



**Summary of Substantive Changes
between the 2015 and the 2016 editions of
NSF/ANSI 61, “Drinking Water System Components - Health Effects”**

Presented to the IAPMO Standards Review Committee on September 12, 2016

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

- Revision made to Section 3.2 and will add material specific analyses under newly created Table 3.2 (see Section 3.2 and new Table 3.2).
- Removed the requirement of providing the expected service life of a product under the information and formulation requirements (see Section 3.2).
- Added fire sprinkler (head) to the list of excepted products specified to contain no lead (see Section 3.5).
- Specifications were harmonized with language regarding testing of copper and copper alloy pipe, tubing, and fittings in Section 4 (see Section 4.5.3.2).
- Revision made to Section 4 and Annex B to harmonize hot water exposure protocols under sections 4 and 8 (see Sections 4.5.4 to 4.7, and Annexes B.4.3 and B.4.4).
- Added criteria and a method for evaluating in-line copper silver ion generators under section 8 (see new Sections 8.6.2, and 8.6.3).
- Revision made to Annex B that extends the use of section 9 extraction water when evaluating lead and copper release from brass and bronze devices (see Sections B2.5, B.9.1, and B.9.8, updated Table B3a and new Table B3b).

3 General requirements

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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 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; or~~

~~—if (1) used in a mechanical device or mechanical plumbing device and (2) the material is not a coating, and (3) the component is not a process media.~~

~~If the product is to be considered compliant to a lead content standard, the lead content (percent by weight) and wetted surface area of each component that comes into contact with the direct flow of water under the normal operation of the product is required. Complete documentation shall be submitted in accordance with NSF/ANSI 372—Drinking water system components—Lead content.~~

~~NOTE 2—A material is defined as a combination of ingredients used to: manufacture (mold, extrude, stamp, cast, machine, mix etc.) a part or component used in the assembly of a device. To include but not be limited to plastics, elastomers, metallic components, media, lubricants, adhesives, process aid, preservatives, coatings and surface treatments.~~

– a complete formulation shall result in the identity by CAS# or chemical name of each component of the formulation including but not limited to the activators, antioxidants, antimicrobials, co-solvents, fillers, initiators, peroxides, pigments, plasticizers, process aids, solvents, stabilizer, surfactants and terminators;

– percent or parts by weight for each chemical in the formulation or reference to a national or international standardized material specification for metallic materials (e.g. UNS copper alloy specifications);

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

– the generic material type is contained in Table 3.1 and if the material is in a high flow device 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; or

– the generic material type is contained in Table 3.1 and if (1) used in a mechanical device or mechanical plumbing device and (2) the material is not a coating, and (3) the component is not a process media; or

– if (1) the material is not listed in Table 3.1, and (2) it is used in a mechanical device or mechanical plumbing device and (3) the material is not a coating, and (4) the component is not a process media, and the material is tested to the requirements of Table 3.2.



If the product is to be considered compliant to a lead content standard, the lead content (percent by weight) and wetted surface area of each component that comes into contact with the direct flow of water under the normal operation of the product is required. Complete documentation shall be submitted in accordance with NSF/ANSI 372 – Drinking water system components – Lead content.

NOTE 2 – A material is defined as a combination of ingredients used to manufacture (mold, extrude, stamp, cast, machine, mix etc.) a part or component used in the assembly of a device. To include but not be limited to plastics, elastomers, metallic components, media, lubricants, adhesives, process aid, preservatives, coatings and surface treatments.

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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 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, or as directed in Table 3.2.

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3.3.2 Established minimum test batteries

The materials listed in Table 3.1 or Table 3.2 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 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.

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Table 3.2

Material specific analyses not listed in Table 3.1 or Materials without Formulation Information (excluding coatings and process media).

Note: 4 page copy of new Table 3.2 was not reproducible and cannot be included.

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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.

— Fire sprinklers (head).

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4 Pipes and related products

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4.5 Extraction procedures

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4.5.3 Exposure water

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4.5.3.2 Copper and copper alloys

Copper and copper alloy pipe and tubing shall be exposed in the pH 6.5 and pH 10 exposure waters as described in Annex B, section B.9. Copper and copper alloy fittings intended to be used with copper and copper alloy 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, as described in Annex B, section B.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:

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4.5.4.2 In-vessel conditioning and exposure

During in-vessel conditioning and exposure, samples shall be placed in containers composed of and covered with a material that is inert to the exposure water ~~and has polytetrafluoroethylene-lined lids~~. The exposure water shall completely immerse the sample. All samples shall be exposed at a surface area-to-volume ratio that is equal to or greater than that of the intended end use. The actual wetted surface area-to-volume ratio achieved during the exposure shall be recorded.

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4.5.5.1 Single time point conditioning – cold and intermittent application

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~~4.5.5.2.1 Intermittent hot water conditioning~~

~~Products that are intended to be in intermittent contact with hot water shall undergo the cold application conditioning according to 4.5.5.1. At the conclusion of the cold application conditioning, the products shall be further conditioned in the exposure water(s) selected in 4.5.3 at either 60 ± 2 °C (140 ± 4 °F) or 82 ± 2 °C (180 ± 4 °F) for two consecutive 60 ± 5 min periods. The exposure water shall be decanted and discarded~~



~~after each 1-h period. Exposure of the sample according to 4.5.6 shall immediately follow completion of the further conditioning.~~

~~NOTE — 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.~~
~~4.5.5.2.2 Continuous hot water conditioning~~

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4.5.6.2.1 Intermittent hot water exposure

Immediately after conditioning, the product shall undergo ~~the cold application~~ exposure according to ~~4.5.6.1 the schedule in Table 4.2~~. Prior to ~~the final 16-h each~~ exposure, 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 initiation of the final 16-h exposure.~~

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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~~ five 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.

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4.5.7.2.2 Continuous hot water exposure

Products that are intended to be in continuous contact with hot water shall be maintained at the selected elevated temperature, either 60 ± 2 °C (140 ± 4 °F) or 82 ± 2 °C (180 ± 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~~ five 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.

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8 Mechanical devices

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8.6.2 Cu/Ag generator electrodes

In addition to the evaluation of the chemical generator under 8.6, the electrodes for Cu/Ag generator shall be evaluated for potential non-silver and non-copper contaminants in accordance with Annex B, section B.4.4.3.3.

The normalized concentration of contaminants shall be calculated in accordance with Annex B, section B.8.5.1 and shall be no greater than their respective SPACs, determined in accordance with Annex A.



Table B3b – Alternate extraction water selection

Material type by section	Analyte of interest	X = Required extraction water selection				
		pH 5 (B.9.3)	pH 10 (B.9.7)	pH 6.5 (B.9.4)	pH 8 (B.9.8)	Reagent Water ³ (B.9.3)
Sections 4, 5, 6, and 8						
Brass and bronze surfaces	all analytes				X	
Chrome, zinc, galvanized, and other non-brass and non-bronze metal surfaces excluding copper pipe ¹	metals	X	X			
	organics				X	
Copper pipe (C12200) and copper alloy fittings used exclusively to join copper pipe	metals	X ²	X	X ²		
	organics				X	
PVC and CPVC materials	metals	X	X			
	organics				X	
Cementitious materials	metals	X	X			
	organics				X	
Asphaltic coatings	metals	X	X			
	organics				X	
All other wetted surfaces	all analytes				X	
¹ Chrome, zinc, and galvanized surfaces refers to those intentionally coated and is not a selection criteria for small areas of overspray. ² The pH 6.5 test water may be used in replacement of the pH 5 test water provided the requirements in 4.5.3.2 are also met. ³ Placeholder for eventual citing of test waters used for process media currently contained in section 7.						

B.4 Mechanical devices

B.4.3 Conditioning

Conditioning shall be conducted either in the device or in a vessel. Table B7 provides examples of typical exposures for the various products covered by this section. The test samples shall be conditioned in accordance with 4.5.5 for single time point evaluations and 4.5.7 for multiple time point evaluations. ~~preconditioned by exposure at room temperature 23 ± 2 °C (73 ± 4 °F) to the extraction water used for testing (Annex B, section B.2.5) for 14 d or less if specified by the manufacturer. The water shall be changed at least 10 times (during the 14-d conditioning period), or fewer if specified by the manufacturer. There shall be a minimum period of 24 h per exposure.~~

B.4.4 Exposure

B.4.4.1 In-line device samples

After conditioning, the samples shall be exposed as described in Annex B, Table B7 in the appropriate extraction media (Annex B, section B.2.5). Samples shall be exposed in accordance with 4.5.6 for single time point evaluations and 4.5.7 for multiple time point evaluations. ~~Devices/components that in actual field~~



~~use are not used with hot water shall be exposed using the sequence shown in Annex B, Table B8. Devices/components that are used in contact with water at a temperature in excess of 23 °C (73 °F) shall be exposed using the same exposure sequence, at the maximum temperature encountered under use conditions. At the conclusion of each of the first two exposure periods defined in Annex B, Table B8, the extractant water shall be discarded. The test sample or exposure vessel shall then be refilled with exposure water, and the exposure continued. At the conclusion of the third exposure period, the The extraction media water shall be collected for analysis as described in Annex B, section B.6.~~

B.4.4.1.1 Manifolds with a single water chamber are exposed as per B.4.4.1.

B.4.4.1.2 Dual chamber manifolds with two non-contiguous water chambers are functionally two separate devices. Dual chamber style manifolds may be exposed at two different temperatures, such that the cold water chamber is exposed at 23 °C (73 °F) and the hot water chamber is ~~seperately~~ separately exposed at the appropriate hot water temperature.

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B.4.4.4 Other mechanical devices

After conditioning, other mechanical devices shall be exposed using the appropriate extraction media (Annex B, section B.2.5) as indicated in Annex B, Table B7. Samples shall be exposed in accordance with 4.5.6 for single time point evaluations and 4.5.7 for multiple time point evaluations with the exception of using Table B.9 in lieu of Table 4.2. ~~Devices that in actual field use are not used with hot water (e.g., distribution system valves), shall be exposed using the sequence shown in Annex B, Table B9. At the conclusion of each of the first two exposure periods defined in Annex B, Table B9, the extractant water shall be discarded. The test sample or exposure vessel shall then be refilled with exposure water, and the exposure continued. At the conclusion of the third exposure period, the The extraction media water shall be collected for analysis as described in Annex B, section B.6.~~

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B.9 Extraction water preparation

B.9.1 Chemical characteristics

~~Five~~ 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; and
- e) pH = 8 ± 0.5, alkalinity of 500 ± 25 ppm, dissolved inorganic carbon of 122 ± 5 ppm, and 2 ± 0.5 ppm of free chlorine

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B.9.8 pH 8 water (from section 9)

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.