Changes to V1M5:
The New TNI Microbiology Standard

Cody Danielson

Oklahoma Department of Environmental Quality

State Environmental Services Division

Summary of Progress

- V1M5 was opened for revision in 2020
- Input considered from broad audience base
  - Public webinars
  - Conferences
  - Public comment
  - SIRs
  - Committee meetings
- Revised Draft Standard voted for approval 7/2024

Summary of Changes

- Goals:
  - To outline minimum requirements of Quality Systems for Microbiology Laboratory
  - To make intent and requirements clear
- Updates:
  - Reorganized to improve readability
  - Reworded to improve clarity

Changes to Sections 2.0, 3.0 and 4.0

- Section 2.0: Scope
  - Added language stating that records must be retained in accordance with V1M2 5.4.6.2
- Section 3.0: Terms and Definitions
  - Added definitions for Positive and Negative Culture Controls
- Section 4.0 (new): Technical Specialist Requirements
  - Additional requirements to those in V1M2
    - Will require one college level Micro course with a lab component

Changes to 7.3.1

- 2016 Standard V1M5

1.7.3	Quality Control
1.7.3.1	Quality and Sterility of Standards, Reagents, Materials, and Media
	The laboratory shall demonstrate and document that the quality of the reagents and media used is appropriate for the test concerned including, but not limited to, test conditions and incubation times.

- V1M5 Revised Draft Standard

7.3	Quality Control
7.3.1	Quality, Selectivity, and Sterility of Standards, Reagents, Materials, and Media
	The laboratory performing the sample analysis, except where specified in Section 7.3.1.d.ii and Section 7.3.1.d.iii, must perform and document the quality of the reagents and media used as appropriate for the analytical method.

Changes to 7.3.1

2016 Standard V1M5

- Sterility checks
- Media checks
- Shelf life/expiration date
- Reagent water testing
- Dilution water testing
- Documentation

V1M5 Revised DS

- Sterility checks
- Media checks
- Dilution water testing
- Reagent water testing
- Documentation
- Shelf life/expiration date

Changes to 7.3.1

- Sterility Checks
  - Requirement to use non-selective media located only in preamble
  - Specified that sterility testing must be done prior to or in conjunction with first use
  - Clarified that sterility of lab-sterilized funnels can be performed on one "*funnel or object representative in size and use*"

Changes to 7.3.1

ii. The laboratory must perform a sterility check on one (1) funnel per lot of pre-sterilized single use funnels ~~using nonselective growth media.~~ .The laboratory must perform a sterility check on one (1) funnel or ~~/~~object representative in size and use per sterilization batch sterilized in the laboratory ~~with non-selective growth media.~~ .

iii. The laboratory must perform a sterility check on at least one (1) container for each lot of purchased, pre-sterilized sample containers ~~with non-selective growth media~~.. The laboratory must perform a sterility check on one (1) container or ~~/~~object representative in size and use per sterilization batch sterilized in the laboratory ~~with non-selective growth media~~..

iv. The laboratory must perform a sterility check on each batch of dilution water prepared in the laboratory and on each lot of pre-prepared, ready-to-use dilution water ~~with non-selective growth media~~.. The concentration of the non-selective growth media must be single strength after the addition of dilution water.

v. The laboratory must perform a sterility check on at least one (1) filter from each new lot of membrane filters ~~with non-selective growth media.~~.

Changes to 7.3.1

- Media
  - Moved reference culture language to the Media section
  - Moved language for culture controls to the Media section
  - Removed duplicative language regarding exp. dates/shelf life
  - Moved requirement for lab to test pH to Media section
  - Clarified that final pH needs to be tested

Changes to 7.3.1

- Dilution Water
  - Removed duplicative language about sterility testing
  - Provided additional examples of dilution water
  - Specified volume verification requirements
- Reagent Water
  - Lab does not need to be accredited if only performing disinfectant residual, conductivity, TOC and HPC for internal RW monitoring
  - Removed requirement for Bacteriological Water Quality Test

Changes to 7.3.2: Method Blanks

- 2016 Standard V1M5

a) For filtration technique, the laboratory shall conduct method blanks per the analytical method. At a minimum, the filtration series shall include a beginning and ending blank. The filtration series may include single or multiple filtration units, which have been sterilized prior to beginning the series.

b) The filtration series is considered ended when more than thirty (30) minutes elapses between successive filtrations. During a filtration series, filter funnels shall be rinsed with three (3) 20-30 ml portions of sterile rinse water after each sample filtration. In addition, laboratories shall insert a method blank after every ten (10) samples or sanitize filtration units by UV light (254-nm) after sample filtration.

- V1M5 Revised Draft Standard

a) For filtration technique, the laboratory must conduct method blanks per the analytical method. The analysis may utilize a filter funnel manifold with single or multiple vacuum supply ports/positions. At a minimum, the filtration series must include a beginning and ending blank for each manifold port/position used. In addition, the laboratory must insert a method blank after every ten (10) samples filtered per port/position unless the laboratory uses single-use funnel sets or sanitizes filtration units by UV light (254-nm) after sample filtration.

b) A filtration series must include filtration units that have been sterilized prior to beginning the series. During a filtration series, filter funnels must be rinsed with three (3) 20-30 ml portions of sterile rinse water after each sample filtration. The filtration series is considered ended when more than thirty (30) minutes elapses between successive filtrations.

Changes to 7.3.3 and 7.3.4

- 7.3.3 Test Variability/Reproducibility
  - Each analyst must count a sample that has been counted by another analyst (rather than same sample)
  - Requires corrective actions if the difference between counts is >10%
- 7.3.4 Sample Specific Controls
  - Removed

Changes to 7.3.6

- Autoclaves
  - If the temperature is verified and there are no leaks, the pressure has been verified
- Incubators, Water Baths
  - Removed requirement for equilibrium testing
  - Added requirement for corrective actions when temperature nonconformance is identified

Questions?

Cody Danielson

cody.danielson@deq.ok.gov

TNI Microbiology Expert Committee Meetings:

Second Tuesday of each month at 1:30 EST

Fill Out an Application to Join:

1. Login to the TNI Member Page
2. Click “Join a Committee”
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