**Module 5 Standard Update - Summary of Suggested Changes – 11-18-20**

| **Original Text** | **Suggested Change** | **Justification** | **Comments** |
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| *Include reference and language.* | *Don't need to work on specific language - just summarize change needed.* | *Why does this need to be changed/updated?* |  |
| **1.7.3.2.a**. - ...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.  **1.7.3.2.b** - ...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. | Specify filtration series blanks for serial dilutions and multiple unit manifolds. Language should match language in new guidance document | Needs clarification |  |
| **1.7.3.1.d.ii** - The laboratory shall monitor the quality of the water for disinfectant residual, specific conductance… | Specific Conductance vs Conductivity | Need to update language to harmonize with other standards |  |
| **1.7.3.1 a** - Sterility Checks – All materials and supplies that are needed to process the sample and are required to be sterile prior to use (whether sterilized in the laboratory or purchased as sterilized) must be checked by the laboratory once per purchased or prepared lot using non-selective growth media as appropriate. | Need to specify QC checks in parent vs. sister laboratories  Should be expanded to include all of the QC checks in 1.7.3.1? | Need to clarify QC checks in parent vs. sister laboratories |  |
| **1.7.3.6.c** - ...Microorganisms may be single-use preparations or cultures maintained for their intended use by documented procedures that demonstrate the continued purity and viability of the organism. | Viability Checks-Possible move to 1.7.3.2 (from 1.7.3.6) and shift .2 .3 .4 and .5 down one number  Could consider checking viability prior to use- not currently stated.  Some of the language here should be referenced or moved to 1.7.3.1.b. | Improve flow of standard information |  |
| **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 as 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: | "Microbiological samples from known chlorinated sources (such as wastewater effluent), unknown  sources where disinfectant (e.g. chlorine) usage is suspected (such as 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. Alternatively, the laboratory does not need to test as above if all the below exemptions are met:"  The preamble in sec 1.7.5 does say to follow the QS module regarding preservation but there could be some language added to make it very clear that these are the exemptions and that they all must be met. | Exemptions section  - Seeking public comment on how we can make this section better and if it needs to be updated at this time |  |
| **1.7.3.1.ii**. The laboratory shall perform a sterility check on one (1) funnel per lot of pre-sterilized single use funnels using non-selective growth media. The laboratory shall perform a sterility check on one (1) funnel per batch of laboratory-sterilized funnels, using non-selective growth media. | 1.7.3.1.ii. The laboratory shall perform a sterility check on one (1) funnel per lot of pre-sterilized single use funnels using non-selective growth media. The laboratory shall perform a sterility check on one (1) funnel/object per sterilization batch sterilized in the laboratory with nonselective growth media. | Clarification on filter funnel sterility checks and creating operational flexibility |  |
| **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. If the laboratory has two (2) or more analysts, each analyst shall count typical results on the same sample. Counts shall be within ten percent (10%) difference to be acceptable. In a laboratory with only one (1) microbiology analyst, the same sample shall be counted twice by the analyst, with no more than a five percent (5%) difference between the counts. | **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, multi-well or other methods which specify a quantitative result, duplicate counts shall be performed monthly on one (1) positive result for each month that the test is performed. If the laboratory has two (2) or more analysts, each analyst shall count typical results on the same sample. Counts shall be within ten percent (10%) difference to be acceptable. In a laboratory with only one (1) microbiology analyst, the same sample shall be counted twice by the analyst, with no more than a five percent (5%) difference between the counts. | Seeking public comment on how we can make this section better and if it needs to be updated at this time |  |