



**Summary of Substantive Changes
between the 2014a and the 2015 editions of
NSF/ANSI 61, “Drinking Water System Components - Health Effects”**

Presented to the IAPMO Standards Review Committee on January 11, 2016

General: The changes to this standard should not have an impact on currently listed products. The substantive changes are:

- Added chlorine terminology for consistency throughout the standard (see Sections 2.10, 5.5, and Annex B).
- Added nanofiltration to exemptions under section 3.2 and 3.3.2, and the formulation exemption to the restriction of lead-containing materials under Section 3.5 for component materials in which the generic material type is contained in Table 3.1 (see Sections 3.2, 3.3, and 3.5).
- Removed the 2.0 square inch restriction on material formulation that was inadvertently left in the last revision (see Section 3.3).
- Revision made to add an option to perform a full 90 days of exposure to establish the Day 90 contaminant concentration where Day 90 assessments are currently allowed (see Sections 4.5.7, 5.5.5.5, and Annex B).
- Revised Table C1 composition ranges to cover specifications in all product standards cited in the table for the materials (see Table C1).
- Added new contaminants and revised the evaluation criteria to existing contaminants for total allowable concentration (TAC), short-term exposure limit (STEL), and single allowable product concentration (SPAC) levels (see Table D1).

2 Definitions

Terms used in this Standard that have a specific technical meaning are defined here.

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[2.10 free available chlorine: The sum of hypochlorous acid and hypochlorite ions.](#)

5 Barrier materials

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5.5 Extraction procedures

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5.5.4 Conditioning (Optional)

Test samples shall be conditioned immediately after curing. This conditioning procedure simulates the disinfection of water mains and storage tanks prior to placing into service, and is based on AWWA Standards C651-05 and C652-02.



Coatings intended for pipes and fittings can be conditioned as follows:

- 1) prepare 50 mg/L [free](#) available chlorine solution using sodium hypochlorite (NaOCl – reagent grade or equivalent);
- 2) using a spray bottle, spray the previously rinsed test samples, wetting all surfaces to be exposed;
- 3) let the test samples stand for at least 3 hours; and
- 4) place the test samples in racks, rinse with cold tap water, and rinse with reagent water, meeting the requirements of Annex B, section B.9.2.1.

Coatings intended for water storage tanks or multiple uses (tanks, pipes, other) may be conditioned as follows:

- 1) prepare 200 mg/L [free](#) available chlorine solution using sodium hypochlorite (NaOCl - reagent grade or equivalent);

Annex B

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B.5 Mechanical plumbing devices

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B.5.5 Extraction water

The extraction water shall be prepared by combining:

- 25 ml of 0.4M sodium bicarbonate;
- chlorine stock solution per Annex B, section B.9.2.4;
- reagent water meeting the requirements of Annex B, section B.9.2.1 (make up to 1 L), and adjust pH as needed using 0.1M HCl; and

This water shall have a pH of 8.0 ± 0.5 , alkalinity of 500 ± 25 ppm, dissolved inorganic carbon of 122 ± 5 ppm, and 2 ± 0.5 ppm of free [available](#) chlorine.

B.9 Extraction water preparation

B.9.1 Chemical characteristics

Four extraction waters shall be available for exposure:

- a) pH = 5, with 2 mg/L [free](#) available chlorine and 100 mg/L hardness;
- b) pH = 6.5, with 2 mg/L [free](#) available chlorine and 100 mg/L hardness;
- c) pH = 8 (organic analysis), with 0 mg/L [free](#) available chlorine and 100 mg/L hardness; and
- d) pH = 10, with 2 mg/L [free](#) available chlorine.

B.9.2 Reagents

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B.9.2.4.2 Determining amount of chlorine stock solution required to obtain 2 ppm residual chlorine

To determine the volume of the chlorine stock solution necessary to add to the extraction water to obtain 2.0 mg/L [free available](#) chlorine residual, the following formula shall be used:



B.9.3 pH 5 water

pH 5 extraction water shall be prepared to contain 100 mg/L hardness and 2 mg/L [free](#) available chlorine. Stock reagent solutions in the amounts shown in Annex B, Table B15 shall be diluted to the desired water volume with reagent water.

B.9.4 pH 6.5 water

pH 6.5 water shall be prepared to contain 100 mg/L hardness and 2 mg/L [free](#) available chlorine. Stock reagent solutions in the amounts shown in Annex B, Table B15 shall be diluted to the desired water volume with reagent water. The pH shall be adjusted to $\text{pH } 6.5 \pm 0.5$ using 0.1M HCl.

B.9.5 pH 8 water (conditioning)

pH 8 conditioning water shall be prepared to contain 100 mg/L hardness and 2 mg/L [free](#) available chlorine. Stock reagent solutions in the amounts shown in Annex B, Table B15 shall be diluted to the desired water volume with reagent water.

B.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 chlorine. Stock reagent solutions in the amounts shown in Annex B, Table B15 shall be diluted to the desired water volume with reagent water.

B.9.7 pH 10 water

pH 10 extraction water shall be prepared to contain 2 mg/L [free](#) available chlorine. Stock reagent solutions in the amounts shown in Annex B, Table B15 shall be diluted to the desired water volume with reagent water.

3.2 Information and formulation requirements

The following information shall be obtained and reviewed for all materials with a water contact surface to determine the appropriate analytical testing and to ensure that the potential health effects of products and materials are accurately and adequately identified:

- the product section(s) under which the product, component, or material is covered and the intended function or end use of the product or the material;
- for assemblies, sub-assemblies, products or components, a list of all materials and their corresponding surface areas that come into direct contact with water;
- when appropriate, the total volume of water that the product can hold when filled to capacity;
- the expected service life of the product;
- the anticipated minimum, maximum, and average volumes of water that come into contact with the product, component, or material during a 24-h period;
- complete formulation information (equal to 100.0%) for each water contact material. This shall include:

NOTE 1 – The complete formulation information may be omitted for a component material if the generic material type is contained in Table 3.1 and:



– its diluted surface area in the application is less than or equal to 0.001 in²/L or 0.0001 in²/L for static or flowing conditions respectively; or

– if the material is in a high flow device *exclusively and* used *exclusively* at public water treatment facilities. For the purposes of this section high flow devices are limited to chemical feeders, disinfectant generators (e.g. chlorine dioxide, hypochlorite, ozone and ultraviolet), electro dialysis technologies, microfiltration technologies, *nanofiltration technologies*, reverse osmosis and ultrafiltration technologies;

3.3.2 Established minimum test batteries

The materials listed in Table 3.1 shall be tested for the indicated analyses and any formulation-dependent analyses identified during the formulation-dependent analyte selection. Products, components, or materials made exclusively from materials in Table 3.1 shall not require testing if:

– their diluted surface area in the application is less than or equal to 0.001 or 0.0001 for static or flowing conditions respectively, or

– the material is in a high flow device *exclusively and* used *exclusively* at public water treatment facilities. For the purposes of this section, high flow devices are limited to chemical feeders, disinfection generators (e.g. chlorine dioxide, hypochlorite, ozone and ultraviolet), electro dialysis technologies, microfiltration technologies, *nanofiltration technologies*, reverse osmosis and ultrafiltration technologies.

3.5 Restriction on use of lead containing materials

There shall be no lead added as an intentional ingredient in any product, component, or material submitted for evaluation to this standard, with the following exceptions:

– Brass or bronze used in products meeting the definition of “lead free” under the specific provisions of the Safe Drinking Water Act of the United States.

– Solders and flux meeting the definition of “lead free” under the specific provisions of the Safe Drinking Water Act of the United States.

– Brass or bronze used in products specifically identified as exemptions within section (a)(4)(B) of the Safe Drinking Water Act of the United States.

– Trace amounts required for operation of products used to monitor the characteristics of drinking water, such as the glass membranes used with some selective ion or pH electrodes.

~~– *Materials of components with a diluted surface area less than or equal to 0.0001 in²/L.*~~

– Materials or components exempted from formulation information requirements as allowed per Section 3.2, Note 1.

NOTE – To the maximum extent possible, lead should not be added as an intentional in any product covered by the scope of this standard. ~~*The exception above relative to the diluted surface area has only been included in recognition of formulation information exemption for applications with this condition.*~~ *The exception above relative to materials and components exempt from formulation information requirements has only been included in recognition*



that the use of lead as an intentional additive is unable to be identified in cases where formulation information is not obtained.

3 General requirements

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3.3 Identification of analytes

For all products and materials, the formulation information required in 3.2 shall be reviewed for completeness (e.g., all formulations total 100.0%), and to determine whether a minimum test battery has been established for each water contact material (see Table 3.1). In addition to selecting the minimum testing parameters described in Table 3.1, a formulation review to identify any formulation-dependent analytes shall be performed for all water contact materials (see 3.3.1).

In instances where the complete formulation has not been obtained for a material that is *less than or equal to 2.0 square inches and* used in a component of a mechanical device or mechanical plumbing device as allowed through Note 1 of 3.2, testing shall include the material specific analyses in Table 3.1.

4.5.7.1 Cold application

Products that are intended to be in contact with only cold water shall be maintained at 23 ± 2 °C (73 ± 4 °F) for 19 d. During the 19-d period, the exposure water shall be changed at least 12 times, with a minimum period of 24 ± 1 h between water changes. At seven of these water changes, extraction water shall be collected for analysis after a 24-h exposure. For extrapolation and normalization purposes, the number of hours elapsed since the most recent water change (or sample collection) and the number of days elapsed since the initiation of the exposure shall be recorded at the time of each extraction water collection.

NOTE – Table 4.3 provides an example multiple time point conditioning/exposure protocol. Alternate protocols shall be permitted as long as the requirements of 4.5.7.1 are met.

At the discretion of the manufacturer, direct measurement of a Day 90 extraction shall be permitted. The products shall be maintained at 23 ± 2 °C (73 ± 4 °F). Extraction water shall be collected for analysis at a minimum of two time points: after Day 1 (representing 14 d of conditioning and 1 d of acute exposure), and after the final exposure terminating on Day 90 (representing 14 d of conditioning, 1 d of acute exposure, and 90 d of chronic exposure). The exposure water shall be changed at least *weekly 4 d/wk* during the interval between the initial and final exposures *and on at least 4 days during the final week of exposure.* *Exposures that are used for the collection of extractant water for analysis shall not exceed 24 ± 1 h in duration.*

4.5.7.2.1 Intermittent hot water exposure

Products that are intended to be in intermittent contact with hot water shall undergo the cold application exposure according to 4.5.7.1. At the initiation of each exposure that will be collected for analysis, the product shall be exposed at the selected elevated temperature, either 60 ± 2 °C (140 ± 4 °F) or 82 ± 2 °C (180 ± 4 °F), for 30 ± 5 min. The product shall then be exposed at 23 ± 2 °C (73 ± 4 °F) for the duration of the exposure period. The exposure water shall not be decanted prior to the completion of the exposure period.



NOTE 1 – Table 4.3 provides an example multiple time point conditioning/exposure protocol. Alternate protocols shall be permitted as long as the requirements of 4.5.7.2.1 are met.

NOTE 2 – The stated duration of the conditioning period at the hot temperature does not include any time needed to elevate the product sample or exposure vessel to the required exposure temperature.

At the discretion of the manufacturer, direct measurement of a Day 90 extraction shall be permitted. At the initiation of each exposure that will be collected for analysis, the products shall be exposed at the selected elevated temperature, either $60 \pm 2 \text{ }^\circ\text{C}$ ($140 \pm 4 \text{ }^\circ\text{F}$) or $82 \pm 2 \text{ }^\circ\text{C}$ ($180 \pm 4 \text{ }^\circ\text{F}$), for 30 ± 5 min. The product shall then be exposed at $23 \pm 2 \text{ }^\circ\text{C}$ ($73 \pm 4 \text{ }^\circ\text{F}$) for the duration of the exposure period. The exposure water shall not be decanted prior to the completion of the exposure period. Extraction water shall be collected for analysis at a minimum of two time points: after Day 1 (representing 14 d of conditioning and 1 d of acute exposure), and after the final exposure terminating on Day 90 (representing 14 d of conditioning, 1 d of acute exposure, and 90 d of chronic exposure). The exposure water shall be changed at least weekly 4 d/wk during the interval between the initial and final exposure and on at least 4 days during the final week of exposure. ~~Exposures that are used for the collection of extractant water for analysis shall not exceed 24 ± 1 h in duration.~~

5.5.5.5 Multiple time point exposure protocol

When the normalized concentration of a contaminant exceeds, or is expected to exceed, its acceptable concentration (see Annex A) when evaluated as a single time point (see 5.5.5.4), determination of the contaminant leaching rate as a function of time shall be considered. The relationship between contaminant concentration(s) and time shall be determined and plotted using a minimum of five data points. Table 5.5 summarizes the multiple time point exposure sequence. For contaminants of interest that do not require over time testing, extraction water shall be collected following the third exposure period (elapsed time 5 d). For paint/coating systems intended for immediate return to service, the first four days of the exposure will be eliminated and the water samples shall be collected at the conclusion of the first 24 hour period following conditioning.

At the discretion of the manufacturer, direct measurement of a Day 90 extraction shall be permitted. The products shall be exposed at the selected application temperature (e.g. $23 +2 \text{ }^\circ\text{C}$; $60 +2 \text{ }^\circ\text{C}$; $82 +2 \text{ }^\circ\text{C}$) for the full duration of the exposure. Extraction water shall be collected for analysis at a minimum of two time points: after Day 1 and after the final exposure terminating on Day 90. The exposure water shall be changed at least weekly during the interval between the initial and final exposure and on at least 4 days during the final week of exposure.

NOTE – Day 1 is defined as the time point at which extractant water for all contaminants is collected for analysis (5 d of elapsed time). Day 90 is defined as 90 d following this time point (95 d of elapsed time).

Annex B

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B.3 Joining and sealing materials

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B.3.7 Multiple time point protocol

When the normalized concentration of a contaminant exceeds, or is expected to exceed, its acceptable level when evaluated as a single time point exposure, determination of the contaminant leaching rate using a multiple time point exposure shall be considered. For the purpose of contaminant concentration evaluation, Day 1 shall be defined as the time point at which extractant water is collected for analysis under the single time point exposure protocol. Day 90 shall be defined as 90 d after this time point. When over time data are used, the Day 1 concentration for the contaminant of concern shall meet the Short Term Exposure Level and Day 90 concentration shall meet the Total Allowable Concentration/Single Product Allowable Concentration respectively. When extrapolation is used, the relationship between contaminant concentration and time shall be determined and plotted using a minimum of five data points.

NOTE – When a multiple time point protocol is employed in the evaluation of a contaminant, consideration shall be given to the availability of appropriate toxicity data to define an acute exposure limit for the contaminant, as required in Annex A, Section A.5, Data requirements for evaluating short-term exposures. Consideration shall also be given to the leaching characteristics of the contaminant. Short Term Exposure Levels shall not exceed the Total Allowable Concentration for nonmetallic contaminants listed in NSF/ANSI 61, Annex D, Table D1 (Drinking water criteria for contaminants regulated by the USEPA and established by Health Canada). Multiple time point analysis shall not be used for lead or any other metal contaminant listed in Table D1.

At the discretion of the manufacturer, direct measurement of a Day 90 extraction shall be permitted. The products shall be exposed at the selected application temperature (e.g. 23 +2 oC; 60 +2 oC; 82 +2 oC) for the full duration of the exposure. Extraction water shall be collected for analysis at a minimum of two time points: after Day 1 and after the final exposure terminating on Day 90. The exposure water shall be changed at least weekly during the interval between the initial and final exposure and on at least 4 days during the final week of exposure.

B.4.5 Multiple time point protocol

When the normalized concentration of a contaminant exceeds, or is expected to exceed, its acceptable level when evaluated as a single time point exposure, determination of the contaminant leaching rate using a multiple time point exposure shall be considered. For the purpose of contaminant concentration evaluation, Day 1 shall be defined as the time point at which extractant water is collected for analysis under the single time point exposure protocol. Day 90 shall be defined as 90 d after this time point. When over time data are used, the Day 1 concentration for the contaminant of concern shall meet the Short Term Exposure Level and Day 90 concentration shall meet the Total Allowable Concentration/Single Product Allowable Concentration respectively. When extrapolation is used, the relationship between contaminant concentration and time shall be determined and plotted using a minimum of five data points.

NOTE – When a multiple time point protocol is employed in the evaluation of a contaminant, consideration shall be given to the availability of appropriate toxicity data to define an acute exposure limit for the contaminant, as required in Annex A, Section A.5, Data requirements for evaluating short-term exposures. Consideration shall also be given to the leaching characteristics of the contaminant. Short Term Exposure Levels shall not exceed the Total Allowable Concentration for nonmetallic contaminants listed in NSF/ANSI 61, Annex D, Table D1 (Drinking water criteria for contaminants regulated by the USEPA and established by Health Canada). Multiple time point analysis shall not be used for lead or any other metal contaminant listed in Table D1.

At the discretion of the manufacturer, direct measurement of a Day 90 extraction shall be permitted. The products shall be exposed at the selected application temperature (e.g. 23 +2 oC; 60 +2 oC; 82 +2 oC) for the full duration of the exposure. Extraction water shall be collected for analysis at a minimum of two



time points: after Day 1 and after the final exposure terminating on Day 90. The exposure water shall be changed at least weekly during the interval between the initial and final exposure and on at least 4 days during the final week of exposure.

B.5 Mechanical plumbing devices

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B.5.6 Multiple time point protocol

When the normalized concentration of a contaminant exceeds, or is expected to exceed, its acceptable level when evaluated as a single time point exposure, determination of the contaminant leaching rate using a multiple time point exposure shall be considered. For the purpose of contaminant concentration evaluation, Day 1 shall be defined as the time point at which extractant water is collected for analysis under the single time point exposure protocol. Day 90 shall be defined as 90 d after this time point. When over time data are used, the Day 1 concentration for the contaminant of concern shall meet the Short Term Exposure Level and Day 90 concentration shall meet the Total Allowable Concentration/Single Product Allowable Concentration respectively. When extrapolation is used, the relationship between contaminant concentration and time shall be determined and plotted using a minimum of five data points.

NOTE – When a multiple time point protocol is employed in the evaluation of a contaminant, consideration shall be given to the availability of appropriate toxicity data to define an acute exposure limit for the contaminant, as required in Annex A, Section A.5, Data requirements for evaluating short-term exposures. Consideration shall also be given to the leaching characteristics of the contaminant. Short Term Exposure Levels shall not exceed the Total Allowable Concentration for nonmetallic contaminants listed in NSF/ANSI 61, Annex D, Table D1 (Drinking water criteria for contaminants regulated by the USEPA and established by Health Canada). Multiple time point analysis shall not be used for lead or any other metal contaminant listed in Table D1.

At the discretion of the manufacturer, direct measurement of a Day 90 extraction shall be permitted. The products shall be exposed at 23 +2 oC with the except for instant hot water dispensers, in which case the manufacturer's specified thermostat setting shall be used. Extraction water shall be collected for analysis at a minimum of two time points: after Day 1 and after the final exposure terminating on Day 90. The exposure water shall be changed at least weekly during the interval between the initial and final exposure and on at least 4 days during the final week of exposure.



Annex C

Table C1 – Acceptable materials

Material	Specific designation	Standard (product) reference	Surface-area-to-volume ratio	End-use temperature	Composition
stainless steel	UNS S30400 (Type 304)	ASTM A 312 ASTM A 269 ASTM A 240	3,484 cm ² /L (540 in ² /L)	30 °C (86°F) 23°C (73°F)	percent composition: carbon (0.08 max.), manganese (2.00 max.), phosphorus (0.0 40 <u>5</u> max.), sulfur (0.030 max.), silicon (0.75 <u>1.00</u> max.), nickel (8.00-11.0), chromium (18.0-20.0), iron (balance)
stainless steel	UNS S30403 (Type 304L)	ASTM A 312 ASTM A 269 ASTM A 240	3,484 cm ² /L (540 in ² /L)	30 °C (86 °F) 23°C (73°F)	percent composition: carbon (0.035 max.), manganese (2.00 max.), phosphorus (0.0 40 <u>5</u> max.), sulfur (0.030 max.), silicon (0.75 <u>1.00</u> max.), nickel (8.00-13.0), chromium (18.0-20.0), iron (balance)
stainless steel	UNS S31600 (Type 316)	ASTM A 312 ASTM A 269 ASTM A 240	3,484 cm ² /L (540 in ² /L)	30 °C (86 °F) 23°C (73°F)	percent composition: carbon (0.08 max.), manganese (2.00 max.), phosphorus (0.0 40 <u>5</u> max.), sulfur (0.030 max.), silicon (0.75 <u>1.00</u> max.), nickel (11 <u>10</u> .00-14.0), chromium (16.0-18.0), molybdenum (2.0-3.0), iron (balance)
stainless steel	UNS S31603 (Type 316L)	ASTM A 312 ASTM A 269 ASTM A 240	3,484 cm ² /L (540 in ² /L)	30 °C (86 °F) 23°C (73°F)	percent composition: carbon (0.035 max.), manganese (2.00 max.), phosphorus (0.0 40 <u>5</u> max.), sulfur (0.030 max.), silicon (0.75 <u>1.00</u> max.), nickel (10.0-15.0), chromium (16.0-18.0), molybdenum (2.0-3.0), iron (balance)