

Department of Health

health

Guidelines for validating treatment processes for pathogen reduction

Supporting Class A recycled
water schemes in Victoria

February 2013

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February 2013 (1211020)

Foreword

Secure and sufficient water supply plays a critical part in ensuring a sustainable future for Victoria. Victorians' interest in sustainable water consumption has led the water industry and the community to explore the use of alternative water supplies – such as stormwater, recycled sewage and greywater – to augment Victoria's fresh water supplies.

These non-traditional methods of sourcing water, and the technologies to support them, are a relatively recent development, and the Victorian government has developed a rigorous regulatory framework to support the management and use of alternative water supplies.

The Department of Health's role in regulating water quality stems from the recognition that safe water is a public health cornerstone that is essential to sustain our health and quality of life. The department safeguards water quality by regulating water businesses, raising awareness, promoting health and wellbeing and by providing technical advice to industry, communities and individuals.

As part of its regulatory function the department has a role in endorsing 'Class A' recycled water schemes for use in residential and commercial developments, for irrigation of public spaces and sporting grounds, and for food crop irrigation. These uses come with a high risk of public exposure, and the department must ensure that the systems used by these schemes continually function reliably to produce water that is appropriate for the required end use and protective of public health.

In this context, these guidelines have been developed to help designers and operators of Class A recycled water schemes to 'validate' recycled water treatment process units, to prove that they reduce pathogens and produce water of a quality that will be safe to use.

The guidelines are the first of their kind, both in Australia and overseas. They have been developed using the best available science and have been subject to extensive national and international peer review and public consultation. The department acknowledges the important contribution made to the development of these guidelines by a wide range of government and industry stakeholders including members of the water industry.

These guidelines, in conjunction with relevant state and national recycled water guidelines, will facilitate efficient decision making in the planning and implementation of Class A recycled water schemes.

The department will continue to work in partnership with the Victorian water industry to facilitate the safe, secure and sustainable use of alternative water supplies in Victoria.



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Acknowledgements

This document has been developed by the Department of Health with support from the Smart Water Fund and Water Futures Pty Ltd. The department wishes to acknowledge the significant contribution from the following national and international experts:

Dr Terry Anderson
Dr Benoit Barbeau
Dr Judy Blackbeard
Dr David Cunliffe
Dr Monica Emelko
Mr Michael Finn
Adjunct Professor Ken Hartley
Mr Edmund Kobylinski
Dr Mark Lechevallier
Dr Karl Linden
Mr Jim Lozier
Dr Peter Mosse
Mr John Poon
Mr Stig Regli
Dr Alan Rimer
Dr Greg Ryan
Dr Richard Sakaji
Mr Andrew Salveson
Dr Bahman Sheikh
Mr Zlatko Tonkovic
Mr Harold Wright

We would also like to thank all those who took the time to provide feedback during the public consultation.

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With support from:
Mr Luc Richard, Ms Vanora Mulvenna, Ms Rachael Poon,
Department of Health Victoria, Dr Daniel Deere, Water
Futures Pty Ltd.

Chapter 7: photo shown on page 41 appears
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Chapter 5, 8 and 9: Photos shown on pages 23, 47
and 57 are by Christian Pearson and appear courtesy
of Melbourne Water.

Contents

1	Introduction	2
1.1	About the guidelines	2
1.1.1	Approval of new Class A recycled water schemes	3
1.1.2	Assessment of existing Class A recycled water schemes	3
1.2	About treatment validation	3
1.2.1	What is validation?	3
1.2.2	The role of validation in the approval process	3
1.2.3	The relationship of validation to AGWR monitoring categories	4
1.2.4	Benefits of the validation approach	5
1.2.5	The validation process	5
2	Guiding principles	7
3	The validation approach	11
3.1	Identification of mechanisms of pathogen reduction	12
3.2	Identification of target pathogens	12
3.3	Specification of log ₁₀ reduction requirements	13
3.4	Identification of influencing factors	13
3.5	Identification of operational monitoring parameters	14
3.6	Identification of validation methodology	14
3.6.1	Validation test program	14
3.6.2	Laboratory grown strain versus indigenous microorganisms	15
3.6.3	Surrogates for validation testing	15
3.6.4	Test operating conditions, monitoring and sampling	15
3.6.5	Quality assurance and quality control	16
3.7	Data collection and analysis	16
3.8	Determination of critical limits	17
3.9	Determination of log ₁₀ reduction value	17
3.10	Re-validation or additional onsite validation testing	18

4	Activated sludge processes	19
4.1	Pre-validation preparation	20
4.2	Validation monitoring	21
4.2.1	Microbial surrogates and indicators	21
4.2.2	Monitoring program	22
4.2.3	Data analysis	22
4.3	Operational monitoring	22
5	Media filtration	23
5.1	Pre-validation preparation	24
5.2	Validation monitoring	26
5.2.1	Microbial surrogates and indicators	26
5.2.2	Monitoring program	27
5.2.3	Data analysis	28
5.3	Operational monitoring	28
6	Membrane filtration	29
6.1	Pre-validation preparation	31
6.2	Validation monitoring	31
6.2.1	Microbial surrogates and indicators	31
6.2.2	Monitoring program – challenge testing	31
6.2.3	Data analysis	32
6.3	Operational monitoring	32
6.3.1	Direct integrity tests	32
6.3.2	Diagnostic testing	33
6.3.3	Indirect integrity testing	34
6.4	Application of membrane filtration for virus removal	34
6.4.1	Additional requirements for membrane filtration with coagulation for virus reduction	35
6.5	Reverse osmosis	37
6.5.1	Challenge testing	38
6.5.2	Operational monitoring	38
6.5.3	Conductivity profiling	38
6.5.4	Mini-challenge study	38
6.6	Research and development	39

7	Membrane bioreactors	41
7.1	Pre-validation preparation	42
7.2	Validation monitoring	43
7.2.1	Microbial surrogates and indicators	43
7.2.2	Validation monitoring program	44
7.2.3	Online monitoring technique and correlation with pathogen reduction	45
7.2.4	Data analysis	46
7.3	Operational monitoring	46
7.4	Research and development	46
8	Oxidant disinfectants	47
8.1	Pre-validation preparation	48
8.1.1	Particles	48
8.1.2	Disinfectant demand	48
8.1.3	Short-circuiting	49
8.2	Validation monitoring	50
8.2.1	Validation monitoring conditions	50
8.2.2	Chlorination, chloramination and chlorine dioxide	50
8.2.3	Ozone	55
8.3	Operational monitoring	56
9	Ultraviolet disinfection	57
9.1	Pre-validation preparation	58
9.1.1	UV dose requirements	58
9.1.2	Particles	59
9.1.3	UV absorbance and fouling	60
9.1.4	Short-circuiting	60
9.2	Validation monitoring	61
9.2.1	Challenge microorganisms	61
9.2.2	Data analysis for UV validation	61
9.2.3	Evaluating the need for re-validation	62
9.3	Operational monitoring	62

References	65
Appendix 1: RWQMP endorsement process	72
Appendix 2: Approach to developing these guidelines	73
A1.1 Adoption of authoritative and evidence-based approaches	73
A1.2 Review of existing validation guidelines, literature and benchmarking	73
A1.3 Knowledge management and implementation	73
Appendix 3: Verification monitoring	74
Appendix 4: Safety in design and operation	75
A4.1 Risk assessment and management	75
A4.1.1 Risk-based systems	75
A4.1.2 Hazard and operability studies	75
A4.1.3 Recycled water quality management plan	75
A4.2 Design and functionality	76
A4.3 Commissioning	76
A4.4 Operation and maintenance	77
A4.5 Operational personnel	77
A4.6 Quality assurance	77
Appendix 5: Example of operational monitoring procedure for membrane filtration	78
Glossary of terms and acronyms	80

Chapter 1

Introduction



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 prior to its use, to reduce hazards to an acceptable level.

The Victorian Government has developed a regulatory framework and guidance to support the safe and effective use of alternative water supplies. Under this framework recycled water is divided into different 'classes'. The required level of treatment and the associated water quality objectives for each class vary depending upon the nature of the end use for the recycled water. As the likelihood of ingesting recycled water increases, so does the required level of treatment.

Microbial water quality objectives for Class A recycled water are determined by a quantitative microbial risk assessment (QMRA), consistent with the *Australian guidelines for water recycling: managing health and environmental risks, Phase 1* (AGWR). QMRA uses quantitative data to measure the public's exposure to pathogens in recycled water and to assess the resulting health risk.

Class A recycled water has the highest microbiological standard and requires the highest level of treatment because it has end uses that carry a high risk of direct human exposure to, or incidental ingestion of, the water. These high-exposure uses include 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.

The Environment Protection Authority (EPA) Victoria is responsible for approving Class A recycled water schemes (the approval process is illustrated in Appendix 1). The requirements for Class A recycled water schemes are described in EPA Victoria's *Guidelines for environmental management: use of reclaimed water* (EPA Victoria publication 464.2) (2003) and *Guidelines for environmental management: dual pipe water recycling – health and environmental risk management* (EPA Victoria publication 1015) (2005).

In its role as Victoria's protector of public health, the department is required to endorse Class A recycled water schemes prior to their submission to EPA Victoria, to ensure that treatment plants can reliably produce recycled water with an appropriate microbial quality.

1.1 About the guidelines

The department has developed these guidelines for use by Class A recycled water scheme proponents (generally water businesses) and water treatment technology manufacturers, researchers and regulators. The guidelines supplement the information provided by EPA Victoria and support the implementation of the validation requirements in the AGWR.

These guidelines were developed using the best available science and extensive peer review and public consultation. The department's approach to developing and reviewing the guidelines is outlined in detail in Appendix 2.

The 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. Algal toxins and chemicals¹ as well as helminth reduction² are not addressed.

1 The principles and approach to validation detailed in these guidelines could be applied to toxins and chemicals. The health risks associated with algal toxins and chemicals should be addressed in the scheme's risk assessment, and the relevant controls detailed in the scheme's health and environmental management plan (HEMP).

2 Helminth reduction 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 activated sludge processes. In general, helminth reduction is most relevant to agricultural irrigation schemes that are typically of a lower quality 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.

The guidelines apply to the design and operation of both new and existing Class A recycled water schemes and describe:

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

1.1.1 Approval of new Class A recycled water schemes

According to EPA Victoria guidelines, proponents of Class A recycled water schemes are required to submit a recycled water quality management plan (RWQMP) to EPA Victoria for approval (refer to Figure 1). The department must endorse the plan prior to its submission to EPA Victoria. This endorsement focuses on assessing the capability of the recycled water treatment system to achieve the defined water quality objectives.

These guidelines should be used in conjunction with the *Guide for the completion of a recycled water quality management plan for Class A water recycling schemes* (2008) that was developed to assist Class A recycled water scheme proponents to complete their RWQMP.

1.1.2 Assessment of existing Class A recycled water schemes

These guidelines provide a benchmark against which scheme managers can assess existing facilities and identify areas for improvement. Scheme managers of existing Class A recycled water schemes are expected to provide a written, scheme-specific report, within eight months of the release of these guidelines. The report should include:

- a gap analysis identifying deviations in the existing scheme from the requirements of these guidelines
- a proposed work program to achieve compliance, including timeframes.

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), the plant must also be validated in accordance with these guidelines.

1.2 About treatment validation

1.2.1 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' ability to remove the target pathogens of concern (for example, through one-off challenge tests) with data from operational monitoring (for example, through disinfectant residual monitoring or membrane integrity testing). The operational monitoring parameters are used to demonstrate that the system is performing reliably and that events or conditions that could lead to system failure are rapidly detected. This allows for immediate corrective action to prevent the supply of substandard water.

1.2.2 The role of validation in the approval process

The validation of treatment processes to produce Class A recycled water quality is a key component of the approval process for Class A recycled water schemes. Treatment validation can be undertaken by a scheme proponent, a manufacturer or a research body. The department requires evidence of treatment validation before it will endorse the supply of Class A recycled water (refer to Figure 1). The evidence of validation is usually provided through the RWQMP.

Typically, treatment validation is undertaken once, unless the system or its operating conditions are modified. However, some treatment process units (for example, membranes that are relied upon for virus reduction) may require ongoing periodic validation.

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

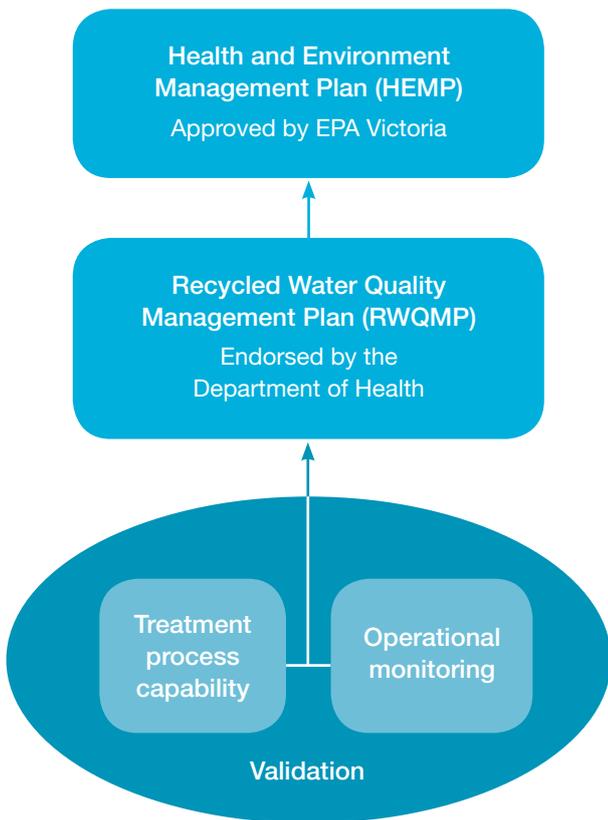
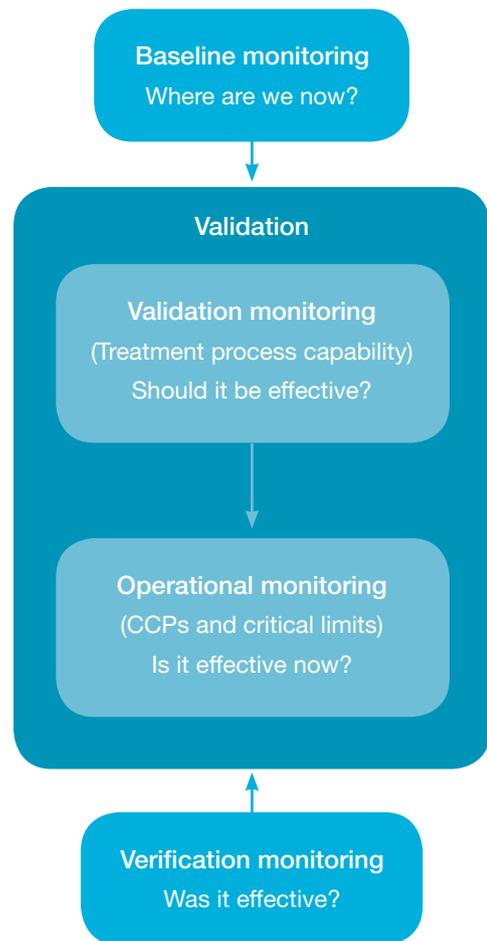


Figure 2: The relationship between ‘treatment validation’ and AWGR monitoring categories



1.2.3 The relationship of validation to AGWR monitoring categories

Treatment validation as described in these guidelines encompasses the activities described in the AGWR as ‘validation monitoring’ and ‘operational monitoring’ (refer to Figure 2).

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, it continues as part of routine operation, providing evidence of control.

Baseline and verification monitoring, while not specifically 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, pH ranges and ammonia levels for chlorine disinfection and ultraviolet transmissivity (UVT) for ultraviolet (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.

1.2.4 Benefits of the validation approach

Treatment validation and the subsequent reliance on operational monitoring parameters to indicate treatment efficacy have replaced older, end-point monitoring approaches³, and are considered far more protective of public health because they:

- provide results in a timeframe that allows rapid response (reliance on verification monitoring may place people at risk for days before a problem is detected)
- demonstrate how effectively 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)
- define the inherent capability of the treatment process to reduce pathogens, and define the range of operating conditions under which the system will perform reliably.

The focus in these guidelines on direct pathogen reduction rather than on prescriptive criteria for treatment process units provides a high level of innovation and flexibility by allowing water quality monitoring criteria to be customised to each treatment process unit. This approach requires strong emphasis on validation for individual treatment process units.

1.2.5 The validation process

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

- quantify its capability to remove or inactivate target pathogens from the key groups of bacteria, viruses and protozoan parasites⁴ – this is usually expressed in terms of 'log₁₀ reduction values' or LRVs, where a 'one-log₁₀ reduction' equates to a 90 per cent reduction of a pathogen, a 'two-log₁₀ reduction' equates to a 99 per cent reduction, a 'three-log₁₀ reduction' equates 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 pathogens.

Following treatment validation, the LRVs of individual treatment process units can be added together to provide a total LRV for the whole treatment process train. Individual treatment process units must be tightly monitored and controlled to ensure they are always providing the required LRV.

Pre-validation of treatment process units (for example, by a manufacturer prior to installation) is acceptable provided the validation methodology is consistent with these guidelines and the validation test conditions apply to the conditions under which the treatment process will operate when it is in place.

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

- activated sludge processes, media filtration and membrane bioreactors
- membrane filtration (microfiltration, ultrafiltration, reverse osmosis)
- disinfection processes (UV disinfection, ozonation, chlorination, chloramination, chlorine dioxide).

³ Historically, end-point water quality monitoring (or 'verification monitoring') was used to indicate treatment efficacy. While it must 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 (refer to Figure 2). Verification monitoring requirements for Victorian Class A recycled water schemes are described in Appendix 3.

⁴ Due to the wide array of pathogens that may be present in sewage, microbial water quality objectives are developed for each of the pathogen groups bacteria, viruses and protozoan parasites – rather than for individual organisms.

The description of the validation approach for specific treatment process units should not influence the selection of particular treatment process units. The most appropriate treatment process unit should be selected based on catchment and feedwater characteristics, intended uses of the treated water and the scale of the scheme. This non-prescriptive approach recognises that sewerage systems and other catchments differ and in some cases specific treatment process units may not be appropriate due to the inherent quality of feedwater. Furthermore, the chemical and physical water quality objectives for a specific end use may influence the choice of the treatment process units.

Where alternative treatment technologies are proposed, scheme proponents must develop a draft validation program, consistent with the guiding principles and validation steps described in sections 2 and 3, for consideration by the department.

Chapter 2 Guiding principles



Guiding principles

These guidelines are underpinned by the following guiding principles. Recycled water scheme proponents do not need to explicitly document compliance with these principles; rather, the principles must inform the design and operation of the recycled water scheme.

Safety is paramount: While recycled water can be a valuable resource, it is derived from high-risk water sources –sewage and greywater. 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 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 relatively high infectivity and resistance to most treatment process units. 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 must 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 by only monitoring the influent and effluent. This method of testing does not provide information on how the specific treatment performance varies under different operating conditions. Furthermore, end-point 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 end-point testing will not indicate how a treatment process unit will perform under higher pathogen concentrations.

Therefore, each individual treatment process unit must be 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 that specific treatment process unit.

In practice, bacterial pathogens are typically less infectious and far more sensitive to treatment processes than viruses and protozoa. Therefore, treatment process trains that have been validated for the required degree of virus and protozoa reduction are often considered to reduce bacterial pathogens to a sufficient degree for the protection of human health. As a result, specific validation for bacterial pathogens may not be required.

Limiting reliance on one treatment type: The maximum LRV that can be attributed to any one treatment type, regardless of its capability, is 4 log₁₀. This approach reflects a risk-based philosophy and supports the adoption of the multiple-barrier approach. Moreover, it is noted that published design criteria for disinfection processes is typically limited to demonstrating 4 log₁₀. 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 log₁₀ 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 an activated sludge plant, membrane filtration, chlorination and UV disinfection)
- the events that lead to failure differ and are independent (such as an increase in ammonia impacting on chlorination mode versus a ruptured membrane surface)
- the operational monitoring techniques are dissimilar and thereby the limitations and measurement of uncertainty are different (such as turbidity versus free chlorine residual)
- instrumentation and control loops must be sufficiently independent so that fault or inaccuracy with one control point does not affect another.

Given the above reasoning, the use of multiple processes of the same type in series cannot be used to gain more than 4 log₁₀ reduction for that process type. For instance, running two chlorination systems in series, each capable of achieving a 4 log₁₀ reduction in their own right, will not provide an 8 log₁₀ 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 log₁₀. Furthermore, the log reductions for multiple equivalent disinfection processes cannot be added together. For instance, two UV systems each achieving 2 LRV of protozoa operating in series does not provide a total of 4 LRV.

For Class A recycled water schemes that require 4 log₁₀ or less pathogen reduction (for example, a scheme where treated greywater is used in a commercial building for toilet flushing), it may be possible to attribute this to only one treatment process unit through validation (for example, membrane filtration), however it is expected that the multiple-barrier approach would still be adopted.

Statistical bounds: The statistical methods used to derive the LRV must be conservative.

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.

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 4 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 Class A 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 type in question and in the microbial aspects of treatment validation is required to ensure that:

- the validation study is conducted in a technically sound and unbiased manner;
- the validation study is consistent with the requirements of these guidelines (including other relevant guidance as specified); and
- the validation report contains accurate data and results.

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 the specifications in the risk management plan and that it is operating within the validated envelope for the duration of the third-party oversight
- the control system, including critical limit alarms and corrective actions, have been tested and verified.

Prior to recycled water being supplied to customers, the scheme proponent must provide written confirmation from the independent third-party confirming the above requirements have been met. This written confirmation must be appended to the RWQMP.

Independent third-party oversight will form part of ongoing scheme audits.

Chapter 3

The validation approach



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 must be used to devise a validation program for consideration by the department. The proposed validation program must be supported by evidence including 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 mechanisms of pathogen removal** by the treatment process unit
2. **identification of target pathogens**, or appropriate surrogates, that are the subject of the validation study for the specific treatment process unit
3. **specification of log₁₀ 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
4. **identification of influencing factors** that affect the efficacy of the treatment process unit 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 mechanisms of pathogen reduction

Successful validation of a treatment process unit relies upon identifying which reduction 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 combines an activated sludge microbial phase with filtration).

The characterisation of the mechanisms that lead to pathogen reduction assists in:

- selecting the target pathogens
- identifying the factors that affect the efficacy of the treatment process in reducing the target pathogens
- identifying appropriate operational monitoring parameters.

3.2 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 pathogen of those that have been evaluated.

Both a protozoan and viral target pathogen must be identified for each process unit. As discussed in the guiding principles (section 2), these represent the pathogen groups of greatest concern in recycled water schemes, as they are more infectious and resistant to treatment than bacteria. Therefore, it is assumed that treatment processes that are validated as being capable of meeting water quality objectives for protozoa and viruses will also be protective for bacterial pathogens. However, monitoring a bacterial indicator such as *E.coli* is generally recommended (unless otherwise indicated), to provide a complete picture of reduction of the three pathogen groups by the treatment process unit.

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

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

The target pathogens and potential surrogates are identified in these guidelines for the validation of common treatment process units (refer to the specific sections on each process unit for further details). Where the target pathogen is unknown, the onus is on the scheme proponent or manufacturer to conduct research to establish the target pathogen. Selection of the target pathogen is based on consideration of a worst-case combination of prevalence; resistance to treatment; survival in the environment; and pathogenicity.

If it is not practicable to use the target pathogen for validation testing, potential surrogates must be identified. Where a suitable surrogate cannot be identified, the target pathogen must be used as the challenge organism. 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.

3.3 Specification of log₁₀ 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 log₁₀ 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 log₁₀ reduction target has been determined, proposed individual LRVs can be assigned to components of the treatment train (refer to Table 1).

Table 1: Example breakdown of a scheme's log₁₀ reduction target

Pathogen group	Target LRV	Treatment process units		
		1	2	3
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 treatment process unit is 4 log₁₀.

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 management framework, 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 must 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 unit, 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. However, in practice, it is often possible to select a few key operational monitoring parameters that effectively demonstrate efficacy. Scheme proponents need to provide evidence that the operational monitoring regime demonstrates treatment 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 unit.

For some treatment process units, the validation study merely involves accessing data from existing process performance tables (for example chlorine CT tables) and demonstrating the contact time. 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

- **For membrane filtration:** challenge testing must be conducted according to the US EPA *Membrane filtration guidance manual* (MFGM) (U.S. EPA 2005) 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 (U.S. EPA 2005). 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) (U.S. EPA 2006c). 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). Tracer studies used to establish the minimum contact time, must be conducted at full-scale, unless plug flow can be assumed (See section 8.1.3).

Computational fluid dynamic (CFD) models must not be used in lieu of validation studies. CFD models provide 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, *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. However, a pilot study must not be used to establish the LRV for the treatment process unit.

Where pre-validated treatment process units or bench-top experimental studies are adopted, it is important to ensure that the 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

Refer to sections 4 to 9 for specific considerations for individual treatment process units.

3.6.2 Laboratory grown strain versus indigenous microorganisms

If there is a consistently sufficient concentration of a suitable indigenous microorganism in the feedwater to the process unit, it may be possible to measure the upstream and downstream concentrations of that microorganism directly in the wastewater being treated. The direct measurement of the indigenous target pathogen is the preferred option for validation, however in most circumstances, 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.

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 concentration of the test solution is based on the target LRV to be demonstrated during the challenge test and the detection limit of the challenge particulate. The challenge test dose must not result in artificially high LRVs due to excessive over-seeding. For example, the MFGM specifies a maximum allowable challenge particulate concentration in the feedwater used during a challenge test to prevent excessive over-seeding that can result in artificially high LRVs through particle aggregation.

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 reduction of the surrogate and the target pathogen (over the \log_{10} reduction range being applied).

Refer to subsequent sections on specific treatment processes units 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 a point after mixing has occurred, prior to and post the treatment process unit.

The validation testing program must be conducted under the expected field operating conditions for the scheme and must be approved by the department (refer to Appendix 1).

Typical and worst-case operating conditions associated with the treatment process unit (i.e. the critical control point for the specific pathogen under examination) must be informed by historical baseline monitoring and underpinned by a risk management framework. 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 for all treatment systems.

The test operating conditions will 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 must specifically identify:

- type of samples (e.g. composite, grab, etc.)
- 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 target pathogen or surrogate must be collected for each operating condition
- sample volumes
- that samples must be collected under steady-state conditions
- sampling locations
- sampling duration
- sampling intervals – where processes are influenced by seasonal factors, the monitoring program must be spread over those seasons to allow for those influences to be reflected in the dataset. Alternatively, if the worst-case season is known, sampling can be confined to that season.

- 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.

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 robust results.

The QC framework must 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.

QA/QC is discussed further in the following section.

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 (American Public Health Association et al. 2012).
- 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 where this is available
 - 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 must be appropriately measured
- all procedures must be performed by qualified personnel and be subject to quality assurance/quality control procedures.

The monitoring program 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 must be used to calculate the LRV.

The raw data and its analysis must 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 4-9.

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 measurement of uncertainty must be included, to the extent practicable, when 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* (International Organization for Standardization 2005), 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 must be carefully selected and calibrated to minimise uncertainty. Measurements must be traceable to a registered standard method, where this is available.

Increasing the sample number and/or sample volume and using more accurate and precise measuring devices will provide the best estimate of the pathogen \log_{10} reduction capability of a treatment process unit.

3.8 Determination of critical limits

A critical limit is a value 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.

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.

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 determined by the test operating conditions during the validation testing program. Therefore, the test operating conditions in the validation study must align with the expected field operating conditions for the scheme.

All operational monitoring, critical limit alarms and corrective actions must be tested and verified by an independent third-party (refer to section 2).

Online monitoring must be as timely as practicable. Monitoring linked to an appropriate alarm 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 detailed in the plans and specifications.

3.9 Determination of \log_{10} reduction value

The removal efficiency of a treatment process unit demonstrated by the challenge test results is determined according to the following equation:

$$\text{LRV} = \log_{10} (\text{feed concentration}) - \log_{10} (\text{product water concentration})$$

In general, a conservative approach is taken to analysing validation data to establish the challenge test LRV.

Unless otherwise specified in this guidance, the lower 5th percentile LRV established during challenge testing must be used.

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

- validated LRV demonstrated during challenge testing, or
- 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 (i.e. the sensitivity of the operational monitoring technique).

The LRV must be no more than $4.0 \log_{10}$ for any treatment process unit process or process type, as discussed 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

The validation study included in the RWQMP applies to the treatment process unit that is specified at plant 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 different to the documented validation test conditions.

Scheme proponents must 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.

Chapter 4 Activated sludge processes



Activated sludge processes

An analysis of national and international pathogen removal data for activated sludge plants has identified that the following default pathogen LRVs for well-designed, managed and operated activated sludge processes may be adopted:

- bacteria 1.0 log₁₀
- viruses 0.5 log₁₀
- protozoa 0.5 log₁₀.

These default LRVs apply to the set of operational conditions for a given activated sludge plant which define its typical performance under average dry weather flow. Wet weather flows are considered outside the operating envelope for these default values. If these default values are adopted then site-specific validation will focus on establishing the operational conditions and associated limits that define optimal performance for the activated sludge process. This is addressed in section 4.1.

Where scheme proponents seek pathogen LRVs greater than these default values, direct validation monitoring as per section 4.2 is required.

Section 4.3 addresses operational monitoring, and applies to both the default values and site-specific LRVs established via direct validation monitoring.

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 indicate that:

- There is no consistent correlation between operational monitoring parameters and pathogen reduction between different plants (Department of Health Victoria 2010).
- The significance of seasonal variation on pathogen load is not well characterised.
- *Cryptosporidium* is typically removed less than *Giardia*. The data available suggests that a 0.5 log₁₀ reduction can be typically achieved (lower fifth percentile value) (Department of Health Victoria 2010; Chauret et al. 1995; Robertson et al. 2000; Rose et al. 1996; Rose et al. 2001; Madore et al. 1987).

- Virus studies are limited and where available focus typically on enteroviruses, although there is more recent data on adenovirus. The data available suggests that a 0.5 log₁₀ reduction can be typically achieved (lower fifth percentile value). The literature, although limited, shows that mean removals of greater than 1 log may be achieved (Rose et al. 1996; Rose et al. 2001; Yanko 1993; Aulicino et al. 1996; Rolland et al. 1983).
- There is no ideal surrogate yet proven for viruses or protozoan parasites for all of the various types of activated sludge plants. Therefore direct pathogen monitoring is required, unless a site specific surrogate is identified (Department of Health Victoria 2010; Rose et al. 1996; Rose et al. 2001; Rolland et al. 1983; Moore et al. 1975).

Notwithstanding these observations, scheme proponents should be capable of demonstrating an understanding of the mechanisms of pathogen reduction in their activated sludge process and how this is controlled.

4.1 Pre-validation preparation

For activated sludge processes where the default LRVs are going to be adopted, pre-validation preparation involves assessing the process within a risk management framework to identify to operational conditions under which the plant performs optimally. This may include a desktop analysis of existing data for the process, or involve additional monitoring if insufficient data exists.

For activated sludge processes where LRVs greater than the default values are sought, this same assessment must be undertaken and the results of it combined with a microbial monitoring program (refer to section 4.2) to develop a validation program that concurrently monitors operational parameters and pathogen reduction. This will allow for the acceptable plant operating conditions that provide the demonstrated LRVs, to be determined.

For either approach, assessing the process within a risk management framework (refer to section 3.4) is underpinned by an understanding of the key mechanisms of pathogen reduction in activated sludge processes. These typically include adsorption of pathogenic microorganisms to suspended solids, removal of solids (with adsorbed pathogens) and predation by other organisms (Kim and Unno 1996; Glass and O'Brien 1980;

Gerba et al. 1978; Stadterman et al. 1994; Medema et al. 1998). The risk management framework needs to identify events that may result in sub-optimal operating conditions (that affect the mechanisms of pathogen removal) and operational monitoring that is indicative of these. At a minimum this should include:

- Loss of the mixed liquor suspended solids (MLSS) in the activated sludge reactor, which would decrease pathogen adsorption to solids leading to reduced removal rates (Shimohara et al. 1985; Suwa and Suzuki 2001; Wen et al. 2009). Operational monitoring parameters may include MLSS concentration in the reactor and sludge age.
- Loss of aeration in the activated sludge reactor, which would reduce pathogen removals due to decreased pathogen - solids adsorption and also poor sludge settling (Omura et al. 1989; Shimohara et al. 1985), Operational monitoring parameters may include dissolved oxygen concentration and ammonia concentration.
- Sludge bulking (mixed liquor does not compact or settle well, and floc particles are discharged in the clarifier effluent) (Van der Drift et al. 1977; Stadterman et al. 1994; Metcalf and Eddy 2003). Operational monitoring parameters may include sludge blanket level, sludge volume index and suspended solids concentration from the clarifier.
- Sludge rising in the clarifier caused by denitrification, resulting in solids carryover (Metcalf and Eddy 2003). Operational monitoring parameters may include sludge

blanket level and suspended solids concentration.

- Sludge foaming caused by filamentous organisms; however, this may have limited effect on pathogen removal rates (Metcalf and Eddy 2003). Operational monitoring parameters may include suspended solids concentration.
- Peak flow events; which could cause clarification failure if not managed, resulting in solids carryover (Metcalf and Eddy 2003). Operational monitoring parameters may include flow or hydraulic retention time, MLSS concentration in the reactor, sludge age and suspended solids concentration.
- Seasonal variation (in temperature, pH and salinity) and sewage catchment characteristics including trade waste inputs impacting on biomass and adsorption capacity (Shimohara et al. 1985; Moore et al. 1975; Wen et al. 2009). Operational monitoring parameters may include MLSS concentration in the reactor, temperature, salinity and pH.

4.2 Validation monitoring

This section only applies if scheme proponents are seeking an LRV greater than the default values for activated sludge processes.

4.2.1 Microbial surrogates and indicators

Microorganisms or surrogates that must be monitored for site-specific validation are provided in Table 2.

Table 2: Microorganisms 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 more resistant) by cell culture or quantitative polymerase chain reaction (QPCR)	20 paired grab samples evenly distributed 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	<i>Cryptosporidium</i>	
Bacteria	<i>E. coli</i>	

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

4.2.2 Monitoring program

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. *In situ* baseline performance data must be used to tailor the validation monitoring program.

The operational monitoring parameters informed by the risk management framework as described in section 4.1 must be monitored concurrently with the microbiological sampling program. The critical limits for these parameters will be confined to the operating envelope observed during the sampling period.

Microbiological samples must be collected for the activated sludge treatment step only (including clarifier where utilised); therefore, the samples are collected from influent to the activated sludge plant and its effluent. Grab samples must be collected. It is acknowledged that pairing samples is difficult. Notwithstanding these challenges, the effluent sample should, as close as practicable, be taken from the same body of water from which the influent sample was taken. 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.

Sampling events must occur across summer and winter months because seasonal variations may impact on the reduction of pathogens (refer to section 4.1). Sampling must be conducted within the proposed operating envelope where recycled water will be supplied, that is, not for bypass conditions if recycled water is not to be supplied during this time.

4.2.3 Data analysis

The LRV attributed to the activated sludge process is the fifth percentile of the paired \log_{10} reductions. The fifth percentile is adopted since it is difficult to correlate pathogen reduction across an activated sludge plant with operational monitoring.

4.3 Operational monitoring

The assessment described in section 4.1 will inform the operational monitoring program. Where validation monitoring is undertaken to derive site-specific LRVs, operational monitoring must 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, the ongoing monitoring of performance and management controls would be expected to involve:

- online measures of activated sludge and clarifier performance such as turbidity, flow and dissolved oxygen or ammonia
- regular observations of clarifier performance such as sludge blanket depth, and sludge settling supplemented with sludge volume index quantification (or equivalent)
- regular quantification of activated sludge properties such as MLSS concentrations and sludge age.
- regular microscopic analysis of activated sludge to ensure that the composition of microorganism populations in the activated sludge can be maintained.

Unlike waste discharge licences, performance would need to be as continuous as operational monitoring allows, since pathogens present an acute risk – this means that plant operation must be monitored and be performing appropriately at all times during recycled water production.

Chapter 5 Media filtration



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, coagulant, process configuration and the operational conditions applied.

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 (Nasser et al. 1995; Levine et al. 2003; Rose et al. 2001; Rose et al. 1996)
- while microspheres and some bacteria show potential as surrogates of parasite removal, they are not appropriate surrogates in all situations (Brown and Emelko 2009; Galofre et al. 2004; Huck et al. 2002; Nieminski and Ongerth 1995; Emelko 2003; Emelko et al. 2003; Emelko and Huck 2004)
- relationships can be highly dependent on the coagulation regime, how the system is operated and the system configuration (Huck et al. 2002; Nasser et al. 1995; Patania et al. 1995; Parkinson et al. 2003; Brown and Emelko 2009)
- 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 (Brown and Emelko 2009; Emelko 2003; Emelko et al. 2003; Emelko and Huck 2004)
- 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 (Patania et al. 1999; Swertfeger et al. 1999; Emelko et al. 2003; Levine et al. 2003; Melia and Shin 2001; Rose et al. 1996).

5.1 Pre-validation preparation

A risk management framework must support the selection of operational monitoring parameters for factors that affect the efficacy of the media filtration process. This section discusses potential pathogen reduction mechanisms and influencing factors that should be considered within the risk management framework and in the design of the validation monitoring program. This should not be considered as an exhaustive list of influencing factors.

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

- Straining – particles larger than the pores in the filter media are captured.
- Adsorption – particles smaller than the water passages in the filter are removed by adsorption processes, either on the filter media or to other particles in the water. Attachment depends on the particles colloidal stability and the attachment forces.
- Sedimentation – particles deviate from fluid streamlines and settle out in the localised spaces in the filter bed.
- Impingement/impaction – particles impinge on the surfaces of the media through inertial force.
- Coagulation/flocculation – particles modified by the added coagulant and flocculant adsorb to the filter media or form larger flocculated particles and are removed from the flow streams.
- Interception – particles remaining centred on fluid streamlines that pass filter media by a distance of half the particle diameter and are intercepted by the filter media. The significance of interception for filtration increases as particle size increases.
- Diffusion – Particles move by Brownian motion and will deviate from the fluid streamlines, due to diffusion, and are collected by the filter media.

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 (Parkinson et al. 2003; Logsdon et al. 1981). Operational monitoring parameters may include flow rate or application rate and effluent turbidity or particle counts.
- Suboptimal chemical pre-treatment during coagulation and flocculation (due to variation in feedwater, coagulant quality and dose, compromised floc formation and transfer onto media) (Adin and Asano 1998; Emelko and Huck 2004; Huck et al. 2001; Patania et al. 1995; Jolis et al. 1996; Tobiasson and O'melia 1988; Emelko et al. 2003). Operational monitoring may include zeta-potential and streaming current or monitoring of the effluent turbidity or particle counts. Regular jar-testing may also help ensure that the proper coagulant regime is in place.
- Breakthrough due to filter head loss (breakthrough of several log₁₀ units have been reported in the early stages of filter head loss) (Parkinson et al. 2003; Huck et al. 2002). Filter-to-waste will minimise particulate breakthrough during early filter head loss build up. Operational monitoring may include effluent turbidity or particle counts.
- End-of-run filtration can lead to decreased pathogen removal. Operational monitoring may include filter run-time or effluent turbidity or particle counts.
- Placing filters offline and online without backwashing and the recycling of backwash waters (Parkinson et al. 2003; Butler and Mayfield 1996). Operational monitoring may include effluent turbidity or particle counts.
- 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 (Kuo 1994). If the floc strength is weak, there is a stronger tendency for the floc particles to be sheared and carried through the filters. Operational monitoring may include effluent turbidity or particle counts

The operating parameters which should be considered in the validation monitoring program include:

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

The risk management framework must also consider chemical risks from trade waste inputs that may affect process performance, including the coagulation process, and how these events will be identified and controlled.

5.2 Validation monitoring

The pathogen reduction capability of a media filtration system must be demonstrated at full-scale (Butler and Mayfield 1996; Dugan et al. 2001; Nieminski and Ongerth 1995). Pilot scale may only be used to establish a correlation between pathogens and potential surrogates.

The operational monitoring parameters informed by the risk management framework described in section 5.1 must be monitored concurrently with the microbiological sampling program described in section 5.2.1. The critical limits for these parameters will be confined to the operating envelope observed during the sampling period.

Direct validation testing must occur under conditions representative of filter performance. Factors such as flow rates and chemical pre-treatment must be included in performance evaluation, while consideration must also be given to filter ripening, steady state operation, end-of-run cycle and breakthrough.

5.2.1 Microbial surrogates and indicators

Microorganisms and surrogates that must be monitored for site-specific validation are provided in Table 3.

Table 3: Microorganisms and surrogates for validation monitoring of media filtration

Pathogen group	Target microorganism	Microbial indicators
Protozoan parasites	<i>Cryptosporidium</i>	Indigenous or seeded <i>Cryptosporidium</i> oocysts. <i>or</i> Indigenous or seeded <i>Clostridium perfringens</i> ; yeasts; or seeded formalin-inactivated oocysts ¹ may be used if demonstrated to be a suitable surrogate as per section 3.6.3 for <i>in situ</i> conditions including but not limited to water characteristics, filter type and coagulant regime. This may be demonstrated at the pilot scale.
Viruses	Enteroviruses (encompassing polioviruses, coxsackievirus, echoviruses, enteroviruses) It should be noted that very few viruses have been investigated.	Indigenous or seeded enteroviruses. <i>or</i> Indigenous somatic or FRNA bacteriophage, or seeded MS2 bacteriophage, may be used if demonstrated to be a suitable surrogate as per section 3.6.3. This may be demonstrated at the pilot scale.
Bacteria	<i>E. coli</i>	Indigenous or seeded <i>E. coli</i>

Note 1: Studies indicate that formalin-inactivated oocysts are not consistently appropriate indicators of *Cryptosporidium* oocyst removal and that this may depend on the feedwater characteristics and coagulation type and regime (Brown and Emelko 2009; Huck et al. 2001; Nieminski and Ongerth 1995; Emelko 2003).

The recommended minimum microbial sampling program is provided in Table 4. This may be tailored to site-specific conditions.

Table 4: Recommended minimum microbial sampling program for media filtration¹

Period	Sampling event ²	Filter cycle				
		Ripening ³	Stable	End of run	Early breakthrough ³	Backwash ⁴
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 ⁵	3	3	3	3	1
	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. 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 stabilising).
4. Monitoring backwash to demonstrate that backwash operation is effective at removing microorganisms from the filter media.
5. Sample analysis QA/QC must be addressed in the validation methodology. For each sampling event, triplicate sampling is recommended to achieve statistical robustness and to assess standard deviations.

5.2.2 Monitoring program

The validation monitoring program must characterise the performance of the media filtration system during all stages of the filter cycle including during vulnerable periods of operation such as end-of-run filtration and late breakthrough.

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.

In situ baseline performance data should be used to tailor the validation monitoring program.

The recycling of untreated backwash water may constitute a significant source of pathogens (Butler and Mayfield 1996; States et al. 1995). Where recycling of untreated backwash water occurs (such as when returned to the head of works), a particle mass balance must be performed to identify whether the recycling of untreated backwash provides an additional pathogen load that needs to be accounted for in the treatment process train.

Samples must 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 the media effluent stream. Samples must 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.

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. The fifth percentile is adopted since it is difficult to correlate pathogen reduction across media filtration with operational monitoring.

5.3 Operational monitoring

The assessment described in section 5.1 will inform the operational monitoring parameters. 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 must be in line with the operating envelope to which the LRV can be attributed, and reflect the typical and worst case performance under which recycled water will be produced. The minimum requirements for operational monitoring are:

- 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 (Le Chevallier and Au 2004). Refer to the *Practical guide to the optimisation of chemical dosing, coagulation, flocculation and clarification* (Mosse et al. 2008).

- Monitoring of the filtration cycle including filter-to-waste times and triggers for backwashing.
- Monitoring of operating conditions for upstream treatment processes that may influence filter performance as informed by the risk management framework (Adin and Asano 1998).
- Monitoring of turbidity and particle size distribution (influent and effluent) as indicators of filter performance.
- An ongoing direct verification program of the filtrate (e.g. *E. coli*).

The triggers and criteria for operational monitoring must be informed by the risk management framework and the site-specific validation monitoring program.

Chapter 6 Membrane filtration



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) (U.S. EPA 2005). 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 remove the target pathogen. 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 integrity testing can be highly sensitive for detecting membrane integrity failures, but while it can be undertaken relatively regularly, it does require the relevant membrane module 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 integrity failures.

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

- 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 (i.e. membrane modules that are free from any integrity breaches)
- challenge test results for compromised membrane modules, if virus reduction is sought (refer to section 6.4).

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 risk analysis must 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
- hydraulic configuration and mode of operation of the membrane module
- integrity of the membrane 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).

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 membrane module to reduce the target pathogens. Challenge testing must be consistent with section 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 under representative hydraulic conditions including maximum operating flux and recovery (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 must be selected on a scientifically defensible basis, taking into consideration the manufacturing variability in the product line and quality assurance and control procedures in place. Two common approaches to module selection discussed in 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.

Variability in pathogen reduction exists between membrane modules. Therefore, notwithstanding the above, at least five membrane modules from different manufactured lots must be evaluated during a challenge test.

The recommended minimum sampling protocol for each module is described in Table 5.

Table 5: Recommended minimum microbial sampling program for membrane filtration

Sampling event	Filter cycle ¹				
	After backwash (e.g. 5 min)	Mid-filter run (e.g. 20 min)	End of filter run (e.g. 30 min)	Blank sample	Spiked sample ²
Number of paired samples per module ³	3	3	3	1	1

Notes:

1. modules must be flushed and sampled to ensure that no disinfectant residual is present
2. any die-off of surrogates in these samples would indicate the presence of an oxidant
3. Sample analysis QA/QC must be addressed in the validation methodology. For each sampling event, triplicate sampling is recommended to achieve statistical robustness and to assess standard deviations.

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-test} . The approach to determining the LRV results is as follows (U.S. EPA 2005):

- If fewer than 20 modules are tested, then the lowest of all representative LRVs is assigned as LRV_{C-test} .
- If more than 20 modules are tested, then the LRV_{C-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 unit must be free of defects and leaks (integrity breaches) that could result in pathogen breakthrough. It is essential that operators have the ability to demonstrate the integrity of the membrane system on an ongoing basis.

The minimum requirements for operational monitoring include:

- daily direct integrity test on each membrane unit
- diagnostic testing
- continuous indirect integrity 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 (including trans-membrane pressure, flow/flux, and temperature).

6.3.1 Direct integrity tests

Direct integrity testing is a critical component of membrane performance monitoring. It represents the most reliable and accurate means of demonstrating the integrity of a membrane unit. The direct integrity test (DIT) applies to the entire membrane unit including membranes, seals, potting material, associated valves and piping, and all other components which could result in contamination of the filtrate.

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

The guidance requires that the DIT 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 (U.S. EPA 2006a), is 3 μm , the lower size range of *Cryptosporidium* oocysts.
- Sensitivity: The maximum LRV that can be verified by the DIT. 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 diffusive airflow or pressure decay must be measured during commissioning. 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 can be calculated using equation 4.1 in the MFGM.

To calculate the minimum test pressure, conservative default values for the pore shape correction factor ($\kappa=1$) and the liquid-membrane contact angle ($\theta=0^\circ$) are provided in the MFGM. The use of values other than the default values provided in the MFGM must be scientifically justified and assessed by an independent third-party.

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 relevant to *in situ* operating conditions, cleaning and backwash regimes, and feedwater characteristics.

The surface tension at the lowest anticipated water temperature must 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 in the MFGM.

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 (Q_{breach}) 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 breach and trigger appropriate actions (refer to section 4.5 of the MFGM). If the direct integrity test result exceeds the upper control limit (UCL), this must trigger a membrane unit being taken offline for diagnostic testing and repair.

The supervisory control and data acquisition (SCADA) system must record the results of each DIT.

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 must 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 testing.

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. An investigation must be initiated where there is a discrepancy between the results of the indirect integrity test and the DIT.

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 filtration systems consistently achieve less than this value.

As particle counting data can vary significantly between instruments and membrane units within the same filtration system, site specific critical limits should be established during commissioning such that a stable baseline count can be determined.

Appendix 5 provides an example of how control limits may be incorporated into an operating procedure for a membrane filtration process.

6.4 Application of membrane filtration for virus removal

This discussion applies to ultrafiltration and microfiltration systems and is limited to hollow fibre configurations (guidance for flat sheet membrane configurations is not available). Where membrane filtration systems are aided by coagulation, additional requirements for validation monitoring apply as per section 6.4.1.

Appendix E of the MFGM describes various issues with applying the membrane validation methodology for awarding virus credits. 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 testing that is 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.

In the absence of a specific integrity test for virus-sized 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.

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

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

Challenge tests using MS2 bacteriophage must be conducted on intact membrane modules in the manner described above and in the MFGM.

- *Step 2: Conduct challenge testing on impaired membrane module*

Challenge test using MS2 bacteriophage must be conducted on at least one impaired membrane module in the manner described above and in the MFGM. For the purposes of this step an impaired membrane is defined as a module with one cut fibre, as close as practicable, to the filter–pot interface (this distance must be provided in the validation report). 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 3: Use a dilution model to establish the number of cut fibres that a particular membrane filtration unit can tolerate while still achieving the required virus LRV*

Use the results from steps 1 and 2 to calculate the theoretical number of broken fibres that a filtration unit can tolerate and still achieve the desired virus LRV.

- *Step 4: Establish a correlation between the direct integrity test results and the number of cut fibres*

During commissioning, cut an increasing number of fibres and record the effect on the membrane filtration unit's direct integrity test results. Derive an equation (a minimum of 5 data points, ranging from one cut fibre to the maximum number of cut fibres that can be tolerated) to describe the relationship between the total number of membrane modules in a unit, the number of cut fibres in the unit and the direct integrity test result.

The critical limit for the direct integrity test will be the lower of:

- The calculated UCL as per section 6.3.1
- The DIT results corresponding to the maximum number of broken fibres (determined in step 4) that a filtration unit can tolerate and still achieve the desired virus LRV.

- *Step 5: Establish the integrity of modules in a product line that are not subject to challenge testing*

For modules not subject to challenge testing 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. This requirement is consistent with MFGM.

- *Step 6: 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 response to the limitations of current membrane integrity test methods in detecting virus-sized integrity breaches 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 unit. The 'worst-case' module selected for the challenge study must have the worst-case record of integrity and have been subjected to the most backwashes, chemically enhanced backwashes and 'clean-in-place' procedures. It may be necessary to test more than one module if there is not one specific 'worst-case' module.

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 clean-in-place. The protocol for the annual challenge test must be included in the RWQMP.

6.4.1 Additional requirements for membrane filtration 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 log₁₀ with a clean membrane, through to 3.0 log₁₀ with coagulation. This cake layer is removed during backwashing and therefore it is not a removal process consistent with the MFGM, which focuses on the unassisted removal efficiency 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 log₁₀ reduction of viruses can be substantially reduced from 3.0 to 0.5 log₁₀.

The validation program and operational monitoring for membrane filtration 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) (Mosse et al. 2008).
- 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. The literature suggests that there is no ideal surrogate for the coagulation-assisted microfiltration process. Scientific evidence must be provided to substantiate the choice of the surrogate.

- 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 microbial sampling program for the challenge test must (refer to Table 6):
 - be conducted onsite at full-scale
 - comprise six sampling events.

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

Table 6: Recommended minimum microbial sampling program for coagulation-membrane filtration validation¹

Period	Sampling event ²	Filter cycle ³				
		Low fouling (after backwash)	Medium fouling	High fouling (before backwash)	Blank sample	Spiked sample ⁴
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 ⁵	3	3	3	1	1
	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. modules must be flushed and sampled to ensure that no disinfectant residual is present
4. any die-off of surrogates in these samples would indicate the presence of an oxidant.
5. Sample analysis QA/QC must be addressed in the validation methodology. For each sampling event, triplicate sampling is recommended to achieve statistical robustness and to assess standard deviations

The following must also be incorporated into the validation study:

- The calculation of removal efficiency must 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.
- Given the coagulation dependence of microfiltration to attain virus \log_{10} removals, it is necessary to establish a robust monitoring strategy for 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 assurance.

6.5 Reverse osmosis

Reverse osmosis (RO) technology is not an absolute barrier for pathogen removal and there are not currently any available online direct integrity tests.

Integrity methods for full-scale high-pressure membrane systems (RO and nanofiltration) have been limited to indirect monitoring of surrogates such as electrical conductivity (EC) and total organic carbon (TOC) monitoring – approaches that can generally only assess pathogen removal up to 2 \log_{10} .

The validation of RO systems must be consistent with the 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 dissolved organic carbon).

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/endcap 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 (2003) showed good correlation between MS2 bacteriophage and the two non-biological 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 with 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 the per cent rejection of a salt solution.

6.5.1 Challenge testing

A challenge test on each membrane unit 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. For microbial challenge tests, the procedure must be consistent with Chapter 3 of the MFGM and must consider the previous discussion on challenge testing in section 6.2. The R-WT challenge test must be undertaken in accordance with the American Society for Testing of Materials International (ASTM) method D 6908-06 (ASTM International 2010b).

The molecular marker (in this case R-WT) must 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. However, these must be conducted at commissioning to ensure the integrity of the installed unit.

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 as an indicator membrane integrity 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 the 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) or 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 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.

If EC is used then, at a minimum, online EC monitoring of the feed and permeate from a skid must be normalised daily (ASTM International 2010a). Furthermore, EC or TOC monitoring of the permeate from each pressure vessel must be conducted at least fortnightly.

6.5.3 Conductivity profiling

Conductivity profiling is a common method of identifying leaks in modules, o-rings and seals (U.S. EPA 2005) Conductivity profiling must be conducted when membrane modules are removed for inspection or are replaced with new modules (See Section 4.8.4 of the MFGM).

6.5.4 Mini-challenge study

Due to the limitations in the indirect monitoring techniques discussed in section 6.5.2, a 'mini-challenge' study using R-WT or indigenous or spiked MS2 bacteriophage must be conducted annually, at a minimum.

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* (ASTM International 2008).

6.6 Research and development

To advance the application of membrane filtration for pathogen reduction, research and development opportunities include:

- identification of a reliable and practical direct integrity monitoring technique for virus reduction of MF and UF membranes
- identification of a reliable and practical direct integrity test of RO
- determination of the extent of contact angle variability based on foulant type and membrane age (due to factors related to mechanical and chemical aging)
- defining the relationship between viruses, surrogates and coagulation regimes. The effect of coagulation differs for various viruses and therefore extrapolation of the data to other viruses is problematic.

Chapter 7 Membrane bioreactors



Membrane bioreactors

Membrane bioreactors (MBR) are 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.

There are two approaches that can be taken in validating an MBR system, the selection of which will be influenced by the specific MBR under consideration:

1. Validating the system solely on size exclusion by the membrane (and not the combination of pathogen reduction mechanisms in the biological treatment process followed by membrane-based size exclusion). This can only be undertaken on membranes that can be subject to a pressure-based direct integrity test (DIT). The validation must be undertaken using a clean water study, where there is no cake layer on the membrane, and must be performed in accordance with section 6 of this guidance and the the US EPA's *Membrane filtration guidance manual* (MFGM) (U.S. EPA 2005). The remainder of this section does not apply to systems validated in this manner.
2. Validating an LRV based on all the mechanisms that occur within the MBR process - i.e. biological and size-exclusion. This can be undertaken for systems with or without the capability to perform a DIT.

Where the first approach (validating the membrane) is taken it is likely that validation will result in a higher LRV being attributed for viruses, due to limitations in the sensitivity of current online indirect monitoring parameters for MBR systems.

The remainder of this section describes a methodology for the second approach. Research is encouraged so that this methodology can be refined as more evidence becomes available. Refer to section 7.4 for specific research needs.

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, storage, site installation and commissioning, and long-term operation. These principles are described in more detail in Section 3 of the MFGM.

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 clean-in-place 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 may influence process effectiveness 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, flux, permeability, filtration resistance, transmembrane pressure and cross-flow velocity
- membrane integrity
- predatory biota and adsorption/detachment processes that affect pathogen removal or inactivation
- 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 chemical oxygen demand concentration

- mechanics of aeration and aeration cycle
- trade waste and hazardous events such as toxic shock loads that impact on mixed liquor and membrane fouling and integrity (a particular issue for small-scale systems, such as those within commercial and residential buildings).

The manner in which these factors impact the mechanisms of pathogen removal must be considered within a risk management framework to identify to operational conditions under which the MBR system performs optimally and how events that disrupt process performance will be identified and controlled.

The concentration of biological material, including pathogens, within MBRs (referred to as the concentration factor) 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 should be considered in the validation study.

7.2 Validation monitoring

7.2.1 Microbial surrogates and indicators

Microorganisms or surrogates for validating MBR systems are provided in Table 7.

Table 7: Microorganisms or surrogates for validation monitoring of MBR

Pathogen group	Target microorganism	Microbial indicators
Viruses	Enteroviruses	Indigenous or seeded cultivable enteroviruses <i>or</i> Indigenous or seeded coliphage, such as somatic or FRNA coliphage, may be used if demonstrated to be a suitable surrogate for <i>in situ</i> conditions (as per section 3.6.3). This relationship may be demonstrated at the pilot scale.
Protozoan parasites	<i>Cryptosporidium</i>	Indigenous or seeded <i>Cryptosporidium</i> <i>or</i> Indigenous or seeded <i>Clostridium perfringens</i> may be used if demonstrated to be a suitable surrogate for <i>in situ</i> conditions (as per section 3.6.3). This relationship may be demonstrated at the pilot scale.
Bacteria	<i>E. coli</i>	Indigenous or seeded <i>E. coli</i>

7.2.2 Validation monitoring program

Samples must be collected representing the MBR step only; therefore, the samples must be collected from primary effluent entering the MBR, and from the MBR permeate.

Sampling events should occur across seasonal extremes because environmental conditions may affect biological activity, nitrification, MLSS characteristics and therefore the \log_{10} reduction of pathogens attributed to the biological inactivation mechanism (Metcalf and Eddy 2003). Sampling must be conducted within the proposed operating envelope for recycled water production, that is, not for bypass conditions (e.g. not during periods where MBR effluent is wasted or during activities such as backwashing). Sampling events must also be conducted across the range of membrane-ripening periods, which may take some weeks to months.

If a series of MBR modules are deployed, a minimum of 5 modules should be tested (consistent with the recommendations of the MFGM and Section 6.2.1 of these guidelines).

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 may include, but are not limited to:

- F/M ratio, SRT and HRT
- pH, ammonia concentration, dissolved oxygen of MBR zone, temperature
- permeate suspended solids concentration and turbidity
- MLSS concentration
- membrane flux, 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 must be conducted for low-, medium- and high-fouling conditions over extreme seasonal periods (such as winter and summer) or intensive monitoring for the worst-case seasonal/diurnal period (if known, 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 risk management framework. 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 through the MBR is considered to be significant. As an example, an unpublished validation study for a MBR system in Victoria adopted a pathogen concentration factor of 50 (i.e. 50 times greater compared with the influent concentration). The concentration factor must be quantified so 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 must be monitored concurrently to define the validated operational monitoring conditions.

The recommended minimum microbial sampling program for MBR validation is provided in Table 8. This may be tailored to site-specific conditions.

Table 8: Recommended minimum microbial sampling program for MBR validation¹

Period	Sampling event ²	Filter cycle		
		Low fouling (after chemical cleaning)	Medium fouling	High fouling (before backwash)
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 ³	3	3	3
	Number of filter cycles (non-consecutive days)	6	6	6

Notes:

1. Concurrently monitor operational parameters.
2. Grab samples rather than composite to avoid impact of interfering factors.
3. Sample analysis QA/QC must be addressed in the validation methodology. Samples must be taken to ensure that no oxidant residual is present. For each sampling event, triplicate sampling is recommended to achieve statistical robustness and to assess standard deviations.

Where pressure-based membrane integrity tests cannot be performed online, the LRV attributed to the system will be limited by the sensitivity of the continuous indirect integrity test (such as turbidity, particle counts or other suitable parameters).

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 test to 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. This approach is based on the assumption that the MLSS concentration in the permeate provides an indication of the pathogen concentration in the permeate. This assumption must be tested during the experimental study.

Step 1: Establish the relationship between the online monitoring technique, 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: 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 pathogen concentration factor, 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 3: 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:

- LRV demonstrated during challenge testing (section 7.2.2)

The LRV derived from the challenge test must be calculated as the lowest of the paired \log_{10} reductions based on the average of triplicate samples, or

- the maximum LRV that can be reliably verified by the online direct/indirect test (section 7.2.3).

7.3 Operational monitoring

The ongoing operational monitoring including critical limits must be informed by the validated operating envelope within which the LRV can be attributed.

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 through monitoring bacteriophage concentrations in the MBR permeate and physicochemical parameters discussed above.

Where membranes are being replaced, new membranes must be subject to a direct integrity test prior to operation.

Where a direct integrity test is not practical, the microbial sampling program (as detailed in Table 7) should be implemented for at least three filter cycles.

7.4 Research and development

To advance the application of MBR for pathogen reduction and to refine the validation methodology described in this section, research and development opportunities include:

- identification of a reliable and practical direct integrity monitoring technique for pathogen reduction through the entire MBR process
- demonstration of whether a relationship exists between the MLSS concentration in the permeate and the concentration pathogens in the permeate
- confirmation of the suitability of enteroviruses as a target virus pathogen
- identification of suitable surrogates for protozoa and virus pathogens for use in challenge testing
- characterisation of the pathogen reduction capability of MBR under typical and worst-case operating conditions and how this may be correlated to an operating envelope
- quantification of the extent to which pathogens concentrate within the reactor under different sludge wasting regimes applicable to MBR
- characterisation of the mechanisms responsible for pathogen reduction in MBR units (including adsorption, predation, biofilm); their significance; and factors that may influence these mechanisms. The outcomes of this research may refine the operational monitoring program.

Chapter 8 Oxidant disinfectants



Oxidant disinfectants

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

For practical purposes, chlorine and chloramine are ineffective at inactivating *Cryptosporidium* oocysts in wastewater. Ozone and chlorine dioxide can be effective at inactivating *Cryptosporidium* oocysts at practically achievable doses, but neither are commonly used disinfectants.

Most oxidant disinfectants are effective against both bacteria and viruses; however there are practical limitations in the case of chloramine.

In developing this section, the following guidance documents were reviewed: Disinfection profiling and benchmarking guidance manual, Alternative disinfectants and oxidants guidance manual, and the Long term 2 enhanced surface water treatment rule toolbox guidance manual (U.S. EPA 1999b, 1999a, 2010). Specific research reports were also used to complete this section.

8.1 Pre-validation preparation

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 major interfering factors since it is very difficult to objectively measure their interfering effect.

Particles from wastewater treatment processes can include small floc particles (often termed 'pin-flocs'), oily suspensions (often termed 'fat balls'), algae 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 difficult to assess whether or not shielding is taking place. Almost all oxidant inactivation experiments and CT values are based on freely suspended mono-dispersed 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 in the test water matrix 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. In order to examine the impact of particle shielding on the inactivation kinetics of an organism, validation experiments require careful design to achieve particle interaction.

8.1.2 Disinfectant demand

Disinfectant demand is a relatively manageable interfering factor, although a number of 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.

Generally, the simplest and most conservative monitoring strategy is adopted, which consists of monitoring the disinfectant concentration 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 product of the validated contact time and the disinfectant concentration still present at the end of that contact time. Alternative methods for calculating CT, as described in the Long term 2 enhanced surface water treatment rule toolbox guidance manual US EPA (U.S. EPA 2010), may be used provided the method is commensurate with the basis under which the CT was originally determined. Alternative methods require a greater amount of process evaluation and monitoring (i.e. measurements at multiple points within the contact chamber) and must be demonstrated to reliably calculate the CT.

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 the 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 equal to the theoretical detention time (TDT) and a tracer test is not required. 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 (Marske and Boyle 1973).

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. In these situations baffling can be used to maximise the basin volume, increase plug flow and minimise short-circuiting.

The US EPA used the studies conducted by Marske and Boyle (Marske and Boyle 1973) 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; and only recommended for use on a limited basis.

However, from a review of the referenced study by Marske and Boyle (Marske and Boyle 1973) 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 not considered possible to reliably estimate the true T_{10} within a storage tank by using default baffle factors.

An acceptable method for deriving contact times in reactors using tracer studies is provided by the US EPA (U.S. EPA 2010, 1999b).

As T_{10} is inversely proportional to the flow rate, tracer studies conducted at only one flow rate must 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, from which interpolation can be used to derive the appropriate T_{10} .

In addition to flow conditions, detention times determined by tracer studies are dependent on the water level in the contact basin. Tracer studies must be conducted with the water level in the contact tank at or slightly below (but not above) the normal minimum operating level.

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 supply recycled water. Separate LRVs are assigned for the three pathogen groups (viruses, protozoa and bacteria).

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. A minimum contact time will need to be demonstrated through a tracer study as per section 8.1.3.

Critical limits must accord with the disinfection conditions under which the CT values were established. Critical limits need to be set for the following parameters:

- oxidant CT or 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
- maximum instantaneous flow rate through the contact tank
- minimum tank hydraulic volume/level
- minimum water temperature
- maximum turbidity and suspended solids concentration.

8.2.2 Chlorination, chloramination and chlorine dioxide

Inactivation of viruses

Chlorine

Coxsackie virus B5 is a viral pathogen that has been shown to be one of the most resistant to free chlorine disinfection among the many viruses that are, or that are similar to, waterborne enteric viruses. Therefore, the free chlorine virus CTs adopted in these guidelines are based on experimental data describing the inactivation of Coxsackie virus B5 by free chlorine from recent work by the Australian Water quality Centre, which was supported by the Smart Water fund, Victoria (Keegan et al. 2012). The findings of the AWQC report (adapted and summarised in Table 9) were undertaken to gather additional data to develop chlorine CTs. The AWQC study built upon the Black et al. (2009) work by adding more turbidity and pH values to the range of data points available to support the development of CTs at various turbidity and pH values. The results from the AWQC study are consistent with the Black et al. (2009) study and are considered to be mutually supportive, fully independent studies, adding to the credibility of both.

This more recent free chlorine CT data is considered to supersede the US EPA CT values that have previously been in widespread use (U.S. EPA 1999b, 1991) as the US EPA values are based on Hepatitis A virus, a less resistant virus than Coxsackie virus B5 to chlorine inactivation.

Chloramines

For chloramines, the CT values published by the US EPA (U.S. EPA 1991, 1999b) are not applicable to wastewater. 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) (U.S. EPA 1991). The existing ammonia in most wastewater has the equivalent effect to the addition of ammonia ahead of chlorine.

An AWQC study investigated the effectiveness of chloramine disinfection on Adenovirus 2 in wastewater (Keegan et al. 2012). Adenovirus 2 was selected for this study as it was considered the most resistant to chloramine of the culturable virus types commonly associated with waterborne enteric infections. The results from this AWQC study have been adapted and summarised in Table 9, and must be used in determining CT requirements for chloramination of wastewater. The results from the AWQC report support the previous findings of Sirikanchana et al. (2008).

As monochloramine, (as distinct from dichloramine, nitrogen trichloride (trichloramine) or other forms of combined chlorine) is the effective disinfectant, the online residual monitoring should be specific to monochloramine. It is possible to directly monitor monochloramine (NH_2Cl), as distinct simply from total, or combined, chlorine. If for some reason direct measurements of monochloramine are not possible and total chlorine residual is used as a surrogate for monochloramine CT, then ammonia must also be monitored online to ensure that the ratio of chlorine to ammonia is $\leq 5:1$.

Studies undertaken by AWQC for Melbourne Water, and analysed by Melbourne Water, (as yet unpublished), support the commonly used rule of thumb for chemical reactions for an approximate doubling in chemical reaction rates for every 10°C increase in temperature (often referred to as a Q_{10} of ≈ 2) when comparing chloramine inactivation in wastewater at 10, 15 and 20°C . However, at present, there is insufficient data to simplistically apply that principle to the CT values given in Table 8. Therefore, further demonstration at a broader range of conditions would need to be undertaken on-site.

Chlorine dioxide

Chlorine dioxide is a strong disinfectant that has shown to be effective at inactivating viruses. The chlorine dioxide CTs published in the US EPA Disinfection profiling and benchmarking guidance manual (1999) should be adopted (refer to Table 9).

Table 9: Viral log₁₀ reduction criteria for oxidant disinfectants

Oxidant	Turbidity (NTU)	Temperature critical limit	pH critical limit ¹	Log ₁₀ reduction credit	CT critical limit ² (mg•min/L)	Reference
Free chlorine	≤ 2.0	≥ 10°C	≤ 7.0	1	≥ 3	Keegan et al. (2012) building on Black et al. (2009)
				2	≥ 4	
				3	≥ 5	
				4	≥ 6	
			≤ 7.5	1	≥ 5	
				2	≥ 7	
				3	≥ 9	
				4	≥ 11	
			≤ 8.0	1	≥ 7	
				2	≥ 10	
				3	≥ 13	
				4	≥ 16	
			≤ 8.5	1	≥ 9	
				2	≥ 13	
	3	≥ 17				
	4	≥ 22				
	≤ 9.0	1	≥ 10			
		2	≥ 16			
		3	≥ 21			
		4	≥ 27			
	≤ 5.0	≥ 10°C	≤ 7.0	1	≥ 3	
				2	≥ 4	
				3	≥ 5	
				4	≥ 7	
			≤ 7.5	1	≥ 6	
				2	≥ 7	
				3	≥ 12	
				4	≥ 15	
≤ 8.0			1	≥ 9		
			2	≥ 13		
			3	≥ 18		
			4	≥ 23		

Oxidant	Turbidity (NTU)	Temperature critical limit	pH critical limit ¹	Log ₁₀ reduction credit	CT critical limit ² (mg•min/L)	Reference
			≤ 8.5	1	≥ 10	
				2	≥ 13	
				3	≥ 21	
				4	≥ 26	
			≤ 9.0	1	≥ 10	
				2	≥ 16	
				3	≥ 23	
				4	≥ 29	
Monochloramine	≤ 2.0	≥ 10°C	≤ 7.0	1	≥ 977	Keegan et al. (2012) building on Sirikanchana et al. (2008)
				2	≥ 1681	
				3	≥ 2386	
				4	≥ 3090	
			≤ 7.5	1	≥ 1236	
				2	≥ 2000	
				3	≥ 2764	
				4	≥ 3528	
			≤ 8.0	1	≥ 1494	
				2	≥ 2318	
				3	≥ 3141	
				4	≥ 3965	
			≤ 8.5	1	≥ 2324	
				2	≥ 3356	
				3	≥ 4386	
				4	≥ 5418	
			≤ 9.0	1	≥ 3154	
				2	≥ 4393	
				3	≥ 5631	
				4	≥ 6870	

Oxidant	Turbidity (NTU)	Temperature critical limit	pH critical limit ¹	Log ₁₀ reduction credit	CT critical limit ² (mg•min/L)	Reference
	≤ 5.0	≥ 10°C	≤ 7.0	1	≥ 1201	Keegan et al. (2012) building on Sirikanchana et al. (2008)
				2	≥ 1914	
				3	≥ 2628	
				4	≥ 3341	
			≤ 7.5	1	≥ 1399	
				2	≥ 2228	
				3	≥ 3057	
				4	≥ 3886	
			≤ 8.0	1	≥ 1596	
				2	≥ 2541	
				3	≥ 3486	
				4	≥ 4431	
			≤ 8.5	1	≥ 2998	
				2	≥ 4254	
				3	≥ 5511	
				4	≥ 6767	
	1	≥ 4400				
	2	≥ 5967				
	3	≥ 7535				
	4	≥ 9102				
Chlorine dioxide	≤ 2.0	≥ 5°C	6 ≤ pH ≤ 9	2	≥ 5.6	(U.S. EPA 1999b)
				3	≥ 17.1	
				4	≥ 33.4	
		≥ 10°C		2	≥ 4.2	
				3	≥ 12.8	
				4	≥ 25.1	
		≥ 15°C		2	≥ 2.8	
				3	≥ 8.6	
				4	≥ 16.7	
		≥ 20°C		2	≥ 2.1	
				3	≥ 6.4	
				4	≥ 12.5	

1. pH must be measured post oxidant addition at a point after mixing has occurred
2. oxidant residual must be measured at the end of the contact time.

Inactivation of bacteria

For bacteria, *E. coli* is the target microorganism for which log₁₀ reduction credits would be assigned for free chlorine, chloramines and chlorine dioxide disinfection. For practical purposes, the log₁₀ reduction credits assigned to bacteria can simply be set at the log₁₀ reduction credits assigned for viruses.

Inactivation of protozoa

Chlorine and Chloramine

Cryptosporidium is not inactivated by chlorine or chloramine at achievable doses during conventional wastewater disinfection, therefore protozoan log₁₀ credits would not apply to these oxidants.

Chlorine dioxide

Cryptosporidium is the pathogen for which log₁₀ reduction credits must be assigned. The CT tables and equations provided by the US EPA (U.S. EPA 2006b) for chlorine dioxide are considered appropriate to derive log₁₀ reduction credits for protozoa in filtered wastewater (since chlorine dioxide does not react with ammonia). These CTs are provided in Table 10.

8.2.3 Ozone

There is limited published information on pathogen ozone CT values in wastewater therefore site-specific studies must be undertaken. In developing these guidelines the following studies were reviewed: Xu et al. 2002; U.S. EPA 1991; Roy et al. 1981; Katzenelson et al. 1979; Roy et al. 1982; Thurston-Enriquez et al. 2005; Burleson et al. 1975; Herbold et al. 1989; Finch and Fairbairn 1991; Harakeh and Butler 1984; Vaughn et al. 1987; Shin and Sobsey 2003.

A key point to note from many of these studies is that the drinking water matrix is quite different to the wastewater matrix in relation to ozone disinfection efficacy. Therefore, specifically targeted studies are currently required for the department to develop ozone CTs for pathogen reduction in recycled water schemes. Melbourne Water is currently completing some extensive studies in this area.

Table 10: CT values for *Cryptosporidium* inactivation by chlorine dioxide (U.S. EPA 2010)

Log ¹⁰ Credit	Water temperature, C°										
	≤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

Inactivation of viruses

A few ozonation studies have used wastewater to provide an indication of virus inactivation (Unpublished data) (Xu et al. 2002). However, these results will need to be validated for site-specific applications. Furthermore, 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.

Inactivation of protozoa

There is insufficient evidence to establish default CT or equivalent values for protozoa in wastewater. It is noted that ozonation behaves quite differently in wastewater as compared with drinking water. Therefore, the US EPA (U.S. EPA 2006b) drinking water criteria are considered unsuitable for wastewater applications. In the absence of default CT values, site-specific studies are required to derive a relationship between ozone disinfection and inactivation of protozoa.

8.3 Operational monitoring

Operational monitoring must encompass the critical limits as determined by validation monitoring, as per section 8.2.1.

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 measured contact time 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.

In measuring residual oxidant, it is important to recognise the limitations of analysers and manage these accordingly so that the analyser output is in fact a true reading. For example in the case of free chlorine, some analysers may result in false positive readings in the presence of chloramines and other interfering factors.

Instruments used to measure residual oxidant must reflect real-time disinfection performance. To achieve this, the time taken for the sample to travel from the sampling point to the analyser and time intervals between samples should be kept to a minimum. The limitations of the instrument (including associated controls to compensate for these limitations) and time delays must be identified in the RWQMP.

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.

As previously discussed, particulates in the water will impact on oxidant disinfection efficacy therefore; the performance of upstream filtration, sedimentation and other forms of solids removal processes must be monitored to ensure that the water quality is commensurate with the conditions from the oxidant disinfection validation study at all times during recycled water production. Optimisation of these processes will improve downstream oxidant disinfection efficacy.

Chapter 9

UV disinfection



UV disinfection

This section covers the validation requirements for UV disinfection.

The UV disinfection guidance provided by the US EPA *Ultraviolet disinfection guidance manual for the final long term 2 enhanced surface water treatment rule* (UVDGM) (U.S. EPA 2006c) is considered the most authoritative guidance document and is therefore adopted for validation of UV reactors.

The validation report submitted to the department must demonstrate compliance with the UVDGM validation methodology, including all QA/QC requirements. The UV dose requirements specified in Table 1.4 of the UVDGM apply.

The UVDGM is considered to have superseded the DVGW (DVGW 2006b, 2006a, 2006c), NSF (NSF International 2004), ONORM (ONORM (Austrian Standards Institute) 2001, 2003) and NWRI guidelines (National Water Research Institute 2012). Unlike UVDGM, these guidelines do not deal comprehensively with concepts such as uncertainty and bias between challenge test microorganisms and target pathogens.

Pre-validated reactor designs, or units built to simulate designs validated elsewhere, are accepted without a requirement to repeat the validation for the specific reactor, provided the validation methodology is consistent with the UVDGM and the validation test conditions are representative of *in situ* conditions.

Some details are provided in this section on the application of the UVDGM to recycled water since the UVDGM is in fact designed to be applied only to drinking water. These differences are namely the influence of particles in wastewater and high UV absorbance. The UV dose requirements were established on particle free water and therefore the influence of particles in wastewater will restrict the application of UV disinfection in some recycled water schemes. Therefore, planning is essential in designing a recycled water scheme to ensure that upstream treatment processes allow for the application of UV disinfection and optimise its efficacy. In relation to UV absorbance, the UVDGM does not provide RED bias figures for UVT levels below 65 per cent, and therefore some modifications have been made. These issues are discussed in more detail in section 9.2.2.

9.1 Pre-validation preparation

UV disinfection is typically highly effective against both bacteria and protozoa; however, relatively high doses are required to inactivate some viruses, specifically adenovirus. Many commercially available pre-packaged UV disinfection systems provide a dose of only 40 mJ/cm² or less, which will provide only minimal viral inactivation.

Prior to undertaking the validation study, a risk analysis should be undertaken. Baseline monitoring data (such as flow, and UV absorbing compounds) should be used to inform the validation testing envelope. Furthermore, treatment processes upstream of the UV reactors should be operated to maximise the removal of particles, increase UVT and reduce the fouling potential, thereby optimising the design and costs of the UV equipment. The UVDGM discusses water quality considerations to be taken into account in the design of UV disinfection systems.

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 UV dose requirements

Table 1.4 of the UVDGM specifies the UV doses required to achieve the target pathogen (*Cryptosporidium*, *Giardia* and viruses) log reductions (from 0.5 to 4 LRV). Under the *Final long term 2 enhanced surface water treatment rule* (40 CFR 141.720(d)(1)), the US EPA developed these UV doses for post-filter applications of UV and for public water systems that met applicable filtration avoidance criteria. These UV dose requirements were experimentally established by irradiating particle free water that had been inoculated with the target pathogens (namely *Cryptosporidium*, *Giardia* and adenovirus).

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. For viruses, adenovirus provides the target pathogen for which \log_{10} reduction credits must be assigned for both low and medium pressure UV systems. 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 the pathogen that must be used for deriving UV disinfection LRVs. To deviate from this position, virtually all other viral enteric pathogens would have to be tested and shown to be much more sensitive to UV than to the next-most resistant viral pathogen.

In establishing the UV dose requirements, the US EPA examined research studies on filtered water, high quality unfiltered water, laboratory water and low turbidity reclaimed wastewater. The US EPA restricted its evaluation to water with turbidity values less than or equal to 1 NTU (U.S. EPA 2003).

Therefore, published UV dose–response values can only be applied to treated wastewater with turbidity values less than or equal to 1.0 NTU. This turbidity is readily achievable with appropriately designed and operated filtration systems.

The UVDGM refers to several studies, whereby tailing has been attributed to the presence of UV-resistant sub-populations of the microorganisms and the presence of particulate-associated and clumped microorganisms.

Where turbidity exceeds 1 NTU in the feedwater to the UV disinfection system, the scheme proponent must conclusively demonstrate that the feedwater matrix (under worst case operating conditions) will not adversely impact on the validated UV dose determined by table 1.4 of the UVDGM. An analysis must be undertaken to assess the risk of particle shielding and its potential to influence the inactivation of the target pathogen taking into consideration the type of particles and particle size distribution. Subject to the outcomes of the analysis, site-specific collimated beam studies on the target organism could be required to ascertain if there is any adverse impact on the validated UV dose determined by table 1.4 of the UVDGM.

Therefore in planning and designing a recycled water plant, scheme proponents should ensure that upstream treatment processes reliably achieve turbidity less than 1 NTU.

9.1.2 Particles

Particles are the more problematic of the interfering factors since it is very difficult to objectively measure their interfering effect. Particles may shield pathogens from UV light and therefore hinder inactivation. 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-dispersed 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.

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 small floc particles, oily suspensions, algae and pathogen aggregates 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 potentially underperform under alternative conditions in ways that might not be readily detectable under routine operation.

9.1.3 UV absorbance and fouling

UV absorbance is a relatively manageable interfering factor although a number of conservative assumptions need to be applied when taking the effects into consideration. UV absorbance, as measured by a sensor, must be used to calculate the claimed UV dose, which is referred to as the Reduction Equivalent Dose (RED).

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. 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 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.

9.1.4 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 (i.e. the RED) 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.

Changing flow rates have 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. The maximum validated flow rate must not be exceeded during operation. If the operating flow rate measures less than the minimum flow rate evaluated during validation testing, the minimum flow rate evaluated during validation testing must be used as the default in the dose-monitoring equation. Interpolation between tested flow rates is acceptable.

9.2 Validation monitoring

The LRV assigned to the UV disinfection step must be validated under the worst-case conditions that will be experienced by the system when it will supply recycled water.

The minimum requirements for validation testing must be consistent with section 5 of the UVDGM. Section 5 of the UVDGM includes a useful checklist of the key elements of the validation test plan.

The validation testing must demonstrate the operating conditions under which the reactor can deliver the necessary UV dose, including flow rate, UV intensity, and UV lamp status. The following must be accounted for in validation testing: the UV absorbance of the water; lamp fouling and aging; measurement uncertainty of on-line sensors; UV dose distributions from the velocity profiles through the reactor; failure of UV lamps or other system components; and inlet and outlet piping or channel configurations of the UV reactor.

Validation testing must include full scale testing of a reactor that is identical to the UV reactor that will be used *in situ*.

9.2.1 Challenge microorganisms

Based on the UVDGM, the challenge microorganism selected for the validation test should ideally have the same sensitivity to UV light (i.e. the same microbial dose-response) as the target pathogen. If medium-pressure (MP) lamps are used, the organism should display a similar action spectrum, which is the relative sensitivity of the organism at other wavelengths compared to its sensitivity at 254 nm. Section 5.3 of the UVDGM provides information on the UV sensitivity of some commonly used challenge microorganisms. Some microorganisms exhibit shoulders or tailing in their UV dose-response which limit the range of UV doses that can be used to validate the reactor.

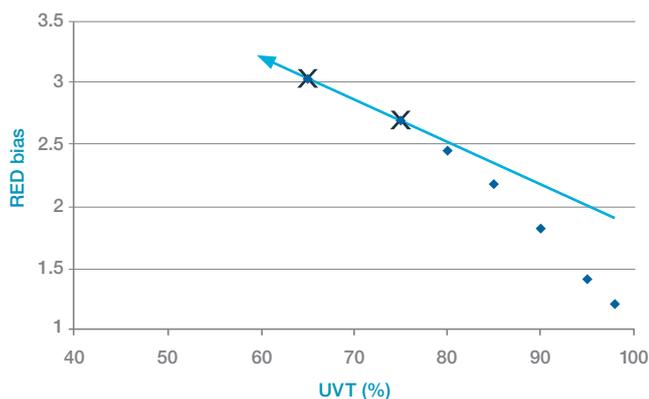
Section 5.9 of the UVDGM describes the recommended procedure for determining the RED bias which is a correction factor that accounts for the difference between the UV sensitivity of the target pathogen and the UV sensitivity of the challenge microorganism.

9.2.2 Data analysis for UV validation

The data analysis and validation of 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 issue with applying the UVDGM to wastewater with low UVT (high UV absorbance – UVA) is that the UVDGM does not have 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. In this case 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. The relationship can then be used to predict the RED bias for lower UVT levels. This approach is illustrated in Figure 3.

Figure 3: 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/cm²/log₁₀ I) and a specific example *Cryptosporidium* LRV (3 log₁₀). 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.

9.2.3 Evaluating the need for re-validation

Validation testing must be conducted again if the modifications to the UV reactor impact on the UV dose delivery or monitoring (e.g. the wetted geometry changes, the lamp technology changes, the UV sensor characteristics, and/or location change). The UVDGM provides guidance on types of UV reactor modifications and provides guidance on when UV reactors should be "re-validated".

9.3 Operational monitoring

The UV disinfection system must be monitored to demonstrate that validated operating conditions are maintained during routine use.

The operational monitoring and associated critical limits are informed by the UV dose-monitoring strategy adopted for the validation study, namely the UV Intensity Setpoint Approach and the Calculated Dose Approach. The UVDGM provides the following descriptions for each approach:

- UV Intensity Setpoint Approach. 'UV dose delivery is indicated by the measured flow rate and UV intensity. Minimum UV dose delivery is verified when the measured UV intensity is above an alarm (minimum) setpoint value defined as a function of the flow rate through the reactor. In a variation of this method, the minimum UV dose can be verified when the measured relative UV intensity (calculated as a function of UVT) is above an alarm (minimum) setpoint value defined as a function of the flow rate through the reactor.'
- Calculated Dose Approach. 'Minimum UV dose delivery is verified when the calculated UV dose (using an equation dependent on flow rate, relative UV intensity, UVT, and sometimes other parameters such as lamp status) is above an alarm (minimum) setpoint value.'

These UV dose-monitoring strategies are discussed in detail in the UVDGM.

UV intensity is an important operational monitoring parameter for both approaches. The UV intensity must be measured at a point after which UV light has passed through the water that is being treated. 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 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 that the UV sensor is appropriately positioned. The UVDGM provides further discussion on the impact of UV sensor positioning for both the UV Intensity Setpoint Approach and Calculated Dose Approach.

In addition to the critical limits associated with the UV dose-monitoring strategy, critical limits may also need to be established for the following parameters depending on the UV reactor type: lamp age; number of lamps that must be on within a lamp bank; lamp power and status; and particles and turbidity.

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. Such a tolerance is not acceptable under these guidelines, as wastewater is a high risk water source that typically starts out being highly contaminated, The UV disinfection system must be operating within the validated range at all times when recycled water is being supplied for its intended use. Attention should be paid to the validation envelope and that the particular combination of process conditions does not result in an operating condition that is outside the validated envelope.

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.

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Appendices



Appendix 2:

Approach to developing these guidelines

A1.1 Adoption of authoritative and evidence-based approaches

The philosophy behind the development of these guidelines was to adopt, where appropriate, existing validation approaches that are authoritative and evidence based. These guidelines were subject to expert peer review and consultation with the water industry.

Where authoritative guidance was not available, the best available science was used. Knowledge gaps and areas of uncertainty have been explicitly acknowledged. When confronted with significant knowledge gaps, a cautious approach to validation was adopted. Identification of knowledge gaps should aid in the prioritisation of research needs.

A1.2 Review of existing validation guidelines, 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, the review of existing validation guidelines and scientific literature has been undertaken in developing these guidelines. This included:

- guidance for specific treatment process units
- first principles and scientific theory on the validation of treatment process units to identify:
 - which theoretical approach to adopt in process validation
 - which target pathogen 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).

A1.3 Knowledge management and implementation

While the science pertaining to the behaviour of viruses and protozoan parasites in recycled water has progressed in recent years, more research is needed to better understand the mechanisms of pathogen reduction employed by some recycled water treatment process units typically used in the industry. These guidelines will assist in identifying future research needs.

The department will provide ongoing review of these guidelines to ensure they remain current and, where appropriate, reflect advances in research. The review process will include national and international expert peer review and consultation with the water industry.

Appendix 3: Verification monitoring

Verification monitoring is endpoint monitoring and is undertaken routinely to assess whether the treatment process train and control philosophy for the plant has worked. 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 (Table 11).

Detection of pathogens or indicators 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 required.

Table 11 Verification monitoring for Class A recycled water¹

Organism	Frequency	Water quality objective	Limit of detection
<i>E. coli</i>	Weekly	No detection	1 cfu per 100 mL, or 1 MPN per 100 mL
Somatic (or FRNA) bacteriophage	Weekly	No detection	1 pfu per 100 mL
<i>Cryptosporidium</i> oocysts	Quarterly	No detection	1 oocyst per 1 L

¹ 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 most current version of the *Standard methods for the examination of water and wastewater* (American Public Health Association et al. 2012) should be adopted.

Appendix 4:

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.

A4.1 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 train 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 train. Any proposed modifications that impact on CCPs must be submitted to the department for consideration.

A4.1.1 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.

A4.1.2 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) (Standards Australia 2003)* 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 maloperation 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.

A4.1.3 Recycled water quality management plan

The treatment plant 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 train 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.

A4.2 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 to enter the supply system.

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 train must be interlocked in the control system to ensure that the supply of recycled water ceases 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 and/or diversion 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. If the treatment process is shut down due to system failure (i.e. failure of a CCP corrective action or critical instrumentation failure), it must not be restarted 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.

A4.3 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 and approval from EPA Victoria has been provided in writing.

A4.4 Operation and maintenance

The scheme proponent must only use the treatment plant and equipment as specified in the RWQMP, and must ensure that the plant and equipment are maintained. Any maintenance/repairs should be carried out using the original equipment supplier approved components, if those parts can affect the performance (membrane modules, UV lamps and UV intensity sensors, etc.).

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.

A4.5 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 treatment 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.

A4.6 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 5: Example of operational monitoring procedure for membrane filtration

Membrane filtration					
Process inputs	Ultrafiltration membrane units are designed to reduce effluent suspended solids, effluent turbidity and effluent pathogens. Inputs include wastewater and treatment chemicals.				
Hazards and hazardous events	Microbiological (pathogens) breakthrough due to deterioration of membrane surface or integrity failures, such as, 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	<p>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.</p> <p>Pre-treatment, for example, pre-filtration and coagulation upstream of the UF membranes to facilitate the removal of particles.</p> <p>Compliance with the manufacturer's specifications for cleaning and backwashing.</p> <p>Quality assurance procedures for chemicals used in the treatment process.</p> <p>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.</p> <p>Standard operating procedures for diagnostics and corrective actions and regular calibration of instrumentation and testing of corrective actions.</p> <p>Use of sanitary practices and QA procedures during maintenance.</p> <p>Prerequisite programs such as trade waste agreements to minimise chemical damage to the membrane. Consider the installation of oxidation-reduction potential (ORP) meters online to detect chemicals exceeding the design threshold.</p>				
Operational monitoring ¹	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				
Alert limits	Filtrate turbidity	DIT (at 110 kPa test pressure for five minutes)	MS2 challenge test	ORP	Flux and trans membrane pressure
	> 0.1 NTU	< 4.0 LRV (equates to PDR > 8 kPa/5min)	< LRV demonstrated by challenge study for intact system	-	-
Critical limits	Two consecutive readings >0.15 NTU	< 3.5 LRV (equates to PDR > 10 kPa/5min)	< LRV attributed to the membrane system	As per validated condition and manufacturer's specifications	

Membrane filtration					
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 module	Annually Select module from membrane unit showing the worst record of integrity.	Continuous online	
Corrective action/s	Immediately initiate DIT. If DIT passes, troubleshoot turbidity meter.	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	<p>Ensure quality assurance processes are available for the entire product chain</p> <p>Identify procedures relevant to this CCP including SOPs, calibration procedures and preventive risk management system</p> <p>Maintain records providing evidence that all elements of the control plan are being implemented and that elements of the control plan are effective</p> <p>Monthly internal audit of records by management</p> <p>Annual independent third-party audit of the control plan</p>				

1 Note: The numerical values in this table are for illustration purposes only. Numerical values have not been validated.

Glossary of terms and acronyms

AGWR	<i>Australian guidelines for water recycling: Managing health and environmental risks (Phase 1) (NRMMC et al. 2006)</i>
AS/NZS	Australian and New Zealand Standard
ASTM	American Society for Testing of Materials International
AHMC	Australian Health Ministers Conference
bacteriophage	Viruses that infect bacterial host cells. They typically consist of a nucleic acid genome surrounded by a protein coat. Coliphages, such as somatic and FRNA coliphages are terms used to describe bacteriophages that can infect and replicate within coliform bacteria, such as <i>E. coli</i> .
BOD	Biochemical oxygen demand
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 (ASTM International 2003).
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 (NRMMC et al. 2006).
CFD	Computational fluid dynamic
CFU	Colony forming unit
challenge test	An empirical study to determine the reduction efficiency, measured as the log ₁₀ reduction value (LRV).
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.
chlorine dioxide	A chemical compound with the formula ClO ₂ . It disinfects by oxidation.
cm	Centimetre
Class A recycled water	A health based microbiological standard for recycled water quality (for non-drinking applications). Uses that require Class A recycled water will potentially not include 'barriers' between the water and direct human contact (EPA Victoria 2003).
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).
coliphage	See "bacteriophage"
composite sample	Formation of a single sample from selective grab samples that then represents water quality over a period of time.

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 (NRMCC et al. 2006).
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 (U.S. EPA 1999b).
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, chloramination, chlorine dioxide disinfection and ozonation.
DIT	Direct integrity test: A physical test applied to a membrane unit to identify and isolate integrity breaches (U.S. EPA 2005).
DVGW	Deutscher Verein des Gas- und Wasserfaches e.V. - Technisch-wissenschaftlicher Verein (German Technical and Scientific Association for Gas and Water)
EC	Electrical conductivity
<i>E. coli</i>	<i>Escherichia coli</i>
EPA Victoria	Environment Protection Authority Victoria
EPHC	Environment Protection and Heritage Council
extrapolate	Estimating beyond the original observation range.
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 low floc strength will move relatively rapidly through a filter due to the shearing forces on any deposited flocs.
flux	Flow per unit of membrane area (U.S. EPA 2005)
free chlorination	Use of uncombined chlorine as a means of disinfection.
FRNA coliphage	F-specific RNA coliphages, also termed male-specific coliphages, or F ⁺ coliphages, that have a RNA genome, and that infect via the F pilus of coliform bacteria. See also “bacteriophage”.
F/M ratio	Food/microorganism ratio
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 (NRMMC et al. 2006).
HAZOP	Hazard analysis and operability study
HEMP	Health and Environmental Management Plan. A plan covering the use of recycled water that details the management of health and environmental risks. The HEMP for a dual pipe scheme is equivalent terminology to the Environment Improvement Plan discussed in the <i>GEM: use of reclaimed water</i> (EPA publication 464.2)(EPA Victoria 2005).
HRT	Hydraulic retention time
independent third-party	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: <ul style="list-style-type: none"> • assess the quality of water, a specific contaminant, group of contaminants or constituent that may signal the presence of something else, or • measure the integrity or efficacy of a treatment process unit.
indirect integrity monitoring	Monitoring some aspect of the filtrate water quality that is indicative of the removal of particulate matter (U.S. EPA 2005).
in situ	In the anticipated real life application.
integrity breach	One or more leaks (in a membrane system) that could result in contamination of the filtrate (U.S. EPA 2005).
interpolate	Estimating within the original observation range.
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). LRV = log ₁₀ (N ₀) – log ₁₀ (N), where N ₀ = concentration of infectious microorganisms before treatment and N = concentration of infectious microorganisms after treatment.
LRV_{C-test}	The overall pathogen removal demonstrated during challenge testing (U.S. EPA 2005).
LRV_{DIT}	Direct integrity test sensitivity in terms of LRV (U.S. EPA 2005).

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.
membrane unit	A group of membrane modules that share common valving which allows the unit to be isolated from the rest of the system for the purpose of integrity testing or other maintenance (U.S. EPA 2005).
MF	Microfiltration: A pressure driven membrane filtration process that typically employs hollow fibre membranes with a pore size range of approximately 0.1 – 0.2 μm (nominally 0.1 μm) (U.S. EPA 2005).
MFGM	United States Environmental Protection Agency: <i>Membrane filtration guidance manual</i> (U.S. EPA 2005)
mg	Milligram
min	Minute
mJ	Millijoule
mL	Millilitre
MLSS	Mixed liquor suspended solids
module	The smallest element of a membrane unit that has a specific surface area (U.S. EPA 2005).
MPN	Most probable number
MS2	MS2 bacteriophage. Also known as male-specific bacteriophage-2.
NATA	National Association of Testing Authorities
NF	Nanofiltration: A pressure driven membrane separation process that employs the principles of reverse osmosis to remove dissolved contaminants from water (U.S. EPA 2005).
NRMCC	Natural Resource Management Ministerial Council
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 (U.S. EPA 1999c).
PDR	Pressure decay rate
PFU	Plaque forming unit
Q_{breach}	Flow of water through a critical breach during filtration (U.S. EPA 2005).
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 (U.S. EPA 2005).
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.
recovery	Ratio of filtrate volume produced to feedwater applied to a membrane over a continuous operating cycle (U.S. EPA 2005).
RED	Reduction equivalent dose is the UV dose derived by entering the log inactivation measured during full-scale reactor testing into the UV dose-response curve that was derived through collimated beam testing. (U.S. EPA 2006c)
recycled water	Water generated from sewage or greywater and treated to a standard that is appropriate for its intended use.
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.
resolution	Smallest integrity breach (leak) that generates a response from a direct integrity test (U.S. EPA 2005).
RO	Reverse osmosis: <ol style="list-style-type: none"> 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 concentrated solution. 2) the pressure-driven membrane separation process that employs the principles of reverse osmosis to remove dissolved contaminants from water (U.S. EPA 2005).

RWQMP	Recycled water quality management plan: A plan that covers the production of Class A recycled water at a treatment plant (EPA Victoria 2005). 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
sensitivity	The maximum LRV that can be verified through operational monitoring (U.S. EPA 2005).
sewage	Material collected from internal household and other building drains. Includes faecal waste and urine from toilets, shower and bath water, laundry water and kitchen water. Sewage in municipal sewerage systems may also include municipal and industrial wastewater.
SOPs	Standard operating procedures
somatic coliphage	Coliphages that have a DNA genome and infect coliform bacteria by directly attaching to the outer cell membrane. See also “bacteriophage”.
SRT	Sludge retention time
SS	Suspended solids
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: <ul style="list-style-type: none"> • 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.
T₁₀	The contact time determined by a tracer study (refers to the detention time experienced by 90% of the water passing through the detention basin) (U.S. EPA 1999b).
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.
TDS	Total dissolved solids
TDT	Theoretical detention time, determined by dividing the volume of a process unit (e.g. detention basin) by the peak hourly flow rate.
TOC	Total organic carbon
TOD	Transferred ozone dose
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 (for instance membrane filtration) that combines with other processes to constitute a treatment process train.

UCL	Upper control limit
UF	Ultrafiltration: A pressure driven membrane filtration process that typically employs hollow fibre membranes with a pore size range of approximately 0.01-0.05 µm (nominally 0.01 µm) (U.S. EPA 2005).
US EPA	United States Environmental Protection Agency
UV disinfection	Ultraviolet disinfection
UVDGM	United States Environmental Protection Agency: <i>Ultraviolet disinfection guidance manual</i> (U.S. EPA 2006c).
UVI	Ultraviolet intensity: The power passing through a unit area perpendicular to the direction of propagation (U.S. EPA 2006c).
UVT	Ultraviolet transmittance: a measure of the fraction of incident light transmitted through a material. The UVT is usually reported for a wavelength of 254 nm and a pathlength of 1 cm (U.S. EPA 2006c)
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 (NRMMC et al. 2006).
verification	An assessment of the overall performance of the treatment system and the ultimate quality of recycled water being supplied to customers (NRMMC et al. 2006).

