World Health Organization

WHO International Scheme to Evaluate Household Water Treatment Technologies

Testing Protocol for Filtration Technologies
Version 2.1

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Glossary

Refer to Harmonized Testing Protocol: Technology Non-Specific Version 2.1.

1 UPDATES FROM PREVIOUS PROTOCOL

Refer to Harmonized Testing Protocol: Technology Non-Specific Version 2.1, Section 1, *Updates from Previous Protocol* for details on changes in the evaluation approach implemented from the previous round of evaluation.

2 PRODUCT INFORMATION REQUIREMENTS

The manufacturer is required to provide detailed product information within the Expression of Interest (EoI)[1] in order to: determine if a product is appropriate for testing; develop the specific test protocols; and conduct the actual testing. This information includes:

Flowing systems (in-line to supplied feed or batch stand-alone):

- Flow rate
- Volumetric capacity
- Power requirements
- Operating pressure
- Maximum operating pressure
- Operation instructions – to include: assembly, conditioning, and use instructions, daily operation and maintenance, replacement components, cleaning, backwashing and short term storage instructions (if any).
- Manufacturer capacity and supporting information upon which capacity is based.

3 PURPOSE

Refer to Harmonized Testing Protocol: Technology Non-Specific Version 2.1.

4 METHOD

4.1 Replicate samples

For flowing systems, three (3) production units shall be selected and run as triplicates (3) in two (2) test waters.

4.2 Test waters

Test water shall be prepared daily. An important aspect is that testing will be simulated to model actual field and use conditions. Two types of test water will be used; a GTW representing high quality groundwater or rainwater, and a CTW with more aggressive water specifications to representing surface-water. The GTW is not technology specific, and, for most technologies and where possible, is the same for all products. The CTW, however, is based on the product's technology. Tables 1 and 2 provide the typical test water characteristics and adjustment materials for all technologies, however it is important to refer to the technology specific protocol for exact and technology specific specification. Following test water preparation, total residual chlorine, pH, turbidity, temperature, total dissolved solids (TDS), and alkalinity shall be measured and reported on the test water tank. When identified as a specification, Total Organic Carbon (TOC) is verified during test water preparation as the weight of the adjustment material addition. Sufficient volume shall be collected to allow for a retain volume for back-up analysis, if needed. The following methods, or equivalent, shall be used:

- Chlorine (total): SM 4500-Cl G or UNE-EN ISO 7393-1
- pH: SM 4500 H+ B
- Turbidity: EPA 180.1

[1] Refer to the WHO website for the most recent EOI: http://www.who.int/household_water/scheme/applicant/en/

- Temperature: SM 2550
- TDS: SM 2540C
- Alkalinity: SM 2320-B
- TOC2: Tannic acid for GTW and humic acid for CTW addition to the test water volume is to be weighted out based on the carbon content of the humic or tannic acid and is calculated to be within the test water specification range. As an alternate, SM 5310C, in water (GTW, lower TOC); SM 5310B, in water (CTW, higher TOC) may be used

4.2.1 Total organic carbon (TOC) specification

Tannic acid preparation

Tannic acid addition shall be from a stock solution prepared as: 6 g of tannic acid powder dissolved in 1 L of reverse osmosis (RO) or deionized water (DI). The prepared solution shall be stored in an amber bottle, protected from light and air and held no longer than 7 days.

The single, above described tannic acid stock shall be made from the dry powder; there shall be no intermediate stock solution. The formula may be scaled up or down provided the relative concentrations are maintained.

Humic acid preparation

Humic acid addition shall be from a stock solution prepared as: 6 g of humic acid powder dissolved in 1 L of RO/DI water. Using sodium hydroxide, the solution is to be adjusted to a pH of 9-10 to increase the solubility of the humic acid, reduce the amount of precipitates and allow for increased stability. The prepared solution shall be stored in an amber bottle, protected from light and air and held no longer than 7 days.

The single, above described humic acid stock shall be made from the dry powder; there shall be no intermediate stock solution. The formula may be scaled up or down provided the relative concentrations are maintained.

4.2.2 General Test Water

Reverse osmosis treated water shall be used as the base water and adjusted to meet the following characteristics presented in Table 1:

2 The two TOC compounds have different characteristics and interactions with different technologies and thus allow for the evaluation under different use conditions and environments, increasing the validity and relevance of the testing. Tannic acid reacts faster with oxidative technologies, is more soluble and less sensitive to the ionic content of the water. Humic acid, with a higher molecular weight, is less stable, may complex with divalent cations present in many waters and typically contains particulate which may assist in the clogging of pores.

Table 1. General Test Water characteristics

Constituent	Specification	Adjustment Materials (CAS#[1])
Chlorine[2] (mg/L)	< 0.05	None
pH	7.0 ± 0.5	Inorganic acid or base: Hydrochloric acid (7647-01-0) Sodium hydroxide (1310-73-2)
TOC (mg/L)	1.05 ± 0.95 mg/L	Tannic acid (1401-55-4, Supplier: Alfa Aesar)
Turbidity (NTU)	< 1 NTU	No adjustment
Temp (°C)	20 ± 3°C	Not applicable
TDS (mg/L)	275 ± 225 mg/L	Sea Salts, Sigma Chemical Company (7732-18-5)
Alkalinity[3] (mg/L as CaCO3)	100 ± 20 mg/L	Sodium bicarbonate (144-55-8)

[1] Chemical Abstract Service registration number. Refer to the definition section of this document for additional information.
[2] All chlorine shall be removed to below detection limits without the aid of added chemical(s) and is commonly accomplished by using activated carbon. Chlorine shall be measured prior to addition of test water adjustment materials. Chloride levels in challenge water may cause interference with analytical technique; measurements shall be made prior to addition of sodium chloride.
[3] Intended to buffer pH. Analyzed values may deviate from this range.

4.2.3 Challenge Test Water

Reverse osmosis-treated water shall be used as the base water and adjusted to meet the following characteristics presented in Table 2:

Table 2. Challenge Test Water characteristics

Constituent	Specification	Adjustment Materials (CAS #[1])
Chlorine[2] (mg/L)	< 0.05	None
pH	9.0 + 0.2	Inorganic acid or base: Hydrochloric acid (7647-01-0) Sodium hydroxide (1310-73-2)
TOC (mg/L)[3]	15 ± 5 mg/L	Humic acid (6813-04-4, Supplier: Alfa Aesar)
Turbidity (NTU)[3]	40 ± 10 NTU	ISO spec. 12103-A2 fine test dust
Temp (°C)	4 + 1°C	Not applicable
TDS (mg/L)	1500 ± 150 mg/L	Sea Salts, Sigma Chemical Company (7732-18-5)
Alkalinity[4] (mg/L as $CaCO_3$)	100 ± 20 mg/L	Sodium bicarbonate (144-55-8)

[1] Chemical Abstract Service registration number. Refer to the definitions of this document for additional information.
[2] All chlorine shall be removed to below detection limits without the aid of added chemical(s) and measured prior to addition of test water adjustment materials) and is commonly accomplished by using activated carbon. Chlorine shall be

measured prior to addition of test water adjustment materials. Chloride levels in Challenge Water may cause interference with analytical technique; measurements shall be made prior to addition of sea salts.
[3]TOC and Turbidity added only at microbiological challenge points, except during a 'clogging point' during which all test water may have elevated TOC and turbidity, depending on the product specific test plan.
[4] Intended to buffer pH. Analyzed values may deviate from this range

4.3 Microbiological organisms and challenge concentrations

Table 3 shows the organisms and American Type Culture Collection numbers (ATCC) used in evaluating performance for all technologies. Note that the pre-treatment challenge concentration for bacteria is higher than necessary to demonstrate Scheme performance targets.

Table 3. Microbiological groups and reduction requirements

Microbial group	Target pre-treatment challenge[1]	Minimum required reduction (log_{10})	
		★★★	★★
Bacteria[2]: *Escherichia coli* (ATCC 11229)	$\geq 10^6$/mL	≥ 4	≥ 2
Virus[3,4]: MS-2 coliphage (ATCC 15597-B1), with host organisms: *E. coli* (ATCC 15597) or *Salmonella typhimurium* (WG49 NCTC 12484) and phiX-174 coliphage (ATCC 13706-B1) with host organisms: *E. coli* (ATCC 13706 or ATCC 700078)	$\geq 10^5$/mL	≥ 5	≥ 3

1 Pre-treatment challenges may constitute greater concentrations than would be anticipated in source waters, but these are necessary to properly test, analyse, and quantitatively determine the indicated log reductions. Pre-treatment challenge must not be less than that required to demonstrate the geometric mean and standard deviation minimum required reduction described below. Pre-treatment concentrations presented in table in harmonized units. Refer to Section 4.3.2 organism methods for actual volumes processed and method sensitivity. Pre-treatment concentrations are intended to allow for the demonstration of: 6 log for bacteria and 5 log for virus.
[2] Virus performance claim will be based on the poorest log reduction of the two phages.
[3] Host selection is dependent on method. Refer to Section 4.3.2 Organism Methods.

4.3.1 Selection of microorganisms

Refer to the Harmonized Protocol V 2.1, Section 4.3.1 Section of microorganisms.

4.3.2 Organism methods

Production and assay procedures for the microbial challenges and equivalent methods shall include, but not be limited to:

- ***E. coli*** (ATCC 11229) shall be prepared using the method specified in Asburg, E.D. Methods of Testing Sanitizers and Bacteriostatic Substances; in *Disinfection, Sterilization, and Preservation* (Seymour S. Block, ed.) (1983). The samples shall be assayed in triplicate with m-Endo medium using Method 9222B in Standard Methods for the Examination of Water and Wastewater (APHA, 2012). The geometric mean and standard deviation of the triplicate assay shall be reported for each water type and across all water types examined.
  - Organisms in stationary phase of growth and suspended in phosphate buffered saline shall be used. Growth phases shall be determined using optical density (OD) and strain specific standard curves developed by the designated testing facility. The growth phase of the cultures shall be confirmed each time the cultures are prepared.
  - Collected samples shall be stored at a temperature between 1 – 8°C and processed within 24

hours.
    - Required sample volume to allow for processing in triplicate and a retain volume: 660 mL

- **Coliphage MS-2** (ATCC 15597-B1) shall be prepared and assayed using:
    - The method in Annex A, Section A.8.2.2 of NSF/ANSI 55: Ultraviolet Microbiological Water Treatment Systems (2012); *E. coli* host ATCC 15597; or
    - NEN-EN-ISO 10705-1 (Detection and enumeration of bacteriophages Part 1: Enumeration of F-specific RNA bacteriophage).
        - *Salmonella typhimurium (WG49)* host NCTC 12484 or *E.coli* host ATCC 15597. Analyses shall be conducted in triplicate; the geometric mean and standard deviation for each water type and across all water types examined shall be reported.
        - Samples shall be stored at a temperature between 1 – 8°C and processed within 24 hours of collection.
        - Required sample volume to allow for processing in triplicate and a retain volume: 12 mL

- **Coliphage phiX-174** (ATCC 13706-B1) shall be prepared and assayed using:
    - The method in Annex A, Section A.8.2.2 of NSF/ANSI 55: Ultraviolet Microbiological Water Treatment Systems (2012); *E. coli* (host) ATCC 700078; or
    - NEN-EN-ISO 10705-1 (Detection and enumeration of bacteriophages Part2: Enumeration of somatic coliphages)
        - *E. coli* host ATCC 700078 or ATCC 13706
        - Analyses shall be conducted in triplicate; the geometric mean and standard deviation for each water type and across all water types examined shall be reported.
        - Samples shall be stored at a temperature between 1 – 8°C and processed within 24 hours of collection.
        - Required sample volume to allow for processing in triplicate and a retain volume: 12 mL

4.4 Other test details

4.4.1 Untreated control

The microbiologically spiked test water to be used as the pre-treatment/influent challenge concentration, shall also serve as the untreated control. See Table 3 for concentrations. A pre-treatment/influent sample shall be collected.

4.4.2 Quality assurance / quality control (QA/QC)

Refer to Harmonized Testing Protocol: Technology Non-Specific Version 2.1.

4.4.3 Product disinfectant residual or wetted contact material of concern

For products that employ a bacteriostatic agent or have a wetted contact material which may have a contaminant leach concern, one product residual sample shall be collected from the effluents at each microbiological challenge point. The concentration of the chemical in the treated water shall not constitute a threat to health. The WHO Guidelines for Drinking-water Quality (2017) shall be used to determine acceptable levels in the treated water.

For ceramic pots and filters, arsenic is considered to be a wetted contact material leach concern. As such, samples shall be collected and analysed for total arsenic at microbiological sample collection points. Additionally, a common bacteriostatic agent used with ceramic technology is silver. Silver residual samples would be required when applied as a coating or impregnated in a ceramic pot or filter system.

It shall be at WHO's discretion as to whether an agent employed as a bacteriostatic agent can be evaluated under the scope of this protocol. If the agent has the potential to inactivate bacteria, a

protocol that utilizes a representative for the protozoan group may be required to evaluate protozoan performance as it may not be possible to base it on bacteria removal.

4.4.4 Neutralization

For products that employ a disinfectant, verification of the efficacy of neutralization of the product residual shall be verified for both test waters (GTW and CTW). The Untreated Control shall address potential issues of toxicity of the neutralizer. Common technologies neutralization shall be accomplished as follows:

- Silver shall be neutralized using sodium thiosulfate and sodium thioglycolate
- Copper shall be neutralized using sodium thiosulfate and sodium thioglycolate with the addition of lecithin and Tween.

Based on available literature, the test organism that is most sensitive to the tested product shall be used for the confirmation of neutralization effectiveness and to address toxicity concerns. The following approach shall be used prior to the test for both GTW and CTW to confirm neutralization effectiveness and that the neutralization is not toxic to the test organisms:

Preparation of test solutions

- In a flask (A), prepare 100 mL of test water with the product at testing concentration, to analyze for neutralizer effectiveness.
- In a second flask (B), prepare 100 ml of test water for use in analyzing neutralizer toxicity
- In a third flask (C), prepare 100 mL of test water for use as a quantitative organism viability control.

Note: This will result in a total of 6 flasks: A, B and C for GTW and CTW each

Procedure

- Add the neutralizer to flask A and B at the test concentration and volume; mix thoroughly
- Add sufficient organism to flasks A, B, and C to achieve a final number of +/- 100 CFU or PFU per plate; mix thoroughly.
- Following a minimum 5 minute wait time, transfer sufficient volume from each flask to process on duplicate plates.
- Dilute a sufficient volume from each flask in a 1:1 ratio (2x dilution) and process duplicate plates.
- The processing method, media, incubation conditions, etc. used should be according to Section 4.3.2 Organism methods.

Note: This will result in 4 plates per flask, 2 each for the diluted and undiluted samples.

Data Analysis

Average the counts for the duplicate replicates from each flask then calculate reduction factors (X) using the following:

- Neutralizer Effectiveness: C/A = X
- Neutralizer Toxicity: C/B = X

The reduction factor (X) shall not be greater than 2 for either test.

- A reduction factor greater than 2 for the Neutralizer Effectiveness test indicates that the neutralizer used was not effective.
- A reduction factor greater than 2 for the Neutralizer Toxicity test indicates that the neutralizer used is toxic to the organism.
- If the reduction factor is greater than 2 for either test, a retest is required utilizing a different neutralization method.

Options for alternate neutralization methods are below and should be chosen based on the outcome of both tests.

- Increase or decrease in neutralizer concentration
- Options that represent a change in protocol and require preapproval from WHO:
  - Use of a different neutralizer
  - Dilution of the sample until the product is no longer at antimicrobial concentration, provided that the organism challenge level and method detection limit are still sufficient to demonstrate the necessary reduction.

During the test

The same three samples (A, B, C) as in the pre-test should be analyzed during the actual test for both spiked test waters for *E. coli* and the phages only, not *Cryptosporidium*.

Note: For each sample 3 consecutive dilutions are analyzed as two plates.

4.4.5 Microbiological sample points

The microbiological addition to the test water and post treatment/effluent sample collection points are determined by the operation of the product. Sampling for microbiological organisms shall be conducted according to a sample schedule, based on the days on test and the technology-specified microbiological sample days. The test duration shall be based on technology resulting in testing to the capacity or until 'clogging' for systems that clog with use.

For systems that experience reduced flow (clogging) with use, the sample schedule may include instruction on end of test if the system's flow or other indicator of 'end of life' has not been reached by Day 4. Instruction will be identified in the product specific test plan for accelerated clogging by the addition of the Table 2 specification for TOC and turbidity during all test water, not just the microbiologically challenged water, for all or some identified volume of the Day 4 volume. This shall be referred to as a 'clogging point' sample.

Gravity flow batch systems

One full batch shall of GTW + the organisms per Table 3 Microbiological groups and reduction requirements shall be processed as seeding and discarded to waste. A full second batch shall be processed with the full batch collected and subsampled for microbiological analyses.

Flowing systems

Following start-up procedures, 10 void volumes of GTW + the organisms per Table 3 Microbiological groups and reduction requirements shall be processed as seeding and discarded to waste (Ex. A VV of 1L would require10L seeding) prior to the collection of a minimum of 3L, or more if required for sample analyses. The collected 3 L sample is to be subsampled for microbiological analyses.

Sample Collection for GTW

- 2 pre-treatment sample analyzed for organism of Table 3 (1/day)
- 2 samples for test water characteristics (1/day)
- 6 post-treatment samples analyzed for organism of Table 3
- Per Section 4.4.3
  - If use a bacteriostatic technology: 2 post-treatment residual samples
  - For ceramic pots and filters: 6 post-treatment arsenic samples

Sample Collection for CTW

- 2 pre-treatment sample analyzed for organism of Table 3 (1/day)

- 2 samples for test water characteristics (1/day)
- 6 post-treatment samples analyzed for organism of Table 3
- Per Section 4.4.3
  - Flowing systems with If use a bacteriostatic technology: 2 post-treatment residual samples
  - For ceramic pots and filters: 6 post-treatment arsenic samples

4.4.6 Conditioning

For systems that require conditioning, conditioning shall be according to the operation manual. The general test plan for the product type provides direction on conditioning prior to testing. Conditioning shall use GTW for short term conditioning (single day) and de-chlorinated tap water for long-term conditioning (greater than a single day). There shall be no microbiological addition during conditioning, and the volume used for conditioning shall not be counted as accumulated volume in determining test volume.

4.4.7 Cycling

Cycling is the starting and stopping of flow as would occur in actual use. Cycling may be appropriate for flowing systems, particularly those plumbed in-line to piped water supplies. For batch systems, cycling shall coincide with batch processing.

4.4.8 End of life

For flowing and batch systems, the manufacturer must provide an explicit indication or assurance of the unit's effective use lifetime to warn the consumer of potential diminished treatment capacity by one of the following:

- Having the unit terminate discharge of treated water
- Sounding an alarm
- Providing single explicit instructions for servicing or replacing units within the recommended use life (measurable in terms of volume throughput, specific timeframe or other appropriate method).

4.4.9 Daily test capacity

For flowing systems, the Operator's Manual may supply the daily capacity of the system and the system shall be run accordingly, but is targeted to not exceed 8 total hours of system flowing in a single test day.

4.4.10 Seeding

To purge the system of the uncontaminated water, a sufficient flow of contaminated test water will be used (referred to as seeding). The systems shall be exposed to a minimum of 10 units void volumes or 1 L, whichever is greater, of microbiologically challenged water per Table 3 immediately prior to sample collection and continued through sample collection. For batch flowing systems, a full batch may be used for seeding and a full batch shall be collected and sub-sampled into prepped bottles for microbiological analysis. Additional full batches may be used if seeding or sample collection volume requires additional volume.

4.4.11 Leakage test

Flowing systems shall not leak during test operation. Any leaking during test operation shall be recorded in the laboratory bench sheets.

4.4.12 Device cleaning

For systems, approaches to restore or maintain flow or performance identified in the Operator Manual shall be permitted during testing. The product-specific test plan for the product type should provide direction on device cleaning during testing.

- The test plan shall detail the trigger to initiate a cleaning or backwash, such as 75% flow reduction, or may be indicated to be performed routinely after an identified accumulated volume, such as every 10 L or prior to storage.
- Unless the product literature includes information that would identify a different product specific trigger, 75% reduction shall be identified in the test plan.
- Device cleaning shall not occur during seeding and sample collection at any sample point, even if the trigger point is achieved during the seeding or collection of sample.
- Changes in flow rate and cleaning performed during the testing shall be recorded in the laboratory bench sheets.

4.4.13 Component replacement

For systems, a component that would not be considered a primary component in providing the microbiological reduction performance may be replaced as needed during the test. An example is a pre-filter for turbidity removal. However, a component which provides microbiological performance shall not be replaced during the testing. The product specific test plan shall provide direction on component replacement during testing.

4.4.14 End of test

The product specific test plan shall provide clear direction on ‘end of test’. For flowing system devices, there shall be two (2) acceptable outcomes for the end of the test:

1. Completion of the sampling schedule outlined in Table 4. The test is complete after the collection of samples on 4 flowing days (test capacity) according to Table 4. The test capacity, as volume, shall be the accumulated volume during the 4 day test.
2. Clogging (defined as a reduction of greater than 75% flow compared to initial flow) that cannot be restored with test permitted component replacement or cleaning procedures. The test capacity, as volume, shall be the accumulated volume during the time on test.

4.4.15 Log reduction calculation

Refer to Harmonized Testing Protocol: Technology Non-Specific Version 2.1.

4.4.16 Acceptable reduction deviation

Refer to Harmonized Testing Protocol: Technology Non-Specific Version 2.1.

4.4.17 Records

Refer to Harmonized Testing Protocol: Technology Non-Specific Version 2.1.

4.4.18 Completeness

Refer to Harmonized Testing Protocol: Technology Non-Specific Version 2.1.

5 PROCEDURE

1. Three systems (3) shall be tested simultaneously.
2. Systems shall be conditioned according to the product use instructions, when use instructions indicate conditioning prior to use.
3. General and Challenge test waters shall meet the characteristics of Tables 1 and 2.
   a. During the first phase of testing GTW shall be used continuously.
   b. During the second phase of testing, CTW shall be used continuously, however, TOC and Turbidity addition shall only be made during microbiological seeding and challenging
   c. All test waters, except conditioning water, shall be verified to be in accordance with Tables 1 and 2. Daily test water characteristics shall be sampled, analyzed and results provided in the final report. Sufficient sample volume shall be collected to allow for a retain volume. One set shall be used for analysis and reporting. The second sample shall be retained for confirmation or retesting purposes, when necessary.
4. Microbiologically spiked challenge water shall be prepared to meet the concentrations of Table 3 (all organism are compatible for combining).
5. Devices shall be operated according to the use instructions.
   a. Test plan permitted system cleanings or backwashes and/or component replacements shall occur as dictated by Operator's Manual's requirements.
   b. The laboratory technician(s) shall note daily starting and ending flow rates, flow rates at sample collection, and any cleaning procedures, and other significant event throughout the testing.
6. Devices shall be operated based on the identified daily use pattern. During overnight storage, the devices shall be prepped according to the manufacturer's instruction for short term storage during normal operation and stored at room temperature.
7. Sampling shall be according to the schedule of Table 4. At each sample point:
   a. Seeding, when required, shall occur as a complete batch of microbiologically spiked (Table 3) test water shall pass through the system as seeding and shall continue through sample collection. If a single batch is less than 1L or does not be exposed the system to a minimum of 10 units void volumes of microbiologically challenged water, additional batches shall be passes to achieve seeding requirements.
   b. Microbiological addition continues during effluent/post-treatment sample collection. A complete batch of microbiologically spiked test water shall be processed by the system, collected, and sub-sampled into appropriately prepped collection vessels for microbiological, arsenic or bacteriostatic agent (when applicable) and analyses. Additional batches of microbiologically spiked test water may be processed, if additional volume is required for analysis.
   c. A sample shall be collected from the pre-treatment/influent challenge and analyzed to confirm influent concentrations. As the influent challenge water for all units was from a single source of microbiologically spiked prepped test water, a single influent sample shall be taken and for analyzed for the organisms of Table 3.The influent microbiological shall be collected immediately from the microbiologically spiked test water after all effluent samples have been collected. A duplicate volume shall be collected and retained as a backup for confirmation or retesting purposes, when necessary.
8. Microbiological influent and effluent concentrations shall be presented in the final report.

Table 4: Sampling schedule

Test Day: Collection point	Test Water	Microbiological Tests	
Day 1: At start	GTW	Influent	Effluent
Day 2: End of the day	GTW	Influent	Effluent
Day 3: Start of the day	CTW	Influent	Effluent
Day 4: End of day	CTW	Influent	Effluent

6 INTERPRETATION OF RESULTS

Refer to Harmonized Testing Protocol: Technology Non-Specific Version 2.1.

References

Refer to Harmonized Testing Protocol: Technology Non-Specific Version 2.1.