Department of Primary Industries
Office of Water

RECYCLED WATER | INFORMATION SHEET NUMBER 7

Validation & Verification – *What's the difference?*

May 2015

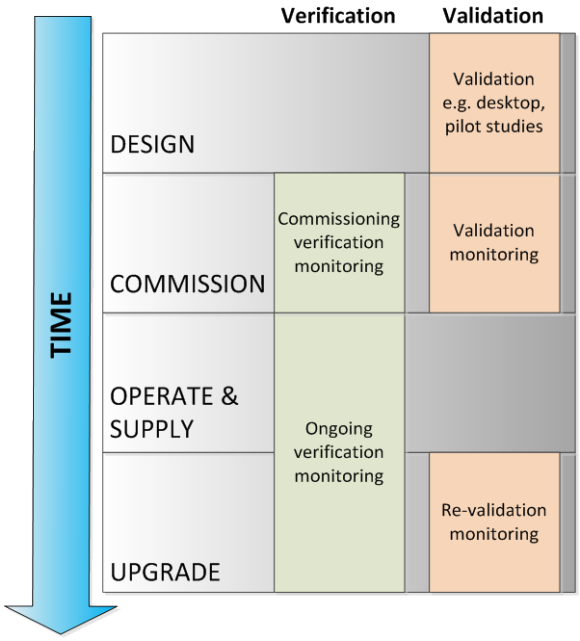
Making the distinction between validation and verification can be difficult since both establish safe supply of recycled water. This information sheet reviews their functions, phases and requirements. Table 1 (back page) compares validation and verification monitoring.

Validation

Validation is the confirmation that a specific treatment technology meets the performance target allocated to that technology.

Validation may be undertaken at the desktop level, for example undertaking calculations confirming that a chlorine contact tank can achieve necessary primary kill. Validation may also occur in the lab as part of pilot trials or in the field as a full scale test.

Figure 1 Phases of validation and verification monitoring



Validation should be considered in the planning stage of any new recycled water scheme. Prior to designing the treatment process, baseline information of the source water should be gathered. This information will underpin a risk assessment process and provide a basis for designing a process capable of removing any contaminants of concern, thus producing water that meets, or exceeds, specified water quality criteria.

Pre-validated systems

Some equipment e.g. certain membranes and UV units are supplied 'pre-validated'. This means the design has been independently tested for a specific range of conditions to meet requirements eg the requirements in US EPA *UV Disinfection guidance manual.*

If pre-validated units are used further validation is not required by the Office of Water. However, these units must be operated within the range of conditions that the unit was validated under.

Validation or pre-validated systems are required for dual reticulation schemes.

Re-validation

Re-validation should occur following any significant change within the scheme. Triggers for revalidation may include:

- the introduction of new processes or equipment
- changes to the source water or product water quality
- increases in hazard concentrations
- identification of new or emerging hazards
- repeated systemic failures
- catchment inputs increasing beyond the maximum flow tested during validation
- addition of a new influent source
- variation in process configuration, operational parameters or mode of operation
- new membrane specification
- new chemical used in treatment processes
- any unscheduled suspension to supply or operation.

What is validation monitoring?

Monitoring undertaken as part of validation is 'indicative' and serves as a basis for making

assumptions as to how the plant will operate under a series of conditions.

Validation monitoring is usually performed prior to supply to end users. It can also occur during design and commissioning (see Figure 1). Re-validation monitoring may be required again for major upgrades or changes to operation or source conditions.

Validation monitoring can involve testing a broad range of conditions within the operating envelope of the process, focusing on high risk conditions. These conditions can be simulated to test the outer bounds within which a particular system, critical control point or process unit operates effectively to produce quality end-product. Typical and worst-case operating conditions associated with the treatment process unit must be informed by historical baseline monitoring and underpinned by a risk management framework.

Validation monitoring should also allow for temporal and seasonal variation where applicable, and should be sufficient to give statistical confidence that the final water quality consistently achieves the required water quality criteria.

Validation requires:

- Identification of mechanisms of pathogen reduction
- Identification of indicator organisms to measure
- Identification of $\log_{10}$ reductions values (LRV)
- Specification of LRV requirements
- Identification of influencing factors
- Identification of operational monitoring parameters
- Data collection and analysis
- Determination of critical limits
- Determination of actual LRV.

What are the requirements of validation monitoring program?

A proposed validation program must be supported by evidence including a comprehensive scientific literature review. It may be necessary to validate individual treatment process units that contributes to the required microbial water quality objectives (LRV).

Validation testing programs must include:

- type of samples
- number of samples to be collected[1]
- sample volumes
- that representative samples are collected
- sampling locations
- sampling duration
- sampling intervals[2]
- sampling equipment required
- operational monitoring requirements[3].

Note 1: If a range of operational conditions (such as flow rates and temperature) are to be tested, then at least three samples must be collected for each operating condition.
Note 2: Where processes are influenced by seasonal factors, 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.
Note 3: Including what parameters to monitor, how often to monitor, and the range of acceptable results.

Who undertakes validation monitoring?

Validation monitoring is recommended to be undertaken by an independent third-party to ensure that the study is conducted in a technically sound and unbiased manner. This has the benefit of expertise and timely analysis of data. However, validation can be conducted internally by the recycled water supplier.

Verification

Verification is undertaken to determine if recycled water was safe to supply to end users. It involves monitoring under actual conditions in a non-simulated environment. Verification should be undertaken for both treatment processes (e.g. laboratory testing) and non-treatment barriers (e.g. on-site audits).

What is verification monitoring?

Verification monitoring is routinely undertaken to confirm if recycled water processes and controls were safe for supply to end-users and to confirm compliance with the recycled water quality management system (RWMS). It is used to confirm product quality, compliance with water quality criteria and identify weaknesses in the existing control measures. Detection of pathogens or indicators is likely to indicate system failure or contamination.

Verification monitoring should be risk-based and can include water quality criteria, soils, plants, terrestrial and aquatic biota, ground and surface water, the infrastructure associated with application or receiving environments and assessment of satisfaction of users of recycled water. Therefore it requires monitoring actual conditions in a non-simulated environment.

When is verification monitoring performed?

Verification is undertaken before operation (commissioning verification) as well as throughout the scheme's operation (ongoing verification) and its schedule should be informed by a risk assessment (see Figure 1).

Commissioning verification

Commissioning verification is performed during the commission phase and will verify the *suitability* of operational parameters and their associated critical limits. It is generally undertaken in conjunction with a planned operational monitoring program.

Commissioning verification should be undertaken in conjunction with a planned operational monitoring program. It is usually more intensive than ongoing verification monitoring and generally, a broader range of parameters are chosen for monitoring (compared with ongoing verification monitoring).

Ongoing verification

Ongoing verification monitoring is performed routinely and *confirms* that CCP's and their assigned critical control limits consistently comply with the required water quality criteria. It is generally undertaken in conjunction with a planned operational monitoring program.

Ongoing verification is undertaken in conjunction with the operational monitoring program. It is usually less intensive than commissioning verification monitoring with fewer parameters monitored.

Verification monitoring programs

Verification monitoring should be risk-based and the recycled water provider should submit results to NOW documentation on the water quality testing to demonstrate that the treatment system is reliable and robust and that the scheme is able to consistently provide the required water quality.

The frequency of verification monitoring should allow for temporal and seasonal variation where applicable, and should be sufficient to give statistical confidence that the final water quality consistently achieves the required water quality criteria. Table 5.6 of the AGWR provide guidance on developing verification schedules.

The requirements of verification monitoring will differ depending on the phase of the plant and the scope of the verification program. However, in general, the requirements of a verification monitoring plan include:

- a list of microbial and chemical parameters to be analysed with a rationale for why these were chosen
- details on sampling locations and sampling methodology
- frequency of sampling.

An example verification sampling program is provided in Table 1.

Table 1 Example verification sampling program[1]

Verification monitoring	Frequency
E. coli	Weekly
Clostridial spores	Weekly
Audit of calibration activities	Monthly
Audit of preventive maintenance activities	Monthly
Audit of operational monitoring activities	Annual

Source: *NSW Guidance for RWMS Table 16*

Where commissioning verification monitoring is being undertaken, part of the aim of the monitoring is to verify the suitability of a CCP and its critical limit. Thus it is important that the value of the operational parameter monitoring the critical limit at the time of sampling is recorded as part of the verification program.

Verification monitoring results

The results of commissioning verification should be compiled and presented in a format that includes:

- parameter
- unit of measurement
- guideline value
- limit of reporting/detection
- laboratory and appropriate accreditation
- analytical method used
- total number of samples
- total number of positive samples
- minimum and maximum concentrations.

Who undertakes verification monitoring?

While commissioning verification can be undertaken in-house, recycled water suppliers may choose to engage an independent third-party to ensure that the verification study is conducted in a technically sound and unbiased manner. This has the benefit of expertise and timely analysis of data.

Designing Validation and Verification Programs

When an independent laboratory will be testing the sample, consult with the laboratory on the length of time between when the sample can be taken and when it must be tested. This may affect the validation and verification schedule. For example many laboratories are not open on Saturday, thus samples that must be tested within 24 hours cannot be scheduled for Friday afternoon.

Ensure the laboratory provides an SOP for the sampling and that the operators are trained appropriately to take the sample.

[1] Table 5.6 AGWR (2006)

Table 2 Validation and verification compared

	Validation	Verification
What is it?	*Validation monitoring* is undertaken to predict if recycled water **will** be safe for supply to end-users. The monitoring is 'indicative' and provides a basis to make assumptions as to how the plant will operate under a series of conditions. It confirms the capability of the process.	*Verification monitoring* is undertaken to determine if the recycled water **was** safe for supply to end-users. The monitoring 'confirms' or 'rejects' the validation monitoring assumptions around the safety of its supply to end-users. Verification involves monitoring actual conditions in a non-simulated environment. It confirms the performance of the system.
Mode of investigation	• In-field with manipulated input variables. • Theoretical.	• In-field – investigation of actual field data.
Monitoring methods	• *Theoretical* - examination of literature to gain indicative data for a particular system, CCP or process unit. • *Pre-validation* - performed on particular process units by an external supplier before installation. • *In-field with manipulated variables* - performed in-field and by simulating conditions. • *Full validation* - generally undertaken for novel processes and provides a comprehensive examination of the system, CCP or unit capabilities.	• *Commissioning verification* – verifies that operational monitoring e.g. CCP limits, is adequate for safe supply. Pre-operational monitoring is more comprehensive then ongoing verification. • *Ongoing verification* – collection of online operation data against a pre-determined schedule to ascertain the effectiveness of a system, CCP or process unit.
When is it performed?	• *Validation* - Performed prior to supply to end-users. It can occur across the design, build and commissioning stage. • *Re-validation* - validation may be required again for major upgrades or changes to operation or source conditions.	• *Commissioning verification* - performed prior to supply to end-users. • *Ongoing verification* - undertaken on an ongoing basis throughout the schemes operation. • Verification monitoring is conducted more frequently during the first weeks and months of operation or when re-commissioning.
Examples of activities	• Pilot studies during the design phase. • Purchase of pre-validated UV and membrane filtration units (refer to USEPA 2006) that match the conditions the scheme will operate under. • Tracer studies – dosing with dye to determine chlorine contact time. • pH, temperature and turbidity measurements to inform the required C.t for chlorination. • UVT to define the lower bound of validation for UV disinfection systems. • Spiking with microbes or chemicals to demonstrate the effectiveness of a system, CCP or process unit. • Ammonia profiling to inform disinfection operation mode.	• Microbial verification testing of surrogates to determine actual log reductions across a system, CCP or process unit. • Determination of hydraulic residence time. • Determination of chlorine contact times. • Monitoring of water quality criteria, soils, plants, terrestrial and aquatic biota, ground and surface water, the infrastructure associated with application or receiving environments and assessment of satisfaction of users of recycled water.

More information

Australian Guidelines for Water Recycling (2006)

For more information visit www.water.nsw.gov.au or contact: rwapprovals@dpi.nsw.gov.au

Published by the Department of Primary Industries, a division of NSW Department of Trade and Investment, Regional Infrastructure and Services.