

# WaterVal Validation Protocol Development Guidance



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WaterVal™ is a research-backed framework that provides a consistent, scientifically robust approach to confirming that water treatment systems can effectively remove contaminants. It is a collaborative effort between key stakeholders in the water industry to gain clarity on the requirements for the design and operation of treatment technologies to streamline the validation process. WaterVal™ is underpinned by Validation Protocols, which are independently developed and agreed methodologies to assess contaminant removal. Each Validation Protocol is based on nine Protocol Elements, ensuring consistency and uniformity for users.

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## Background

This 'WaterVal Validation Protocol Development Guidance' (guidance document) sets out a generic approach for the development of a validation protocol for a water treatment technology for the removal of pathogens or chemical contaminants. A protocol template document is provided on the WaterVal website for developing a protocol.

The guidance has been written with the objective of being 'generic and universal'. The aim of this is to facilitate the creation of treatment barrier protocols for the broadest range of:

- contaminants
- source waters
- treatment barriers

The purpose of a protocol is to provide the user with a clear, consistent, and efficient method for the validation of a treatment barrier. The objective of the protocol is to demonstrate that the treatment process removes contaminants that pose a risk to the health of the public or the environment.



## Guiding Principles

The following is a list of the key guiding principles for a protocol:

- **Describe the scientific basis for validation** - When a protocol is developed, and log reduction value (LRV) credits are assigned, there needs to be a detailed description of where the scientific evidence came from and the assumptions, approximations, and levels of conservatism that were built into any data analysis used to arrive at the LRV credits.
- **Protocol developers are to refer to the protocol quality checklist** - The checklist details the type of information and guidance that must be provided for each element of a protocol.
- **Facilitate the implementation of protocols**
  - Each protocol needs to include a validation report template as an attachment. The report template should be designed to streamline validation program submission to regulators.
  - The protocol should be developed within the context of an overall Water Quality Risk Management approach.
  - The application of a protocol must meet the requirements of applicable water quality regulations and guidelines in the relevant jurisdiction/s, while also meeting any requirements of relevant health and environmental regulators.
- **Consider how readable and understandable the protocols are** - Make the protocol language as clear and specific as possible. Consider checking the text of the protocol with a readability score checker (e.g. the Flesch Reading Ease Formula) and edit accordingly.
- **Include practical methods for validation program implementation** - Protocols should strive to provide simple methods that are cost effective and straightforward to implement to determine LRVs. They should also offer flexible options to choose more complex methods to achieve higher LRVs.
- **Identify triggers for protocol revisions** - Examples of triggers for a protocol review include:
  - Where previous limitations of the science have been addressed with new knowledge.
  - Where limitations of the technology/treatment barrier have been addressed with improvements.
  - Where there has been improved analytical capability for identifying the target contaminants (either in terms of presence or removal).
  - Where there has been an industry-wide change or trend in the treatment barrier or a combined treatment train. For example: a new treatment barrier protocol written for a combined treatment train of coagulation, flocculation plus ultrafiltration membranes, where previously only ultrafiltration membranes have been considered.
  - Where there is an improved monitoring capability, such as new online monitoring technologies.



# Quality checklist

The following protocol quality checklist details the type of information and guidance that must be provided:

- Across all sections of a treatment barrier protocol (general requirements)
- For each individual element of a treatment barrier protocol (element-specific requirements)

*Table 1 Protocol Quality Checklist*

| <b>General requirements for treatment barrier protocols</b>  |                          |
|--|--------------------------|
| The language used is clear, specific, and precise.   | <input type="checkbox"/> |
| For each element in the protocol – where applicable, provide detail of where the scientific evidence came from and the assumptions, approximations, conservatism built into the data analysis. | <input type="checkbox"/> |
| References are provided, which directly link to the scientific evidence.   | <input type="checkbox"/> |
| Where possible, a practical example of how the element is implemented is provided, or the user can be directed to a case study listed in the references.                                       | <input type="checkbox"/> |

| <b>Requirements for Introduction of treatment barrier protocols</b>  |                          |
|--|--------------------------|
| The treatment technology is specified, along with any limitations or constraints on protocol usage for sub-categories of the technology  | <input type="checkbox"/> |
| The applicable source waters are specified, along with any limitations or constraints on application of the protocol to specific waters  | <input type="checkbox"/> |
| The contaminant class/es the protocol is targeting are specified.  | <input type="checkbox"/> |
| Inclusion of a list of the 9 Elements of the protocol, referring to the relevant section of the protocol where the element is addressed.   | <input type="checkbox"/> |
| Information on how the protocol fits into an over-arching water quality risk management framework, including understanding source water risks, system assessment, and the role of the regulator. | <input type="checkbox"/> |



### Requirements for Element 1

The scientific basis of the mechanisms of contaminant removal is adequately described.

### Requirements for Element 2

The scientific basis for identifying the target contaminants, or appropriate surrogates, is adequately described.

For chemical protocols: a mechanistic chemical classification framework is provided, that reflects the mechanism by which chemicals are rejected by the treatment barrier.

### Requirements for Element 3

The scientific basis for identifying the influencing factors that affect the efficacy of the treatment barrier to reduce the target contaminant, is adequately described.

Clearly articulate the most important influencing factors on treatment barrier performance.

Description of any treatment barrier failure mechanisms that affect the efficacy of treatment.

For chemical protocols: Emphasise the need for periodic monitoring of the feed, to ensure that significant changes have not occurred in the chemical distribution or total load.

### Requirements for Element 4

The scientific basis for identifying the operational monitoring parameters that can be measured and that will relate with the reduction of the target contaminant or class of contaminants, is adequately described.

Directly link the most important influencing factors identified in Element 3, to the appropriate monitoring methods in Element 4.

For chemical protocols: describe the broader framework in performance monitoring to achieve a maximum operational LRV credit, reflecting the increased number of ways by which chemicals are removed by a treatment barrier (as compared to pathogens).



### Requirements for Element 5

The scientific basis for identifying a validation methodology to demonstrate the capability of the treatment barrier, is adequately described.

In the case of pathogens: where possible, include a tiered validation approach for Element 5.

For validation purposes, specify the monitoring methods which are used as treatment barrier integrity indicators, and those which are used for assigning LRV credits.

### Requirements for Element 6

The scientific basis for the proposed method to collect and analyse data to formulate evidence-based conclusions, is adequately described.

### Requirements for Element 7

The scientific basis for the proposed method to determine the critical limits as well as an operational monitoring and control strategy, is adequately described.

### Requirements for Element 8

The scientific basis for the proposed method to determine the LRV for each contaminant group or class in each specific treatment barrier performing within defined critical limits, is adequately described.

Describe the minimum statistical standards, including number of samples/measurements needed to ensure confidence in the LRV.

### Requirements for Element 9

The scientific basis for the proposed method to determine the LRV for each contaminant group or class in each specific treatment barrier performing within defined critical limits, is adequately described.

Provide a list of the specific conditions that would trigger the requirement for revalidation of the treatment barrier.



# Glossary

Protocols, where appropriate, should align with the Validation Guidance (see WaterVal website). All protocols should contain a glossary of terms, and, where applicable, adopt the same terms as used in the glossary from the Validation Guidance.

The table below gives a list of the minimum glossary terms to be included in a protocol, with additional terms to be added to the glossary based on their relevance to the specific protocol developed.

*Table 2 Recommended Glossary Terms*

| Term                                | Definition from Validation Guidance  |
|-------------------------------------|--|
| <b>Acceptable level</b>             | A level of hazard in water at or below which the water is safe according to its intended use.  |
| <b>Control</b>                      | When used as a noun: the state wherein correct procedures are being followed, and any established criteria are being met.<br>When used as a verb: to take all necessary actions to ensure and maintain compliance with established criteria and procedures.  |
| <b>Control measure</b>              | Any action or activity that can be used to prevent or eliminate a hazard or reduce it to an acceptable level.  |
| <b>Correction</b>                   | Action to eliminate a detected nonconformity.  |
| <b>Corrective action</b>            | Any action taken when a deviation occurs to re-establish control, segregate, and determine the disposition of the affected product, if any, and prevent or minimize reoccurrence of the deviation.   |
| <b>Critical control point (CCP)</b> | A step in the process at which control measure(s) is (are) applied to prevent or reduce a significant hazard to an acceptable level and defined critical limit(s) and measurement enable the application of timely corrections.  |
| <b>Critical limit</b>               | Measurable value which separates acceptability from unacceptability  |
| <b>Health-based target</b>          | Measurable health, water quality, or performance objectives that are established based on a judgement of safety and on risk assessments of waterborne hazards  |
| <b>Indicator</b>                    | A parameter (biological, chemical, or physical) or a combination of parameters that can be used to: <ul style="list-style-type: none"><li>• Assess the quality of water, a specific contaminant, group of contaminants or constituent that may signal the presence of something else, or</li><li>• Measure the integrity or efficacy of a treatment barrier (i.e. an <b>integrity indicator</b>)</li></ul> |



| Term                             | Definition from Validation Guidance   |
|----------------------------------|---|
| <b>Log reduction value (LRV)</b> | Log10 reduction value: Used in reference to physical-chemical treatment of water to remove or inactivate contaminants (1 log10 = 90 per cent or 10-fold reduction, 3 log10 = 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 contaminant before treatment and $N$ = concentration of contaminant after treatment.  |
| <b>Operational monitoring</b>    | The planned sequence of measurements and observations used to assess and confirm that individual barriers and preventive strategies for controlling hazards are functioning properly and effectively.   |
| <b>Reference contaminant</b>     | Represents groups of contaminants, considering variations in characteristics, behaviours, and susceptibilities of each group to different treatment processes.  |
| <b>Surrogate</b>                 | <p>A challenge organism, particulate or chemical that is a substitute for the target contaminant of interest. For a surrogate to be suitable it must be either:</p> <ul style="list-style-type: none"> <li>• Reduced (removed or inactivated) by the treatment barrier to an equivalent or lesser extent than the target contaminant (i.e. <b>performance surrogate</b>), or</li> <li>• Possible to demonstrate a reproducible correlation from literature, laboratory, or field trials between reduction of the surrogate and the target contaminant.</li> </ul> |
| <b>Target contaminant</b>        | The contaminant, or class of contaminants, that has been demonstrated to be the most resistant to the specific treatment barrier in question and therefore is the subject of the validation study.  |
| <b>Validation</b>                | Obtaining evidence that a control measure or combination of control measures, if properly implemented, will ensure the effective control of the hazard(s). This evidence includes substantiating the operational criteria and associated critical limits.   |
| <b>Verification</b>              | Verification is the use of methods, procedures, or tests, in addition to those used in operational monitoring, to determine whether the performance of the combination of control measures complies with the stated objectives.   |



## Scope

It is important that the Introduction section describes the specific characteristics of the treatment technology, the applicable water source(s), and the contaminant class(es) the protocol applies to including:

- The treatment barrier technology, including specifics of which technology sub-categories it is applicable to. For example, a reverse osmosis chemical protocol may specify that it applies only to spiral wound polyamide membrane modules.
- The source water categories that the protocol applies to. For example, an MBR pathogen protocol may specify that it only applies to wastewater that has undergone primary treatment.
- The applicable contaminant class(es) the protocol is relevant to. All protocols will specify whether they are written specifically for the validation of treatment barrier performance for the removal or inactivation of
  - Pathogens
  - chemicals
  - some combination of the above

The introduction section of a protocol should also include the following information relevant to scheme proponents or operators:

- Guidance for the protocol user regarding having an awareness of the applicable water quality guidelines, regulations, and the role of the regulator, for the relevant jurisdiction.
- Knowing your system and source water risk. This may be a statement of where the protocol fits into an overarching Water Quality Risk Management Framework.
- A conceptual discussion of how source water risk relates to both the choice of treatment and validation approach.
- It needs to emphasise that before a validation study using the protocol is undertaken, a water quality risk assessment for the system has been done, the source risk has been classified and the minimum source water classification LRV requirements have been established.

### Pathogen protocols

For protocols targeting pathogen removal, the introduction will make mention of the need to have conducted a source water risk assessment from a health-based targets (HBTs) perspective for pathogens (e.g. a QMRA, sanitary survey, or similar).

### Chemical protocols

For protocols targeting chemical removal, the introduction will make mention of the need to have conducted a source water risk assessment based on persistence, bioaccumulation, and toxicity (PBT) of chemicals.



# The Nine Elements of a WaterVal Protocol

The WaterVal protocol framework includes nine elements that must be addressed within each protocol to ensure consistency and uniformity in approach (Figure 1):

- **Element 1** - Identify the mechanisms of contaminant removal by the treatment barrier.
- **Element 2** - Identify the target contaminant, or appropriate surrogates, that are the subject of the validation study. Ensure that the target contaminant or surrogates are present at an appropriate concentration.
- **Element 3** - Identify the influencing factors that affect the efficacy of the treatment barrier to reduce the target contaminant.
- **Element 4** - Identify the operational monitoring parameters that can be measured continually (ideally) and that will relate with the reduction of the target contaminant or class of contaminants.
- **Element 5** - Identify a validation methodology to demonstrate the capability of the treatment barrier.
- **Element 6** - Describe a method to collect and analyse data to formulate evidence-based conclusions.
- **Element 7** - Describe a method to determine the critical limits as well as an operational monitoring and control strategy.
- **Element 8** - Describe a method to determine the LRV for each contaminant group or class in each specific treatment barrier performing within defined critical limits.
- **Element 9** - Provide a means for re-validation or additional onsite validation where proposed modifications are inconsistent with the previous validation test conditions.

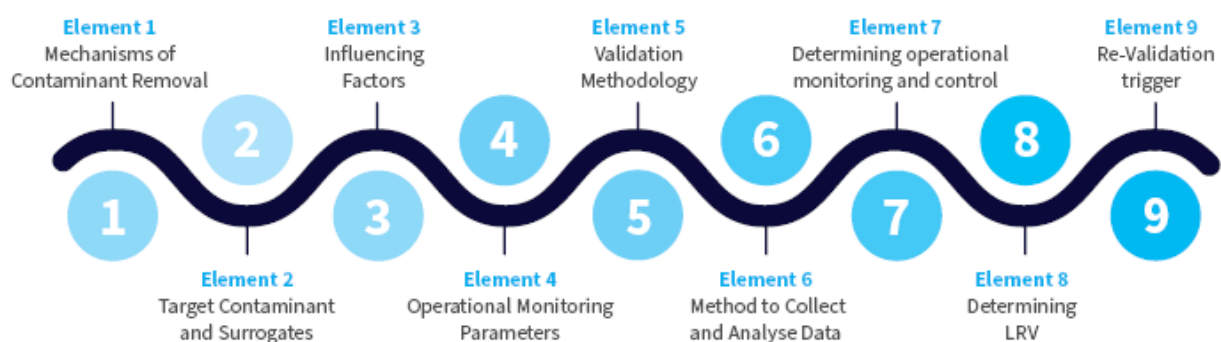


Figure 1 WaterVal protocol validation framework



# 1

---

## Identify the mechanisms of contaminant removal by the treatment barrier.

The successful validation of a treatment barrier, or combination of units, relies upon identifying which reduction mechanisms apply to a given barrier process and characterising how they specifically affect the target contaminant(s).

Mechanisms of reduction or removal may include inactivation or oxidation (Chlorine, UV, Ozone), physical removal (straining, filtration, adsorption, coagulation, flocculation, sedimentation), degradation (microbial biodegradation) or predation. A single treatment process may integrate multiple contaminant reduction mechanisms. For example: a membrane bioreactor, which combines an activated sludge microbial phase, combined with filtration.

The characterisation of the mechanisms that lead to contaminant reduction or removal assists in:

- Selecting the target contaminant(s) for which the protocol is relevant.
- Identifying the factors that affect the efficacy of the treatment process in reducing the target contaminant(s)
- Identifying appropriate operational monitoring parameters.

# 2

---

## Identify the target contaminants, or appropriate surrogates, that are the subject of the validation study. Ensure that the target contaminants/surrogates are present at an appropriate concentration.

The target contaminant, or class of contaminants, should utilise the contaminant that is the most resistant to reduction or removal by the specific treatment barrier that is being validated. It is considered potentially unsafe, or not operationally robust, to use anything other than the most resistant.

If it is not practicable to use the target contaminant for validation, surrogates can be used. In this context, a surrogate is a challenge organism or chemical that is a substitute for the target contaminant of interest.

**In the case of chemical protocols:** a mechanistic chemical classification framework should be used that reflects the mechanism by which chemicals are rejected or removed by the treatment barrier. Within this classification framework it needs to be acknowledged which chemical classes or subclasses of chemicals will show a rejection or removal that is too low, or too inconsistent, to assign an LRV.

For a surrogate to be suitable, it must be reduced (removed or inactivated) by the treatment barrier to an equivalent or greater extent than the target contaminant. If this cannot be achieved, or demonstrated, it must be possible to demonstrate a reproducible correlation, from the scientific literature, or laboratory or field trials, between the reduction of the surrogate and the target contaminant (over the  $\log_{10}$  reduction range being applied).

The availability of reliable analytical methods for the target contaminant is also an important consideration in the design of any validation study.



# 3

## Identify the influencing factors that affect the efficacy of the treatment barrier to reduce the target contaminant.

Identifying the factors that influence treatment efficacy relies on a detailed understanding of the mechanisms that are responsible for the removal of the contaminant. 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 the identification of these factors and within the validated range. The outcomes of a validation study are only applicable to treatment barriers that are operated within the validated operational envelope.

Influencing factors may include, but are not limited to, feedwater characteristics (biological and/or 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).

One example is spiral wound reverse osmosis membranes, where a range of membrane module mechanical failures can impact treatment. The membrane can fail in different locations e.g. separating layer, O-rings, glue lines and the response of indicators can vary between failure modes.

Element 3 should provide a limited and realistic list of influencing factors. Additionally, consideration needs to be given to the link between Element 4 and Element 3, to ensure that the major influencing factors can be measured.

For the applicable source waters, how the source water interacts with the chosen treatment process should be considered, particularly how this may affect the influencing factors.

Also, it needs to be acknowledged that there may be no data available on the impact of certain source waters on treatment performance. In this case, extra challenge testing would be needed, which is specific to the treatment barrier and performance goal, if a source water with limited published scientific data is planned to be used.

**In the case of chemical protocols:** where applicable, describe how the variation in chemical inputs to some water catchments or wastewater treatment plants may impact treatment performance, and the need for periodic monitoring of feed water quality to ensure that significant changes have not occurred in the chemical distribution or total load of the feedwater.



# 4

## Identify the operational monitoring parameters that can be measured continually (ideally) and that will relate with the reduction of the target contaminant or class of contaminants.

Operational monitoring parameters are used to measure the performance of the treatment process and relate to the reduction/removal of the target contaminant (i.e. treatment efficacy).

Continuous monitoring of operational parameters provides assurance that the system is under control and alerts operators when treatment efficacy is reduced to an unacceptable level. This would trigger corrective actions to prevent water that is not fit-for-purpose, being delivered to the end user.

In theory, every major influencing factor that may affect the efficacy of the treatment process would have an operational monitoring parameter. However, in practice, it is often possible and more practical to select a few key operational monitoring parameters.

**In the case of chemical protocols:** include consideration of any additional performance monitoring that may be needed, being mindful of the increased number of ways by which chemicals, as distinct from pathogens, are rejected/removed by a treatment barrier.

A risk management framework, such as the hazard analysis and critical control point (HACCP) system, should be used to identify both factors that affect treatment efficacy and the associated operational monitoring that must be undertaken to indicate when these factors are not within an acceptable range.



# 5

## Identify a validation methodology to demonstrate the capability of the treatment barrier.

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

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

Key Concepts include:

- The challenge test methodology (including the test operating conditions)
- Whether indigenous contaminants or spiking will be used.
- Whether surrogates will be used and the conditions of their production
- What will be monitored?
- Where samples will be collected
- Number of samples to be collected.
- The quality assurance and quality control (QA/QC) applied to the production of results.

**In the case of pathogen protocols:** where possible, provide recommendations and guidance around a tiered validation approach for Element 5.

The tiered alternatives for validation may include:

- Tier 1 – adopting predefined, conservative LRVs based on the statistical analysis of historical barrier performance data and associated operating conditions.
- Tier 2 – conducting challenge testing under the most conservative operating conditions expected for the specific system being validated to determine the minimum expected LRV, and implementing regular testing of target pathogens or surrogates.
- Tier 3 - Under this approach an investigation is undertaken incorporating challenge testing to demonstrate the correlation between online parameter(s) and the pathogen removal performance of the MBR. This allows critical limits to be established that are specific to the LRVs claimed. Refer to the Membrane Bioreactor protocol for an example of the Tier 3 approach to validation.

The validated LRV credit is determined by the minimum LRV that can be consistently demonstrated using an appropriate performance surrogate during operations, with the process operating within a pre-defined operating envelope.

A clear distinction should be made between what constitutes a barrier integrity indicator and what are performance surrogates (refer to Glossary). This is because the value of a validated LRV credit for a particular contaminant class may be substantially more or less than that demonstrated by a treatment barrier integrity indicator.



# 6

## 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 are collected, appropriate sampling methods and techniques are required to be followed. The recommended standard is the Standard Methods for the Examination of Water and Wastewater (American Public Health Association et al. 2023 or most recent version), or other recognised and accredited testing methodologies (such as test methods detailed in Australian Standards).

Preferably, the laboratory that is used for sample analysis should be accredited by the National Association of Testing Authorities (NATA) for the test methods that are used. 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.
- Where field and laboratory equipment are used to obtain a result, the equipment must be maintained and calibrated.
- Limits of detection must be appropriately stated for the method used.
- All procedures must be performed by qualified personnel and be subject to quality assurance/quality control procedures, consistent with the requirements of the accreditation standard ISO 17025.

The monitoring program for the validation study must ensure that the data collected is sufficient to undertake a statistically valid analysis.

In analysing data, it is necessary to account for validation uncertainty, including biases and errors inherent in sample collection, measurements, laboratory equipment, experimental design, and analytical techniques. The measurement uncertainty (MU) for results must be calculated and quoted, to the extent practicable, when attributing an LRV to the treatment barrier.

Furthermore, during validation testing, all equipment must be carefully selected and calibrated to minimise MU. Measurements must be traceable back 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 contaminant LRV of a treatment barrier.



# 7

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

A critical limit is a specific value for a measured parameter at a critical control point (CCP) that separates acceptability from unacceptability for hazard control.

The critical limit(s) specific will correspond to the boundary of the operational envelope, outside of which the treatment process is performing inadequately or operating beyond its validated test conditions. Validated LRVs only apply to those periods when the operational conditions for the treatment process are within the critical limits.

Determining critical limits is essential to ensuring the water supplied is safe. Critical limits need to be established for all critical control parameters. They will be determined by the test operating conditions used during the validation testing program.

To be useful, the test operating conditions in the validation study must align with the expected field operating conditions, or a reasonable subset of such conditions for the treatment technology.

# 8

## Describe a method to determine the LRV for each contaminant group or class in each specific treatment barrier performing within defined critical limits.

The removal efficiency of a treatment process demonstrated by the challenge test results is determined using 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, the lower 5th percentile LRV (mean of the distribution of numbers minus 1.96 standard deviations (SD)) established during challenge testing must be used. The confidence in the challenge test LRV must also be established, such that the number of measurements should be sufficient to ensure that the standard error on the mean (SEM) of values ( $=\text{SD}/\text{SQRT}(\text{number of samples})$ ) used to calculate the LRV is less than 0.1.

The LRV that may be attributed to a treatment barrier 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 barrier to reduce the target pathogen (i.e. the sensitivity of the operational monitoring technique).

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



# 9

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## 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 barrier 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 barrier (including changes or modifications to critical system components, such as UV lamps or membrane modules), or changes to the control philosophy or operational monitoring parameters (including critical limits) that differ to the documented validation test conditions.

Under Element 9, the protocol must provide specific information on the factors that would necessitate, or the triggers for, revalidation.

This section of the protocol would emphasise the need to specify technology-specific influencing factors and provide recommendations for revalidation if the factors change and sit outside of the validated operational envelope.

Examples of specific triggers that may necessitate revalidation include:

- Returning a treatment barrier to service after a long period being offline. One example would be where a plant has been in an extended period in mothball or maintenance mode and has not been producing water. Where it's difficult to fully determine effects of any equipment deterioration.
- After process configuration changes that impact treatment barrier monitoring and performance.
- Changes to regulatory requirements, requiring additional challenge testing.
- After renewals or upgrades, where treatment barrier performance will be affected.



## References

References used in the protocols should be inclusive of the following:

- References which directly link to the evidence as to the scientific basis and state of the science, including any scientific limitations, assumptions, and levels of conservatism.
  - Practical examples of the application of the elements of the protocols to related validation activities.
  - References which provide practical examples or case studies that would assist in the design of a program of testing relevant to that protocol.
  - Worked examples in the references, to aid in guiding the implementation of validation programs.
- 

## Appendix

It is recommended that each protocol be accompanied with a Validation Report Template. A template document is provided on the WaterVal website for developing this.