Justification Form

Standard Update - Summary of Changes and Justification

#	Original Text	Change	Justification
1	Sections 4 – 8	Re-numbered due to deletion of Section 4	Clarity – note that previous numbering is different, such that 'Original Text 6.2.1' now equates to 5.2.1
2	**4.0 Technical Specialist Requirements** 4.1 Any technical specialist responsible for microbiological testing must meet the requirements of TNI Module 2, Section 6.2.2.2. The following requirements must also be met:	Removed entirely	All Technical Specialist requirements are covered in Module 2
3	6.2.1 Compare the method results to that of a reference method.	5.2.1 Compare the method results to that of a reference method and demonstrate evaluation for acceptability against an established accuracy criteria. In the absence of applicable method or regulatory requirements, the laboratory must define acceptance criteria.	Added clarity in the absence of method requirements such that the laboratory must define acceptance criteria if none previously exists. This form was used wherever this possibility exists.
4	7.2.2 a) Prepare at least four (4) aliquots at a concentration of a countable range for plate methods or working range for most probable number (MPN) type methods.	6.2.2 a) Concurrently prepare at least four aliquots according to the method at a concentration in the countable range for plate methods or working range for most probable number (MPN) type methods.	Added clarity by stating to concurrently prepare 4 aliquots, indicating that this is to be done at the same time.
5	7.2.2 c) When it is not possible to determine mean and standard deviations, such as for presence/absence, the laboratory must assess performance against established and documented criteria.	6.2.2 d) When it is not possible to determine mean and standard deviations, such as for presence/absence, the laboratory must assess performance against established criteria. In the absence of applicable method or regulatory requirements, the laboratory must define acceptance criteria.	Added clarity in the absence of method requirements such that the laboratory must define acceptance criteria if none previously exists. This form was used wherever this possibility exists.
6	7.3.1 NOTE: This ongoing demonstration may include, but is not limited to, any one of the following:	6.3 This ongoing DOC must be one of the following:	The Committee feels that the language found in 6.3 covers any option for an ongoing DOC, and the removal of the 'NOTE' makes this enforceable when it otherwise wouldn't have been.

7	7.3.1 b) AND OTHERS target organism	6.3 b) AND OTHERS target organism(s)/analyte(s) of interest	Added clarity as this is not always ‘organisms’. Adding ‘analyte of interest’ should cover any possibilities.
8	8.2.1.1 All materials and supplies that are needed to process the sample and are required to be sterile must be checked	7.2.1.1 Each lot of media, materials and supplies purchased, provided and used by the laboratory must be checked to demonstrate the absence of organism(s)/analytes of interest	Added clarity as ‘sterility’ may not be the requirement, such as with Legionella where absence of the organism/analyte of interest is the requirement.
9	8.2.1.1 a) One item from each purchased pre-sterilized lot, or one item or object representative in size and use per sterilization batch sterilized by the laboratory, must be tested.	7.2.1.1 When materials and supplies have been purchased by the laboratory pre-sterilized and a method blank utilizing the item(s) is analyzed prior to or in conjunction with first use, a Certificate of Analysis may be used to satisfy the sterility check. Materials and supplies which have been sterilized in the laboratory must be tested to verify sterility once per batch or lot.	Clarify that a COA can be used to fulfill sterility requirements for those items purchased pre-sterilized by the laboratory.
10	8.2.1.1 Sterility Checks – All materials and supplies that are needed to process the sample and are required to be sterile must be checked by the laboratory once per purchased lot or prepared batch prior to or in conjunction with first use. The materials to be checked must include, but are not limited to: media, filter funnels, sample containers, dilution water, buffers, and membrane filters. a) One item from each purchased pre-sterilized lot, or one item or object representative in size and use per sterilization batch sterilized by the laboratory, must be tested. b) Non-selective, single strength growth media must be used as appropriate for the item under test. The concentration of non-selective growth media must be single strength after the addition of a liquid item (e.g., dilution water, buffers, etc). c) Chromo/fluorogenic media must be tested with sterile deionized water. d) Where media are made as concentrates	7.2.1.1 Sterility Checks – Each lot of media, materials and supplies purchased, provided and used by the laboratory must be checked to demonstrate the absence of organism(s)/analytes of interest. Sterility checks meet the requirement to demonstrate the absence of organism(s)/analytes of interest. When materials and supplies have been purchased by the laboratory pre-sterilized and a method blank utilizing the item(s) is analyzed prior to or in conjunction with first use, a Certificate of Analysis may be used to satisfy the sterility check. Materials and supplies which have been sterilized in the laboratory must be tested to verify sterility once per batch or lot. The materials and supplies to be checked include, but are not limited to: media, filter funnels, sample containers, dilution water, buffers, and membrane filters. When the laboratory performs sterility	Order of presentation and certain language changed for clarity. Not a one-to-one change – please review in its entirety. Of note, method requirements for time/temperature of incubation was added; sterilization checks may be done via a representative item that was sterilized by the laboratory. ‘materials to be checked must include’ changed to ‘materials and supplies to be checked include, but are not limited to’.

	(e.g., double strength), the media must be diluted to working strength with sterile deionized water before testing. e) All media must be incubated uninoculated using appropriate incubation time and temperature. f) Certificates of analysis provided by vendors must be verified by the laboratory and retained in accordance with TNI Module 2 Section 5.6.4.2.a.	checks: a) Chromo/fluorogenic media must be tested with sterile reagent water (as defined in 7.2.1.4.a). b) Each type of media must be incubated uninoculated using appropriate incubation time and temperature per each method. c) For each sterilization batch performed by the laboratory, one representative item of similar size, material type and use must be tested. d) Non-selective, single strength growth media must be used for sterility checks as appropriate for the item under test. The concentration of non-selective growth media must be single strength after the addition of a liquid item (e.g., dilution water, buffers, etc.).	
11	8.2.1.2 a) Each test reagent must be analyzed with one (1) known negative and one (1) pure (single organism/analyte of interest) positive control as appropriate to the method and produce typical results. The laboratory must have a procedure for this testing. A negative control demonstrates that the medium or test reagent does not support the growth of non-target organism(s)/analyte(s) of interest or does not exhibit the typical positive reaction of the target organism(s)/analyte(s) of interest.	7.2.1.2 a) Each test reagent must be analyzed with a positive control which verifies that the media/reagent produces the correct response. For selective media, the positive must be a known which is pure (single organism/analyte of interest) and produce typical results. Nonselective media is used to determine that growth is possible and therefore evidence of growth is deemed a positive. As there is no specific target organism for non-selective media, any organism that produces evidence of growth, such as turbidity or colonies, would be deemed appropriate. b) Each selective test reagent must be analyzed with a known negative control. A negative control demonstrates that the medium or test reagent does not support the growth of non-target organism(s)/analyte(s) of interest or does not exhibit the typical positive reaction of the target organism(s)/analyte(s) of interest.	Separated positive and negative controls for clarity. Positives for selective media require a known pure organism/analyte of interest, but positives for non-selective media only require a response since that proves growth is possible. Similarly, negatives for selective test reagents require known negatives, but non-selective media must demonstrate lack of positive reaction.

12	8.2.1.2 b) When microorganisms are used for positive and negative controls, the laboratory must use reference cultures that have been obtained from a recognized national collection, organization, or a manufacturer recognized by the accreditation body.	7.2.1.2 c) When microorganisms are used for positive and negative controls for selective media and/or selective test reagents, the laboratory must use reference cultures traceable to national or international sources.	Clarity made that the microorganisms must be traceable without describing how they must be traceable
12	8.2.1.4 a) The laboratory must monitor the quality of the reagent water used in the laboratory, including reagent water purchased from an outside source, which will come into contact with test organisms and is used in preparation of media, solutions, and buffers, for bactericidal and inhibitory substances. The water must be distilled water, deionized water, or reverse-osmosis-produced water.	7.2.1.3 a) For all laboratory-prepared water types used in testing that have a regulation-, method-, or standard-defined acceptable pH, the laboratory must verify and record the final pH prior to first use. b) When types of water used in testing are purchased by the laboratory, the laboratory must review the certificate of analysis to verify that the pH is suitable for the method prior to first use. If the certificate of analysis does not include pH, the laboratory must verify and record the pH prior to first use. c) When types of water used in testing are also purchased or prepared in at-use volume for dilutions, the laboratory must verify and record each working volume once per lot or prepared batch prior to first use.	Added clarity on requirements for testing and the ability to use certificate of analysis in addition to laboratory testing.
13	8.2.1.4 b)-f) **[NOTE there was no e]** b) The laboratory must 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. If the laboratory performs these tests internally for the purpose of reagent water quality monitoring, the laboratory does not need to be accredited for these tests. When the laboratory subcontracts work, this work must be placed with a laboratory accredited to this Standard for the tests to be performed or with a laboratory that meets applicable statutory and regulatory requirements for performing the tests and	7.2.1.4 a) Laboratory reagent water must be distilled, deionized, or reverse-osmosis-produced water prepared in the laboratory or purchased from an outside source. The laboratory must monitor the quality of the reagent water used in testing. i. The laboratory must monitor the quality of the water for disinfectant residual, conductivity, total organic carbon (TOC), 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. ii. The laboratory must monitor the quality of the water for Cd, Cr, Cu, Ni, Pb, and Zn annually.	Clarified requirements for testing of reagent water, including acceptance criteria and accreditation.

	submitting the results of tests performed. c) The laboratory must monitor the quality of the water for Cd, Cr, Cu, Ni, Pb, and Zn annually. When the laboratory subcontracts work, this work must be placed with a laboratory accredited to this Standard for the tests to be performed or with a laboratory that meets applicable statutory and regulatory requirements for performing the tests and submitting the results of tests performed. d) Results of the above analyses must meet method or regulatory specifications. In the absence of method or regulatory specifications, the laboratory must define acceptance criteria. f) Once opened, container(s) of purchased reagent water in use must be retested at the frequency outlined above.	b) Because the supporting tests specified in 7.2.1.4 a) i. and ii. above are not for compliance testing, the laboratory does not need to be accredited for these tests provided these tests follow the relevant sections of Module 2, the reference method, and/or relevant state or federal regulatory requirements. c) Each reagent water quality parameter which the laboratory subcontracts must be analyzed by a laboratory accredited to this Standard or by a laboratory that meets applicable statutory and regulatory requirements for performing the tests and submitting the results of tests performed, as applicable. d) Results of the above analyses must meet applicable method or regulatory requirements. In the absence of applicable method or regulatory requirements, the laboratory must define acceptance criteria. e) Once opened, container(s) of purchased reagent water in use must be retested at the frequency outlined in Sections 7.2.1.4 a) i. and ii. above. The laboratory must ensure that each lot of purchased reagent water meets applicable method or regulatory requirements. In the absence of applicable method or regulatory requirements, the laboratory must define acceptance criteria.	
14	8.2.2.2 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.	7.2.2.1 All filtration units in a filtration series must have been sterilized prior to beginning the series. During a filtration series, filter funnels must be rinsed with three 20-30 mL portions of sterile rinse water after each sample filtration. The filtration series is considered ended when more than thirty minutes elapses between successive filtrations.	The requirement was clarified so that it could not be read as not requiring that all of the filtration units must be sterilized prior to beginning.
15	8.2.3 For all methods that specify a quantitative	7.2.3 Duplicate counts must be performed	Requirement clarified such that all

	result, a duplicate count must be performed monthly on at least 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, each analyst must perform a count a sample that has also been counted by another analyst. The difference between the counts must be no more than ten percent (10%) or corrective action must be taken. In a laboratory with only one (1) analyst, the same sample must be counted twice by the analyst, with no more than a five percent (5%) difference between the counts or corrective action must be taken.	on all methods that result in a quantitative value. The count must be performed on a positive sample during each month that the test is performed. These counts may be performed on environmental samples or quality control samples. 7.2.3.1 When a laboratory has multiple analysts, all analysts who perform counting during a given month must perform a count on the same sample as another analyst. There must be no more than ten percent difference between any two analysts. 7.2.3.2 In a laboratory with one analyst, the sample must be counted twice by the analyst with no more than five percent difference. 7.2.3.3 If the difference exceeds the requirements of Sections 7.2.3.1 or 7.2.3.2, corrective measures must be identified and implemented. 7.2.3.4 The laboratory must document how acceptability is evaluated.	analysts who count in a given month must be included in this process. The limit of the difference is clarified as no more than 10% between any two analysts, or corrective measures must be implemented. The section was also divided to aid in clarity.
16	8.2.5.2 a) The laboratory must 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 must be appropriate quality to meet specification(s) in the method. The graduation and range of the temperature measuring devices must be appropriate for the required accuracy of the measurement. Verification must be performed as per TNI Module 2, Section 5.5.13.1.	7.2.4.2 a) The laboratory must use temperature measuring devices such as liquid-in-glass thermometers, thermocouples, or platinum-resistance thermometers to verify equipment temperatures. The temperature measuring devices must be of appropriate accuracy, range, graduation and/or resolution to meet specification(s) in the method.	Clarity added that the device used must also be of the appropriate accuracy and resolution.
17	8.2.5.2 b) Sterilization Equipment i. Autoclaves 1. The laboratory must evaluate the performance of each autoclave initially by establishing its functional properties and performance, for example, heat distribution	7.2.4.2 b) Sterilization Equipment i. Autoclaves 1. The laboratory must evaluate the performance of each autoclave initially by establishing its functional properties and performance, for example, heat distribution	Section re-organized for clarity. Similar language used in multiple sections for clarity. Clarified requirement for verification of sterility monthly when used.

	characteristics with respect to typical uses. Autoclaves must meet specified temperature tolerances. Pressure cookers must not be used for sterilization of growth media. 2. The laboratory must demonstrate proper sterilization temperature by use of a continuous temperature recording device or by use of a maximum registering thermometer with every cycle. The laboratory must, at least once during each month that the autoclave is used, demonstrate the effective sterilization with use of appropriate biological indicators. The laboratory must use temperature-sensitive tape with the contents of each autoclave run to indicate that the autoclave contents have been processed. 3. The laboratory must maintain records of autoclave operations for every cycle. Records must include: date, contents, maximum temperature reached, pressure, time in sterilization mode, total run time (may be recorded as time in and time out), and analyst's initials. 4. Autoclave maintenance, internally or by service contract, must be performed annually, and must include a pressure check and verification of temperature device. Records of the maintenance must be maintained in equipment logs. If the temperature is verified to be acceptable and it has been determined and documented that the autoclave has no leaks, it is acceptable to state the pressure has been verified. 5. The laboratory must verify the autoclave timing device quarterly and document the actual time elapsed. When discrepancies are identified, the laboratory must implement and document appropriate corrective actions. ii. Ovens At least once during each month that an oven	characteristics with respect to typical uses. Autoclaves must meet specified temperature tolerances. Pressure cookers must not be used for sterilization of growth media. 2. The laboratory must demonstrate proper sterilization temperature by use of a continuous temperature recording device or by use of a maximum registering thermometer with every cycle. 3. Monthly, when the autoclave is in use, the laboratory must demonstrate effective sterilization with use of appropriate biological indicators. The incubation time and temperature of the biological indicators must follow the manufacturer instructions. 4. The laboratory must use an appropriate indicator, such as temperature-sensitive tape, with the contents of each autoclave sterilization cycle to indicate that the autoclave contents have been processed. 5. The laboratory must maintain records of autoclave operations for every cycle. Records must include: date, contents, maximum temperature reached, pressure, sterilization cycle time elapsed, total run time (may be recorded as time in and time out), and analyst's initials. 6. Autoclave maintenance, internally or by service contract, must be performed annually, and must include a pressure check and verification of temperature device. Records of the maintenance must be maintained. If the temperature is verified to be acceptable and it has been determined and recorded that the autoclave has no leaks, it is acceptable to state the pressure has been verified. 7. When used to sterilize media, the laboratory must verify the autoclave timing	

	is used to sterilize, the laboratory must demonstrate the effective sterilization with use of appropriate biological indicators. The laboratory must maintain records for each cycle that include date, cycle time, temperature, contents, and analyst's initials. The laboratory must use temperature sensitive tape with the contents of each run to indicate that the contents have been processed.	device quarterly and record the actual sterilization cycle time elapsed. When discrepancies are identified, the laboratory must implement and record appropriate corrective actions. ii. Ovens Monthly, when the oven is used to sterilize, the laboratory must demonstrate effective sterilization with use of appropriate biological indicators. The incubation time and temperature of the biological indicators must follow the manufacturer instructions. The laboratory must use an appropriate indicator, such as temperature sensitive tape, with the contents of each oven sterilization cycle to indicate that the contents have been processed.	
18	8.2.5.2 c) Volumetric Equipment The laboratory must verify equipment used for measuring volume. Class A glassware are exempt from any verification requirements. Verification must be either volumetric, as compared to Class A, or gravimetric. When neither of these methods are appropriate, it is the responsibility of the laboratory to document that other approaches to verification are at least equivalent. In addition to the requirements in Module 2, the below requirements must be met: i. Reusable volumetric equipment, such as filter funnels, bottles, and non-Class A glassware must be verified prior to first use. ii. Disposable volumetric equipment, such as filter funnels, sample bottles, sample analysis vessels, and disposable pipettes must be checked once per lot prior to first use. iii. Verification of volume must be considered acceptable if the accuracy is within 2.5% of expected volume.	7.2.4.2 c) Volumetric Equipment - The laboratory must verify the volumetric accuracy of equipment used for measuring volume. Verification must be either volumetric, as compared to Class A, or gravimetric. When neither of these methods are appropriate, it is the responsibility of the laboratory to demonstrate that other approaches to verification are at least equivalent. Verification of volume must be within 2.5% of expected volume to be considered acceptable for volumetric accuracy.	Simplified and clarified the requirements. Anything already stated in Module 2 was removed as it is a stated requirement in Module 2.
19	8.2.5.2 f) Labware (Glassware and	7.2.4.2 f) Labware	Clarified the requirement that

	Plasticware) i. The laboratory must have a documented procedure for washing labware, if applicable. If used, these detergents must be designed for laboratory use. iv. Washed labware must be tested at least once daily, each day of washing, for possible acid or alkaline residue by testing at least one (1) piece of labware with a suitable pH indicator such as bromothymol blue.	i. The laboratory must have a demonstrated procedure for washing labware, if applicable. When washing labware, the detergent used must be designed for laboratory use. iv. One representative piece of labware from each batch that is washed in the laboratory must be tested for possible acid or alkaline residue using a suitable pH indicator, such as bromothymol blue.	detergent must be designed for laboratory use. Clarified that a representative piece of labware must be checked per batch. Section re-named to just 'Labware' to avoid any missing possible terms.
20	8.4 Sample Handling Receipt of samples must comply with TNI Module 2, Sections 5.8.6 and 5.8.7, as well as: 8.4.1 If the arrival temperature of a representative sample container meets the method or regulatory temperature requirement, the sample shall be considered acceptable. 8.4.2 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) must 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: a) The laboratory can show that the received sample containers are from its 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 (1) 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	7.3 Sample Handling 7.3.1 Samples which require thermal preservation but do not meet the maximum temperature requirement may be considered acceptable if appropriate evidence of sample cooling is present. 7.3.2 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) must be checked for absence of disinfectant residual in the laboratory. Alternatively, the laboratory does not need to test as above if all of the following are met: a) The laboratory can show that the received sample containers are from its laboratory or have been appropriately verified to have contained sodium thiosulfate; 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	Sample receipt requirements re-worded for clarity and conciseness based on suggested language. Efficacy of chlrine removal clarified as applying to containers supplied by the laboratory or otherwise verified (such as by verifying the type of container by a manufacturer's mark on the bottle).

	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.	checked to ensure efficacy of the sodium thiosulfate to 5 mg/L chlorine or 15 mg/L chlorine as appropriate and the check is recorded; d) Disinfectant residual is checked in the field and actual concentration is recorded with sample submission.	