NSF/ANSI 61

Drinking Water System Components

Health Effects

2 Definitions

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

2.1 analytical summary: A list of the analytes and analytical procedures, both chemical and microbiological, that are selected to determine whether a product is conformant to the requirements of the Standard; analytes may be either product-specific or formulation-dependent.

2.2 at the tap: Referring to the point of delivery or point of use for drinking water.

2.3 cold water application: A product application that is not intended to result in exposure for extended periods to water in excess of ambient water temperature.

2.4 contaminant: A physical, chemical, biological, or radiological substance or matter in water.

NOTE – Consistent with the definition in the Federal Safe Drinking Water Act, a contaminant can have either a beneficial or detrimental effect on the potability of water.

2.5 diluted surface area (DSA)*:* The surface area/volume ratio of a product, component, or material calculated using its actual wetted surface area, the field static and/or field flow volumes directed by the standard for the end use for which the product is being evaluated. The calculation shall use the normalization equation specific to that end use. The values for lab surface area and lab volume in the normalization equation shall be entered as 1 for the purposes of this determination causing the DSA ratio to equal the calculated NF factor. The volume of chemical generated or water treated shall be for a 24 hour period.

Rationale: The current example evaluates the diluted surface area to the volume of water treated in a 4 hour period for chemical generators, whereas membranes or UV systems would be evaluated to the volume of water treated in 24 hours. The basis of the diluted surface area assumption was based on maximum extraction levels ever observed though testing at NSF normalized to a 24 hr exposure. Therefore it is proposed that the "volume of water treated during a period of time equal to the laboratory test" be changed to "the volume of water to which the product is exposed in a 24 hour period" in this example.

Example calculation: For a component of a chemical generator that has an actual surface area of 5 in^2, and the unit treats a minimum daily water volume of 500,000 liters per day. ~~, assuming that the static volume of the unit is 6 L, the unit generates 10 L of chemical in a 4-h period and the~~

~~chemical is dosed to the drinking water stream at 20 ppm (or 10 L of chemical to 500,000 L of treated water).~~ (Refer to annex B for definition of normalization terms):

$$\text{DSA } (in^2/L) = NF = N1 * N2 * N4$$

$$= \frac{SA_F}{SA_L} \times \frac{V_L}{V_{F(static)}} \times \frac{V_{F(static)}}{V_{F\ (flowing)}} \times \frac{V_{TC}}{V_{WT}}$$

~~$$= \frac{5}{1} \times \frac{1}{6} \times \frac{6}{10} \times \frac{10}{500{,}000}$$~~

$$= \frac{5}{1} \times \frac{1}{500{,}000}.$$

$$= 0.00001\ in^2/L$$

where:

SA_F = surface area exposed in the field;

SA_L = 1 (per DSA definition); ~~surface area exposed in the laboratory;~~

V_L = 1 (per DSA definition); ~~volume of extraction water used in the laboratory;~~

$V_{F(static)}$ cancels out of the equation for this example; ~~= volume of water to which the product is exposed under static conditions;~~

$V_{F(flowing)} = V_{TC}$ and the two cancel out of the equation in this example (i.e. The volume of solution leaving the chemical generator ($V_{F(flowing)}$) is the same as that being used to treat the water (V_{TC})) ~~volume of water to which the product is exposed under flowing conditions during a period. of time equivalent to the laboratory test.~~

V_{WT} = volume of raw water treated with the concentrated chemical when dosed at the prescribed feed rate during a 24 hour period. ~~of time equivalent to the laboratory test~~

Rationale: Simplified example.

2.6 direct additives: A treatment chemical and its contaminants directly added to water during the production of drinking water.

2.7 distribution system: The system of conduits or the network of pipelines (located primarily in the streets) through which a primary domestic water supply is distributed to consumers. In plumbing codes, this term is applied to all the hot and cold water piping installed in buildings.

2.8 drinking water: Water intended for human consumption.

2.9 drinking water treatment unit system: A complete water treatment device, including all components needed to connect the device to a potable water supply.

2.10 good manufacturing practices: The practice of maximizing the purity of products and materials by maintaining and practicing appropriate quality control and quality assurance procedures.

2.11 hot water application: A product application that is intended to result in exposure for extended periods to water that has been raised from ambient temperature.

2.12 indirect additives: Contaminants that are extracted into drinking water through contact with the surfaces of materials, components, or products used for its treatment, storage, transmission, or distribution.

2.13 manufacturer: A corporation, company, or individual that produces, formulates, packages, or repackages products, components, and materials that are intended to be in contact with drinking water.

2.14 maximum contaminant level (MCL): The maximum concentration of a regulated contaminant that is permitted in a public drinking water supply, as defined under the Federal Safe Drinking Water Act.

> NOTE – If the manufacturer requests review to relevant alternate regulatory requirements, the certifying agency can consider alternative regulatory levels, e.g., Canadian Maximum Acceptable Concentrations (MACs).

2.15 normalization: The process of adjusting laboratory extraction results by accounting for differences between laboratory and field surface area-to-volume ratios to reflect the contaminant concentration at the tap.

2.16 normalized concentration: A value for a contaminant concentration from a laboratory extraction test that has been adjusted to reflect the potential contaminant concentration at the tap.

2.17 point-of-entry (POE) system: A system with a minimum initial clean-system flow rate of no less than 15 L/min at 103 kilopascals pressure drop and 18+/-5 oC water temperature (not less than 4 gal/min at 15 psig pressure drop and 65+/-10 oF water temperature) used to treat the water supply at a building or facility for drinking, washing, and flushing or for other non-consumption water supply purposes.

2.18 point-of-use (POU) system: A plumbed-in or faucet-mounted system used to treat the drinking and/or cooking water at a single tap or multiple taps but not used to treat the majority of water used for washing and flushing or other non-consumption purposes at a building or facility. Any batch system or device not connected to the plumbing system is considered a point-of-use system.

2.19 short-term exposure level (STEL): A maximum concentration of a contaminant that is permitted in drinking water for an acute exposure calculated in accordance with annex A of this Standard.

2.20 single product allowable concentration (SPAC): The maximum concentration of a contaminant in drinking water that a single product is allowed to contribute as defined by annex A of this Standard.

2.21 total allowable concentration (TAC): The maximum concentration of a nonregulated contaminant allowed in a public drinking water supply as defined by annex A of this Standard.

2.22 transmission system: A system of conduits through which a primary water supply is transmitted to the distribution system.

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3 General requirements

3.1 General

3.1.1 Product and material information described in 3.2 shall be used to determine the specific section (4 through 9) under which a product or material shall be evaluated.

3.1.2 Products or materials whose intended uses fall under more than one section of this Standard shall be evaluated under the section with the most rigorous evaluation conditions.

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

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 in^2/L or 0.0001 in^2/L for static or flowing conditions respectively~~,~~ or
- if the material is in a high flow device exclusively used 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), electrodialysis technologies, microfiltration technologies, reverse osmosis and ultrafiltration technologies.

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 the annex G.

Rationale: Treatment equipment are the most common products that have significant diluted surface areas, and this addition simplifies the evaluation process. The formula has been retained to allow for other products to be considered under the diluted surface area exemption.

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);

– when the chemical composition of an ingredient or component cannot be determined based on the information submitted by the material supplier, the information shall be obtained by the certifier from the ingredient supplier prior to determining all formulation dependant analytes;

– the composition of the materials ingredients and their components shall be known to determine the identity of formulation specific analytes.

~~NOTE – 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 or 0.0001 for static or flowing conditions respectively.~~
Rationale: Editorial. This section is duplicated in NSF 61-2008 and is a mistake.

– an indication as to whether the chemical is an ingredient, reactant, or processing aid.

– the maximum temperature to which the product, component, or material is exposed during its intended end use;

– a description/classification of the manner in which the product or material is manufactured (including any process parameters that affect product surface areas in direct contact with water), handled, and packaged. The manufacturing process variability shall be verified by the manufacturer as to its effect on contaminant leachate levels, and the manufacturer shall establish and demonstrate appropriate ongoing process controls to ensure ongoing product conformance with this Standard;

NOTE – The methods used to alter the water contact surfaces of product components during manufacturing, either mechanically (e.g., metal cutting, molding, stamping) or chemically (e.g., washing, coating, plating, brite-dip cleaning), may have a significant effect upon contaminant leachate performance.

– when available, a list of the known or suspected impurities within the product or material and the maximum percent or parts by weight of each impurity;

– when available, the solubility, hydrolysis products, and extraction rates of chemicals within the product or material; and

– when available, a list of published and unpublished toxicological studies relevant to the chemicals and impurities present in the product, component, or material.

3.2.1 Information and formulation requirements for regenerated/reactivated media

In addition to the information formulation requirements of 3.2, the following information is required for the formulation review and preparation of the analytical summary for regenerated and reactivated media.

– A description of the regeneration/reactivation process and process controls, such as time, temperature, chemical regenerants, and any QC tests associated with the regeneration/reactivation process to ensure contaminants are removed from the spent media so that it complies with the requirements of this standard.

– A copy of the procedure detailing the evaluation, and conclusion associated with the review of data from spent media sources identifying all regulated contaminants, or other contaminants of concern that are removed from water and any contaminant spills or unusual water conditions.

– A copy of the data, and a copy of the documentation associated with the evaluation of the data from the spent media source(s) associated with a specific lot of reactivated or regenerated media for which a retained sample is available for testing.

3.2.1.1 Incoming shipments of media to be regenerated/reactivated

The following information shall be provided by the water system and maintained by the processing plant for each shipment of spent media received for regeneration/reactivation:

– Identification of the type of the spent media, spent media source, and application of use (e.g. production of drinking water);

– Identification of the original media, including manufacturer or previous regeneration/reactivation facility, trade designation, mesh size and compliance with this standard for each spent media source;

– Regulated contaminants or other contaminants of concern removed from water, including any contaminant spills or unusual water quality conditions;

– Statement as to whether the spent media has been knowingly exposed to:

  – Activated carbon: polychlorinated biphenyls (PCBs), dioxins or 1,2 dibromo-3chloropropane (DBCP);

  – Other media: herbicides, pesticides, polychlorinated biphenyls (PCBs), dioxins or 1,2 dibromo-3chloropropane (DBCP);

– Statement to verify that the spent media source is from a public water system (publicly or privately owned) as defined by US EPA regulations (40 CFR 141.2), or equivalent regulations in Canada and other countries where applicable.

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 decribed 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).

3.3.1 Formulation-dependent analysis selection

For all water contact materials, the formulation information described in 3.2 shall be reviewed, and formulation-dependent analytes shall be identified for each water contact material. The criteria for selection of a formulation-dependent analyte shall include, but not be limited to, the following:

– known or suspected toxicity of the substance or its byproduct(s);

– high water solubility of the substance;

– monomer(s) of polymeric ingredients;

– solvents and co-solvents used in the polymerization process or those used in the material formulation;

– antioxidants, antimicrobials, curing agents, initiators, peroxides, pigments, plasticizers,
process aids, stabilizer and terminators and their impurities, degradation and hydrolysis products;

– high probability of extraction of a substance or its byproduct(s) at toxicologically significant concentrations; and

– extraction or migration information for the substance provided by the manufacturer or that present in the public literature.

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 used 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), electrodialysis technologies, microfiltration technologies, reverse osmosis and ultrafiltration technologies.

Rationale: Treatment equipment are the most common products that have significant diluted surface areas, and this addition simplifies the evaluation process. The formula has been retained to allow for other products to be considered under the diluted surface area exemption.

3.4 Products manufactured from annex C acceptable materials

Products manufactured entirely from annex C materials shall not be required to undergo extraction testing for material-specific analytes of interest. However, extraction testing for contaminants contributed by processes specific to a production site shall be considered

formulation-dependent analytes. Annex C contains the evaluation requirements for qualification as an acceptable material.

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