



**Summary of Substantive Changes  
between the 2018 and 2019 editions of  
NSF/ANSI/CAN 61 “Drinking Water System Components - Health Effects”**

**Presented to the IAPMO Standards Review Committee on July 13, 2020**

**General:** The changes to this standard may have an impact on currently listed products. The substantive changes are:

- Added an exclusion for Copper (C12200) pipe to requiring analysis for regulated metals release under the pH 5 test condition provided the manufacturer includes a statement to clarify that condition (see Section 4.5.3.2)
- Added stainless steel inserts to normalization of contaminant concentrations (see Section 4.7.2.2)
- Added guidance on potassium-40 subtraction for gross beta particle emissions and threshold for gross beta speciation and added methods for nitrosamine analysis (see Section N-1.7.4.5)
- Added test water pH tolerances, allowance of UV treatment to reagent water, and allowance for adjustments in how water is produced (see Section N-1.9)
- Added Polystyrene material type and required analyses to material specific analysis (see Table 3.1)

Section 3, General Requirements: Clarified the conditions for evaluation of products as follows:

**3.1 General**

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[3.1.3 Within the applicable section of this Standard, products shall be evaluated under the most rigorous conditions unless results from a less rigorous test can be mathematically extrapolated to ensure compliance with the most rigorous condition.](#)

[3.1.4 The most rigorous condition is associated with the shortest conditioning period, longest exposure period, highest surface area to volume ratio, and highest exposure temperature, unless demonstrated otherwise with empirical data.](#)

~~*NOTE—Rigorous conditions are typically associated with shorter conditioning periods, longer exposure periods, higher surface area to volume ratios, and higher exposure temperatures.*~~

Section 4.5, Extraction procedures: Added an exclusion for Copper (C12200) pipe as follows:

**4.5.3 Exposure water**

**4.5.3.1 General**

*Exposure water selection shall be determined by the analytes of interest identified on the analytical summary (see Section 4.5.1). Exposure water(s) shall be selected in accordance with N-1.2.5.*

**4.5.3.2 Copper (C12200) pipe, tubing and fittings**

[Copper \(C12200\) pipe, tubing and fittings evaluated under Section 4 of this Standard shall not require analysis for regulated metals release under the pH 5 test condition provided the following use limitation statement is included in the manufacturer’s use instructions or product literature that references this Standard:](#)



“Copper [tube, pipe, or fitting] (Alloy [alloy designation]) has been evaluated by [Testing Organization] to NSF/ANSI/CAN 61 for use in drinking water supplies of pH 6.5 and above. Drinking water supplies that are less than pH 6.5 may require corrosion control to limit leaching of copper into the drinking water”

**4.5.3.2 4.5.3.3 Copper and copper alloys other than C12200**

Copper and copper alloy pipe and tubing comprised of alloys other than C12200 shall be exposed in either the pH 5 (N-1.9.3) or the pH 6.5 (N-1.9.4) exposure waters (at the discretion of the manufacturer) and in the pH ~~108~~ (B-9.8N-1.9.8) exposure waters as described in N-1.9. Copper and copper alloy fittings comprised of alloys other than C12200 intended to be used with copper and copper alloy pipe and tubing shall be exposed in either the pH 5 (N-1.9.3) or the pH 6.5 (N-1.9.4) exposure waters (at the discretion of the manufacturer) and in the ~~108~~ (B-9.8N-1.9.8) exposure water, as described in ~~Annex B, Section B.9 N-1.9~~. For all copper and copper alloy pipes, tubing, and fittings tested using the pH 6.5 exposure water, the manufacturer’s literature shall indicate this use limitation by inclusion of the following statement in the use instructions or product literature that references this Standard:

“Copper [tube, pipe, or fitting] (Alloy [alloy designation]) has been evaluated by [Testing Organization] to NSF/ANSI/CAN 61 for use in drinking water supplies of pH 6.5 and above. Drinking water supplies that are less than pH 6.5 may require corrosion control to limit leaching of copper into the drinking water.”

Section 4.7, Normalization of contaminant concentrations: Added stainless steel inserts as follows:

**4.7.2 Products other than pipe**

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**4.7.2.2 Products other than fire sprinklers**

The SAF shall be calculated from the assumed length of pipe corresponding to the segment of the system in which the product is used (e.g., 100 ft of pipe in the service line or 280 ft of pipe in the residence). The VF (static) component of the N1 term shall be the volume of water contained within the assumed length of pipe. For fittings, the actual inner diameter of the pipe used with the fittings shall be used to calculate both SAF and VF(static). PVC, CPVC and PP transition fittings with stainless steel or copper alloy inserts (except for stainless steel or copper alloy inserts intended for use with PEX tubing), unions and repair couplings are specifically excluded from this evaluation.

For PVC, CPVC and PP transition fittings with stainless steel or copper alloy inserts (except for stainless steel or copper alloy inserts intended for use with PEX tubing), unions and repair couplings, the SAF shall be the wetted surface area of a single product. The VF(static) component of the N1 term shall be the volume of water a single product contains when filled to capacity, except that VF(static) shall equal 1 L (0.26 gal) for all products that contain less than 1 L (0.26 gal) of water when filled to capacity.

NOTE — These products shall be evaluated in this manner because the materials (stainless steel or copper alloy or repair coupling material) will not repeat within the piping system. When a material does repeat within the system, it shall be evaluated as a pipe or fitting, as appropriate. PVC, CPVC and PP transition fittings with a stainless steel or copper alloy insert intended for use with PEX tubing are excluded because the remainder of the PEX system may also be plumbed with stainless steel or copper alloy fittings. Thus, the stainless steel or copper alloy material would repeat throughout the PEX system.



Normative Annex 1 (formerly Annex B), Product / material evaluation:

B.2.5.3 Copper and copper alloys: Revised the evaluation of copper and copper alloy pipe, tubing and fittings to match changes in Sections 4.5.3.2 and 4.5.3.3 as follows:

**~~B.2.5.3 Copper and copper alloys~~**

~~Pipe and tubing manufactured from copper alloy C12200 shall be exposed in the pH 6.5 (see Section B.9.4) and in the pH 10 (see Section B.9.7) extraction waters. The manufacturer's use instructions shall indicate this use limitation.~~

~~Copper and copper alloy fittings intended to be used with copper pipe and tubing shall be exposed in either the pH 5 or the pH 6.5 exposure waters (at the discretion of the manufacturer) and in the pH 10 exposure water. When the pH 6.5 exposure water is chosen, the manufacturer's literature shall indicate this use limitation.~~

**B.3.2.4 N-1.3.2.4 Solders**

~~These products shall be prepared by placing the solder in a ceramic combustion boat (96 × 12 × 10 mm). The amount of solder used shall be sufficient to cover the bottom of the boat. The boat (with solder) shall then be placed in a muffle furnace that has been set to a temperature 20 °C (36 °F) above the liquidus temperature of the product being evaluated. For example, 95/5 tin/antimony solder has a melting range of 232 to 240 °C (450 to 464 °F). The oven shall be set at 260 °C (500 °F) for this solder hot enough to melt the solder within 2 minutes. The boat (with solder) shall be placed in the oven and allowed to heat until the solder has melted (approximately 1 to 2 min). The boat shall be allowed to cool and the solder piece removed.~~

N-1.7.4 Organic Analysis: Added guidance on potassium-40 subtraction for gross beta particle emissions and threshold for gross beta speciation as follows:

**N-1.7.4.5 Nitrosamine analysis**

Analysis for N-nitrosodimethylamine, N-nitrosomethylethylamine, N-nitrosodiethylamine, N-nitrosodi-n-propylamine, N-nitrosopyrrolidine, N-nitrosomorpholine, N-nitrosopiperidine, and N-nitrosodi-n-butylamine shall be in accordance with US EPA Method 521 (US EPA-600/R-05/054) or an alternate validated method with equivalent sensitivity.

Analysis for N-nitrosodiphenylamine shall be performed in accordance with US EPA Method 521 (US EPA-600/R-05/054) or in accordance with US EPA Method 625 (US EPA-600/4-84-053). Methods for Organic Chemical Analysis of Municipal and Industrial Wastewater, June 1984/11 as described in N-1.7.4.2.1.

**N-1.7.5.1 Potassium-40 correction for gross beta**

If the normalized concentration for gross beta exceeds the health effects evaluation criteria, analysis shall be completed for the naturally occurring potassium-40 beta particle activity from the same or equivalent sample used for the gross beta particle activity. As indicated in the Code of Federal Regulations (CFR 40 § 141.26(b)(4))<sup>16</sup>, the potassium-40 beta particle activity (pCi/L) is calculated by multiplying elemental potassium concentrations (in mg/L) by a factor of 0.82. The gross beta particle and photon activity attributable to potassium-40 is then subtracted from the total gross beta particle activity value. The potassium-40 corrected gross beta particle and photon activity shall be compared against the health effects evaluation criteria.



### **N-1.7.5.2 Requirements for gross beta speciation**

When the potassium-40 corrected gross beta particle and photon activity exceeds a normalized concentration of 15 pCi/L, the beta emitting radioisotopes shall be speciated. Speciation testing is required for all radioisotopes at risk of exceeding the health effects evaluation criteria. Appendix I in US EPA Implementation Guidance for Radionuclides (2002) details a list of radioisotopes and associated doses (in pCi/L) to produce a 4 mrem/y dose<sup>17</sup>. The USEPA Implementation Guidance for Radionuclides (2002)<sup>18</sup> provides example calculations to determine the fractional contribution in mrem/yr dose for each speciated radioisotope. The fractional contributions shall be summed for comparison to the health effects evaluation criteria.

N-1.9 Extraction water preparation: Added test water pH tolerances, allowance of UV treatment to reagent water, and allowance for adjustments in how water is produced as follows:

#### **B.9 N-1.9 Extraction water preparation**

##### **B.9.1 N-1.9.1 Chemical characteristics**

Five extraction waters shall be available for exposure:

- 1) pH =  $5 \pm 0.3$ , with  $2 \pm 0.5$  mg/L free available chlorine and 100 mg/L hardness
- 2) pH =  $6.5 \pm 0.3$ , with  $2 \pm 0.5$  mg/L free available chlorine and 100 mg/L hardness
- 3) pH =  $8 \pm 0.3$  (organic analysis), with no chlorine added and 100 mg/L hardness
- 4) pH =  $10 \pm 0.3$ , with  $2 \pm 0.5$  mg/L free available chlorine
- 5) pH =  $8 \pm 0.3$ , alkalinity of  $500 \pm 25$  ~~ppm~~ mg/L, dissolved inorganic carbon of  $122 \pm 5$  ~~ppm~~ mg/L, and  $2 \pm 0.5$  ~~ppm~~ mg/L of free chlorine.

All exposure water that is used to determine compliance to this Standard shall ~~be prepared fresh daily used within 24 hours of preparation~~ and stored in a closed container.

NOTE — The hardness values above are expected concentrations based on buffer additions and are not intended to be a specification.

#### **B.9.2 N-1.9.2 Reagents**

##### **B.9.2.1 N-1.9.2.1 Reagent water**

Reagent water shall be produced through one or more of the following treatment processes: distillation, reverse osmosis, ion exchange, or other equivalent treatment processes. The reagent water shall have the following general water characteristics:

- electrical resistivity, minimum 18 MΩ-cm at 25 °C (77 °F); and
- total organic carbon (TOC) maximum 100 µg/L.

For each specific analyte of interest, the reagent water shall not contain the target analyte at a concentration greater than half the designated analytical report limit of that analyte. If trace organic contaminants may be present at levels greater than half the designated analytical report limit of that target analyte, it is permissible to treat the reagent water with TOC destructive UV (185nm) to reduce those contaminants to acceptable concentrations. This UV treatment often results in a decrease in electrical resistivity of the reagent water to below 18 MΩ-cm, which is allowed in this circumstance.

##### **B.9.2.4.1 N-1.9.2.4.1 Determining chlorine stock solution strength**

The strength of the chlorine stock solution shall be determined by diluting 1.0 mL to 1.0 L (0.26 gal) with reagent water. The solution shall be analyzed immediately for ~~total residual~~ free available chlorine. This determination shall be referred to as A.



**B.9.3 N-1.9.3 pH 5 water**

pH 5 extraction water shall be prepared to contain ~~100 mg/L hardness and~~  $2 \pm 0.5$  mg/L free available chlorine. Stock reagent solutions in the amounts shown in Table ~~B.15 N-1.15~~ shall be diluted to the desired water volume with reagent water. The pH shall be adjusted to  $pH 5 \pm 0.3$  using 0.1M HCl or 0.1M NaOH as needed.

**B.9.4 N-1.9.4 pH 6.5 water**

pH 6.5 water shall be prepared to contain ~~100 mg/L hardness and~~  $2 \pm 0.5$  free available chlorine. Stock reagent solutions in the amounts shown in Table ~~B.15 N-1.15~~ shall be diluted to the desired water volume with reagent water. The pH shall be adjusted to  $pH 6.5 \pm 0.5-0.3$  using 0.1 M HCl.

NOTE — It is recommended that the pH 6.5 water be protected from exposure to air during its formulation and use to minimize pH drift. Unused exposure water should be maintained under a nitrogen blanket, and product samples should be plugged or tightly covered to minimize exposure to air.

**B.9.5 N-1.9.5 pH 8 water (conditioning)**

pH 8 conditioning water shall be prepared to contain ~~100 mg/L hardness and~~  $2 \pm 0.5$  mg/L free available chlorine. Stock reagent solutions in the amounts shown in Table ~~B.15 N-1.15~~ shall be diluted to the desired water volume with reagent water. The pH shall be adjusted to  $pH 8 \pm 0.3$  using 0.1M HCl or 0.1M NaOH as needed.

**B.9.6 N-1.9.6 pH 8 water (organic analysis)**

pH 8 organic extraction water shall be prepared to contain ~~100 mg/L hardness and 0 mg/L free available~~ no chlorine added. Stock reagent solutions in the amounts shown in Table N-1.15 shall be diluted to the desired water volume with reagent water. The pH shall be adjusted to  $pH 8 \pm 0.3$  using 0.1M HCl or 0.1M NaOH as needed.

**B.9.7 N-1.9.7 pH 10 water**

pH 10 extraction water shall be prepared to contain  $2 \pm 0.5$  mg/L free available chlorine. Stock reagent solutions in the amounts shown in Table ~~B.15 N-1.15~~ shall be diluted to the desired water volume with reagent water. The pH shall be adjusted to  $pH 10 \pm 0.3$  using 0.1M HCl or 0.1M NaOH as needed.

**B.9.7 N-1.9.8 pH 8 water (from Section 9)**

The extraction water shall be prepared by combining:

- 25 mL of 0.4 M sodium bicarbonate;
- chlorine stock solution per N-1.9.2.4; and
- reagent water meeting the requirements of N-1.9.2.1 (make up to 1 L), and adjust pH as needed using 0.1 M HCl.

Chemical concentrations, form, and amounts of ingredients can be adjusted such that the final pH 8 test water meets the extraction water characteristics as outlined in N-1.9.1, bullet 5.

Table 3.1, Material-specific analyses: Polystyrene material type and required analyses was added to the table. The reference to US EPA Method 521 was removed from Table 3.1, footnote 13.

Table 7.1 Product-specific minimum test batteries for process media products: The table was revised to remove radionuclides analysis from the required minimum test battery for several process media products.



Table N-1.3b Alternate extraction water selection: Revised the evaluation of copper and copper alloy pipe, tubing and fittings and updated the alternate exposure water selection for several materials:

Table ~~B-3b~~ [N-1.3b](#) *Alternate extraction water selection:*

Table N-1.15, 1 L volume of extraction water: Footnote was added to Table N-1.15 as follows:

Table ~~B-15~~ [N-1.15](#), *1 L volume of extraction water:*

<sup>1</sup>Volumes are per 1.0 L of extraction water produced.