# What Regulators look for in validation

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# What is Validation?

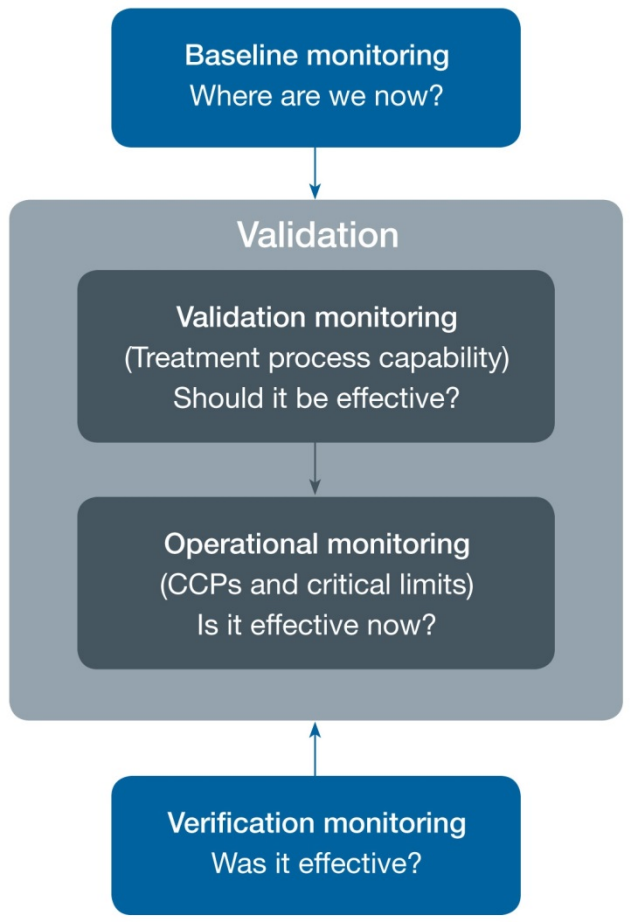
**Validation is the body of scientific evidence that demonstrates:**

The treatment process is capable of achieving the required water quality objectives

AND

The process control and operational monitoring that provides ongoing assurances that the water quality objectives are being met continually

# What is validation?



# Why do we need to validate?

- Sewage is a high risk water source that contains disease causing pathogens
- No other public health measure has had a greater impact in reducing disease and extending life than the separation of drinking water supplies and the public from sewage.

# What are we trying to achieve?

- aim is to ensure that recycled water is safe for use
- a systematic approach from source to point of use
- reduces reliance on end-point recycled water testing (too little, too late).

# What do regulators look for in validation?

- evidence-based approach
  - scientifically defensible & verifiable
  - statistically valid.
- operational monitoring that can be correlated to pathogen reduction
- defined critical limits
- independent third party oversight.

# NatVal Framework

- the regulators see the benefits of establishing a national validation framework that will ensure national consistency
- regulators are represented on the ‘Protocol Development Group’ (PDG)
- regulators support the PDG’s draft validation protocol.

# Testing the validation protocol

1. identify the mechanisms of pathogen removal by the treatment process unit
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
3. identify the influencing factors that affect the efficacy of the treatment process unit to reduce the target pathogen
4. identify the operational monitoring parameters that can be measured continually (ideally) and that will relate with the reduction of the target pathogen
5. identify the validation methodology to demonstrate the capability of the treatment process unit
6. collect and analyse data to formulate evidence-based conclusions
7. determine the critical limits as well as an operational monitoring and control strategy
8. determine the LRV for each pathogen group (protozoa, virus or bacteria) in each specific treatment process until performing within defined critical limits
9. re-validate or additional onsite validation where proposed modifications are inconsistent with the previous validation test conditions

√ USEPA Ultraviolet Disinfection Guidance Manual

√ (with caveats) German DVGW