



TNI Microbiology EC: 2016 Standard - Module 5

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2009 is a good standard so why a new one?

- Still a bit over carry over from the 2003
- 2016 – Experts are the writers
- Microbiologists speaking the same language.
- Tried to anticipate some challenges
- All prior SIRs were considered in this revision.



Updates to V1M5

□ Section 1.2

- *The essential quality control procedures applicable to microbiological analysis are included in this module. Additional quality control or **program** requirements that are either specified by method, regulation or project shall be met by laboratories.*



Updates to V1M5

- Section 1.2
 - Added Clarity
 - Reinforce the concept minimum requirements
 - Default to the use of the data



Updates to V1M5

- 1.5 Method Validation –
 - a. For methods **other than reference methods**, validation must comply with Volume 1, Module 2. This validation must include the minimum requirements outlined in Sections 1.5.1, 1.5.2, and 1.5.3 of this module.
 - b. For both reference and non-standard methods, laboratories shall participate in proficiency testing programs **where available**.
 - 1.5.2 Precision – Perform at least ten (10) replicate analyses with both the proposed and reference method, using a **sample containing** the target microorganisms of choice. The results shall show that the **precision of the proposed method is statistically equivalent or better than that of the reference method.**”



Updates to V1M5

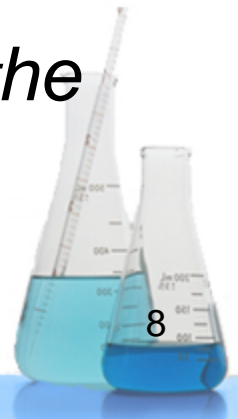
- Section 1.5
 - Added Clarity
 - Allow use of statistically better method
 - Allow for improvement



Updates to V1M5

- 1.6.2.2.e

*Compare the information from c) above to the corresponding acceptance criteria for precision and accuracy in the method (if applicable) or in laboratory-generated acceptance criteria such as **relative standard deviation** (if there are not established mandatory criteria). If all parameters meet the acceptance criteria, the analysis of actual samples may begin. If any one of the parameters does not*



Updates to V1M5

- Section 1.6.2.2.e
 - Added Clarity
 - Added guidance for labs



Updates to V1M5

- 1.6.3.2 added clarity
 - *c. Acceptable results for blind proficiency test sample **or sample set, as required by program**, for target organisms in each field of accreditation.*

 - *f. If a) through e) are not technically feasible, then analysis of real-world samples with results within a **predefined acceptance criteria** (as defined by the laboratory or method) shall be performed.*



Updates to V1M5

- Section 1.6.3.2
 - Added Clarity
 - Added guidance for labs



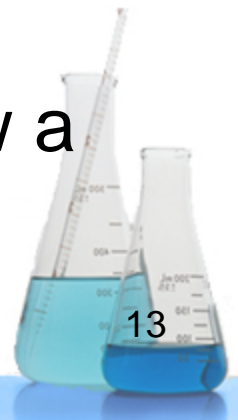
Updates to V1M5

- 1.7.3 Quality Control – Basic Outline
 - 1.7.3.1 Quality and Sterility of Standards, Reagents, Materials and Media
 - ✦ A. Sterility Checks
 - ✦ B. Media
 - ✦ C. Shelf Life
 - ✦ D. Reagent Water
 - ✦ E. Dilution Water
 - ✦ F. Documentation



Updates to V1M5

- 1.7 QC Sections – The whole section reorganized to specify the “before” requirements and the “during” requirements.
 - Previous section 1.7.3.5 of the 2009 TNI std (media checks, reagent water checks, supply checks) and sterility checks have been combined into section 1.7.3.1 to represent the “before”
 - Method blanks are done “during” – now a completely separate section



Updates to V1M5

- Section 1.7 QC regarding Blanks and check
 - Added Clarity
 - Sterility and performance checks are for materials
 - Blanks are for method and technique



Updates to V1M5 Section 1.7 cont

- 1.7.3.1.d.vi

*Purchased reagent water that has been **opened** for longer than the testing intervals specified in items i) through iv), or in the accredited method shall either be re-tested or discarded.*

- 1.7.3.1.e

e. Dilution Water, however used, includes buffer water and/or peptone water. The quality of the dilution water shall be monitored for sterility, pH and volume once per lot or batch whether purchased or lab prepared.



Updates to V1M5

- Sections 1.7.1.1.d.vi and 1.7.3.1.e
 - Added guidance for labs
 - Dilution water \neq reagent water
 - Individual requirements for each more clear.



Updates to V1M5 Section 1.7 cont.

□ 1.7.3.3 Test Variability/ Reproducibility

For methods that specify counts (i.e. cfu/100mL or MPN/100mL) such as membrane filter, plated media or other methods which specify a quantitative result, duplicate counts shall be performed monthly on one (1) positive sample, for each month that the test is performed.



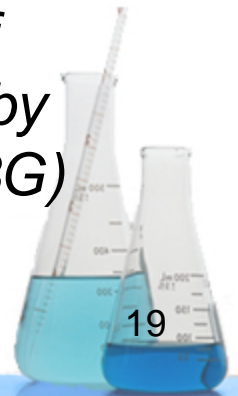
Updates to V1M5

- Sections 1.7.1.1.d.vi and 1.7.3.1.e
 - Added guidance for labs
 - Applies to any method where a number is reported.



Updates to V1M5

- 1.7.3.6 Selectivity – added phrases to improve clarity and flexibility
 - a. *All growth and recovery media shall be checked to assure that the target organism(s) respond in an acceptable and predictable manner **once per lot or batch**.*
 - b. *To ensure that analysis results are accurate, target organism identity shall be verified as specified in the method (e.g., by use of the completed test, or by use of secondary verification tests such as a catalase test, or by the use of a **selective medium** such as brilliant green (BG) or *E. coli* (EC **or EC + MUG** broth).*



Updates to V1M5

- 1.7.3.6.d.ii.2 – added clarity

*Each pre-prepared, ready-to-use lot of medium (including chromo/fluorogenic reagent) and each batch of medium prepared in the laboratory shall be tested with at least **one or more known pure positive culture controls (i.e. target organism) as appropriate to the method (i.e. quantitative results for quantitative method)**. This shall be done prior to first use of the medium.*



Updates to V1M5

- Sections 1.7.3.3.6.ii.2
 - Added guidance for labs
 - Like for like
 - Get a number not just “present” for qualitative tests

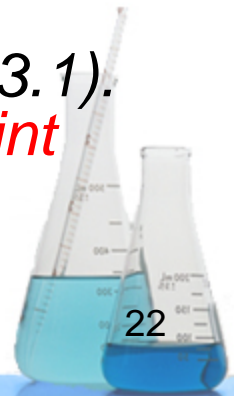


Updates to V1M5

□ 1.7.3.7.b.i

*The laboratory shall use temperature measuring devices such as liquid-in-glass thermometers, thermocouples, or platinum resistance thermometers to **assess and document equipment temperatures**. The temperature measuring devices shall be appropriate quality to meet specification(s) in the method.*

*The graduation **and range** of the temperature measuring devices shall be appropriate for the required accuracy of **the** measurement. **Temperature measuring devices** shall be verified to national or international standards for temperature. Verification shall be **performed** at least annually (see TNI Volume 1, Module 2, Section 5.5.13.1). **This verification may be accomplished by a single point provided that it represents the method mandated temperature and use conditions.***



Updates to V1M5

- Sections 1.7.3.7.b.i
 - Added guidance for labs
 - Single point calibration
 - Appropriate use conditions



Updates to V1M5

- 1.7.3.7.b.ii –
 - Ovens and autoclaves in the same section.
 - Now “Sterilization Equipment”



Updates to V1M5

- 1.7.3.7.b.iii Volumetric Equipment clarifying language added: *The laboratory shall verify equipment used for measuring volume as follows:*
- Added 1.7.3.7.b.iii.4 –
4. Verification of volume shall be considered acceptable if the accuracy is within 2.5% of expected volume. This verification can be volumetric as compared to Class A or gravimetric.



Updates to V1M5

- Sections 1.7.3.7.b.iii and iii.4
 - Clarification
 - All pieces measuring volume not just pipettes.
 - Acceptance criteria for the volumetric check.
 - Only a baseline. Program requirements supersede



Updates to V1M5

Section 1

The laboratory shall establish the uniformity of temperature distribution and equilibrium conditions in incubators and water baths prior to first use after installation or service. The equilibrium check shall include time required after test sample addition to re-establish equilibrium conditions under full capacity load appropriate for the intended use.



1.7.3.7.b.v Cont

Section 2

During periods when samples are under test, the laboratory shall have a system in place to monitor and document the temperature of incubators and water baths twice daily, at least four hours apart. “Under test” is defined as the time period that the sample is in the incubation phase of the method. Data loggers, continuous temperature monitoring devices, or other temperature monitoring equipment can be used as long as they can be calibrated in accordance with TNI V1 M2 Section 5.5.13.1 for Support Equipment. Records shall be maintained in accordance with V1M2 4.13 Records Maintenance

NOTE: There is no intent to take the temperature of incubation units during periods when there are no samples under test.



Updates to V1M5

- 1.7.3.7.b.v
 - SIR regarding frequency of temp readings
 - Flexibility for staffing issues and periods of non-use
 - Clarification on equilibrium condition testing



Updates to V1M5

- 1.7.3.7.b.vi- Inhibitory Residue Testing
 3. *Labware that is washed and reused shall be tested for possible presence of residues that may inhibit or promote growth of microorganisms by performing the Inhibitory Residue Test **initially** and each time the lab changes the detergent **formulation** or washing procedures.*



Updates to V1M5

- 1.7.3.7.b.vi
 - Reduced frequency of Inhibitory Residue Testing
 - In line with EPA cert manual



Updates to V1M5

- 1.7.5 Sample Handling –

Receipt of samples must comply with V1 M2 Sections 5.8.6 and 5.8.7, as well as:

*1.7.5.1 Samples that require thermal preservation shall be considered acceptable if the arrival temperature of a representative sample container meets the method or mandated temperature requirement. Samples that are delivered to the laboratory on the same day they are collected may not meet the requirements of **this section or the method or the regulatory requirement**. In these cases, the samples **may** be considered acceptable if the samples **are** received **on ice with evidence that the cooling process has begun**.*



NOTE: The intent is for the samples to be preserved immediately and analyzed as soon as possible.



Updates to V1M5

- 1.7.5
 - Reasonable latitude in sample receipt
 - Clarify “cooling process”



Updates to V1M5

□ 1.7.5 – REMOVE THE MONTHLY Cl₂ CHECK

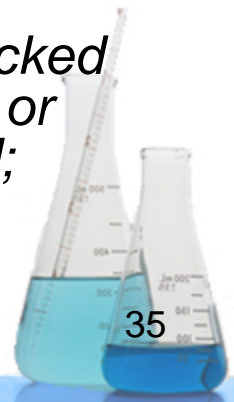
1.7.5.2 *Microbiological samples from known chlorinated sources (such as wastewater effluent), unknown sources where **disinfectant (e.g. chlorine)** usage is suspected (such a new client or a new source) and all potable water supplies (including source water) shall be checked for absence of **disinfectant** residual **in the laboratory unless all of the following conditions are met:***

a. *The laboratory can show that the received sample containers are from their laboratory **or have been appropriately tested and documented;***

b. ***Sufficient** sodium thiosulfate was in each container before sample collection to neutralize at minimum 5 mg/l of chlorine for drinking water and 15 mg/l of chlorine for wastewater samples;*

c. *One container from each batch of laboratory prepared containers or lot of purchased ready-to-use containers is checked to ensure efficacy of the sodium thiosulfate to 5 mg/l chlorine or 15 mg/l chlorine as appropriate and the check is documented;*

d. ***Disinfectant** residual is checked in the field and actual concentration is documented with sample submission.*



Updates to V1M5

- 1.7.5.2 An important note:
 - Exemption
 - Not a requirement
 - Each sample checked if all 4 conditions are not met





One Pretty Big Change

“The laboratory
shall.....”



Updates to V1M5

- Passive vs. active voice.
- Active voice as much as possible.
- Will help the assessors and the labs.
- Had been assumed that the lab shall....but not always the case.
- Enough flexibility for ABs to make some reasonable calls.



Take home message:

- Examples provided are not the only way
- Be creative- find what works for your lab
- New and Better std
- Talk to the ABs – we all have the same goal



Thank You

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