due to the narrow range of viruses tested, due to the fact that these values were derived in experiments undertaken in ozone-demand-free water, not wastewater, and due to the choice of a virus that was not the most resistant of those evaluated	US EPA 1991[57], Roy et al.[73]	The use of CT values from ozone-demand-free-water, such as those used by the US EPA in its drinking water regulations, is not acceptable for the disinfection of wastewater
The relative resistance of viruses to ozone is unknown. Observations in the literature are provided in **Table 17**.	The most resistant viruses need to be used for evaluating processes	Refer to **Table 17**	Validation studies should address the most resistant viruses
The relative resistance of viruses to ozone in wastewater may be different to that in drinking water due to the side reactions that may occur	A range of the most resistant viruses need to be used for evaluating processes	First principles	Validation studies should address a range of the most resistant viruses
Ozone inactivation curves are highly biphasic with the first 1 to 3 log_{10} reductions being much more easily achievable than subsequent log_{10} reductions	Dose–response curves cannot be extrapolated beyond the observed range and CT values for log_{10} reductions cannot be added	Roy et al.[73]; Katzenelson et al.[74]	Extrapolation beyond the log_{10} reduction demonstrated empirically is not acceptable Addition of log_{10} reductions from multiple process steps to give log_{10} reductions above that demonstrated is not acceptable
Ozone inactivation is not particularly pH dependent in the range 6 to 9 but is temperature dependent	pH can vary within the normal range for wastewater (6 to 9) without affecting log_{10} credits, but log_{10} credits will be temperature dependent.	US EPA[57]; Roy et al.[73]	Validation studies must be undertaken under the lowest temperature conditions for which log_{10} reduction credits are sought
CTs are dose dependent	Dose–response relationships established at very different doses from those applied cannot be applied to other doses	Thurston-Enriquez et al.[75]	The log_{10} credit only applies for the ozone dose range empirically tested
Ozone inactivation curves are extended in secondary treated wastewater, under otherwise identical conditions, relative to drinking water	The use of CT values from drinking water is not acceptable for the disinfection of wastewater	Burleson et al.[76]	Log_{10} credits will only be assigned based on studies carried out in wastewater
Particles and aggregates can inhibit the ability of ozone to disinfect	CT values from studies carried out in filtered effluent are not applicable to unfiltered effluent	Herbold et al.[77]	Log_{10} credits will only be assigned to filtered wastewaters that have removed interfering particles
Phage tested to date are not conservative surrogates for viral inactivation by ozone	Previously used phage, such as f-specific coliphage, MS2 and f_2 are not acceptable surrogates for virus inactivation by ozone	Finch and Fairbairn[78]; Harakeh and Butler[60]; Xu et al.[62]	Specific pathogens rather than phage should be used for validation unless alternative phage to those tested to date are used
Virus serotype, growth method and preparation method affect results	Virus preparation must be carefully controlled in conducting studies of viral inactivation	Various studies	The precise virus used, preparation method and assay method must be appropriate

Table 17: Examples of ozone inactivation studies and observed CTs

Pathogen	CT	Log_{10} reduction observed	Conditions	Compare value (2 log_{10})	Report
PV 2	0.72	2	0.15 mg/L 4.83 min* ODFW 20ºC pH 7.2 CFCMR	0.72	Roy et al.[73]
EV 1	0.15	2	0.15 mg/L 1.02 min ODFW 20ºC pH 7.2 CFCMR	0.15	Roy et al.[73]
PV 1	0.08	2	0.15 mg/L 0.50 min ODFW 20ºC pH 7.2 CFCMR	0.08	Roy et al.[73]
CSV B5	0.07	2	0.15 mg/L 0.48 min ODFW 20ºC pH 7.2 CFCMR	0.07	Roy et al.[73]
EV 5	0.03	2	0.15 mg/L 0.22 min ODFW 20ºC pH 7.2 CFCMR	0.03	Roy et al.[73]
CSV A9	0.02	2	0.15 mg/L 0.12 min ODFW 20ºC pH 7.2 CFCMR	0.02	Roy et al.[73]
PV 1	0.22	2	0.15 mg/L 1.47 min ODFW 5ºC pH 7.2 CFCMR	0.22	Roy et al.[73] (used by US EPA[57] with 3 x safety factor for the SWTR)
ADV 40	0.02	2.6	0.49 mg/L dose 0.1 mg/L residual 0.25 min BDDFW 5ºC pH 7 Batch tests	0.02	Thurston-Enriquez et al.[75]
FCV	0.02	1.9	0.06 mg/L dose 0.02 mg/L residual 0.25 min BDDFW 5ºC pH 7 Batch tests	0.01	Thurston-Enriquez et al.[75]
PV 1	0.0002	4	Initial dose 0.17 mg/L Constant dose 0.10 mg/L 0.002 min PBS 20ºC pH 7 CFCMR	0.0001	Herbold et al.[77]
HAV	0.08	4	Initial dose 0.29 mg/L Constant dose 0.10 mg/L 0.8 min PBS 20ºC pH 7	0.04	Herbold et al.[77]

Pathogen	CT	Log_{10} reduction observed	Conditions	Compare value (2 log_{10})	Report
			CFCMR		
E. coli	0.06	4	Initial dose 0.15 mg/L Constant dose 0.10 mg/L 0.6 min PBS 20ºC pH 7 CFCMR	0.03	Herbold et al.[77]
HRV	0.01	3	Initial ozone dose 0.1 mg/L 0.1 min ODFPCB 4ºC pH 7 Batch	0.007	Vaughn et al.[79]
MS2	0.01	4	Initial dose 0.29 mg/L Constant dose 0.10 mg/L 0.8 min ODFPB 22ºC pH 7 Batch	0.005	Finch and Fairbairn[78]

CFCMR: continuous flow completely mixed reactor
ODFW: ozone-demand-free water
BDDFW: buffered disinfectant-demand-free water
BODFW: buffered ozone-demand-free water
PBS: phosphate buffered saline
ODFPCB: ozone-demand-free phosphate carbonate buffer
ODFPB: ozone-demand-free phosphate buffer

ADV: adenovirus
Bs: *Bacillus subtilis*
Cp: *Clostridium perfringens*
CSV: coxsackie virus
EC: enterococci
EnV: enterovirus
EV: echovirus
F^+: F-specific RNA coliphage
f_2: bacteriophage f_2
Fc: faecal coliforms
HAV: hepatitis A virus
HNV: human norovirus
HRV: human rotavirus
Lp: *Legionella pneumphila*
PV: polio virus
SRV: simian rotavirus
**estimated

Table 18: Approximate ranking of pathogen resistance to ozone from a range of studies

Study							Possible rank (most to least resistant)
Roy et al.[73]	Vaughn et al.[79]	Herbold et al.[77]	Shin and Sobsey[80]	Thurston-Enriquez et al.[75]	Xu et al.[62]	Harakeh and Butler[60]	
					Cp		1
		Bs					2
		Lp s6					3
PV 2							4
		HAV					5
		E. coli					6
					Fc≈Ec		6
EV 1							7
		PV1					7
PV 1							7
			PV1				7
						HRV	7
						PV1	7
						SRV	7
						EV1	7
					EnV≈F^+		8
						CSV B5	9
CSV B5							9
EV 5							10
CSV A9							11
				ADV40			12
						f_2	12
			HNV				12
	SRV						12
	HRV						12
				FCV			13
			MS2				13

ADV: adenovirus
Bs: *Bacillus subtilis*
Cp: *Clostridium perfringens*
CSV: coxsackie virus
EC: enterococci
EnV: enterovirus
EV: echovirus
F^+: F-specific RNA coliphage
f_2: bacteriophage f_2
Fc: faecal coliforms
HAV: hepatitis A virus
HNV: human norovirus
HRV: human rotavirus
Lp: *Legionella pneumphila*
PV: polio virus
SRV: simian rotavirus