**TNI Environmental Laboratory Standard – Volume 1 Module 5 Update - Summary of Suggested Changes - 7-26-21**

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|  | **Current Text** | **Change Made** | **Justification** |
| 1 | 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. | 1.7.3.1 Quality, Selectivity, and Sterility of Standards, Reagents, Materials, and Media  The laboratory performing the sample analysis, except where specified in Section 1.7.3.1.d.ii and Section 1.7.3.1.d.iii, shall perform and document the quality of the reagents and media used as appropriate for the analytical method. | Addressed SIR 331 to clarify QC checks in parent vs. sister laboratories |
| 2 | 1.7.3.1.a.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.a.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 non-selective growth media. | Update of language needed to clarify filter funnel sterility checks and create operational flexibility |
| 3 | 1.7.3.1.b.i All media shall be tested for performance (e.g., for selectivity, sensitivity, sterility, growth promotion, and growth inhibition). These tests shall be performed at a minimum with first use. | 1.7.3.1.b.i All media shall be tested prior to or at minimum in conjunction with first use for sterility following Section  1.7.3.1.b.ii. All media shall be tested prior to or at minimum in conjunction with first use for selectivity to ensure the target organism(s) respond in an acceptable and predictable manner once per lot or batch. For selectivity the laboratory shall: | Addressed SIR 406 to clarify timing of performance testing |
| 4 | 1.7.3.6 Selectivity  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 5Green Lactose Bile Broth (BGLB) or EC or EC + MUG broth).  c) In order to ensure identity and traceability, reference cultures used for positive and negative controls shall be obtained from a recognized national collection, organization, or manufacturer recognized by the accreditation body. 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.  i. Reference cultures may be revived (if freeze-dried) or transferred from slants and subcultured once to provide reference stocks. The reference stocks shall be preserved by a technique that maintains the characteristics of the strains. Reference stocks shall be used to prepare working stocks for routine work. If reference stocks have been thawed, they shall not be refrozen and re-used.  ii. Working stocks shall not be sequentially cultured more than five (5) times and shall not be sub-cultured to replace reference stocks.  d) Culture Controls (i.e. working cultures)  i. Negative Culture Controls  a. Negative culture controls demonstrate that the medium does not support the growth of non-target organisms or does not exhibit the typical positive reaction of the target organism(s).  b. Each pre-prepared, ready-to-use lot of selective medium (including chromofluorogenic reagent), and each batch of selective medium prepared in the laboratory, shall be analyzed with one (1) or more known negative culture controls (i.e. non-target organisms), as appropriate to the method. This shall be done prior to first use of the medium.  ii. Positive Culture Controls  a. Positive culture controls demonstrate that the medium can support the growth of the target organism(s), and that the medium produces the specified or expected reaction to the target organism(s).  b. 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 (1) or more known pure positive culture controls (i.e. target organism) as appropriate to the method and that produce typical results based on the method. This shall be done prior to first use of the medium. | 1.7.3.1.b.i All media shall be tested prior to or at minimum in conjunction with first use for sterility following Section  1.7.3.1.b.ii. All media shall be tested prior to or at minimum in conjunction with first use for selectivity to ensure the target organism(s) respond in an acceptable and predictable manner once per lot or batch. For selectivity the laboratory shall:  a) Ensure that 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 Lactose Bile Broth (BGLB) or EC or EC + MUG broth).  b) Ensure identity and traceability, by utilizing reference cultures used as positive and negative controls, obtained from a recognized national collection, organization, or manufacturer recognized by the accreditation body. 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.  i. Reference cultures may be revived (if freeze-dried) or transferred from slants and sub-cultured once to provide reference stocks. The reference stocks shall be preserved by a technique that maintains the characteristics of the strains. Reference stocks shall be used to prepare working stocks for routine work. If reference stocks have been thawed, they shall not be refrozen and re-used.  ii. Working stocks shall not be sequentially cultured more than five (5) times and shall not be sub-cultured to replace reference stocks.  iii. Negative culture controls demonstrate that the medium does not support the growth of non-target organisms or does not exhibit the typical positive reaction of the target organism(s). Positive culture controls demonstrate that the medium can support the growth of the target organism(s), and that the medium produces the specified or expected reaction to the target organism (s). Each pre-prepared, ready-to-use lot of selective medium (including chromoflourogenic reagent) and each batch of selective medium prepared in the laboratory, shall be analyzed with one (1) or more known negative culture control(s) (i.e., non-target organisms) and at least one (1) or more known pure positive culture control(s) (i.e., target organism), as appropriate to the method and that produce typical results based on the method. | Update of language needed to improve flow of standard information. Section 1.7.3.6 was moved to and combined with language in 1.7.3.1.b |
| 5 | 1.7.3.1.d.ii The laboratory shall monitor the quality of the water for disinfectant residual, specific conductance, total organic carbon, and heterotrophic bacteria plate count monthly (when in use), when maintenance is performed on the water treatment system, or at startup after a period of disuse longer than one month. Analysis may be performed by another certified laboratory. | 1.7.3.1.d.ii The laboratory shall monitor the quality of the water for disinfectant residual, conductivity, total organic carbon, and heterotrophic bacteria plate count monthly (when in use), when maintenance is performed on the water treatment system, or at startup after a period of disuse longer than one month. Analysis may be performed by another certified laboratory. | Update of language needed to harmonize with other standards regarding specific conductance versus conductivity |
| 6 | 1.7.3.2.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. | 1.7.3.2.a For filtration technique, the laboratory shall conduct method blanks per the analytical method. The filtration series may include single or multiple filtration units, which have been sterilized prior to beginning the series. At a minimum, the filtration series shall include a beginning and ending blank for each filtration unit. | Update of language needed to clarify requirement for beginning and ending blanks per filtration unit |
| 7 | 1.7.3.3 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 For all methods that specify a quantitative result, duplicate counts must be performed monthly on one (1) positive sample for each month that the test is performed. These counts may be performed on environmental samples or quality control samples. If the laboratory has multiple analysts, all analysts must count results on the same sample, when possible, with no more than ten percent (10%) difference between the counts. In a laboratory with only one (1) analyst, the same sample shall be counted twice by the analyst, with no more than a five percent (5%) difference between the counts. | Addressed SIR 379 to clarify test variability/reproducibility requirements for all methods that specify a quantitative result |
| 8 | 1.7.3.7.b.i Temperature Measuring Devices  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. | 1.7.3.7.b.i Temperature Measuring Devices  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. Verification shall be performed as per TNI Volume 1, Module 2, Section 5.5.13.1. | Update of language needed because Module 2 now includes some of the language, and restating was redundant |
| 9 | 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: | Update of language needed to clarify the requirement and the allowed exemptions |