WaterVal

Streamlining Technology Validation

Protocol Template

About the Australian Water Recycling Centre of Excellence
The Centre is an Australia-wide, independent research organisation established in 2009 by Commonwealth funding, and the support (financial and in-kind) of the Queensland government. The Centre manages a $42 million research program, co-ordinating more than 40 projects with the support of over 110 partners from the research, government, utility, private enterprise sectors. Our overall objective is to demonstrate how water recycling can be a practical and viable option to achieving water security.

About WaterVal
WaterVal, consistent validation for the water industry – Responding to the Australian water sector's request for more cost-effective application of technologies, the Centre, working alongside regulators, water utilities and the private sector, has developed a way to achieve national consistency in the validation of treatment technologies. This validation framework (WaterVal) is underpinned by Protocols, which are independently developed and agreed methodologies to assess pathogen removal by treatment technologies. The framework and protocols are applicable to a broad range of water sources, and complement the objectives of the Australian Guidelines for Water Recycling and the Australian Drinking Water Guidelines.

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Introduction

This document sets out a generic approach for the development of a protocol for the validation of water recycling treatment technology. The following are the key elements agreed by the WaterVal Protocol Development Group which protocols should achieve.

1. Identify the mechanisms of pathogen removal by the treatment process unit

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(s).

Mechanisms of reduction may include inactivation (Chlorine, UV, Ozone) or physical removal (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 pathogen(s)
- identifying the factors that affect the efficacy of the treatment process in reducing the target pathogen(s)
- identifying appropriate operational monitoring parameters.

2. Identify the target pathogens, or appropriate surrogates, that are the subject of the validation study. Ensure that the target pathogens/surrogates are present in an appropriate concentration

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.

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 can be used. 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 log10 reduction range being applied).

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.

4. Identify the influencing factors that affect the efficacy of the treatment process unit to reduce the target pathogen

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).

5. Identify the operational monitoring parameters that can be measured continually (ideally) and that will relate with the reduction of the target pathogen

Operational monitoring parameters are 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.

A risk management framework, such as the hazard analysis and critical control point (HACCP) system, should 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.

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

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

The validation methodology will involve a testing program that includes quantifying the reduction of the target pathogen or appropriate surrogate (either indigenous or challenge-spiked) , while concurrently monitoring the operational parameters to confirm that the system is within some defined specification (operational envelope).

Key Concepts include:

- The challenge test methodology (including the test operating conditions)
- Whether laboratory grown strain or indigenous pathogens will be used
- Whether surrogates will be used and their conditions of production
- What will be monitored
- Where samples will be collected
- How many samples will be collected
- QA/QC

7. Describe a method to collect and analyse data to formulate evidence-based conclusions

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.

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.

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 log10 reduction capability of a treatment process unit.

8. Describe a method to determine the critical limits as well as an operational monitoring and control strategy

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 or outside the test envelop. 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 log10 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.

9. Describe a method to determine the LRV for each pathogen group (protozoa, virus or bacteria) in each specific treatment process unit performing within defined critical limits

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

$$\text{LRV} = \log10(\text{feed concentration}) - \log10(\text{product water concentration})$$

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

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

10. Provide a means for re-validation or additional onsite validation where proposed modifications are inconsistent with the previous validation test conditions

A validation study applies to the treatment process unit that is specified during the study. 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.

Describe the modifications/changes that would require re-validation.