

Bridging the GAPS: Approaches for Treating Water On-Farm

Developing On-farm Agricultural Water Treatment Programs

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Bridging the GAPs: Approaches for Treating Irrigation Water On-Farm

The goal of this series of modules on water treatment is to equip growers with the knowledge to successfully implement water treatment systems on their farms. Fruit and vegetable growers are continually assessing their operations to determine where they can limit risk and increase productivity. As a result, many have expressed interest in learning more about how on-farm preharvest water treatment systems work and how they may fit within their current setup.



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These four modules help growers to: 1) understand the background for water treatment; 2) learn about different approaches to treating water on-farm; 3) how to implement these systems to meet requirements of the Produce Safety Rule; and 4) how to verify that the system is operating as intended.

W 920-A, Agricultural Water Treatment and FSMA

W 920-B, Agricultural Water Treatment Tools

W 920-C, Developing On-farm Agricultural Water Treatment Programs

W 920-D, Implementing Agricultural Water Treatments on the Farm





Developing On-farm Agricultural Water Treatment Programs

Module 3



Learning Objectives

1. Explain activities tied to monitoring, verification and validation
2. Understand the difference between critical limits and operating limits
3. Develop a SOP outlining key factors for implementation (recordkeeping requirements)



Validation and Verification

Validation asks whether the hazard analysis was complete and if the control measures were effective

- Element of verification
- “Are you doing the right thing?”

Verification asks whether the system is being implemented according to the plan

- “Do what you say!”



How To Validate A Water Treatment Method

- What does validation involve?
 - Scientific validation studies, industry adopted standards, or other technical review
- Validation studies may be performed by manufacturer/supplier
- Any studies should target foodborne pathogens of interest for your commodity and their indicators
 - Bacteria: Shiga-toxigenic *E. coli* and *Salmonella*
 - Protozoa: *Cyclospora*
 - Indicator organisms: generic *E. coli* or coliforms, linkage to your on-farm treatments

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Discuss that target foodborne pathogens are many times driven by previous outbreaks, STEC and Salmonella are common bacterial targets, but protozoa, such as Cyclospora may also increase in importance

If using a study which utilizes indicator organisms, it is important that a strong correlation is shown between the indicator organism reduction and target foodborne pathogen(s)



Target Organisms For Validation

- For production agricultural water treatment target organisms of validation should include
 - **Human pathogens or**
 - **Indicator organisms (i.e., generic *E. coli*)**
- Validation of chemical or device treatments for plant pathogens or algae are not sufficient



How To Validate A Water Treatment Method on the Farm

- Other considerations beyond bacterial inactivation
- Water quality
 - Turbidity
 - Total dissolved solids
 - pH
 - Hardness
- Be patient, the adoption of these technologies is occurring before many systems can be extensively validated
 - A lot of work currently taking place
 - Stay engaged to remain informed

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Water quality can significantly impact efficacy of treatments. When reviewing scientific literature, it is important to find studies that utilize water that has similar properties to your irrigation water.



How To Validate A Water Treatment Method on the Farm

- Once you know what the lower and upper limits (critical limits) are for the treatment you are using, based on a validation study, you must show that you can keep values within that range on your farm
- These on-farm studies will involve collecting data at increased frequencies to demonstrate control over critical parameters



How To Validate A Water Treatment Method

- Example:

- Monitor free chlorine concentrations every 30 minutes at treatment location and throughout system to document control
 - Helps operators understand lag between adjustment done at the treatment system compared to last sprinkler head
- Collect water samples in treated and untreated water for indicator organism testing
 - Document reduction in coliforms and/or *E. coli*

$$\% \text{ Reduction } E. coli = \left(\frac{\text{No. of } E. coli \text{ in untreated water} - \text{No. of } E. coli \text{ in treated water}}{\text{No. of } E. coli \text{ in untreated water}} \right) \times 100$$

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Collect data as frequently as it is feasible given the size of the system and the resources that you have. Some continuous monitoring equipment may be used just for purposes of on-farm studies when starting a new system. This information can help you understand the variability within your irrigation system and help you establish appropriate operating limits and monitoring frequencies.

On farm-validation may also include microbial analysis demonstrating reduction of an indicator organism (such as generic *E. coli* or coliforms) in untreated and treated water. When utilizing the formula above, you can calculate % reduction. Some water sources will have very low populations of generic *E. coli* and % reduction of coliforms may be a more appropriate approach when calculating % reduction on farm.



How To Validate A Water Treatment Method

- Untreated water: 324 CFU *E. coli*/100ml
- Treated water: 10.5 CFU *E. coli* /100ml

$$\% \text{ Reduction } E. coli = \left(\frac{\text{No. of } E. coli \text{ in untreated water} - \text{No. of } E. coli \text{ in treated water}}{\text{No. of } E. coli \text{ in untreated water}} \right) \times 100$$

$$\left(\frac{324 - 10.5}{324} \right) \times 100 = 96.75\% \text{ Reduction } E. coli$$

- Many water sources naturally have very low populations of *E. coli*, in these cases, it is also helpful to calculate % reduction of total coliforms

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Collect data as frequently as it is feasible given the size of the system and the resources that you have. Some continuous monitoring equipment may be used just for purposes of on-farm studies when starting a new system. This information can help you understand the variability within your irrigation system and help you establish appropriate operating limits and monitoring frequencies.

By demonstrating reduction of indicator organisms, this will help demonstrate proper on-farm implementation of treatment systems.



Critical Limits

- A maximum and/or minimum value to which a parameter must be controlled to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified hazard
 - Human pathogen
 - Microbial indicator
- Critical limits should relate to a process that can be easily measured



Critical Limits – There May Be More Than One!

- Antimicrobial pesticide products
 - Chemical concentrations
 - Contact times
 - pH
 - Turbidity
- Antimicrobial devices
 - Temperatures
 - Membrane pore size
 - UV dose
 - Contact times
 - Turbidity



How To Validate A Water Treatment Method on the Farm

- Once you show that you can implement the system on-farm, you can transition into normal operating procedures following the developed SOPs
- Frequency of non-continuous monitoring (e.g., active compound concentration) should be supported from on-farm validation studies
- Validation is necessary for both chemicals and pesticide devices

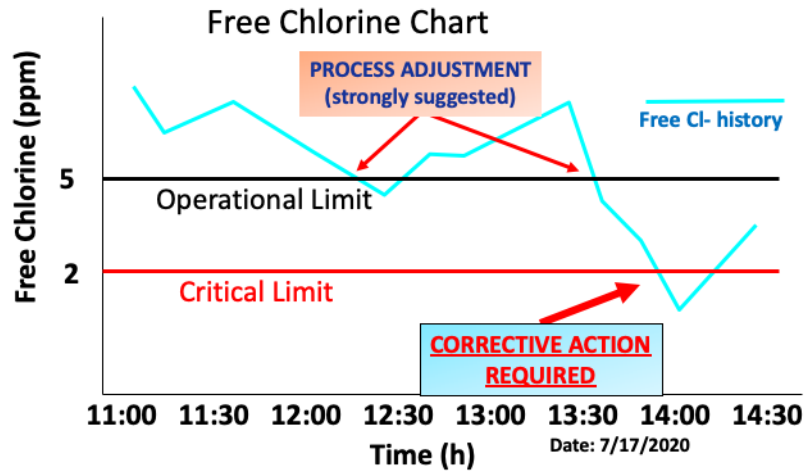


Critical vs. Operating Limits

- **Operating limit:** a criterion that is more stringent than a critical limit and that is used by an operator to reduce the risk of deviation above or below your critical limits
- **Process adjustment:** an action taken by an operator to bring the process back within operating limits



Example of Operating and Critical Limits, and Corrective Action- Example Only!





What needs to be in a water treatment SOP?

- SOPs outline what tasks need to be done and how to perform them
- Write clear and concise SOPs that anyone could follow
 - To test an SOP's effectiveness, growers should give it to someone else to read
 - Growers should watch someone carry out the task to see if it is clear what needs to be done
- Although written SOPs are not required by the PSR, written SOPs help ensure proper compliance and implementation of critical tasks such as water treatment



What needs to be in a water treatment SOP?

- A water treatment SOP may include:
 1. Step-by-step instructions to ensure the water treatment is correctly implemented by following the SOP
 2. Location and name of any supplies needed
 3. When and how often practices should be completed
 4. What records are needed/necessary
 5. What critical limits need to be met
 6. What is being monitored
 7. What corrective actions to do if critical limits are not met



Monitoring

- Conducting a planned sequence of observations or measurements to assess whether a process, point or procedure is under control and to produce an accurate record for future use in verification
- Without adequate monitoring, there is no way to know (or prove) if critical limits are being met



Monitoring

- The purpose of monitoring is to:
 - Track the operation of the process
 - Identify trends
 - Identify when there is a loss of control
 - Provide written documentation that the process is in control



Monitoring Determines

- If the control measures are being taken to manage risk
- If the critical limits are being met
- Involves:
 - What?
 - How?
 - Frequency?
 - Who?



Monitoring – What?

- A measurement or observation
 - Determines if operating within the critical limit
- Examples:
 - Time
 - Antimicrobial pesticide product active compound concentration
 - Free chlorine, chlorine dioxide, peroxyacetic acid
 - Temperature
 - pH
 - % UV intensity



Monitoring – How?

- Physical or chemical measurements
 - Quantitative critical limits
- Observations
 - If qualitative (not recommended)
- Needs to be real-time and accurate



Examples of How to Monitor

- Timer
- Thermometer
- pH meter
- Scales
- Test strips
- Titration
- Analytical equipment
- Gas analyzer



Frequency?

- Continuous
- Periodic (non-continuous)
- Example:
 - Chlorine injection with in-line monitoring
 - Periodic checks with test strips to monitor concentration
- As you develop your program- ask yourself questions about feasibility for monitoring, how much product will be impacted if outside of critical limits

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Continuous monitoring, as the name implies, is going to provide constant feedback on your monitoring system and is more accurate.

Periodic monitoring will provide a snapshot in time of your monitoring system. The frequency will vary based on the standard operating procedure developed by each farm.



Who will monitor?

- A person who:
 - Has clearly defined responsibilities
 - Has been trained
 - Follows clearly delineated procedures
 - Has initial responsibility for corrective actions
 - Is responsible for recordkeeping



Corrective Actions

- Procedures to be followed when a critical limit is not met
- Contains multiple components
 - Correct and eliminate the cause of the deviation and restore process control
 - Short-term: increase concentration of compound, increase frequency of concentration checks until two in range
 - Long-term: determine what may have caused drop in compound concentration and determine if it can be prevented in the future
- Identify the area within plots that were impacted during deviation



Corrective Actions

- Corrective actions should be in place to:
 - Fix or correct the cause of non-compliance (e.g., untreated or improperly treated water)
 - Assess and determine what should be done with product that may have been exposed to untreated water
 - Maintain records of the non-compliance and corrective actions that have been taken



So, what can I do with produce that has been exposed to untreated water?

- Does a risk exist?
 - Microbial populations of indicator organisms may indicate low probability of risk
 - On-farm microbial water quality may be better than that used in validation studies
- Need to know the microbial quality of the water = **collect** water samples when a deviation is recognized



So, what can I do with produce that has been exposed to untreated water?

- Can another corrective measure be used?
 - Time interval between application and harvest
 - Must be validated with scientific literature that supports approach
 - Need to know the microbial quality of the water = **collect** water samples when a deviation is recognized
- Divert for alternative use (i.e., commercial process exemption)
- Destroy if other corrective measure or diversion not possible



Corrective Action Decision Making

- Responsibility for decision-making should be clearly defined during assignment of monitoring responsibilities
- Proper documentation is critical



Corrective Actions Records

- Maintain separate corrective action procedure/form with:
 - Product identification
 - Description of problem
 - Corrective action
 - Fate of product
 - Person responsible for corrective action
 - Determination of root cause
 - Actions to prevent future occurrence
 - Results of evaluations
 - Follow-up to ensure corrective actions were followed



Corrective Actions Records

- Tied to produce disposition (i.e., what you do with the affected produce)
 - Reasoning behind decisions
 - Fields affected
 - Corrective action
 - Alternative corrective measure used
 - Assurance of commercial processing
 - If destroyed, who destroyed it with signature and date



Verification

- Those activities, other than monitoring, that establish the validity of the treatment and that the system is operating according to the plan



How many people have a refrigerator?

How many people have a thermometer?

Well, then how do you know your refrigerator is below 40F? If it is the mountains turn blue on your beer because your beer is as cold as the Rockies, that is not verification- you need a thermometer!



Elements Of Verification

- Calibration of monitoring devices
 - Thermometers, pH meters, ORP meter
- Review of calibration records
- Targeted sampling and testing*
- Record review
 - Monitoring records
 - Corrective action records

*You can not test your way to food safety!



Verification - Calibration Activities

- pH meter is calibrated against buffer standards when it is used to measure the final pH of the product
- Test strips within dates of use, measure appropriate chemicals within range of use
- ORP meter calibration





Verification - Calibration Activities



- When and how are calibrations performed?
 - On equipment and instruments used in monitoring or verification
 - At a frequency to ensure accuracy of measurements
 - By checking accuracy against a recognized standard at or near the condition that the instrument or equipment will be used



Routine and Preventive Maintenance

- Extremely important for devices
- Helps prevent device failures resulting in a need for corrective actions
 - Examples: UV light bulb replacement in a UV device, replacement of tubing and seals for chemigation equipment



Verification – Records Review

- Monitoring activities have been performed as specified
- Corrective actions have been performed whenever monitoring indicated non-compliance from critical limits
- Equipment has been calibrated at the frequencies specified
- Records must be reviewed, dated, and signed by the supervisor or responsible party within a reasonable time after the records are made



Recordkeeping

- Records of monitoring
- Records of corrective actions
- Records of verification activities
- Validation to support established critical limit (i.e., scientific study, EPA registration)
- Records of training for individuals monitoring water treatment



Monitoring Records Should Include:

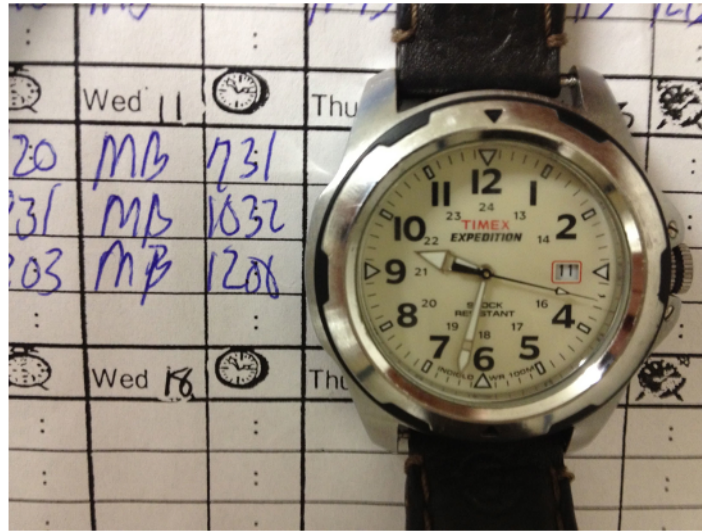
- Form title
- Firm name and location
- Time and date
- Water use identification (i.e., fields and commodities applied to)
- Actual observation or measurement
 - At time observed
- Critical limits
- Operator's signature or initials
- Date of review, and reviewer signature or initials



Recordkeeping Don'ts:

- Incomplete records
 - A check-mark where a temperature or other “data” should be recorded
 - Lack of signature or initials
 - No date or time
 - “Doctoring records”
- Verifying signature the same as monitoring
- Improper filing of records
- Keeping quality and safety records together

What's Wrong With This Picture?





Records Retention

- Two years past the date of the record creation
- Retention on the farm
 - Readily available following oral or written request



So, if I treat my water and I keep all these records, I don't have to test my water?

- Technically yes, this would satisfy the requirements of the PSR, but...
- Audit schemes or buyer requirements may require additional/alternative water testing programs



Summary

- Validation is essential
- You will be tasked with performing on-farm validation, which can be used to establish monitoring frequency
- Monitoring records for agricultural water treatments required by the PSR
- Developing water treatment SOPs are beneficial to ensure consistent water treatment and reducing chances of non-compliance



Questions?

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