

Drinking water system components Health effects

NSF International Standard/ American National Standard

Developed by a consortium of:

- NSF International
- The American Water Works Association Research Foundation
- The Association of State Drinking Water Administrators
- The American Water Works Association

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NSF International Standard/
American National Standard
for Drinking Water Additives —

**Drinking water system components —
Health effects**

Standard Developer
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Contents

1	Purpose, scope, and normative references.....	1
1.1	Purpose.....	1
1.2	Scope.....	1
1.3	Normative references.....	1
1.4	Limitations.....	3
1.5	Alternate products or materials.....	3
1.6	Significant figures.....	4
2	Definitions.....	4
3	General requirements.....	6
3.1	General.....	6
3.2	Information and formulation requirements.....	6
3.3	Identification of analytes.....	7
3.4	Products manufactured from annex C acceptable materials.....	8
	Table 3.1 – Material-specific analyses.....	8
4	Pipes and related products.....	10
4.1	Scope.....	10
4.2	Definitions.....	10
4.3	General requirements.....	10
4.4	Sample requirements.....	11
4.5	Extraction procedures.....	11
4.6	Analysis.....	16
4.7	Normalization of contaminant concentrations.....	16
4.8	Evaluation of contaminant concentrations.....	18
	Table 4.1 – Example single time point conditioning schedule.....	18
	Table 4.2 – Single time point exposure schedule.....	19
	Table 4.3 – Example multiple time point conditioning/exposure schedule.....	20
	Table 4.4 – Pipes – normalization factors and assumptions.....	21
	Table 4.5 – Fittings (installed at regular intervals) – normalization factors and assumptions.....	22
	Table 4.6 – Example normalization calculations.....	23
5	Barrier materials.....	24
5.1	Scope.....	24
5.2	Definitions.....	24
5.3	General requirements.....	25
5.4	Sample requirements.....	25
5.5	Extraction procedures.....	26
5.6	Analysis of extraction water.....	29
5.7	Normalization.....	29
5.8	Evaluation of contaminant concentrations.....	31
	Table 5.1 – Paint and coating system sample preparation.....	32
	Table 5.2 – Single time point exposure sequence.....	32
	Table 5.3 – Multiple time point exposure sequence.....	32
	Table 5.4 – Surface-area-to-volume ratios for tanks or storage vessels.....	33
6	Joining and sealing materials.....	34
6.1	Coverage.....	34
6.2	Definitions.....	34
6.3	Material and extraction testing requirements.....	34
6.4	Items of special significance.....	34
7	Process media.....	34

7.1	Scope	34
7.2	Definitions	34
7.3	General requirements	35
7.4	Sample requirements	36
7.5	Extraction procedures	36
7.6	Analysis	39
7.7	Normalization	39
	Table 7.1 – Product-specific minimum test batteries for process media products	41
	Table 7.2 – Process media exposure weight-per-volume ratios	41
	Table 7.3 – Maximum conditioning expansion rates for filtration and adsorption media	42
	Table 7.4 – Exposure schedule for process media of ≥ 0.25 mm in diameter	42
8	Mechanical devices	42
8.1	Coverage	42
8.2	Definitions	42
8.3	Device, component, or material requirements	43
8.4	In-line devices, components, and materials	43
	Table 8.1 – Examples of mechanical devices	45
9	Mechanical plumbing devices	46
9.1	Coverage	46
9.2	Definitions	47
9.3	Device, component, or material requirements	47
9.4	Exposure and normalization	48
9.5	Evaluation of normalized contaminant concentrations	49
10	Instructions and information	49
Annex A	A1
A.1	General requirements	A1
A.2	Definitions	A1
A.3	Data requirements for published risk assessments	A4
A.4	Data requirements for new or updated risk assessments	A5
A.5	Data requirements for evaluating short-term exposures	A6
A.6	Risk estimation for published assessments	A7
A.7	Risk estimation using new and updated risk assessments	A8
A.8	Risk estimation for short-term exposure (STEL calculation)	A14
A.9	Development of chemical class-based evaluation criteria	A15
A.10	Key elements of a risk assessment for drinking water additive chemicals	A16
	Table A1 – Qualitative risk assessment data requirements	A25
	Table A2 – Quantitative risk assessment data requirements	A26
	Table A3 – TACs for qualitative risk assessment	A27
	Table A4 – Uncertainty factors	A27
Annex B	B1
B.1	Background	B1
B.2	General evaluation requirements	B1
B.3	Joining and sealing materials	B4
B.4	Mechanical devices	B6
B.5	Mechanical plumbing devices	B9
B.6	Collection and preservation of extraction media after exposure	B12
B.7	Analysis methods	B12
B.8	Normalization	B18
B.9	Extraction water preparation	B24
	Figure B1 – Exposure sequence for mechanical plumbing device	B27
	Table B1 – NSF/ANSI 61 products	B28

Table B2 – Exposure summary	B28
Table B3 – Extraction water selection	B29
Table B4 – Test samples joining and sealing materials	B29
Table B5 – Exposure sequence for cold applications	B29
Table B6 – Exposure sequence for hot applications	B29
Table B7 – Product exposure ¹	B30
Table B8 – In-line device exposure sequence	B30
Table B9 – Other mechanical device exposure sequence	B30
Table B10 – Extractant water collection and preservation	B31
Table B11 – Normalization factors, assumptions, and examples pertaining to – <i>water main joining and sealing materials</i>	B32
Table B12 – Data available for determination of lead test statistic	B38
Table B13 – Values of k_1 for determining test statistic Q	B38
Table B14 – Values of k_2 for determining retest statistic R	B38
Table B15 – 1-L volume of extraction water	B39
Annex C	C1
C.1 Purpose	C1
C.2 Evaluation of acceptable materials	C1
C.3 Extraction testing	C1
C.4 Documentation	C1
Table C1 – Acceptable materials	C2
Annex D	D1
D.1 General	D1
D.2 USEPA and Health Canada drinking water criteria	D1
D.3 NSF International peer-reviewed drinking water criteria	D1
D.4 Drinking water criteria based on USEPA guidance concentrations	D2
D.5 Threshold of evaluation (TOE) chemical list	D2
Table D1 – U. S. Environmental Protection Agency and Health Canada	D3
Table D2 – NSF International peer-reviewed drinking water criteria	D8
Table D3 – Drinking water criteria based on USEPA guidance concentrations	D12
Table D4 – Threshold of evaluation chemicals ¹	D24
Annex E	E1
E.1 General	E1
E.2 NSF International drinking water criteria (not externally peer-reviewed)	E1
E.3 Informational threshold of evaluation chemicals	E2
Table E1 – NSF International drinking water criteria (not externally peer reviewed)	E3
Table E2 – Threshold of evaluation chemicals having datasets from which specific TAC/SPAC values, or CBEL values, could be set using Annex A ¹	E5
Annex F	F1
F.1 Background	F1
F.2 Incorporation of revisions into standard	F2
F.3 Revisions	F2
Table D1 – U. S. Environmental Protection Agency and Health Canada	F3
F.4 Additional information on lead	F5
F.5 References	F6

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Foreword²

In response to a competitive request for proposals from the U. S. Environmental Protection Agency (USEPA), a Consortium led by NSF International (NSF) agreed to develop voluntary third-party consensus standards and a certification program for all direct and indirect drinking water additives. Other members of the Consortium include the American Water Works Association Research Foundation, the Association of State Drinking Water Administrators, the Conference of State Health and Environmental Managers, and the American Water Works Association. (COSHEM has since become inactive as an organization.) Each organization was represented on a steering committee with oversight responsibility for the administration of the cooperative agreement. The Steering Committee provides guidance on overall administration and management of the cooperative agreement. Currently, the member organizations remain active in an oversight role.

Two standards for additives products were developed. NSF/ANSI 60: – *Drinking water treatment chemicals — Health effects* covers many of the water treatment chemicals, also known as direct additives. This Standard, NSF/ANSI 61: *Drinking water system components — Health effects*, covers all indirect additives products and materials. Testing to determine the potential of a product to impart taste and/or odor to drinking water is not included in this Standard.

NSF/ANSI 61 was developed to establish minimum requirements for the control of potential adverse human health effects from products that contact drinking water. It does not attempt to include product performance requirements that are currently addressed in other voluntary consensus standards established by such organizations as the American Water Works Association, the American Society for Testing and Materials, and the American National Standards Institute. Because this Standard complements the performance standards of these organizations, it is recommended that products also meet the appropriate performance requirements specified in the standards of such organizations.

NSF/ANSI 61, and subsequent product certification against it, has replaced the USEPA Additives Advisory Program for drinking water system components. USEPA terminated its advisory role in April 1990. For more information with regard to USEPA's actions, refer to the July 7, 1988 *Federal Register* (53FR25586).

This Standard and the accompanying text are intended for voluntary use by certifying organizations, utilities, regulatory agencies, and/or manufacturers as a basis of providing assurances that adequate health protection exists for covered products. Product certification issues, including frequency of testing and requirements for follow-up testing, evaluation, enforcement, and other policy issues, are not addressed by this Standard.

This version includes the following revisions:

- Removal of the exclusion of point-of-entry drinking water treatment devices and creation of new exposure protocols for POE devices based on a combination of aspects from NSF 61 and the DWTU materials safety exposure protocol (Joint Committee Issue 55).
- Addition of a requirement to section 10 that clarifies for consumers in the product literature, information, and instructions that point-of-entry drinking water treatment unit systems certified under NSF/ANSI 61 for materials safety may not necessarily be likewise certified for contaminant reduction or structural integrity performance (Joint Committee Issue 57).
- A change in the exposure test water for process media in section 7 (Joint Committee Issue 57).

² The information contained in this Foreword is not part of this American National Standard (ANS) and has not been processed in accordance with ANSI's requirements for an ANS. Therefore, this Foreword may contain material that has not been subjected to public review or a consensus process. In addition, it does not contain requirements necessary for conformance to the Standard.

- Incorporation of an informative annex (Annex F, to become normative on July 1, 2012) lowering the drinking water criteria for lead (Joint Committee Issue 70).
- Addition of Short Term Exposure Limits to Table D2 – NSF International peer-reviewed drinking water criteria (Joint Committee Issue 71).
- Addition of explicit and uniform guidance for over time testing protocols to sections 4, 5, 6, 8, and 9 on multiple time point protocols (Joint Committee Issue 72).
- Identification of flexible plumbing connectors under the scope of section 9 and transfer of the evaluation of riser tubing from section 4 to section 9 (Joint Committee Issue 74).

This Standard was developed by the NSF Joint Committee on Drinking Water Additives using the consensus process described by the American National Standards Institute.

Suggestions for improvement of this Standard are welcome. Comments should be sent to Chair, Joint Committee on Drinking Water Additives, c/o NSF International, Standards Department, P. O. Box 130140, Ann Arbor, Michigan 48113-0140, USA.

Consortium organizations³

NSF International

Popularly referred to as NSF, NSF International is a noncommercial agency. It is incorporated under the laws of Michigan as a not-for-profit organization devoted to research, education, and service. It seeks to solve problems involving man and his environment. It wishes to promote health and enrich the quality of life through conserving and improving that environment. Its fundamental principle of operation is to serve as a neutral medium in which business and industry, official regulatory agencies, and the public come together to deal with problems involving products, equipment, procedures, and services related to health and the environment. It is conceived and administered as a public service organization.

NSF is perhaps best known for its role in developing standards and criteria for equipment, products, and services that bear upon health. NSF was the lead organization in the Consortium responsible for developing this Standard. NSF conducts research; tests and evaluates equipment, products, and services for compliance with standards and criteria; and grants and controls the use of NSF registered Marks.

NSF offers product certification (Listing Services) for all products covered by its standards. Each program has established policies governing the associated product evaluation, Listing Services, follow-up, and enforcement activities. The NSF Listing Mark is widely recognized as a sign that the product or service to which it relates complies with the applicable NSF standard(s).

AWWA Research Foundation

The mission of the American Water Works Association Research Foundation (AWWARF) is to sponsor practical, applied research on behalf of the drinking water industry of North America. The scope of the research program embraces all aspects of water supply operation, from development and maintenance of water resources to treatment technologies and water quality issues, from storage and distribution system operations to health effects studies and utility planning and management activities. AWWARF serves as the centralized industry institution for planning, managing, and funding cooperative research and development in drinking water, including the subsequent transfer of technology and results for practical application by the water utility community.

AWWARF's purpose in this cooperative program is to provide a communication link with the water utilities throughout North America and serve as the focal point for identification of research needs of the water supply industry with respect to the additives program.

The Association of State Drinking Water Administrators

The Association of State Drinking Water Administrators (ASDWA) is a nonprofit organization whose eligible membership is comprised of drinking water program administrators in each of the 50 states and seven U. S. territories. Through the organization, representatives speak with a collective voice to Congressional committees, the United States Environmental Protection Agency (EPA), professional and trade associations, water utilities, and the general public on issues related to state drinking water programs. With its mission of protecting the public health through assurance of high-quality drinking water, and promoting responsible, reasonable, and feasible drinking water programs at the state and federal levels, the Association is a valued contributor to the consortium, and to the program. It provides the link between the additives program and the state drinking water programs.

³ The information contained in this section is not part of this American National Standard (ANS) and has not been processed in accordance with ANSI's requirements for an ANS. Therefore, this section may contain material that has not been subjected to public review or a consensus process. In addition, it does not contain requirements necessary for conformance to the Standard.

The Conference of State Health and Environmental Managers

The Conference of State Health and Environmental Managers (COSHEM), known formerly as the Conference of State Sanitary Engineers (CSSE), is currently inactive as an organization. It brought to the consortium expertise and involvement of state health and environmental program managers. The Conference was the focal point for health concerns of all state environmental programs, including drinking water, wastewater, air, solid and hazardous wastes, radiology, occupational health, and food. A standing committee on water supply focused on drinking water issues and kept the membership informed. The Conference played an important role early in the program through two-way communication with state health and environmental program decisionmakers.

American Water Works Association

The purpose of the American Water Works Association (AWWA) is to promote public health, safety, and welfare by improving the quality and increasing the quantity of water delivered to the public, and to developing and furthering an understanding of the problems relating thereto by:

- advancing the knowledge of the design, construction, operation, water treatment, and management of water utilities;
- developing standards for procedures, equipment, and materials used by public water supply systems;
- advancing the knowledge of problems involved in the development of resources, production, and distribution of safe and adequate water supplies;
- educating the public on the problems of water supply and promoting a spirit of cooperation between consumers and suppliers in solving these problems; and
- conducting research to determine the causes of problems with providing a safe and adequate water supply, and proposing solutions thereto in an effort to improve the quality and quantity of the water supply provided to the public.

AWWA brings to the Consortium its established position as the largest public drinking water association in North America, with a broad membership that includes utilities, consultants, manufacturers/distributors/agents, contractors, and other organizations with a direct interest in drinking water.

NSF/ANSI Standard for Drinking Water Additives —

Drinking water system components – Health effects

1 Purpose, scope, and normative references

1.1 Purpose

This Standard establishes minimum health effects requirements for the chemical contaminants and impurities that are indirectly imparted to drinking water from products, components, and materials used in drinking water systems. This Standard does not establish performance, taste and odor, or microbial growth support requirements for drinking water system products, components, or materials.

1.2 Scope

1.2.1 This Standard is intended to cover specific materials or products that come into contact with: drinking water, drinking water treatment chemicals, or both. The focus of the Standard is evaluation of contaminants or impurities imparted indirectly to drinking water. The products and materials covered include, but are not limited to, process media (e. g., carbon, sand), protective materials (e. g., coatings, linings, liners), joining and sealing materials (e. g., solvent cements, welding materials, gaskets), pipes and related products (e. g., pipes, tanks, fittings), mechanical devices used in treatment/transmission/distribution systems (e. g., valves, chlorinators, separation membranes, point-of-entry drinking water treatment systems), and mechanical plumbing devices (e. g., faucets, endpoint control valves).

1.2.2 Point-of-use drinking water treatment devices are not covered by the scope of this Standard.

1.2.3 Fire hydrants are not covered by the scope of this Standard.

1.3 Normative references

The following documents contain requirements that, by reference in this text, constitute requirements of this Standard.

APHA, *Standard Methods for the Examination of Water and Wastewater*, twentieth edition⁴

ASTM A240/A240M-05. *Standard Specification for Chromium and Chromium-Nickel Stainless Steel Plate, Sheet, and Strip for Pressure Vessels and for General Applications*⁵

ASTM A269-04. *Standard Specification for Seamless and Welded Austenitic Stainless Steel Tubing for General Service*⁵

⁴ American Public Health Association (APHA), 800 I Street, NW, Washington, DC 20001

⁵ ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2859

ASTM A312/A312M-05. *Standard Specification for Seamless, Welded, and Heavily Cold Worked Austenitic Stainless Steel Pipes*⁵

ASTM A789/A789M-05. *Standard Specification for Seamless and Welded Ferritic/Austenitic Stainless Steel Tubing for General Service*⁵

ASTM A790/A790M-05. *Standard Specification for Seamless and Welded Ferritic/Austenitic Stainless Steel Pipe*⁵

ASTM A815/A815M-04. *Standard Specification for Wrought Ferritic, Ferritic/Austenitic, and Martensitic Stainless Steel Piping Fittings*⁵

ASTM C31/C31M-00e1. *Standard Practice for Making and Curing Concrete Test Specimens in the Field*⁵

ASTM C109/C109M-99. *Standard Test Method for Compressive Strength of Hydraulic Cement Mortars*⁵

ASTM C 183-02. *Standard Practice for Sampling and the Amount of Testing of Hydraulic Cement*⁵

ASTM C192/C192M-00. *Standard Practice for Making and Curing Concrete Test Specimens in the Laboratory*⁵

ASTM C511-98. *Standard Specification for Moist Cabinets, Moist Rooms, and Water Storage Tanks Used in the Testing of Hydraulic Cements and Concretes*⁵

ASTM C778-00. *Standard Specification for Standard Sand*⁵

ASTM D2855-96. *Standard Practice for Making Solvent-Cemented Joints with Poly(Vinyl Chloride) (PVC) Pipe and Fittings*⁵

ASTM D3182-89 (1994). *Standard Practice for Rubber – Materials, Equipment, and Procedures for Mixing Standard Compounds and Preparing Standard Vulcanized Sheets*⁵

ASTM E29-02 *Standard Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications*⁵

ASTM F493-97. *Standard Specification for Solvent Cements for Chlorinated Poly(Vinyl Chloride) (CPVC) Plastic Pipe and Fittings*⁵

ANSI/AWWA B100-96. *AWWA Standard for Filtering Material*⁶

ANSI/AWWA C652-92. *AWWA Standard for Disinfection of Water-Storage Facilities*⁶

NSF/ANSI 60 – 2003. *Drinking water treatment chemicals – Health effects*

OECD, *OECD Guidelines for the Testing of Chemicals*, May 1996⁷

SSPC-PA2– 2004 *Steel Structures Painting Manual Volume 2. Paint Application Specification*⁸

⁶ American Water Works Association (AWWA), 6666 Quincy Avenue, Denver, CO 80235-9913

⁷ Organization for Economic Cooperation and Development (OECD), 2 Rue Andre-Pascal, 75775 Paris Cedex 16, France

⁸ SSPC (The Society for Protective Coatings), 40 24th Street, 6th Floor, Pittsburgh, PA 15222-4656

The Society for Protective Coatings, *Steel Structures Painting Manual*. Volume 2. Reference Paint Application Specification No. 2 (SSPC-PA2)⁸

USEPA-570-9-82-002. *Manual for the Certification of Laboratories Analyzing Drinking Water*, October 1982⁹

USEPA-600/4-79-020. *Methods for the Chemical Analysis of Water and Wastes*, March 1983⁹

USEPA-600/4-80-032. *Prescribed Procedures for Measurement of Radioactivity in Drinking Water*⁹

USEPA-600/4-84-053. *Methods for Organic Chemical Analysis of Municipal and Industrial Wastewater*, June 1984⁹

USEPA, *Health Effects Testing Guidelines*, 40 CFR Part 798¹⁰

USEPA, *Good Laboratory Practice Standards*, 40 CFR Part 160¹⁰

USEPA, *Guidelines Establishing Test Procedures for the Analysis of Pollutants*, 40 CFR Part 136¹⁰

USEPA, *National Primary Drinking Water Regulations*, 40 CFR Part 141¹⁰

USFDA, *Good Laboratory Practice for Non-Clinical Laboratory Studies*, 21 CFR 58¹¹

USFDA, *Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives in Food*¹¹

1.4 Limitations

The requirements of this Standard are limited to addressing potential health effects, except where specific application and performance standards are referenced. This Standard does not establish taste and odor requirements for drinking water system products and materials. The criteria set forth in this Standard cover products created by good manufacturing practices and generally recognized manufacturing processes. As the presence of unusual or unexpected impurities is frequently dependent upon the method of manufacture and the quality of raw material used, products prepared by other than recognized methods of manufacture or with unusual raw materials shall be fully evaluated in accordance with 3 of this Standard (general requirements). Products that have been evaluated and found to meet other NSF standards having health requirements equivalent to this Standard as indicated in each section shall be acceptable for drinking water applications without separate evaluation under this Standard.¹²

1.5 Alternate products or materials

While specific materials are stipulated in this Standard, drinking water system products or components that incorporate alternate materials shall be acceptable when it is verified that the product or component meets the applicable requirements of the Standard based on its end use.

⁹ USEPA, Environmental Monitoring and Support Laboratory, Cincinnati, OH 45268

¹⁰ Superintendent of Documents, U. S. Government Printing Office, Washington, DC 20402

¹¹ USFDA, 5600 Fishers Lane, Rockville, MD 20857

¹² Final acceptance of a product for drinking water application is the responsibility of the appropriate federal, state, or local regulatory agent.

1.6 Significant figures

For determining conformance with the specifications in this standard, the Absolute Method in ASTM E29 *Standard Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications* shall be used.

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.

Example calculation: For a component of a chemical generator that has an actual surface area of 5 in², 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):

$$\begin{aligned}
 \text{DSA (in}^2\text{/L)} &= \text{NF} = \text{N1} * \text{N2} * \text{N4} \\
 &= \frac{\text{SA}_F}{\text{SA}_L} \times \frac{\text{V}_L}{\text{V}_{F(\text{static})}} \times \frac{\text{V}_{F(\text{static})}}{\text{V}_{F(\text{flowing})}} \times \frac{\text{V}_{\text{TC}}}{\text{V}_{\text{WT}}} \\
 &= \frac{5}{1} \times \frac{1}{6} \times \frac{6}{10} \times \frac{10}{500,000} \\
 &= 0.00001 \text{ in}^2\text{/L}
 \end{aligned}$$

where:

SA_F = surface area exposed in the field;

SA_L = surface area exposed in the laboratory;

V_L = volume of extraction water used in the laboratory;

V_{F(static)} = volume of water to which the product is exposed under static conditions; and

$V_{F(\text{flowing})}$ = volume of water to which the product is exposed under flowing conditions during a period of time equivalent to the laboratory test.

V_{TC} = volume of concentrated treatment chemical contacted or generated by the device 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 period of time equivalent to the laboratory test

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.

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 reviewed 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 assembled products or components, a list of all of components and 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 for each water contact material as applicable'

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.

- the composition of the formulation (e. g., percent or parts by weight for each chemical in the formulation or reference to a standardized material specification);

- a chemical abstract number (CAS no.), name, trade designation, and supplier for each chemical present in the formulation and a Material Safety Data Sheet (MSDS), when available; and
- 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.

3.3 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%), and to determine whether a minimum test battery has been established for each water contact material (see table 3.1). The availability of an established minimum test battery shall not preclude performance of a formulation review to identify any formulation-dependent analytes (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;
- 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.

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 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.

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.

Table 3.1 – Material-specific analyses

Material type	Required analyses
Pipe/fitting/device materials	
asphaltic-coated ductile iron	GC/MS base/neutral scan (specific for carbonyls and non-aromatic hydrocarbons) ¹ , volatile organic chemicals (VOCs), polynuclear aromatic hydrocarbons (PNAs), regulated metals ² , molybdenum, vanadium, manganese
brass	regulated metals ² , zinc, nickel
concrete	regulated metals ²
copper	regulated metals ²
galvanized steel	regulated metals ² , zinc, nickel
stainless steel	regulated metals ² , nickel
Plastic materials	
acetal (AC)/polyoxymethylene (POM)	formaldehyde, VOCs, regulated metals ² , phenolics (by GC/MS base/acid scan) ¹ , acetal oligomers (by GC/MS base/acid scan) ¹
acrylonitrile-butadiene-styrene (ABS)	acrylonitrile, 1,3-butadiene, styrene, regulated metals ² , VOCs, phenolics (by GC/MS base/acid scan) ¹
cross linked polyethylene (PEX)	GC/MS ¹ , VOCs, regulated metals ² , phenolics (by GC/MS base/acid scan) ¹ , methanol, <i>tert</i> -butyl alcohol ³
nylon 6	caprolactam, nitrogen-containing extractants (by GC/MS base/neutral scan) ¹ , VOCs, regulated metals ² , phenolics (by GC/MS base/acid scan) ¹
other nylons	nitrogen-containing extractants (by GC/MS base/neutral scan) ¹ , VOCs, regulated metals ² , phenolics (by GC/MS base/acid scan) ¹ , nylon monomers
polybutylene (PB)	VOCs, regulated metals ² , phenolics (by GC/MS base/acid scan) ¹
polyethylene (PE)	VOCs, regulated metals ² , phenolics (by GC/MS base/acid scan) ¹
polyphenylene oxide (PPO)	dimethyl phenol, VOCs, regulated metals ² , phenolics (by GC/MS base/acid scan) ¹
polyphthalamide (PPA)	hexamethylene diamine, terephthalic acid, isophthalic acid, VOCs, regulated metals ² , phenolics (by GC/MS base/acid scan) ¹
polypropylene (PP)	VOCs, regulated metals ² , phenolics (by GC/MS base/acid scan) ¹
polysulphone including poly[phenylene sulphone] (PPSU)	sulphone monomer, VOCs, regulated metals ² , phenolics (by GC/MS base/acid scan) ¹
polyurethane (PUR)	GC/MS ¹ , VOCs, regulated metals ² , phenolics (by GC/MS base/acid scan) ¹
polyvinyl chloride (PVC) and chlorinated polyvinyl chloride	regulated metals ² , phenolics ¹ , VOCs, tin ⁴ , antimony ⁵ , residual vinyl chloride monomer (RVCM) ⁶

Table 3.1 – Material-specific analyses

Material type	Required analyses
(CPVC)	
polyvinyl chloride (flexible)	VOCs, regulated metals ² , phenolics (by GC/MS base/acid scan) ¹ , phthalates ⁷ , RVCM ⁶ , tin ⁴ , zinc ⁸
Elastomer materials	
ethylene-propylene-diene monomer (EPDM)	GC/MS ¹ , VOCs, phenolics (by GC/MS base/acid scan) ¹ , phthalates ⁷ , PNAs ¹
fluoroelastomer	GC/MS ¹ , VOCs, phthalates ⁷
isoprene	GC/MS ¹ , VOCs, phenolics (by GC/MS base/acid scan) ¹ , phthalates ⁷ , PNAs ¹ , isoprene monomer
neoprene	GC/MS ¹ , VOCs, phenolics (by GC/MS base/acid scan) ¹ , phthalates ⁷ , PNAs ¹ , chloroprene
nitrile-butadiene rubber (NBR, BUNA-N)	GC/MS ¹ , VOCs, phenolics (by GC/MS base/acid scan) ¹ , phthalates ⁷ , PNAs ¹ , 1,3-butadiene, acrylonitrile
styrene-butadiene rubber (SBR)	GC/MS ¹ , VOCs, phenolics (by GC/MS base/acid scan) ¹ , phthalates ⁷ , PNAs ¹ , 1,3-butadiene, styrene
Barrier materials	
asphaltic coatings	regulated metals ² , molybdenum, vanadium, manganese, VOCs, GC/MS base/neutral scan (specific for carbonyls and non-aromatic hydrocarbons) ¹ , PNAs ¹
epoxy coatings (liquid and powder)	GC/MS (base/neutral/acid scan), bisphenol A, bisphenol A-diglycidyl ether ⁹ , bisphenol A-diglycidyl ether ⁹ , bisphenol A-propoxylate ⁹ , epichlorohydrin, VOCs, solvent and reactive diluent additives ¹⁰
polyester coatings	GC/MS (base/neutral/acid scan), VOCs, residual monomers ¹¹
polyurethane coatings	GC/MS (base/neutral/acid scan), VOCs
Portland and hydraulic cements	GC/MS ¹ , regulated metals ² , dioxins and furans, radionuclides, glycols and ethanolamines ¹²

¹ see annex B, section B.7

² antimony, arsenic, barium, beryllium, cadmium, chromium, copper, lead, mercury, selenium, thallium

³ *tert*-Butyl alcohol analysis is required for PEX materials except those crosslinked via e-beam methodology.

⁴ The analysis for tin is required when tin-based stabilizers are used.

⁵ The analysis for antimony is required when antimony-based stabilizers are used.

⁶ The level of RVCM within the walls of PVC or CPVC products and materials shall be directly determined (annex B, section B.7).

⁷ The analysis for phthalates is required when phthalate ester plasticizers are used. Analysis shall be for the specific phthalate ester(s) used in the formulation.

⁸ The analysis for zinc is required when zinc-based stabilizers are used.

⁹ Analysis shall be performed using liquid chromatography with ultraviolet detection (LC/UV).

¹⁰ Analysis shall be performed for the specific solvent and reactive diluent additives used in the individual product formulation, such as benzyl alcohol.

¹¹ Analysis shall be performed for residual concentrations of the specific ester monomers used in the individual product formulation.

¹² Glycol and ethanolamine analyses shall be performed on cements containing these compounds as grinding aids.

– concluded –

4 Pipes and related products

4.1 Scope

4.1.1 The requirements in this section apply to pipes and pipe-related products and the water-contact materials associated with these products. Pipe-related products include, but are not limited to, the following items: fittings, couplings, flexible and rigid tubing, dip tubes, hoses, well casings, drop pipes, screens, and pipe-related coatings.

4.1.2 Coatings and other barrier materials not exclusively intended for application to pipes or pipe-related products are evaluated under 5.

NOTE – Coatings and other barrier materials that meet the requirements of 5 at a specific surface area to volume ratio shall be considered to meet the requirements of a pipe or pipe-related product application for a surface area-to-volume ratio less than or equal to the ratio accepted under the 5 evaluation.

4.1.3 Individual ingredients of cement-based pipes and related products (including Portland and blended hydraulic cement and admixtures) are evaluated under 5.

4.1.4 Products and materials intended to join or seal pipes or pipe-related products are evaluated under 6.

4.2 Definitions

4.2.1 cold water application: A product application that is intended to result in continuous exposure to water of ambient temperature. Products are tested for an end-use temperature of 23 ± 2 °C (73 ± 4 °F).

4.2.2 commercial hot water application: A product application that is intended to result in continuous or intermittent exposure to water that has been raised from ambient temperature. Intermittent exposure is defined as any hot water contact that is not continuous. Products are tested for an end-use temperature of 82 ± 2 °C (180 ± 3 °F).

4.2.3 domestic hot water application: A product application that is intended to result in continuous or intermittent exposure to water that has been raised from ambient temperature. Intermittent exposure is defined as any hot water contact that is not continuous. Products are tested for an end-use temperature of 60 ± 2 °C (140 ± 3 °F).

4.2.4 nominal diameter: A designation system used to specify a pipe size, where the designation for a specific size is approximately equal to the average inside diameter of the pipe.

4.3 General requirements

4.3.1 The product size with the most conservative normalization condition shall be evaluated. Successful evaluation of such a product shall qualify all products of less conservative normalization conditions, provided that the materials of construction are identical as specified in 4.4.1.

NOTE – For products of 1.3 to 10 cm (0.5 to 4 in) nominal diameter and products of 10 cm (4 in) diameter and greater, the most stringent normalization condition is typically the smallest inner diameter product within the nominal diameter range. Products of less than 1.3 cm (0.5 in) nominal diameter are assumed to have limited exposure in the distribution system (see assumptions in tables 4.4 and 4.5). Successful qualification of products of less than 1.3 cm (0.5 in) nominal diameter may not demonstrate the acceptability of all products 1.3 cm (0.5 in) nominal diameter and greater.

4.3.2 Residual vinyl chloride evaluation

Polyvinyl chloride and chlorinated polyvinyl chloride products and materials shall be evaluated for the level of residual vinyl chloride monomer (RVCM) in the product wall or in the material according to annex B, section B.7.

4.4 Sample requirements

4.4.1 General

A sample can represent a product line of various sizes when:

- materials are of the same alloy, composition, or formulation;
- materials have undergone the same manufacturing process, e. g., casting or extrusion;
- designs and manufacturing processes are analogous; and/or
- it has the most stringent normalization requirements (see 4.3.1).

4.4.2 Materials

When a material is proposed for evaluation, a representative sample of the material shall be used. Material test samples (e. g., plaque or sheet) shall be used only if no chemical or physical difference exists between the material sample and the material as it is used in applications covered by 4. A material intended to be processed by more than one method (e. g., injection molding, extrusion, or stamping) shall be tested in each of its processed forms.

4.4.3 Finished products

When a finished product (e. g., pipe or fitting) is proposed for evaluation, a sample of the finished product shall be used for testing except in the following specific instances:

- concrete cylinders, cubes, or other concrete surrogate samples can be evaluated on behalf of concrete-lined pipes and other concrete-based products;
- coatings, applied to the appropriate substrate, can be evaluated on behalf of products whose entire water contact surface is covered by the coating; or
- finished products shall be permitted to be evaluated using material samples if a finished product evaluation is impractical for one or more of the following reasons:
 - an internal volume greater than 20 L (5.3 gal);
 - a weight greater than 34 kg (75 lb); or
 - *in situ* manufacture of the finished product.

Material samples shall be permitted to be evaluated on behalf of a finished product if the first and second criteria listed under 4.4.1 are satisfied.

4.5 Extraction procedures

4.5.1 Analytical summary

An analytical summary shall be prepared for each product or material. The analytical summary shall consist of the formulation-dependent analytes identified in 3.2 and the applicable material-specific analytes listed in table 3.1.

4.5.2 Preparation of test samples

4.5.2.1 In all cases, test samples shall be prepared so that the laboratory surface-area-to-volume ratio is equal to or greater than the surface-area-to-volume ratio at which the product is intended to be used in the field.

NOTE – To facilitate the exposure of product samples that are connected to pipe or tubing products under normal installation conditions (e. g., fittings), the samples may be attached to lengths of pipe or tubing of the appropriate nominal diameter. When a test sample is prepared in this manner, the exposed surface area of the fitting test sample shall represent a percentage of the total exposed surface area (test sample plus the attached pipe or tubing) that is equal to or greater than the percentage specified in the table 4.5 normalization assumptions, for the specific nominal diameter and end use of the product (flexible or rigid piping system). The pipe or tubing material shall also be present in the method blank as required in annex B, section B.2.8.1.

4.5.2.2 Unless the manufacturer's instructions direct otherwise, test samples shall be rinsed in cold tap water until any extraneous debris or contamination that occurred during shipping and handling is removed. The samples shall then be rinsed in reagent water that meets the requirements of annex B, section B.9.2.1

4.5.2.3 If the exterior surface of a product is to be exposed, all markings that are not integral to the product (e. g., ink markings) shall be removed.

4.5.2.4 When the test sample contains internal threaded outlets, 75% of the threaded surface area shall be covered by insertion of a threaded component of the appropriate diameter to produce a watertight seal.

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 4.5.1). Exposure water(s) shall be selected in accordance with annex B, section B.2.5.

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 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:

"Copper [tube, pipe, or fitting] (Alloy [alloy designation]) has been evaluated by [Testing Organization] to NSF/ANSI 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."

4.5.4 Conditioning and exposure options

4.5.4.1 In-product conditioning and exposure

During in-product conditioning and exposure, the test sample shall be filled completely with exposure water. The product having the greatest surface area-to-volume ratio (typically the smallest diameter) shall be preferentially used. When necessary to prevent the loss of exposure water, samples shall be capped with inert materials (e. g., glass).

4.5.4.2 In-vessel conditioning and exposure

During in-vessel conditioning and exposure, samples shall be placed in containers composed of 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.

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.

4.5.4.3 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 contaminants 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.

4.5.5 Single time point conditioning protocols

A separate sample shall be conditioned for each type of exposure water selected in 4.5.3.

4.5.5.1 Single time point conditioning – cold application

Products that are intended to be in contact with only cold water shall be conditioned in the exposure water(s) selected in 4.5.3 at 23 ± 2 °C (73 ± 4 °F) for 14 d. During the 14-d period, the exposure water shall be changed at least 10 times with a minimum period of 24 ± 1 h between water changes. The free available chlorine concentration during the conditioning period shall be 2 mg/L. After the 14-d conditioning period, the exposure water in the product or in the vessel shall be decanted and discarded. Shortened conditioning periods shall be used at the request of the manufacturer. Exposure of the sample according to 4.5.6 shall immediately follow conditioning.

NOTE – Table 4.1 provides an example single time point conditioning protocol. Alternate protocols shall be permitted as long as the requirements of 4.5.5.1 are met.

4.5.5.2 Single time point conditioning – hot applications

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 ± 3 °F) or 82 ± 2

°C (180 ± 3 °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

Products that are intended to be in continuous contact with hot water shall be conditioned in the exposure water(s) selected in 4.5.3 at either 60 ± 2 °C (140 ± 3 °F) or 82 ± 2 °C (180 ± 3 °F) for 14 d. During the 14-d period, the exposure water shall be changed at least 10 times with a minimum period of 24 ± 1 h between water changes. The free available chlorine concentration during the conditioning period shall be 2 mg/L. After the 14-d conditioning period, the exposure water in the product or in the vessel shall be decanted and discarded. Shortened conditioning periods shall be permitted at the request of the manufacturer. Exposure of the sample according to 4.5.6 shall immediately follow conditioning.

NOTE – Table 4.1 provides an example single time point conditioning protocol. Alternate protocols shall be permitted as long as the requirements of 4.5.5.2 are met.

4.5.6 Single time point exposure protocols

Products to be evaluated at a single time point shall be exposed according to the schedule in table 4.2. The first two 24-h exposure periods shall be optional at the discretion of the manufacturer. A separate sample shall be exposed for each type of exposure water selected in 4.5.3. For each sample, the exposure water shall be of the same pH as the water used for conditioning of the sample.

4.5.6.1 Single time point exposure – cold application

Immediately after conditioning, the product shall be exposed at 23 ± 1 °C (73 ± 2 °F) according to the schedule in table 4.2.

4.5.6.2 Single time point exposure – hot applications

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. Prior to the final 16-h exposure, the product shall be exposed at the selected elevated temperature, either 60 ± 1 °C (140 ± 2 °F) or 82 ± 1 °C (180 ± 2 °F), for 30 ± 5 min. The product shall then be exposed at 23 ± 1 °C (73 ± 2 °F) for the duration of the exposure period. The exposure water shall not be decanted prior to initiation of the final 16-h exposure.

4.5.6.2.2 Continuous hot water exposure

Immediately after conditioning, the product (in-product exposures) or the exposure vessel (in-vessel exposures) shall be filled with fresh exposure water of the applicable pH (see 4.5.3). The product shall then be exposed at the selected elevated temperature, either 60 ± 1 °C (140 ± 2 °F) or 82 ± 1 °C (180 ± 2 °F), according to the schedule in table 4.2.

4.5.7 Multiple time point conditioning/exposure protocols

For the purpose of determining a contaminant leaching rate as a function of time, extractant water samples shall be collected during the conditioning period of products for which multiple time point exposure has been elected, according to the protocols in 4.5.7.1 and 4.5.7.2. A separate sample shall be conditioned and exposed for each type of exposure water selected in 4.5.3.

4.5.7.1 Cold application

Products that are intended to be in contact with only cold water shall be maintained at 23 ± 1 °C (73 ± 2 °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 ± 1 °C (73 ± 2 °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 4 d/wk during the interval between the initial and final exposures. Exposures that are used for the collection of extractant water for analysis shall not exceed 24 ± 1 h in duration.

4.5.7.2 Hot applications

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 ± 1 °C (140 ± 2 °F) or 82 ± 1 °C (180 ± 2 °F), for 30 ± 5 min. The product shall then be exposed at 23 ± 1 °C (73 ± 2 °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 ± 1 °C (140 ± 2 °F) or 82 ± 1 °C (180 ± 2 °F), for 30 ± 5 min. The product shall then be exposed at 23 ± 1 °C (73 ± 2 °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 4 d/wk during the interval between the initial and final exposures. Exposures that are used for the collection of extractant water for analysis shall not exceed 24 ± 1 h in duration.

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 ± 1 °C (140 ± 2 °F) or 82 ± 1 °C (180 ± 2 °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 4.5.7.2.2 are met.

At the discretion of the manufacturer, direct measurement of a Day 90 extraction shall be permitted. The products shall be maintained at the selected elevated temperature, either 60 ± 1 °C (140 ± 2 °F) or 82 ± 1 °C (180 ± 2 °F). Extraction water shall be collected for analysis at at least 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 4 d/wk during the interval between the initial and final exposures. Exposures that are used for the collection of extractant water for analysis shall not exceed 24 ± 1 h in duration.

4.5.8 Collection and preservation of extraction water

Immediately after exposure, extraction waters collected for analysis shall be poured into previously prepared sample containers for storage until analysis, as specified in annex B, section B.6.

4.6 Analysis

4.6.1 Extraction waters shall be analyzed with the methods listed in annex B, section B.7.

4.6.2 Samples requiring analysis for residual vinyl chloride monomer shall be evaluated according to the method in annex B, section B.7.

4.7 Normalization of contaminant concentrations

4.7.1 General

The concentration of analytes detected in the extraction water shall be multiplied by a calculated normalization factor (NF) to account for differences between laboratory and field surface-area-to-volume ratios. The normalization factor shall be based on calculations and assumptions relevant to the end use of the product.

The general formula for the derivation of the normalization factor is described in the following equations:

$$NF = N1 \times N2$$

$$N1 = \frac{SA_F}{SA_L} \times \frac{V_L}{V_{F(\text{static})}}$$

$$N2 = \frac{V_{F(\text{static})}}{V_{F(\text{flowing})}}$$

where:

SA_F = surface area exposed in the field;

SA_L = surface area exposed in the laboratory;

V_L = volume of extraction water used in the laboratory;

$V_{F(\text{static})}$ = volume of water to which the product is exposed under static conditions; and

$V_{F(\text{flowing})}$ = volume of water to which the product is exposed under flowing conditions during a period of time equivalent to the laboratory test.

When the length of the exposure being normalized is other than 16 h in length, the normalized value shall be adjusted to reflect a 16-h exposure (e. g., multiply the normalized value by 0.7 when a 24-h exposure was used). The nominal diameter of the product shall determine which assumptions are used for normalization (see tables 4.4 and 4.5). The actual inner diameter of the product shall be used for the normalization calculations of surface area and volume.

NOTE – Adjustment of the normalized contaminant concentration for the duration of the exposure period shall consider the extraction kinetics of the contaminant under evaluation. For contaminants that do not exhibit linear extraction kinetics, adjustment for the duration of exposure shall be done in accordance with the demonstrated kinetics of the contaminant or shall not be applied if this information is not available.

4.7.2 Products installed at regularly repeating intervals

For products installed at regularly repeating intervals (e. g., pipes, fittings), the SA_F 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 $V_{F(\text{static})}$ 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 SA_F and $V_{F(\text{static})}$.

4.7.3 Products not installed at regularly repeating intervals

Products not installed at regularly repeating intervals shall be identified through review of the manufacturer's recommended product end use. For products not installed at regularly repeating intervals (e. g., transition fittings, repair couplings, drop ear elbow fittings, and copper stub outs), the SA_F shall be the wetted surface area of a single product. The $V_{F(\text{static})}$ component of the N1 term shall be the volume of water a single product contains when filled to capacity, except that $V_{F(\text{static})}$ 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.

4.7.4 Sample calculations for normalization of products in 4 are provided in table 4.6.

4.7.5 Selection of normalization conditions

Pipe and fitting products with a nominal diameter greater than or equal to 10 cm (4 in) shall be normalized to the flowing condition. Pipe and fitting products with a nominal diameter of less than 10 cm (4 in) shall be normalized to the static condition when the value of N2 is less than or equal to 0.1. Pipe and fitting products with a nominal diameter of less than 10 cm (4 in) shall be normalized to the flowing condition when the value of N2 is greater than 0.1.

4.7.6 Multiple time point exposure calculations

Laboratory values from each time point at which extractant water was collected (a minimum of five data points shall be required for extrapolation) shall be normalized as indicated in 4.7.1, depending on product end use. A decay curve of these normalized contaminant concentrations in relation to elapsed exposure time shall be plotted. Contaminant concentrations shall be determined for two time points as follows: at Day 1 (representing 14 d of conditioning and 1 d of acute exposure) and at Day 90 (representing 14 d of conditioning, 1 d of acute exposure, and 90 d of chronic exposure) shall be extrapolated from this curve (see 4.5.7).

If direct measurement of a Day 90 exposure has been performed, laboratory values from each time point at which extractant water was collected (a minimum of two time points as defined in 4.5.7.1 and 4.5.7.2) shall be normalized as indicated in 4.7.1, depending on product end use.

4.8 Evaluation of contaminant concentrations

4.8.1 Contaminants measured in a single time point extraction

For pipe and fitting products, normalized static contaminant concentrations shall be no greater than their respective MCLs or TACs, and normalized flowing contaminant concentrations shall be no greater than their respective SPACs calculated in accordance with annex A.

4.8.2 Contaminants measured in a multiple time point extraction

Normalized Day 1 contaminant concentrations shall not exceed the short-term exposure level (STEL) as defined in annex A, section A.5.

Normalized extrapolated or directly measured Day 90 contaminant concentrations shall not exceed the limits defined in 4.8.1.

4.8.3 Residual vinyl chloride monomer (RVCM)

The average RVCM concentration shall be less than or equal to 3.2 mg/kg as evaluated in the product wall.

Table 4.1 – Example single time point conditioning schedule

Conditioning time	Elapsed time	Comment
24 ± 1 h	1 d	Exposure water is decanted and discarded; the exposure vessel or product is refilled with exposure water and conditioning is continued.
24 ± 1 h	2 d	Exposure water is decanted and discarded; the exposure vessel or product is refilled with exposure water and conditioning is continued.
24 ± 1 h	3 d	Exposure water is decanted and discarded; the exposure vessel or product is refilled with exposure water and conditioning is continued.
24 ± 1 h	4 d	Exposure water is decanted and discarded; the exposure vessel or product is refilled with exposure water and conditioning is continued.
72 ± 1 h	7 d	Exposure water is decanted and discarded; the exposure vessel or product is refilled with exposure water and conditioning is continued.
24 ± 1 h	8 d	Exposure water is decanted and discarded; the exposure vessel or product is refilled with exposure water and conditioning is continued.
24 ± 1 h	9 d	Exposure water is decanted and discarded; the exposure vessel or product is refilled with exposure water and conditioning is continued.
24 ± 1 h	10 d	Exposure water is decanted and discarded; the exposure vessel or product is refilled with exposure water and conditioning is continued.
24 ± 1 h	11 d	Exposure water is decanted and discarded; the exposure vessel or product is refilled with exposure water and conditioning is continued.
72 ± 1 h	14 d	Exposure water is decanted and discarded; conditioning is terminated.

Table 4.2 – Single time point exposure schedule

Exposure time	Elapsed time¹	Comment
24 ± 1 h (optional)	15 d (optional)	Extraction water is decanted and discarded; the exposure vessel or product is refilled with exposure water and exposure is continued.
24 ± 1 h (optional)	16 d (optional)	Extraction water is decanted and discarded; the exposure vessel or product is refilled with exposure water and exposure is continued.
16 h	17 d (15 d if the two optional exposure periods are not elected)	Extraction water is collected for analysis.
¹ Elapsed time indicated includes the 14 d of conditioning preceding the exposure.		

Table 4.3 – Example multiple time point conditioning/exposure schedule

Exposure time	Elapsed time	Sample collection
24 ± 1 h	1 d	Extraction water is collected for analysis at completion of the exposure period; the product or exposure vessel is refilled with exposure water and the exposure is continued.
24 ± 1 h	2 d	Extraction water is collected for analysis at completion of the exposure period; the product or exposure vessel is refilled with exposure water and the exposure is continued.
24 ± 1 h	3 d	Extraction water is decanted and discarded; the product or exposure vessel is refilled with exposure water and the exposure is continued.
24 ± 1 h	4 d	Extraction water is collected for analysis at completion of the exposure period; the product or exposure vessel is refilled with exposure water and the exposure is continued.
72 ± 1 h	7 d	Extraction water is decanted and discarded; the product or exposure vessel is refilled with exposure water and the exposure is continued.
24 ± 1 h	8 d	Extraction water is collected for analysis at completion of the exposure period; the product or exposure vessel is refilled with exposure water and the exposure is continued.
24 ± 1 h	9 d	Extraction water is decanted and discarded; the product or exposure vessel is refilled with exposure water and the exposure is continued.
24 ± 1 h	10 d	Extraction water is collected for analysis at completion of the exposure period; the product or exposure vessel is refilled with exposure water and the exposure is continued.
96 ± 1 h	14 d	Extraction water is decanted and discarded; the product or exposure vessel is refilled with exposure water and the exposure is continued.
24 ± 1 h	15 d	Extraction water is collected for analysis at completion of the exposure period; the product or exposure vessel is refilled with exposure water and the exposure is continued.
72 ± 1 h	18 d	Extraction water is decanted and discarded; the product or exposure vessel is refilled with exposure water and the exposure is continued.
24 ± 1 h	19 d	Extraction water is collected for analysis at completion of the exposure period; the exposure is terminated.

Table 4.4 – Pipes – normalization factors and assumptions

Product nominal diameter	Assumptions	Exposure type	N1	N2 (flowing condition)
non-copper pipe nominal ≥ 10 cm (4 in)	<ul style="list-style-type: none"> – water is exposed to the same material from the treatment plant to the service line – a 16-h exposure period is evaluated 	in-product	1	1
		in-vessel	calculated according to 4.7.1	1
10 cm (4 in) > nominal ≥ 1.3 cm (0.5 in)	<ul style="list-style-type: none"> – a 16-h exposure period is evaluated – residential water usage is 681 L (180 gal) per 24 h – 100 ft of service line from water main to residence 	in-product	1	calculated according to 4.7.1
		in-vessel	calculated according to 4.7.1	calculated according to 4.7.1
nominal < 1.3 cm (0.5 in)	<ul style="list-style-type: none"> – a maximum run of 7.6 m (25 ft) of small diameter product is installed – for products with an internal volume less than 1 L (0.26 gal), $V_{F(\text{static})}$ is set equal to 1 L – a 16-h exposure period is evaluated – residential water usage is 681 L (180 gal) per 24 h – 280 ft per residence (140 ft each for hot and cold sides) 	in-product	1	calculated according to 4.7.1
		in-vessel	calculated according to 4.7.1	calculated according to 4.7.1
copper pipe ≥ 10 cm (4 in)	<ul style="list-style-type: none"> – utilized as main distribution lines within buildings¹ – a 16-h exposure period is evaluated 	in-product	1	0.55
		in-vessel	calculated according to 4.7.1	0.55

¹ The N2 value for copper products used as main distribution lines in buildings was calculated based on the static volume of a piping network of up to 20 mi and an average flow of 100 gpm.

Table 4.5 – Fittings (installed at regular intervals) – normalization factors and assumptions

Product nominal diameter	Assumptions	Exposure type	N1	N2 (flowing condition)
Nominal ≥ 10 cm (4 in)	<ul style="list-style-type: none"> – water is exposed to the same material from the treatment plant to the service line – fittings represent 2% of the distribution system surface area – a 16-h exposure period is evaluated 	in-product	0.02	1
		in-vessel	calculated according to 4.7.1 and multiplied by 0.02	1
10 cm (4 in) > nominal ≥ 1.3 cm (0.5 in)	<ul style="list-style-type: none"> – fittings represent 2% of the piping system for products 10 cm (4 in) > nominal ≥ 2.5 cm (1.0 in) (rigid and flexible systems) – fittings represent 6% of the piping system surface area for products 2.5 cm (1.0 in) > nominal ≥ 1.3 cm (0.5 in) (rigid systems)¹ – fittings represent 3% of the piping system surface area for products 2.5 cm (1.0 in) > nominal ≥ 1.3 cm (0.5 in) (flexible systems)¹ – a 16-h exposure period is evaluated – residential water usage is 681 L (180 gal) per 24 h – 100 ft of service line from water main to residence 	in-product	0.02, 0.06, or 0.03 depending on product diameter and end use (flexible or rigid system)	calculated according to 4.7.1
		in-vessel	calculated according to 4.7.1 and multiplied by 0.02, 0.06, or 0.03 depending on product diameter and end use (flexible or rigid system)	calculated according to 4.7.1
nominal < 1.3 cm (0.5 in)	<ul style="list-style-type: none"> – a maximum run of 7.6 m (25 ft) of small diameter product is installed – fittings represent 6% of the residential system surface area for rigid piping systems¹ – fittings represent 3% of the residential system surface area for flexible piping systems¹ – a 16-h exposure period is evaluated – residential water usage is 681 L (180 gal) per 24 h – 280 ft of pipe per residence (140 ft) each for hot and cold sides) 	in-product	0.06 or 0.03 depending on product end use (flexible or rigid system)	calculated according to 4.7.1
		in-vessel	calculated according to 4.7.1 and multiplied by 0.06 or 0.03 depending on product end use (flexible or rigid system)	calculated according to 4.7.1

¹ For products that may be used with either rigid or flexible systems, fittings shall be assumed to represent 6% of the piping system surface area.

Table 4.6 – Example normalization calculations

In-product exposure of a 30.5 cm (1 ft) length of 15.2 cm (6 in) i. d. pipe	
Parameters: SA _F = 1459 cm ² (226 in ²) SA _L = 1459 cm ² (226 in ²) V _{F(static)} = 5.6 L (1.5 gal) V _L = 5.6 L (1.5 gal)	normalized flowing concentration = $\frac{226 \text{ in}^2}{226 \text{ in}^2} \times \frac{1.5 \text{ gal}}{1.5 \text{ gal}} \times 1 \times \text{laboratory concentration}$
In-vessel exposure of a 2.5 cm (1 in) i. d. pipe	
Parameters: SA _F / V _{F(static)} = 1575 cm ² /1 L (924 in ² /1 gal) SA _L = 247 in ² (1 594 cm ²) V _L = 0.2 gal (0.8 L)	normalized static concentration = $\frac{924 \text{ in}^2}{247 \text{ in}^2} \times \frac{0.2 \text{ gal}}{1 \text{ gal}} \times \text{laboratory concentration}$
In-product exposure of a 63.5 cm (25 ft) length of 0.6 cm (0.25 in) i. d. pipe	
Parameters: SA _F = 1520 cm ² (235.6 in ²) SA _L = 1520 cm ² (235.6 in ²) V _{F(static)} = 0.24 L (0.064 gal) – default to 1 L (0.26 gal) V _L = 0.24 L (0.064 gal)	normalized static concentration = $\frac{235.6 \text{ in}^2}{235.6 \text{ in}^2} \times \frac{0.064 \text{ gal}}{0.26 \text{ gal}} \times \text{laboratory concentration}$
In-product exposure of a 25.4 (10 in) long 15.2 (6 in) i. d. fitting	
Parameters: SA _F = 1216.1 cm ² (188.5 in ²) SA _L = 1216.1 cm ² (188.5 in ²) V _{F(static)} = 4.6 L (1.2 gal) V _L = 4.6 L (1.2 gal)	normalized flowing concentration = $\frac{188.5 \text{ in}^2}{188.5 \text{ in}^2} \times \frac{1.2 \text{ gal}}{1.2 \text{ gal}} \times 1 \times 0.02 \times \text{laboratory concentration}$
In-vessel exposure of a 1.3 cm (0.5 in) i. d. fitting used with flexible piping systems	
Parameters: SA _F / V _{F(static)} = 3040 cm ² /1 L (1885 in ² /1 gal) SA _L = 1594 cm ² (247 in ²) V _L = 0.8 L (0.2 gal)	normalized static concentration = $\frac{1885 \text{ in}^2}{247 \text{ in}^2} \times \frac{0.2 \text{ gal}}{1 \text{ gal}} \times 0.03 \times \text{laboratory concentration}$
In-vessel exposure of a 0.6 cm (0.25 in) i. d. fitting used with rigid piping systems	
Parameters: SA _F / V _{F(static)} = 908 in ² /1 gal (1523 cm ² /1 L) SA _L = 865 in ² (5 581cm ²) V _{F(static)} = 0.064 gal (0.24 L) – default to 0.26 gal (1 L) V _L = 0.4 gal (1.3 L)	normalized static concentration = $\frac{236 \text{ in}^2}{865 \text{ in}^2} \times \frac{0.4 \text{ gal}}{0.26 \text{ gal}} \times 0.06 \times \text{laboratory concentration}$
In-vessel exposure of a 1.3 cm (0.5 in) i. d. fitting used as a repair coupling	
Parameters: SA _F / V _{F(static)} = 3040 cm ² /1 L (1885 in ² /1 gal) V _{F(static)} = 0.003 L (0.0009 gal) default to 1 L (0.26 gal) SA _L = 5581cm ² (865 in ²) V _L = 1.3 L (0.4 gal)	normalized static concentration = $\frac{1.6 \text{ in}^2}{865 \text{ in}^2} \times \frac{0.4 \text{ gal}}{0.26 \text{ gal}} \times \text{laboratory concentration}$
NOTE – Definitions for SA _F , SA _L , V _{F(static)} , V _{F(flowing)} , and V _L are found in 4.7.1.	

5 Barrier materials

5.1 Scope

The requirements of this section apply to products and materials intended to form a barrier providing containment of drinking water or to prevent drinking water contact with another surface. The products and materials that are covered include, but are not limited to, non-residential storage tanks, coatings, paints, linings and liners, bladders, diaphragms, and constituents of concrete and cement-mortar (e. g., Portland and blended hydraulic cements, admixtures, sealers, and mold release agents). These products and materials can be field-applied, factory-applied, precast, or cast in place.

5.2 Definitions

5.2.1 admixture: A material other than water, aggregates, hydraulic cement, and fiber reinforcement used as an ingredient of concrete or mortar and added to the batch immediately before or during its mixing.

5.2.2 aggregate: Granular material, such as sand, gravel, or crushed stone, used with a cementing medium to form hydraulic-cement concrete or mortar.

5.2.3 barrier material: A material in contact with drinking water that serves a containment or separation purpose.

5.2.4 blended hydraulic cement: A hydraulic cement consisting of two or more inorganic constituents (at least one of which is not Portland cement or Portland cement clinker) that separately or in combination contribute to the strength-gaining properties of the cement.

5.2.5 coating/paint: A material applied to a surface where a direct bond to the substrate is formed.

5.2.6 concrete: A composite material that consists essentially of a binding medium within which are embedded particles or fragments of aggregate; in hydraulic-cement concrete, the binder is formed from a mixture of hydraulic cement and water.

5.2.7 diaphragm/bladder: A flexible membrane that separates the surrounding media from the drinking water.

5.2.8 form/mold release agent: A material applied to the inside of a form or mold used to cast concrete or cement-mortar, which prevents adhesion of the concrete or cement-mortar to its surface.

5.2.9 hydraulic cement: A cement that sets and hardens by chemical interaction with water and that is capable of doing so under water.

5.2.10 liners/linings: Prefabricated materials applied, bonded, or attached to a surface that is subject to direct/indirect contact with drinking water.

5.2.11 mortar: A mixture of water, cement, and sand.

5.2.12 Portland cement: A hydraulic cement (usually containing calcium sulfate) produced by pulverizing Portland cement clinker (a partially fused substance consisting primarily of hydraulic calcium silicates).

5.2.13 potable water contact area of tanks: The potable water contact areas of tanks shall include both the area normally submerged during use, and areas where water may condense and fall back into the tank, such as ceilings.

5.2.14 sealer: A liquid that is applied as a coating to the surface of hardened concrete or cement-mortar, either to prevent or to decrease the penetration of liquid or gaseous media during service exposure.

5.3 General requirements

5.3.1 Product labeling

Products or product containers shall be marked and shall include, at a minimum, product identification, batch number, or date of manufacture. When it is not feasible to mark the product or material, the manufacturer shall maintain identification records.

5.3.2 Paints and coatings

For all paints and coatings, the manufacturer shall submit detailed use instructions. Use instructions shall specify the appropriate preparation and application procedures, including order of application for multiple layer systems, substrate preparation (including use of specific primer), subcomponent mixing, induction time, thinning, application method, application thickness(es), curing schedule, and final cure time prior to water immersion.

Coating systems that are composed of multiple products (e. g., primer, intermediate coat/s, and top coat, including any thinners) shall be evaluated as applied systems.

5.4 Sample requirements

When required for evaluation, a sample of the product or material equivalent to that used in field applications shall be obtained.

A single sample can represent a product line of similar formulations (e. g., different colors of the same coating product line) when:

- the sample selected for testing contains all the formulation ingredients of toxicological concern (see 3.2) at concentrations equal to or greater than the products it is selected to represent; and
- product application conditions for the sample selected for testing (e. g., application thickness/es, cure times, solvent concentrations) are equal to or more severe than the products it is selected to represent; and
- for multiple component formulations, the mixing ratio/s of the selected sample is/are identical to that of the products it represents.

5.4.1 Cement samples

Cement samples, weighing a minimum of 9 kg (20 lbs), shall be collected in accordance with the applicable sections of ASTM C 183. To minimize contamination, all sample collection tools shall be cleaned and wiped with isopropyl alcohol before use. Collected samples shall be placed in moisture-proof containers. To minimize organic contamination, sample containers shall not be filled near a running motor or any type of exhaust system.

5.4.2 Concrete cylinder samples

Concrete test cylinders for the evaluation of cast-in-place or precast concrete structures shall be submitted with specific information on the composition of the concrete mix design for the specific installation, including the specific sources of cement, aggregate, admixtures, and any other additives. Specific information on the tank dimensions and water storage capacity shall also be provided. Concrete

batch tickets, collected at the site of production, shall serve as evidence of the concrete mix actually used in the structure being evaluated.

5.4.3 Other barrier materials

Samples of barrier materials shall be collected at the point of manufacture.

5.5 Extraction procedures

5.5.1 Analytical summary

An analytical summary shall be prepared for each product. The analytical summary shall consist of the formulation-dependent analytes identified through the formulation review (see 3.2) and the applicable material-specific analytes listed in table 3.1.

5.5.2 Preparation of test samples

5.5.2.1 In all cases, test samples shall be prepared so that a minimum surface-area-to-volume ratio of 50 cm²/L (29 in²/gal) is achieved during the exposure, and so that the entire surface to be exposed is covered by exposure water. Samples shall be rinsed with cold tap water and then in reagent water that meets the requirements of annex B, section B.9.2.1, unless the manufacturer's instructions direct otherwise.

5.5.2.2 Field-applied paint and coating systems

Field-applied paint & coating systems shall be applied in accordance with the manufacturer's published use instructions (see 5.3.2) under the supervision of the testing laboratory. Products shall be applied to a glass slide when appropriate. Products requiring a reactive substrate shall be applied to the appropriate alternate substrate. Coating products shall be applied using application conditions as specified by the manufacturer in the product use instructions, e. g., the highest recommended percentage of thinner, the shortest curing period between coats or layers, the maximum recommended film thickness per coat, and the shortest final curing period prior to immersion. For exothermic coatings with a maximum field use thickness in excess of 120 mil (3.0 mm), an additional evaluation at the manufacturer's minimum recommended field use thickness shall be conducted. The maximum dry film thickness per coat attested to by the testing laboratory shall be based on the average per coat dry film thickness evaluated.

NOTE – The practical application of coatings may result in spots of coating thicknesses in excess of the maximum dry film thickness per coat attested to by the testing laboratory. Acceptable variations from the maximum dry film thicknesses can occur. The average of spot measurements on each 10 m² (100 ft²) area shall not exceed the specified maximum thickness, and no single spot measurement shall be more than 120% of it. Spot measurements are defined as the average of at least three gauge readings within a 1.5 in (4 cm) diameter circle.

Multiple layer paint and coating systems that require the application of distinct coating product formulations in sequence shall be applied in a stepped manner so as to expose all layers. Multiple coats of the same product (of the same color) applied in sequence shall not constitute multiple layers and shall not be applied in a stepped manner. Multiple coats of the same product (of different colors) applied in sequence shall not constitute multiple layers and shall not be applied in a stepped manner, unless deemed necessary by the testing laboratory to address potential health effects concerns from the differences in color formulations. Stepped coating systems shall be applied per the dimensions in table 5.1.

5.5.2.3 Factory-applied or cured systems

Paint and coating systems requiring factory application, factory curing, or both shall be prepared in accordance with the manufacturer's published use instructions under the supervision of the testing laboratory. These products shall be applied in accordance with the manufacturer's published use instructions (see

5.3.2). Products shall be applied to a glass slide when appropriate. Products requiring a reactive substrate shall be applied to the appropriate alternate substrate. Coating products shall be applied using application conditions as specified by the manufacturer in the product use instructions, e. g., the highest recommended percentage of thinner, the shortest curing period between coats or layers, the maximum recommended film thickness per coat, and the shortest final curing period prior to immersion. For exothermic coatings with a maximum field use thickness in excess of 120 mil (3.0 mm), an additional evaluation at the manufacturer's minimum recommended field use thickness shall be conducted. The maximum dry film thickness per coat attested to by the testing laboratory shall be based on the average per coat dry film thickness evaluated.

NOTE – The practical application of coatings may result in spots of coating thicknesses in excess of the maximum dry film thickness per coat attested to by the testing laboratory. Acceptable variations from the maximum dry film thicknesses can occur. The average of spot measurements on each 10 m² (100 ft²) area shall not exceed the specified maximum thickness and no single spot measurement shall be more than 120% of it. Spot measurements are defined as the average of at least three gauge readings within a 1.5 in (4 cm) diameter circle.

Multiple layer paint and coating systems, which require the application of distinct coating product formulations in sequence, shall be applied in a stepped manner so as to expose all layers. Multiple coats of the same product (of the same color) applied in sequence shall not constitute multiple layers and shall not be applied in a stepped manner. Multiple coats of the same product (of different colors) applied in sequence shall not constitute multiple layers and shall not be applied in a stepped manner, unless deemed necessary by the testing laboratory to address potential health effects concerns from the differences in color formulations. Stepped coating systems shall be applied per the dimensions in table 5.1.

NOTE – It is recognized that a coating system may be applied using a combination of factory and field application techniques. This is considered acceptable as long as the coating system is tested to the manufacturer's recommended application conditions, as specified in 5.5.2.2 and 5.5.2.3.

5.5.2.4 Products requiring cement mortar cubes

Test sample mortar cubes shall be prepared in accordance to the applicable sections of ASTM C 109. Mix water shall meet reagent water requirements (see annex B, section B.9.2.1). Sand shall be washed in accordance with the procedures in ASTM C 778. Mixing tools and other items coming into contact with the mortar shall be washed with soap and water, rinsed with tap water, rinsed with reagent water, and rinsed with isopropyl alcohol. The mortar shall be placed in polyethylene or polypropylene lined molds; no form release agents shall be used. Specimens shall be removed from the molds after 24 h and placed in glass or polyethylene beakers and covered with an inverted watch glass supported on glass Rebel hooks (or other devices to prevent air seal of the vessel) and placed for 28 d ± 12 h, or fewer as specified by the manufacturer, in a moist cabinet meeting the requirements of ASTM C 511. The specimens shall be removed from the moist cabinet and air dried at 23 ± 2 °C (73 ± 4 °F) and 50 ± 2% relative humidity for 7 d.

5.5.2.4.1 Portland and hydraulic cements

Test cubes for Portland and blended hydraulic cements shall be prepared in accordance with 5.5.2.4.

5.5.2.4.2 Admixtures

Admixtures shall be added to the cement-mortar or concrete mixture using the manufacturer's highest recommended admixture dosage. The test samples shall be prepared as described in 5.5.2.4.

5.5.2.4.3 Sealers

These products shall be applied per the manufacturer's recommendations to the test cubes prepared in accordance with 5.5.2.4. The coated cubes shall be allowed to cure for the manufacturer's recommended time period.

5.5.2.4.4 Form and mold release agents

These products shall be applied per manufacturer specifications to the mold used during the preparation of the test cubes (see 5.5.2.4).

5.5.2.5 Concrete water storage tanks

Concrete test cylinders (4" x 8") shall be prepared according to ASTM C 31 or ASTM C 192, and moist cured in an ASTM C 511 cabinet for a minimum of 3 d. Cylinder molds shall be manufactured of virgin materials free of detectable concentrations of any interfering contaminants.

5.5.3 Exposure water

Exposure water selection shall be determined by the analytes of interest identified on the analytical summary (see 5.5.1). Exposure water(s) shall be selected in accordance with annex B, section B.2.5.

5.5.4 Conditioning

Test samples shall be conditioned immediately after curing. This conditioning procedure simulates the disinfection of water storage tanks prior to placing into service. The method, described below, is based on Method 2 of AWWA C652-92.

- 1) prepare 200 mg/L 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 30 min; and
- 4) place the test samples in racks, rinse with cold tap water, and rinse with reagent water that meets the requirements of annex B, section B.9.2.1.

5.5.5 Exposure protocols

For all test samples, exposure shall commence immediately after the conditioning step. If immediate exposure is not possible, the test samples shall be dried in a laminar flow hood and exposed within 4 h. Successful evaluation at an elevated exposure temperature shall preclude testing at a lower exposure temperature. A separate sample shall be exposed for each type of exposure water selected in 5.5.3.

The exact surface area-to-volume ratio achieved during the exposure shall be recorded.

5.5.5.1 Cold application

Cold application product samples, as designated by the manufacturer, shall be placed in an exposure vessel and completely covered with exposure water of the applicable pH (see 5.5.3). The exposure vessel shall be placed in a 23 ± 2 °C (73 ± 4 °F) environment for the duration of the exposure period.

5.5.5.2 Domestic hot application

Products that are intended for domestic hot applications as designated by the manufacturer (e. g., for use in single-family dwellings) shall be placed in an exposure vessel and completely covered with exposure water of the applicable pH (see 5.5.3). The exposure vessel shall be placed in a 60 ± 2 °C (140 ± 4 °F) environment for the duration of the exposure period.

5.5.5.3 Commercial hot application

Products that are intended for commercial hot applications, as designated by the manufacturer, (e. g., for use in multiple-family dwellings, restaurants, or hospitals) shall be placed in an exposure vessel and completely covered with exposure water of the applicable pH (see 5.5.3). The exposure vessel shall be placed in an 82 ± 2 °C (180 ± 4 °F) environment for the duration of the exposure period.

5.5.5.4 Single time point exposure protocol

When normalized contaminant concentrations from the product (e. g., flexible membrane liners) are expected to be less than their acceptable concentrations (see annex A) when tested at a single time point, the product shall be exposed according to the protocol in table 5.2. Extraction water samples shall be collected at the conclusion of the final exposure period.

5.5.5.5 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.

5.5.6 Collection and preservation of extraction water

Immediately after the exposure period, the extraction water shall be poured into previously prepared sample containers for storage as detailed in annex B, section B.6, until analysis. Extraction water for solvent analysis shall be collected in a sample bottle containing sodium thiosulfate in a quantity sufficient to neutralize any residual chlorine, if applicable.

5.6 Analysis of extraction water

Extraction waters shall be analyzed with the methods listed in annex B, section B.7.

5.7 Normalization

5.7.1 Normalization for tanks/storage vessels

5.7.1.1 The following equation shall be used to calculate the normalized concentration of each contaminant for tanks or other storage vessels:

$$\text{normalized contaminant concentration} = \text{laboratory contaminant concentration} \times \frac{SA_F}{V_F} \times \frac{V_L}{SA_L} \times \frac{24 \text{ h}}{\text{hours of exposure}}$$

where:

SA_F/V_F = Surface area to volume ratio for the specified tank capacity, as defined in table 5.4

SA_L = Surface area exposed in the laboratory

V_L = Volume of extraction water used in the laboratory

When the length of the exposure being normalized is other than 24 h in length, the normalized value shall be adjusted to reflect a 24-h exposure.

Products used as barriers for tanks or storage vessels shall use the surface-area-to-volume ratios shown in table 5.4. Surface-area-to-volume ratios for products used as barriers in tanks or storage vessels with a capacity other than those shown in table 5.4 shall be determined on a case-by-case basis, as described in 5.7.1.2.

5.7.1.2 Calculation of the surface-area-to-volume ratio for tanks or storage vessels

The following assumptions shall be used in determining the surface-area-to-volume ratio for each nominal tank capacity:

- the tank has a smooth interior surface;
- the tank is cylindrical in shape;
- the tank is installed in a vertical position; and
- the roof (ceiling) of the tank is in contact with drinking water.

The following equation shall be used to calculate the surface-area-to-volume ratio for tanks or storage vessels of capacities that do not appear in table 5.4:

$$\text{surface area to volume ratio (in}^2\text{/L)} = 119.5 \times \frac{(0.1702 \times Y/X)^{0.66} \times (X + \frac{1}{2})}{Y}$$

where:

X = the length/diameter ratio of the tank or storage vessel

Y = the volume (in gallons) of the tank or storage vessel

5.7.2 Normalization for all other end uses

For barrier materials that have end uses other than in tanks or storage vessels, normalization shall be performed using the following equation, or to the normalization requirements of the section of this Standard which addresses the specific end use of the barrier material.

$$NF = N1 \times N2$$

$$N1 = \frac{SA_F}{SA_L} \times \frac{V_L}{V_{F(\text{static})}}$$

$$N2 = \frac{V_{F(\text{static})}}{V_{F(\text{flowing})}}$$

where:

SA_F = surface area exposed in the field;

SA_L = surface area exposed in the laboratory;

V_L = volume of extraction water used in the laboratory;

$V_{F(\text{static})}$ = volume of water to which the product is exposed under static conditions; and

$V_{F(\text{flowing})}$ = volume of water to which the product is exposed under flowing conditions during a period of time equivalent to the laboratory test.

When the length of the exposure being normalized is other than 24 h in length, the normalized value shall be adjusted to reflect a 24-h exposure (e. g., multiply the normalized value by 24/72 when a 3-d exposure was used).

5.7.3 Over time exposure calculations

Laboratory values from each time point for which extractant water was collected (a minimum of five data points is required) shall be normalized as indicated in 5.7.1 or 5.7.2, depending on product end use. A decay curve of these normalized contaminant concentrations in relation to elapsed exposure time shall be plotted. A contaminant concentration at Day 90 of exposure shall be extrapolated from this data.

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 after this time point (95 d of elapsed time).

5.8 Evaluation of contaminant concentrations

5.8.1 Contaminants measured at a single time point

Normalized contaminant concentrations shall be no greater than their respective SPACs determined in accordance with annex A.

5.8.2 Contaminants measured over time

Normalized Day 1 contaminant concentrations shall not exceed the short-term exposure level (STEL) as defined in annex A, section A.5. Extrapolated Day 90 contaminant concentrations shall not exceed their respective SPACs determined in accordance with annex A.

Table 5.1 – Paint and coating system sample preparation

Number of layers in system	Layer	Panel surface area exposed for each layer
one layer	—	entire panel
two layer	primer layer	$\frac{1}{3}$
	top layer	$\frac{2}{3}$
three layer	primer layer	$\frac{1}{6}$
	intermediate layer	$\frac{1}{3}$
	top layer	$\frac{1}{2}$
four layer	primer layer	$\frac{1}{12}$
	first intermediate layer	$\frac{1}{6}$
	second intermediate layer	$\frac{1}{4}$
	top layer	$\frac{1}{2}$

NOTE – A layer is one or more coats of the same coating material.

Table 5.2 – Single time point exposure sequence

Length of exposure	Elapsed time	Sample collection
24 ± 1 h	1 d	discard extractant water and refill
24 ± 1 h	2 d	discard extractant water and refill
48 ± 4 h	4 d	discard extractant water and refill
24 ± 1 h	5 d	extractant water collected for analysis at conclusion of exposure period

NOTE – Sample exposures are sequential: decant and discard extraction water, refill container, and continue exposure.

Table 5.3 – Multiple time point exposure sequence

Length of exposure	Elapsed time	Sample collection
24 ± 1 h	1 d	extractant water collected for analysis
24 ± 1 h	2 d	extractant water collected for analysis
48 ± 4 h	4 d	discard extractant water and refill
24 ± 1 h	5 d	extractant water collected for analysis
6 ± 1 d	11 d	discard extractant water and refill
24 ± 1 h	12 d	extractant water collected for analysis
6 ± 1 d	18 d	discard extractant water and refill
24 ± 1 h	19 d	extractant water collected for analysis
6 ± 1 d	25 d	discard extractant water and refill
24 ± 1 h	26 d	extractant water collected for analysis
6 ± 1 d	32 d	discard extractant water and refill
24 ± 1 h	33 d	extractant water collected for analysis

NOTE – Sample exposures are sequential: decant required volume for analysis when indicated, discard any remaining extraction water, refill container, and continue exposure.

Table 5.4 – Surface-area-to-volume ratios for tanks or storage vessels

Nominal capacity (gal)	Surface area (ft ²) ¹	Length/diameter ratio	Surface-area-to-volume ratio (in ² /1 L)
5	5.3	5.0	40.4
10	8.4	5.0	32.0
25	15.5	5.0	23.6
50	22.0	3.0	16.8
75	28.9	3.0	14.6
100	35.0	3.0	13.3
200	55.1	2.9	10.5
300	71.3	2.7	9.0
400	85.8	2.6	8.2
500	99.0	2.5	7.5
600	110	2.3	7.0
700	121	2.2	6.6
800	132	2.1	6.3
900	141	1.9	5.9
1,000	150	1.8	5.7
1,500	196	1.8	5.0
2,000	238	1.8	4.5
3,000	312	1.8	4.0
4,000	378	1.8	3.6
5,000	438	1.8	3.3
6,000	495	1.8	3.1
7,000	548	1.8	3.0
8,000	600	1.8	2.9
9,000	648	1.8	2.7
10,000	696	1.8	2.6
20,000	1,104	1.8	2.1
30,000	1,447	1.8	1.8
40,000	1,753	1.8	1.7
50,000	2,034	1.8	1.6
60,000	2,297	1.8	1.5
70,000	2,545	1.8	1.4
80,000	2,782	1.8	1.32
90,000	3,010	1.8	1.27
100,000	3,228	1.8	1.23
200,000	5,125	1.8	0.97
250,000	5,946	1.8	0.90
500,000	9,439	1.8	0.72
750,000	12,370	1.8	0.63
1,000,000	14,980	1.8	0.57
1,500,000	19,630	1.8	0.50
2,000,000	23,780	1.8	0.45
5,000,000	43,810	1.8	0.33
7,500,000	57,400	1.8	0.29
10,000,000	69,530	1.8	0.26

¹ Surface area calculations include the sides, floor, and roof (ceiling) of a tank.

6 Joining and sealing materials

6.1 Coverage

This section covers materials that join or seal pipes and related products (e. g., tanks); protective (barrier) materials; and mechanical devices that contact drinking water.

6.2 Definitions

6.2.1 flux: A formulation intended to remove traces of surface oxides, to promote wetting, and to protect surfaces to be soldered or brazed from oxidation during heating.

6.2.2 gaskets and sealing materials: Materials used to fill a hole or joint to prevent leakage.

6.2.3 joining materials: Materials that form a bond when used to put parts together.

6.2.4 lubricant: A substance interposed between two surfaces for the purpose of reducing the friction or wear between them.

6.3 Material and extraction testing requirements

Samples for testing shall be prepared as specified by the manufacturer's written instructions, and exposed as outlined in annex B. Any contaminants extracted shall have normalized concentrations no greater than the limits specified in annex A.

6.4 Items of special significance

The manufacturer shall supply written information relative to the product's intended end uses and applications.

7 Process media

7.1 Scope

The requirements in this section apply to process media products intended for the reduction of dissolved or suspended materials present in drinking water. The products that are covered include, but are not limited to, process media used in the following processes: ion exchange, adsorption, oxidation, aeration, and filtration.

7.2 Definitions

7.2.1 adsorption: The retention of a gas, liquid, solid, or dissolved material onto the surface of a solid.

7.2.2 adsorption media: A process media material upon which a gas, liquid, solid, or dissolved material will be retained.

7.2.3 aeration: The process of bringing water into contact with air in order to expedite the transfer of gas between the two phases.

7.2.4 aeration packing media: Media used in aerators to increase the surface area of the liquid being processed, resulting in increased liquid-to-air contact and improved gas transfer.

7.2.5 filtration: The process of passing a dilute liquid suspension through filter media to reduce the concentration of suspended or colloidal matter.

7.2.6 filtration media: Process media through which a liquid is passed for the purpose of filtration.

7.2.7 ion exchange: A chemical process in which ions are reversibly interchanged between a liquid and a solid.

7.2.8 ion exchange resins: Process media consisting of insoluble polymers having functional groups capable of exchanging ions.

7.2.9 low-density process media: Process media such as diatomaceous earth, perlite, or other media, which have a bulk density of less than 500 g/L and are used for filtration purposes.

7.2.10 oxidative media: Process media that chemically facilitate oxidation on the media surface and thereby enhance removal of ions from water.

7.2.11 process media: Water insoluble material used to reduce the concentration of dissolved or suspended substances in water through such operations as ion exchange, aeration, adsorption, oxidation, and filtration.

7.2.12 reductive media: Process media that chemically facilitate reduction on the media surface and thereby enhance removal of ions from water.

7.3 General requirements

7.3.1 Manufacturer use instructions

All process media products shall be accompanied by detailed manufacturer use instructions that shall also appear on the product packaging or other technical literature. For process media products that are dosed (e. g., powdered activated carbon), use instructions shall include the maximum dose at which the product can be acceptably used (as determined by evaluation to the requirements of this section).

7.3.2 Product labeling

Process media product containers shall facilitate traceability to the production location and shall, at a minimum, contain the following information:

- manufacturer's name and address;
- production location identifier;
- product identification (product type and, when applicable, trade name);
- net weight;
- when applicable, mesh or sieve size;
- lot number; and
- when appropriate, special handling, storage, and use instructions.

7.3.3 Product line evaluation

When a line of products is manufactured to the same material formulation and contains identical ingredients, product evaluation shall be preferentially conducted on the product form that has the highest surface-area-to-volume ratio (smallest particle size). Products of a lower surface-area-to-volume ratio (larger particle size) shall be considered to have met the requirements of this section when a higher surface-area-to-volume ratio product, belonging to the same line of products and having an identical use, has been demonstrated to meet the requirements of this section.

7.4 Sample requirements

A representative sample of the media shall be reduced to three test samples, each of a sufficient quantity for the extraction procedures described in 7.5. The three test samples shall be placed and stored in airtight, moisture-proof, sealed glass containers. If a glass container is inappropriate, containers made from some other inert material recommended by the manufacturer shall be used. Each container shall be clearly labeled with product name, type of sample, manufacturer name, sampling data, production location, lot number, and the name of the individual who collected the sample. One sample shall be used for exposure and analysis; the remaining two samples shall be retained for re-evaluation purposes.

7.5 Extraction procedures

7.5.1 Analytical summary

An analytical summary shall be prepared for each product. The analytical summary shall consist of the formulation-dependent analytes identified in accordance with 3.3 and the applicable product-specific minimum test batteries listed in table 7.1.

7.5.2 Wetting

Point-of entry system media receive wetting as specified in 7.5.5.4.

Process media that receive conditioning shall be immersed completely (wetted) in tap water prior to conditioning and exposure. The weight of the sample to be wetted shall be at least equal to the amount of media required to perform the exposure at the specified weight-to-volume ratio (see tables 7.2 and 7.3).

NOTE – For example, a media for which 2 L (0.53 gal) of extractant water is required to perform the selected analyses, and the media is exposed at 25 g/L, a minimum of 50 g of media is wetted.

For low-density process media, 0.5 L (0.13 gal) of the process media shall be wetted; the weight of this volume of media shall be measured and recorded prior to wetting.

Following the specified wetting period, the sample shall be completely drained and the water discarded.

7.5.2.1 Granular activated carbon

Granular activated carbon (GAC) test samples shall be wetted for 16 ± 1 h.

7.5.2.2 Other process media products

All other process media that receive conditioning shall be wetted for 60 ± 10 min.

7.5.3 Conditioning (backwashing)

Point-of entry system media receive conditioning as specified in 7.5.5.4.

7.5.3.1 Filtration and adsorption media

Wetted filtration or adsorption media (excluding diatomaceous earth, perlite, and powdered activated carbon (PAC) products, and other media of < 0.25 mm diameter) shall be placed in a conditioning chamber (a glass column with a minimum inner diameter of 2 in). The amount of media conditioned shall be sufficient to meet or exceed its specific weight-per-volume ratio (see table 7.2) and to generate sufficient exposure water to complete the selected analyses. Tap water shall be directed slowly upward through the conditioning system until the entire amount of media is flooded. The media shall then be backwashed at a flow rate that fluidizes the media or attains sufficient transport velocities to remove extraneous particulate matter; the maximum wetted media expansion rates for various process media

products are indicated in table 7.3. Filtration and adsorption media shall be subjected to the prescribed backwash for 30 ± 2 min.

7.5.3.2 Diatomaceous earth, perlite, PAC, and other process media

Diatomaceous earth, perlite, PAC, and all other process media with functions other than filtration or adsorption shall not be conditioned unless the manufacturer's use instructions stipulate a specific conditioning protocol.

7.5.3.3 Special post-conditioning procedures for sand and anthracite products

Upon completion of the backwash, 1% to 1.5% of the sand or anthracite column (by height) shall be scraped away and discarded.

7.5.4 Exposure water

All exposure water that is being used to determine compliance to this Standard shall be prepared fresh daily and stored in a closed container.

7.5.4.1 Adsorption media

Adsorption media shall be exposed in a pH 5 sodium dihydrogen phosphate buffer, prepared by mixing 0.1 M NaH_2PO_4 , 0.04 M MgCl_2 , and reagent water that meets the requirements of annex B, section B.9.2.1, at a ratio of 1:1:18, respectively.

7.5.4.2 All other process media

All other process media shall be exposed, based on a formulation review and determination of the most severe condition(s), to one or more appropriate extraction waters as detailed in annex B, section B.9 and Table B3.

7.5.5 Exposure protocols

Table 7.2 contains the weight-per-volume ratios for exposure of process media.

7.5.5.1 Adsorption media

7.5.5.1.1 Media of < 0.25 mm in diameter

Immediately after completion of wetting, the media sample shall be exposed in an appropriately sized vessel. The amount of media exposed per volume of exposure water (see 7.5.4.1) shall be sufficient to meet or exceed its specific weight-per-volume ratio according to table 7.2, and to generate sufficient exposure water to complete the selected analyses. The vessel shall be covered and placed on a magnetic stirrer for 60 ± 5 min. Immediately after the exposure period, the liquid portion of the exposure shall be passed through a Whatman¹³ #41 filter and a 0.45 μ filter, and the resulting filtrate shall be collected. The solid portion of the exposed sample remaining on the filter shall be dried and weighed, and used to calculate the evaluation dose.

7.5.5.1.2 Media of ≥ 0.25 mm in diameter

Immediately after completion of conditioning, the media sample shall be exposed in an appropriately sized vessel. The amount of media exposed per volume of exposure water (see 7.5.4.1) shall be sufficient to meet or exceed its specific weight-per-volume ratio in table 7.2 and to generate sufficient exposure water to complete the selected analyses. The contents of the vessel shall be mixed to ensure

¹³ Whatman PLC, 27 Great West Road, Brentford, Middlesex TW8 9BW, UK

that the entire sample is in contact with the exposure water. The vessel shall be sealed with polytetrafluoroethylene (PTFE), and the sample shall be exposed according to the schedule outlined in table 7.4. The weight-to-volume ratio shall be recorded at the time of exposure and shall represent the evaluation dose.

7.5.5.2 Filtration media, ion exchange resins, synthetic media, and all other process media

Immediately after completion of wetting, or conditioning if applicable, the media sample shall be exposed in an appropriately sized vessel. The amount of media exposed per volume of exposure water (see 7.5.4) shall be sufficient to meet or exceed its specific weight-per-volume ratio in table 7.2 and to generate sufficient exposure water to complete the selected analyses. The contents of the vessel shall be mixed to ensure that the entire sample is in contact with the exposure water. The vessel shall be sealed with PTFE, and the sample shall be exposed according to the schedule outlined in table 7.4. The weight-to-volume ratio shall be recorded at the time of exposure and shall represent the evaluation dose.

7.5.5.3 Aeration packing media

Aeration packing media shall be exposed in appropriately sized vessels at a surface-area-to-volume ratio greater than or equal to its manufacturer's recommended field surface-area-to-volume ratio and in a volume of exposure water sufficient to complete the selected analyses. The vessel shall be sealed with PTFE, and the sample shall be exposed according to the schedule outlined in table 7.4.

NOTE – The volume of extraction water can be proportionately increased if an additional amount of media was prepared in order to complete the selected analyses.

7.5.5.4 Point-of-entry system media

Point-of-entry system media shall be exposed at a weight to volume ratio greater than or equal to that specified in table 7.2.

7.5.5.4.1 Point-of-entry system media shall be placed in a suitable exposure vessel and shall be installed, flushed, and conditioned in accordance with the manufacturer's instructions using the exposure water specified in 7.5.4 at an initial inlet static pressure of 340 kPa (50 psig).

7.5.5.4.2 After media are flushed and conditioned in accordance with 7.5.5.4.1, the exposure vessel shall be refilled with the exposure water specified in 7.5.4 and maintained for 24 h at a temperature of 23 ± 2 °C (73 ± 3 °F). A 2-L water sample shall then be collected in accordance with 7.5.5.4.3. The exposure vessel shall then be flushed with 5 unit volumes and maintained for another 24 h at an ambient temperature of 23 ± 2 °C (73 ± 3 °F). A second 2-L water sample shall be collected in accordance with 7.5.5.4.3. The exposure vessel shall then be flushed with 5 unit volumes, refilled, and maintained for a third period of 24 h at a temperature of 23 ± 2 °C (73 ± 3 °F). A third 2-L water sample shall be collected in accordance with 7.5.5.4.3.

7.5.5.4.3 A minimum sample volume of 2 L shall be collected at each sample point. If the water holding volume of the exposure vessel is greater than 2 L, the entire volume shall be collected in a suitable collection vessel, and a 2-L subsample obtained from this volume. If the water holding volume of the exposure vessel is less than 2 L, sufficient vessels shall be exposed to provide the required 2 L volume of extractant water.

7.5.5.4.4 All samples collected shall be composited.

7.5.6 Collection and preservation of extraction water

Immediately after exposure, extraction waters shall be poured into previously prepared sample containers for storage until analysis, as specified in annex B, section B.6.

7.6 Analysis

Extraction waters shall be analyzed with the methods listed in annex B, section B.7.

7.7 Normalization

The concentration of analytes present in the extraction water shall be multiplied by calculated normalization factors to account for differences between the actual laboratory evaluation ratio and the weight-per-volume ratio in table 7.2.

7.7.1 Process media except for activated carbon media and aeration packing media

The concentration reported by the laboratory shall be normalized with the following equation (Equation 1):

$$\text{normalized contaminant concentration} = \text{laboratory contaminant concentration} \times \frac{\text{weight per volume ratio (mg/L)}}{\text{laboratory evaluation ratio (mg/L)}}$$

This equation shall be used to normalize filtration media, ion exchange resins, synthetic media, and other media to the weight-per-volume ratios listed in table 7.2.

7.7.2 Activated carbon media for non-point-of-entry system applications

The concentration reported by the laboratory shall be normalized with the following equation:

$$\text{normalized contaminant concentration} = \text{laboratory contaminant concentration} \times \frac{250 \text{ mg/L}}{\text{laboratory evaluation ratio (mg/L)}}$$

Equation 2 shall be used to normalize activated carbon media (granular or powdered) to a weight-per-volume ratio of 250 mg/L.

7.7.3 Filter precoat media (e. g., perlite, diatomaceous earth) for non-point-of-entry system applications

The concentration reported by the laboratory shall be normalized with the following equation:

$$\text{normalized contaminant concentration} = \text{laboratory contaminant concentration} \times \frac{\text{manufacturer's use concentration (mg/L)}}{\text{laboratory evaluation ratio (mg/L)}}$$

Equation 3 shall be used to normalize dosed media (except PAC) to the manufacturer's recommended maximum use concentration.

7.7.4 Aeration packing media

The concentration reported by the laboratory shall be normalized with the following equation (Equation 4):

$$\text{normalized contaminant concentration} = \text{laboratory contaminant concentration} \times \frac{SA_F}{SA_L} \times \frac{V_F}{V_{F(\text{flowing})}}$$

where:

SA_L = surface area attained during laboratory exposures;

V_L = volume of exposure water used during laboratory exposures;

SA_F = surface area of the product under field conditions; and

$V_{F(\text{flowing})}$ = minimum volume of water to which the product is exposed in the field under flowing conditions during a period of time equivalent to the laboratory evaluation.

NOTE – When manufacturer use instructions indicate that the aeration product can be subjected to static conditions in the field, normalized concentrations shall be modified to reflect the static condition. For the static condition, the $V_{F(\text{flowing})}$ parameter shall be substituted with $V_{F(\text{static})}$, which is equal to the volume of water contacting the media under static conditions in the field.

7.7.5 Process media except for activated carbon media and aeration packing media

The concentration reported by the laboratory shall be normalized with the following equation:

$$\text{normalized contaminant concentration} = \text{laboratory contaminant concentration} \times \frac{\text{manufacturer's recommended use concentration (mg/L)}}{\text{laboratory evaluation ratio (mg/L)}}$$

The concentration of contaminants known to be associated with any non-media materials or ingredients that could not be dissociated from the media, or materials that would have been released into the effluent of the system in the absence of the physical barrier provided by the media (e. g., the binder used to produce carbon blocks), shall require additional normalization to account for differences between laboratory exposed surface areas and those normally wetted under normal use conditions. This normalization adjustment shall be performed in accordance with annex B, section 8.

NOTE – For instance, carbon block end caps may have more wetted surface area exposed without the carbon block attached to normal system components.

7.8 Evaluation of contaminant concentrations

7.8.1 For process media, normalized contaminant concentrations shall be no greater than their respective SPACs, determined in accordance with annex A.

7.8.2 For aeration packing media and point-of-entry media that require evaluation to the static condition, the normalized static contaminant concentrations shall be no greater than their respective MCLs or TACs, determined in accordance with annex A.

Table 7.1 – Product-specific minimum test batteries for process media products

Product	Primary use	Analytes
activated alumina	adsorption	metals ¹ , nickel, and aluminum
aluminum silicates (e. g., zeolites)	filtration	metals ¹ , GC/MS (base neutral acid scans), and radionuclides
anthracite	filtration	metals ¹ , GC/MS (base neutral acid scans), and radionuclides
diatomaceous earth media	filtration	metals ¹ and radionuclides
garnet	filtration	metals ¹ , GC/MS (base neutral acid scans), and radionuclides
granular activated carbon (GAC)	adsorption	metals ¹ , GC/MS (base neutral acid scans), and radionuclides
gravel	filtration	metals ¹ , GC/MS (base neutral acid scans), and radionuclides
ilmenite	filtration	metals ¹ , GC/MS (base neutral acid scans), and radionuclides
ion exchange resins	ion exchange	residual monomer, other formulation dependent
oxidative media (e. g., manganese green sand)	oxidation	metals ¹ , GC/MS (base neutral acid scans), and radionuclides
perlite	filtration	metals ¹ , GC/MS (base neutral acid scans), and radionuclides
powdered activated carbon (PAC)	adsorption	metals ¹ , GC/MS (base neutral acid scans), and radionuclides
sand	filtration	metals ¹ , GC/MS (base neutral acid scans), and radionuclides
synthetic media	aeration, filtration	formulation dependent

¹ Metals = antimony, arsenic, barium, beryllium, cadmium, chromium, copper, lead, mercury, selenium, thallium

Table 7.2 – Process media exposure weight-per-volume ratios

Media type	Weight-per-volume ¹
adsorption media: activated alumina GAC and PAC	625 ± 25 g/L 25 ± 5 g/L
anthracite and gravel ² : ≤ 3/8" diameter particles > 3/8" diameter particles	625 ± 25 g/L 1250 ± 25 g/L
filter precoat media (e. g, perlite, diatomaceous earth)	10 times the manufacturer's recommended use concentration
filtration media other than anthracite or gravel	625 ± 25 g/L
ion exchange resins	625 ± 25 g/L
synthetic media	625 ± 25 g/L
point-of-entry system media	Manufacturer's recommended use concentration ³

¹ Weight-per-volume of the product on an "as shipped" basis.

² For the size range specified, not more than 8% by weight shall be either finer than or coarser than the designated size limit (AWWA B100-96).

³ For point-of-entry application media, this shall be the maximum value recommended by the manufacturer of the ratio of the weight of media¹ per 'unit void volume' of a point-of-entry system.

Table 7.3 – Maximum conditioning expansion rates for filtration and adsorption media

Media type	Maximum laboratory expansion rate of wetted media (by height) (%)
activated alumina	25 ± 5%
aluminum silicates (zeolites)	25 ± 5%
anthracite	25 ± 5%
garnet	30 ± 5%
granular activated carbon	30 ± 5%
gravel	10 ± 5%
ilmenite	30 ± 5%
manganese greensand	30 ± 5%
sands	20 ± 5%

Table 7.4 – Exposure schedule for process media of ≥ 0.25 mm in diameter

Time	Temperature	Comment
60 ± 5 min	23 ± 1 °C (73 ± 2 °F)	Exposure water is drained/decanted and discarded; the exposure vessel is refilled and exposure is continued.
60 ± 5 min	23 ± 1 °C (73 ± 2 °F)	Exposure water is drained/decanted and discarded; the exposure vessel is refilled and exposure is continued.
60 ± 5 min	23 ± 1 °C (73 ± 2 °F)	Exposure water is collected and filtered for analyses.

8 Mechanical devices

8.1 Coverage

This section covers devices, components, and materials used therein, that are used in treatment/transmission/distribution systems, and are in contact with drinking water intended for human ingestion, drinking water treatment chemicals, or both. Examples are listed in table 8.1. Point-of-use drinking water treatment devices and fire hydrants are not covered by the requirements in this section.

8.2 Definitions

8.2.1 cold water application: A product application that is intended to result in continuous exposure to water of ambient temperature. Products are tested for an end-use temperature of 23 ± 2 °C (73 ± 4 °F).

8.2.2 commercial hot water application: A product application that is intended to result in continuous or intermittent exposure to water that has been raised from ambient temperature. Intermittent exposure is defined as any hot water contact that is not continuous. Products are tested for an end-use temperature of 82 ± 2 °C (180 ± 3 °F).

8.2.3 domestic hot water application: A product application that is intended to result in continuous or intermittent exposure to water that has been raised from ambient temperature. Intermittent exposure is defined as any hot water contact that is not continuous. Products are tested for an end-use temperature of 60 ± 2 °C (140 ± 3 °F).

8.2.4 in-line device: A device (used to measure or control the flow of water) installed on a service line or building distribution system downstream of the water main and upstream of endpoint devices.

8.2.5 building distribution system: A continuous system of piping and related fittings, beginning at the tap on the main, that is intended to convey potable water to points of usage.

8.3 Device, component, or material requirements

8.3.1 General

Devices, components, or materials shall be considered to have met the requirements of this section if at least one of the following conditions is met:

- the devices, components, or materials covered under this section are tested and evaluated according to the procedures specified in annex B, sections B.4 and B.8; or
- the devices, components, or materials meet the requirements of 8.3.2.

When all components or materials, or both, of a device meet the requirements of this section, the device shall also meet the requirements of this section. When all materials of a component meet the requirements of this section, the component shall also meet the requirements of this section.

8.3.2 Evaluation of devices, components, or materials tested to other sections of this Standard

Devices, components, or materials that have been tested to other sections of the Standard shall meet the following criteria:

- they shall be made of the same alloy(s), composition(s), or formula(s);
- they shall have undergone analogous manufacturing processes;
- they shall have been tested at a temperature that meets or exceeds the required exposure temperature in annex B, section B.4;
- they shall have been conditioned for a period of time not more than 14 d, and exposed for a period of time not less than 12 h for in-line devices or 24 h for other mechanical devices; and
- the concentration(s) of the extracted contaminant(s) shall be normalized to the requirements of annex B, section B.8.

8.3.3 Metallic contaminants

When a device or component is qualified through the separate testing of two or more components, the normalized concentrations for each specific metallic contaminant from individual components shall be summed. The total of the normalized metallic contaminant concentrations shall meet the requirements of annex B, section B.8.

8.4 In-line devices, components, and materials

Samples for the testing of in-line devices, components, and materials (see 8.1) shall be selected according to the requirements of annex B, sections B.2.3 and B.4.1. Extraction waters shall be selected according to annex B, section B.2.5. In-line product samples shall be conditioned as indicated in annex B, section B.4.3. After conditioning, the samples shall be exposed as indicated in annex B, section B.4.4.1 and table B8. Normalization shall be as specified in annex B, sections B.8.3 and B.8.4, as applicable.

8.5 Point-of-entry systems, components, and media

8.5.1 Point-of-entry systems

Samples for the testing of point-of-entry systems shall be selected according to the requirements of annex B, sections B.2.3 and B.4.1. Extraction waters shall be selected according to annex B, section

B.2.5. Samples shall be installed, conditioned, and exposed as indicated in annex B, section B.4.4.3. Normalization shall be as specified in annex B, sections B.8.3 and B.8.4, as applicable.

8.5.2 Point-of-entry system components and materials

The evaluation of point-of-entry components that require exposure under pressure to ensure evaluation of all normally wetted surfaces shall be performed according to 8.5.1.

For all other point-of-entry components and materials, samples for the testing shall be selected according to the requirements of annex B, sections B.2.3 and B.4.1. Extraction waters shall be selected according to annex B, section B.2.5. Samples shall be conditioned as indicated in annex B, section B.4.3. Following conditioning, the samples shall be exposed as indicated in annex B, section B.4.4. Normalization shall be as specified in annex B, sections B.8.3 and B.8.4, as applicable.

Brine systems and brine system components (e. g., brine tanks, salt grids float valves) of point-of-entry systems shall not require extraction testing.

8.5.3 Point-of-entry system media

Media used in point-of-entry systems submitted for evaluation separately from a complete point-of-entry system shall be evaluated to the requirements of 7. Media used in point-of-entry systems submitted for evaluation as part of a complete point-of-entry system shall be evaluated to the requirements of 8.5.1.

Evaluations of softener regeneration salts are performed under NSF/ANSI 60: Drinking water treatment chemicals – Health effects.

8.6 Chemical feeders and generators

Samples for the testing of chemical feeders and generators shall be selected according to the requirements of annex B, sections B.2.3 and B.4.1. Chemical feeder and generator samples shall be conditioned as indicated in annex B, section B.4.3. Following conditioning, the samples shall be exposed as indicated in annex B, section B.4.4.2. Normalization shall be as specified in annex B, section B.8.5.

8.7 Other mechanical devices, components, and materials

Samples for the testing of all other mechanical devices, components, and materials shall be selected according to the requirements of annex B, sections B.2.3 and B.4.1. Extraction waters shall be selected according to annex B, section B.2.5. Other mechanical product samples shall be conditioned as indicated in annex B, section B.4.3. Following conditioning, the samples shall be exposed as indicated in annex B, section B.4.4.3 and table B8. Normalization shall be as specified in annex B, sections B.8.3, B.8.4, and B.8.6, as applicable.

Table 8.1 – Examples of mechanical devices

This table is a generic listing of the types of devices covered in this section of the Standard. This table is not intended to be a complete list of all types of mechanical devices. Inclusion of a product does not indicate either a use endorsement of the product or an automatic acceptance under the provisions of this Standard.

chemical feeders – dry feeders (e. g., pellet droppers)	switches and sensors (e. g., water level, pressure, temperature, pH)
pressure gas injection systems pumps	
vacuum injection systems	valves and related fittings (transmission/distribution system)
disinfection/generators – chlorine dioxide – hypochlorite – ozone – ultraviolet	treatment devices used in water treatment facilities (excludes point-of-use devices) – aeration technologies – clarifiers – electro dialysis technologies – microfiltration technologies – mixers – point-of-entry drinking water treatment unit systems – reverse osmosis technologies – screens – strainers – ultrafiltration technologies
electrical wire (e. g., submersible well pump wire)	
pumps	
in-line devices – building distribution system – backflow preventers – building valves – check valves – compression fittings – corporation stops – curb stops – expansion tanks – meter couplings in-line devices specifically excluded – boiler feed valves – drilling and tapping machines – temperature and pressure relief valves – valves with hose thread outlets – water meter test benches	– meter stops – pressure regulators – pressure tanks – service saddles – strainers – valves and fittings – water meters
example point-of-entry (POE) drinking water treatment systems for evaluation under this standard – water softeners – iron filters – whole house/building mechanical sediment filters – whole house/building GAC chlorine reduction filters – whole house UV systems	
example drinking water treatment units that shall not be evaluated as POE under this standard – faucet mount filters – plumbed-in to separate tap – pour-through pitchers – refrigerator filters	

9 Mechanical plumbing devices

9.1 Coverage

This section covers mechanical plumbing devices, components, and materials that are typically installed within the last liter of the distribution system (endpoint devices) and are intended to dispense water for human ingestion. In-line devices are excluded from this section. Point-of-use and point-of-entry water treatment devices are excluded.

9.1.1 Endpoint devices specifically included in the coverage of this section are:

- single-handle and two-handle lavatory faucets (for example: centersets, widespread, mini-spread, and basin cocks), except as exempted in 9.1.2;
- two-hole and single-hole bar faucets;
- single-handle and two-handle kitchen faucets (for example: top mounts, concealed fittings, and wall mounts);
- hot and cold water dispensers;
- drinking fountains, drinking fountain bubblers, and water coolers;
- glass fillers;
- residential refrigerator ice makers;
- flexible plumbing connectors and flexible risers intended for potable water applications;
- supply stops and endpoint control valves; and
- commercial kitchen devices (see 9.2.3), limited to the following:
 - pot and kettle fillers (see 9.2.7);
 - devices with extended standpipes or risers (see 9.2.5); and
 - pre-rinse assemblies that include an auxiliary spout or other outlet.

NOTE 1 – Only the commercial kitchen devices listed above shall be evaluated using the 18.9 L (5 gal) normalization.

NOTE 2 – The base device to which the pre-rinse component is added shall be considered a commercial kitchen device only if it meets the definition of either a pot and kettle filler (see 9.2.7) or a device with extended standpipes or risers (see 9.2.5).

9.1.2 Endpoint devices specifically exempted from the coverage of this section are:

- bath and shower valves, shower heads of all types, and Roman tub valves;
- all drains;
- backflow prevention devices;

- flexible plumbing connectors and flexible risers not intended for potable water applications (i . e. washing machines, dishwashers, etc.);
- pre-rinse assemblies that do not include an auxiliary spout or other outlet; and
- all endpoint devices that are not specifically intended to dispense water for human consumption, including utility, laundry, laboratory, bidet, and shampoo fittings; faucets with a hose thread spout end or with a quick disconnect end; faucets that are self-closing, metering, or electronically activated; and nonlavatory hand wash stations.

9.1.3 Endpoint devices that are exempted from the scope of this section shall be permitted to be evaluated at the option of the manufacturer. With the exception of exempted pre-rinse assemblies, all exempted devices shall be evaluated using the 1 L (0.26 gal) draw. Exempted pre-rinse assemblies shall be evaluated using the 18.9 L (5 gal) draw.

9.2 Definitions

9.2.1 cold mix volume adjustment factor (CMV): The cold water volume of a device divided by the total water volume of the device.

9.2.2 cold water volume: The volume of water contained within the portion of a device that is normally contacted by cold water (from inlet to outlet) when the device is connected to hot and cold water supplies under normal operating conditions. The volume excludes the volume of water contained within the portion of the device that is normally contacted only by hot water.

9.2.3 commercial kitchen device: An endpoint device whose sole application is the delivery of water for food preparation in commercial kitchens.

9.2.4 endpoint device: A single device typically installed within the last 1 L (0.26 gal) of the water distribution system of a building.

9.2.5 extended standpipe or riser device: An endpoint device that includes a vertical component having a minimum height of 41 cm (16 in) measured from the deck to the outlet of the endpoint device, and whose sole application is the delivery of water for food preparation in commercial kitchens.

9.2.6 in-line device: A device (used to measure or control the flow of water) installed on a service line or building distribution system downstream of the water main and upstream from endpoint devices.

9.2.7 pot and kettle filler: An endpoint device whose sole application is the delivery of water to fill pots and kettles in commercial kitchens.

9.2.8 pre-rinse assembly: An endpoint device with a hose and spray whose application is water delivery for the rinsing of tableware in commercial kitchens.

9.2.9 water distribution system (building): A continuous system of piping, devices, and related fittings, beginning after the water meter and water meter setting equipment, that is intended to convey potable water in a building to points of usage.

9.3 Device, component, or material requirements

9.3.1 General

Devices, components, or materials shall be considered to have met the requirements of this section if at least one of the following conditions is met:

- The devices, components, or materials covered under this section are tested and evaluated according to procedures specified in annex B, sections B.5 and B.8; or
- The devices, components, or materials meet the requirements of 9.3.2.

When all components or materials, or both, of a device meet the requirements of this section, the device shall also meet the requirements of this section. When all materials of a component meet the requirements of this section, the component shall also meet the requirements of this section.

9.3.2 Evaluation of devices, components, or materials tested to other sections of this Standard

Devices, components, or materials that have been tested to other sections of this Standard shall:

- be made of the same alloy(s), composition(s), or formula(s);
- have undergone analogous manufacturing processes;
- have been tested at a temperature that meets or exceeds the required exposure temperature in annex B, section B.5;
- have been conditioned for a period of time not more than 19 d and exposed for a period of time not less than 16 h; and
- have the concentration(s) of the extracted contaminant(s) normalized to the requirements of annex B, section B.8.

9.3.3 Metallic contaminants

When a device or component is qualified through the separate testing of two or more components, the normalized concentrations for each specific metallic contaminant from individual components shall be summed. The total of the normalized metallic contaminant concentrations shall meet the requirements of 9.5.

9.4 Exposure and normalization

Samples for testing shall be prepared and exposed, and the extractant water analyzed as required in annex B, section B.5. The number of samples tested shall be determined as outlined in annex B, section B.5.

Exposure of endpoint samples, except for hot water dispenser samples, shall be performed at 23 ± 2 °C (73 ± 4 °F).

For kitchen faucets with side spray components, the side spray component shall be prepared and exposed simultaneously with the remainder of the device. At the option of the manufacturer, a separate exposure may be performed for the side spray component.

The concentration of extracted contaminants shall be normalized to end-use conditions according to the normalization procedure outlined in annex B, section B.8 for endpoint devices, components, and materials. All endpoint devices, components, and materials other than commercial kitchen devices shall be evaluated using the highest surface-area-to-volume product as the test sample, and shall be normalized using the 1 L (0.26 gal) first draw. Commercial kitchen devices shall be evaluated using the highest surface-area-to-volume product as the test sample, and shall be normalized using the 18.9 L (5 gal) first draw.

9.5 Evaluation of normalized contaminant concentrations

9.5.1 Evaluation of lead

NOTE – Revisions to lead requirements of this section have been made and are located in Annex F of this Standard. Please refer to that annex for additional details. The revisions contained in Annex F are informational at this time and are scheduled to be incorporated into this section July 1, 2012.

For endpoint devices other than commercial kitchen devices, the lead test statistic Q shall not exceed 11 µg when normalized for the 1 L (0.26 gal) first draw sample. For commercial kitchen devices, the lead test statistic Q shall not exceed 11 µg when normalized for the 18.9 L (5 gal) first draw sample.

NOTE – The limit of 11 µg for lead is based on a limit of 15 µg total lead, including lead contributed from the device interior as well as from sources other than the device, which is assumed to be 4 µg.

For kitchen faucets that have been exposed simultaneously with the side spray component, the lead test statistic Q value for the entire assembly shall not exceed 11 µg. When the kitchen faucet and the side spray component have been exposed separately, the lead test statistic Q value for the faucet and side spray shall be added and shall not exceed 11 µg .

9.5.2 Evaluation of non-lead contaminants

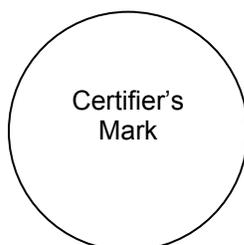
For endpoint devices other than commercial kitchen devices, the normalized concentration of a nonlead contaminant shall not exceed its SPAC (calculated in accordance with annex A) when normalized for the 1 L (0.26 gal) first draw sample. For commercial kitchen devices, the normalized concentration of a nonlead contaminant shall not exceed its SPAC when normalized for the 18.9 L (5 gal) first draw sample.

For kitchen faucets that have been exposed simultaneously with the side spray component, the normalized concentration of a non-lead metal contaminant for the entire assembly shall not exceed its SPAC. When the kitchen faucet and the side spray component have been exposed separately, the normalized concentration of a non-lead metal contaminant for the faucet and side spray shall be added and shall not exceed its SPAC.

10 Instructions and information

When product literature, instructions, or information for a point-of-entry drinking water treatment unit system shows conformance with the materials safety requirements of this Standard as attested by a certification agency, and when the POE treatment system is not likewise certified by that same agency for drinking water contaminant reduction performances, such literature, instructions, and information shall state in comparable proximity and with comparable prominence either:

- the name of the entity that has tested and substantiated the claimed contaminant reduction performances for that water treatment product; or
- that the product is not certified for contaminant reduction performance by the certification agency. The following is an example of an accepted option.



Point-of-Entry System Tested and Certified by [Name of Certifier]
under NSF/ANSI Standard 61 for Materials Safety Requirements
Only. Not Certified for Contaminant Reductions or Structural In-
tegrity by [Name of Certifier]

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Annex A (normative)

Toxicology review and evaluation procedures

A.1 General requirements

This annex defines the toxicological review and evaluation procedures for the evaluation of substances imparted to drinking water through contact with drinking water system components. It is intended to establish the human health risk, if any, of the substances imparted to drinking water under the anticipated use conditions of the product. Annex D (normative) and annex E (informative) of this Standard contain evaluation criteria that have been determined according to the requirements of this annex.

The following general procedure shall be used to evaluate drinking water substances under this Standard:

- a) A determination shall be made as to whether a published (publicly available in printed or electronic format) and peer-reviewed quantitative risk assessment for the substance is available.
- b) When a quantitative risk assessment is available, the reviewer shall determine whether the assessment is currently used in the promulgation of a drinking water regulation or published health advisory for the substance (see the requirements of annex A, section A.3):
 - If the assessment is used in the promulgation of a drinking water regulation, the Single Product Allowable Concentration (SPAC) shall be derived from the regulatory value(s); or
 - If the assessment is not the basis of a drinking water regulation, the assessment and its corresponding reference dose shall be reviewed for their appropriateness in evaluating the human health risk of the drinking water substance.

NOTE – During the review of an assessment used in the promulgation of a drinking water regulation, it is recommended that the regulatory authority be contacted to verify that the assessment under consideration is current.

- c) If a published and peer-reviewed quantitative risk assessment is not currently available for the substance, the Total Allowable Concentration (TAC) and SPAC shall be derived after review of the available toxicology data for the substance (see annex A, section A.4).
 - When the data requirements for qualitative risk assessment are satisfied (see annex A, section A.4.2 and table A1), a qualitative risk assessment shall be performed according to annex A, section A.7; or
 - When the data requirements for quantitative risk assessment are satisfied (see annex A, section A.4.3 and table A2), a quantitative risk assessment shall be performed according to annex A, section A.7.

Figure A1, annex A, provides an overview of the toxicity data review requirements of this annex.

A.2 Definitions

A.2.1 benchmark dose: The lower 95% confidence limit on the dose that would be expected to produce a specified response in X% of a test population. This dose may be expressed as BMD_x (adapted from Barnes et al., 1995).

NOTE – For the purposes of this Standard, the benchmark dose shall be calculated at the 10% response level.

A.2.2 continuous data: A measurement of effect that is expressed on a continuous scale, e. g., body weight or serum enzyme levels (USEPA, 1995).

A.2.3 critical effect: The first adverse effect, or its known precursor, that occurs as the dose rate increases (USEPA, 1994).

A.2.4 ED₁₀: Effective dose 10; a dose estimated to cause a 10% response in a test population (USEPA, 1996a).

A.2.5 genetic toxicity: Direct interaction with DNA that has the potential to cause heritable changes to the cell.

A.2.6 health hazards (types of) (USEPA, 1994 and 1999)

A.2.6.1 acute toxicity: Effects that occur immediately or develop rapidly after a single administration of a substance. Acute toxicity may also be referred to as immediate toxicity.

A.2.6.2 allergic reaction: Adverse reaction to a chemical resulting from previous sensitization to that chemical or to a structurally similar one.

A.2.6.3 chronic effect: An effect that occurs as a result of repeated or long-term (chronic) exposures.

A.2.6.4 chronic exposure: Multiple exposures occurring over an extended period of time or a significant fraction of an animal's or individual's lifetime.

A.2.6.5 chronic toxicity: The capability of a substance to cause adverse human health effects as a result of chronic exposure.

A.2.6.6 irreversible toxicity: Toxic effects to a tissue that cannot be repaired.

A.2.6.7 local toxicity: Effects that occur at the site of first contact between the biological system and the toxicant.

A.2.6.8 reversible toxicity: Toxic effects that can be repaired, usually by a specific tissue's ability to regenerate or mend itself after chemical exposure.

A.2.6.9 systemic toxicity: Effects that are elicited after absorption and distribution of a toxicant from its entry point to its target tissue.

A.2.7 LED₁₀: Lowest effective dose 10; the lower 95% confidence limit on a dose estimated to cause a 10% response in a test population (USEPA, 1996a).

A.2.8 lowest observed adverse effect level (LOAEL): The lowest exposure concentration at which statistically or biologically significant increases in frequency or severity of effects are observed between the exposed population and its appropriate control group (USEPA, 1994).

A.2.9 margin of exposure (MOE): The LED₁₀ or other point of departure, such as an NOAEL, divided by the environmental dose of interest (USEPA, 1996a).

A.2.10 model: A mathematical function with parameters that can be adjusted so that the function closely describes a set of empirical data. A mathematical or mechanistic model is usually based on biological or

physical mechanisms and has model parameters that have real-world interpretations. Statistical or empirical models are curve-fitted to data where the math function used is selected for its numerical properties and accuracy. Extrapolation from mechanistic models (e. g., pharmacokinetic equations) usually carries higher confidence than extrapolation using empirical models (e. g., logit) (USEPA, 1994).

A.2.11 no observed adverse effect level (NOAEL): An exposure concentration at which no statistically or biologically significant increases in the frequency or severity of adverse effects are observed between an exposed population and its appropriate control. Some physiological effects may be produced at this concentration, but they are not considered toxicologically significant or adverse, nor are they considered precursors to adverse effects (USEPA, 1994).

A.2.12 non-regulated substance: A substance for which a statutory concentration limit does not exist.

A.2.13 peer review: A documented critical review of a scientific or technical work product conducted by qualified individuals or organizations who are independent of those who performed the work, but who are collectively equivalent or superior in technical expertise to those who performed the work. It includes an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to the work product and the documentation that supports the conclusions reached in the report. Peer review is intended to ensure that the work product is technically adequate, competently performed, and properly documented, and that it satisfies established requirements (USEPA, 1998).

A.2.14 point of departure: A data point or an estimated point that can be considered to be in the range of observation. The standard point of departure is the LED₁₀, which is the lower 95% confidence limit on a dose associated with 10% extra risk (adapted from Barnes et al., 1995).

A.2.15 qualitative risk assessment: An estimation of the risk associated with exposure to a substance using a non-quantitative methodology.

A.2.16 quantal data: A dichotomous measure of effect; each animal is scored “normal” or “affected,” and the measure of effect is the proportion of scored animals that are affected (USEPA, 1995).

A.2.17 quantitative risk assessment: An estimation of the risk associated with exposure to a substance using a methodology that employs evaluation of dose response relationships.

A.2.18 range of extrapolation: Doses that are outside the range of empirical observation in animal studies, human studies, or both (adapted from Barnes et al., 1995).

A.2.19 range of observation: Doses that are within the range of empirical observation in animal studies, human studies, or both (adapted from Barnes et al., 1995).

A.2.20 reference dose (RfD): An estimate (with uncertainty spanning approximately an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime (USEPA, 1994).

A.2.21 regulated substance: A substance for which a quantitative human health risk assessment has been performed and utilized in promulgation of a statutory concentration limit for drinking water.

A.2.22 toxicodynamics: Variations in the inherent sensitivity of a species or individual to chemical-induced toxicity, resulting from differences in host factors that influence the toxic response of a target organ to a specified dose (TERA, 1996).

A.2.23 toxicokinetics: Variations in absorption, distribution, metabolism, and excretion of a compound that account for differences in the amount of parent compound or active metabolite(s) available to a target organ (TERA, 1996).

A.2.24 treatment technique: A technology or one or more procedures used to control the concentration of a substance in a drinking water supply when it is neither technically nor economically feasible to ascertain the concentration of the substance (U. S. Safe Drinking Water Act, 1996).

A.2.25 weight of evidence: The extent to which the available biomedical data support the hypothesis that a substance causes cancer or other toxic effects in humans (adapted from USEPA, 1994).

A.3 Data requirements for published risk assessments

A.3.1 General requirements

Evaluation of all published risk assessments shall include review of the written risk assessment document and a determination of whether additional toxicity data exist that were not considered in the assessment. If additional toxicity data are identified that were not considered in the risk assessment, the risk assessment shall be updated in accordance with annex A, section A.4.

The following shall be documented when utilizing an existing risk assessment:

- the source of the risk assessment;
- identification and discussion of any data not addressed by the assessment; and
- comparison and contrast of the existing risk assessment to the requirements of annex A, section A.4, with respect to selection of uncertainty factors or other assumptions.

A.3.2 Substances regulated by USEPA or Health Canada

If a substance is regulated under the USEPA's National Primary Drinking Water Regulations and EPA has finalized a Maximum Contaminant Level (MCL) or other means of regulation such as a treatment technique (see annex A, section A.2.24), no additional collection of toxicological data shall be required prior to performance of the risk estimation (see annex A, section A.6.1). Where Health Canada has finalized a Maximum Allowable Concentration (MAC), no additional toxicological evaluation shall be required prior to performance of the risk estimation (see annex A, section A.6.1). Annex D contains a list of regulatory values (MCL or MAC) and their corresponding SPACs. This list includes consensus evaluation criteria for substances that are regulated by both countries.

A.3.3 Substances regulated by other agencies

If a substance is regulated by agencies including the U. S. Food and Drug Administration (Code of Federal Regulations, Title 21 Food and Drug Regulations), or state, national, or international regulatory bodies other than those specified in annex A, section A.3.2, the relevance of the regulation to drinking water shall be evaluated. This evaluation shall include a review of the quantitative risk assessment that supports the regulation, and a determination of whether additional toxicity data exist that have not been considered in the current assessment. No additional collection of toxicological data shall be required when the regulation provides sufficient information for performance of the risk estimation (see annex A, section A.6.1). If additional toxicity data are identified that were not considered in the current risk assessment, a revised risk assessment incorporating those data shall be performed as indicated in annex A, sections A.4 and A.7.

A.3.4 Evaluation of multiple published risk assessments

When multiple published assessments are available for a specific substance, the available assessments shall be reviewed and a rationale shall be provided for the selection of the assessment considered to be the most appropriate for the evaluation of human exposure through drinking water. Factors used to determine the appropriate assessment shall include, but not be limited to, the following:

- completeness and currency of the data review of each assessment;
- technical competence of the organization(s) that sponsored the assessment; and
- species and route(s) of exposure for which the assessment was performed.

When multiple published risk assessments are reviewed and are determined to be of equivalent quality, the following hierarchy shall be used to select the appropriate assessment, based on sponsoring organization:

- 1) USEPA;
- 2) Health Canada;
- 3) international bodies such as the World Health Organization (WHO) or the International Programme on Chemical Safety (IPCS);
- 4) European bodies such as the Drinking Water Inspectorate (DWI) and KIWA; or
- 5) entities such as other federal or state regulatory agencies, private corporations, industry associations, or individuals.

A.4 Data requirements for new or updated risk assessments

A.4.1 General requirements

For each substance requiring a new or updated risk assessment, toxicity data to be considered shall include, but not be limited to, assays of genetic toxicity, acute toxicity (1- to 14-d exposure), short-term toxicity (14- to 28-d exposure), subchronic toxicity (90-d exposure), reproductive toxicity, developmental toxicity, immunotoxicity, neurotoxicity, chronic toxicity (including carcinogenicity), and human data (clinical, epidemiological, or occupational) when available. For a fuller understanding of the toxic potential of the substance, supplemental studies shall be reviewed, including, but not limited to, mode or mechanism of action, pharmacokinetics, pharmacodynamics, sensitization, endocrine disruption, and other endpoints, as well as studies using routes of exposure other than ingestion. Structure activity relationships, physical and chemical properties, and any other chemical specific information relevant to the risk assessment shall also be reviewed.

Toxicity testing shall be performed in accordance with the most recent adopted toxicity testing protocols such as those described by the Organization For Economic Cooperation and Development (OECD)¹⁴, U. S. Environmental Protection Agency (USEPA), and U. S. Food and Drug Administration (FDA)¹⁵. All studies shall be reviewed for compliance with Good Laboratory Practice (21 CFR, Pt 58/40 CFR, Pt 792).

NOTE – Review of the study according to the approach suggested in Klimisch et. al, 1997 may also be used to determine the quality of reported data.

A weight-of-evidence approach shall be employed in evaluating the results of the available toxicity data. This approach shall include considering the likelihood of hazard to human health and the conditions under which such a hazard may be expressed. A characterization of the expression of such effects shall also be included, as well as the consideration of the substance's apparent mode of action. The quality and quantity of toxicity data available for the substance shall determine whether the evaluation is performed using a qualitative risk assessment approach (see annex A, section A.4.2) or a quantitative risk assessment approach (see annex A, section A.4.3).

¹⁴ Organization for Economic Cooperation and Development, 2 Rue André Pascal, F-75775, Paris Cedex 16, France

¹⁵ U. S. Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857

A.4.2 Data requirements for qualitative risk assessment

Toxicity testing requirements for the qualitative risk assessment procedure are defined in annex A, table A1. A minimum data set consisting of a gene mutation assay and a chromosomal aberration assay shall be required for the performance of a qualitative risk assessment. Modifications in the specified toxicity testing requirements (inclusions or exclusions) shall be permitted when well supported by peer-reviewed scientific judgment and rationale.

NOTE – Modifications may include, but are not limited to, the following types of considerations: alternate assays of genetic toxicity, and supplemental toxicity studies other than those specified.

Required studies and available supplemental studies shall be reviewed in order to perform a qualitative risk estimation in accordance with annex A, section A.7.2.

A.4.3 Data requirements for quantitative risk assessment

Toxicity testing requirements for the quantitative risk assessment procedure are defined in annex A, table A2. A minimum data set consisting of a gene mutation assay, a chromosomal aberration assay, and a subchronic toxicity study shall be required for the performance of a quantitative risk assessment. The required studies and preferred criteria are defined in annex A, table A2. Modifications to the minimum data set shall be permitted when well supported by peer-reviewed scientific judgment and rationale.

NOTE – Modifications may include, but are not limited to, acceptance of studies using alternate routes of exposure, alternate assays of genetic toxicity, and supplemental toxicity studies other than those specified.

Required studies, additional studies, and available supplemental studies shall be reviewed in order to perform a quantitative risk estimation in accordance with annex A, section A.7.3.

Additional studies for the evaluation of reproductive and developmental toxicity (as specified in annex A, table A2) shall be required to be reviewed when:

- results of the required minimum data set studies and any supplemental studies indicate toxicity to the reproductive or endocrine tissues of one or both sexes of experimental animals; or
- the compound under evaluation is closely related to a known reproductive or developmental toxicant.

A.5 Data requirements for evaluating short-term exposures

Extractants from products used in contact with drinking water may be elevated initially but rapidly decline with continued product contact with water. Examples include, but are not limited to, solvent-containing coatings and solvent cements. Short-term exposure paradigms, appropriate for potentially high initial substance concentrations, shall be used to evaluate potential acute risk to human health of short-term exposures. The short-term exposure period shall be defined as the first 14 d of in-service life of the product.

Sound scientific judgment shall be used to determine whether calculation of a Short-Term Exposure Level (STEL) is appropriate for a given contaminant. The NOAEL or LOAEL for the critical short-term hazard of the substance shall be identified. The following types of studies shall be considered for identification of short-term hazard:

- short-term (less than 90 d duration) toxicity study in rodents or other appropriate species with a minimum 14-d post-treatment observation period, clinical observations, hematology and clinical chemistry, and gross pathology (preferably an oral study in rodents);

- reproduction or developmental assays (for substances that have these endpoints as the critical effects); or
- subchronic 90-d study in rodents or other species (preferably an oral study in rats).

The critical study shall be used to calculate a Short-Term Exposure Level (STEL) in accordance with annex A, section A.8.

Selection of uncertainty factors for calculation of a STEL shall consider the quality and completeness of the database for assessing potential short-term effects. Selection of uncertainty factors shall also consider data that quantify interspecies and intraspecies variations. Other parameters that shall be considered in the determination of a STEL include identification of any sensitive subpopulations, the potential for adverse taste and odor, and solubility limitations at the calculated STEL. The STEL shall be calculated using assumptions to protect for a child's exposure to the contaminant in the absence of data that demonstrate adults are more sensitive than children. In the absence of appropriate data to calculate a STEL, see annex A, section A.7.1.2.

A.6 Risk estimation for published assessments

Calculation of the SPAC is intended to account for the potential contribution of a single substance by multiple products or materials in the drinking water treatment and distribution system. In any given drinking water treatment and distribution system, a variety of products and materials may be added to, or may contact, the treated water prior to ingestion. The SPAC calculation is intended to ensure that the total contribution of a single substance from all potential sources in the drinking water treatment and distribution system does not exceed its acceptable concentration.

A.6.1 SPAC calculation for regulated substances

To calculate the SPAC, an estimate of the number of potential sources of the substance from all products in the drinking water treatment and distribution system shall be determined. The SPAC shall be calculated as follows:

$$\text{SPAC (mg/L)} = \frac{\text{promulgated regulatory value (mg/L)}}{\text{estimated number of drinking water sources}}$$

In the absence of specific data regarding the number of potential sources of the substance in the drinking water treatment and distribution system, the SPAC shall be calculated as 10% of the promulgated regulatory value.

A.6.2 SPAC calculation for other published risk assessments

Review of the risk assessment shall include evaluation of the risk estimation, if one is provided. If the existing risk estimation has been performed in a manner consistent with the procedures in annex A, section A.7.3 for non-carcinogenic or carcinogenic endpoints, the SPAC shall be calculated as follows:

$$\text{SPAC (mg/L)} = \frac{\text{estimated risk estimation (mg/L)}}{\text{estimated number of drinking water sources}}$$

In the absence of specific data regarding the number of potential sources of the substance in the drinking water treatment and distribution system, the SPAC shall be calculated as 10% of the existing risk estimation.

If the existing risk estimation is not consistent with annex A, section A.7.3, or if a risk estimation is not provided, a TAC and SPAC shall be calculated for the substance according to the procedures in annex A, section A.7.3.

A.7 Risk estimation using new and updated risk assessments

The method of risk estimation used for new and updated risk assessments shall be determined by the quantity and quality of toxicity data identified for the contaminant of concern (see annex A, section A.4). When available toxicity data are insufficient to perform the qualitative or quantitative risk assessments, or when toxicity data are available but the normalized contaminant concentration does not exceed the applicable threshold of evaluation value, a threshold of evaluation shall be determined for the substance according to annex A, section A.7.1 if applicable. For all other data sets, the risk estimation shall be performed according to annex A, section A.7.2 or A.7.3.

A.7.1 Threshold of evaluation

The following thresholds of evaluation shall be considered when available toxicity data do not meet the minimum requirements to perform a risk estimation using either the qualitative or quantitative approach. Application of the threshold of evaluation shall also be considered for the evaluation of normalized contaminant concentrations that do not have existing risk assessments and that do not exceed the defined threshold of evaluation concentrations. In this case, a qualitative review of the available data shall be performed to determine whether adverse health effects can result at the threshold of evaluation exposure concentrations defined in annex A, section A.7.1.1.

A.7.1.1 Threshold of evaluation for chronic exposure

Performance of a risk assessment shall not be required for an individual substance with a normalized concentration less than or equal to the following threshold of evaluation values:

- static normalization conditions:
toxicity testing shall not be required for an individual substance with a normalized concentration less than or equal to the threshold of evaluation value of 3 µg/L.
- flowing normalization conditions:
toxicity testing shall not be required for an individual substance with a normalized concentration less than or equal to the threshold of evaluation value of 0.3 µg/L.

These threshold of evaluation values shall not apply to any substance for which available toxicity data and sound scientific judgement such as structure activity relationships indicate that an adverse health effect results at these exposure concentrations.

A.7.1.2 Threshold of evaluation for short-term exposure

If an appropriate short-term toxic effect is not identified by the available data, the initial (Day 1) laboratory concentration shall not exceed 10 µg/L. This threshold of evaluation value shall not apply to any chemical for which available toxicity data and sound scientific judgment such as structure activity relationships indicate that an adverse health effect can result at the 10 µg/L concentration upon short-term exposure to the chemical.

A.7.2 TAC determination for qualitative risk assessment

TACs for qualitative risk assessments shall be determined as indicated in annex A, table A3.

A.7.3 TAC calculation for quantitative risk assessment

The procedure used to calculate the TAC for a new risk assessment (including qualitative assessments that are updated upon generation of new data) shall be determined by the toxicologic endpoint identified as the critical effect (see annex A, section A.2.3). For a substance with a non-carcinogenic endpoint, a TAC shall be calculated according to annex A, section A.7.3.1. For a substance with carcinogenic potential, a TAC shall be calculated according to annex A, section A.7.3.2.

The minimum data set for the quantitative risk assessment (as defined in annex A, section A.4.3 and table A2) shall first be evaluated for genotoxic potential according to the requirements of annex A, table A3. Based on the review of genotoxic potential, the need for supplemental studies or chronic toxicity and carcinogenesis data shall be determined.

A.7.3.1 Assessment of noncarcinogenic endpoints

For noncarcinogenic endpoints, the TAC shall be calculated using either the NOAEL/LOAEL procedure outlined in annex A, section A.7.3.1.1, or the benchmark dose (BMD) procedure outlined in annex A, section A.7.3.1.2, as appropriate. The rationale for the selection of the procedure shall be provided in the assessment.

NOTE – Selection of the appropriate TAC calculation procedure will depend on the characteristics of the data set identified for the substance. Simple data sets consisting of a small number of studies may be best evaluated using the procedure in annex A, section A.7.3.1.1. Complex data sets consisting of several studies, or involving reproduction or developmental endpoints, may be best evaluated using the benchmark dose procedure in annex A, section A.7.3.1.2. The appropriateness of the fit of the data to the BMD shall also be considered.

A.7.3.1.1 NOAEL or LOAEL approach

The substance data set shall be reviewed in its entirety, and the highest NOAEL for the most appropriate test species, relevant route of exposure, study duration, mechanism, tissue response, and toxicological endpoint shall be identified. If an NOAEL cannot be clearly defined from the data, the lowest LOAEL for the most appropriate test species, relevant route of exposure, and toxicological endpoint shall be utilized.

The general procedure for calculating the TAC using this approach is as follows:

a) Determine the critical study and effect from which the NOAEL or LOAEL will be identified according to the following hierarchy (USEPA, 1993 and Dourson et al., 1994):

- 1) adequate studies in humans;
- 2) adequate studies in animal models most biologically relevant to humans (e. g., primates), or that demonstrate similar pharmacokinetics to humans;
- 3) adequate studies in the most sensitive animal species (the species showing an adverse effect at the lowest administered dose using an appropriate vehicle, an adequate study duration, and a relevant route of exposure); and
- 4) effects that are biologically relevant to humans.

b) Calculate the reference dose (RfD) according to the following equation (based on USEPA, 1993):

$$\text{RfD (mg/kg/d)} \times \frac{\text{NOAEL or LOAEL (mg/kg/d)}}{\text{UF}} \times \frac{\text{number of days dosed per week}}{7 \text{ d}}$$

NOTE – When other than daily dosing was used in the critical study, the RfD calculation shall be adjusted to reflect a daily dosing schedule.

- c) Calculate the TAC based on the RfD with adjustment for significant contribution(s) of the substance from sources other than drinking water according to the following equation:

$$\text{TAC (mg/L)} = \frac{[\text{RfD (mg/kg/d)} \times \text{BW (kg)}] - [\text{total contribution of other sources (mg/d)}]}{\text{DWI (L/d)}}$$

where:

NOAEL = Highest NOAEL for the critical effect in the most appropriate species identified after review of data set. If an NOAEL is not defined, the LOAEL shall be used with a corresponding adjustment in the uncertainty factor (see annex A, table A4);

BW = Assumed body weight of individual to be protected in kg (generally 10 kg for a child and 70 kg for an adult);

UF = Uncertainty factor (total) based upon the applicability of the test data in extrapolating to actual conditions of human exposure (see annex A, table A4). These are often referred to as safety factors; and

DWI = Drinking Water Intake: the assumed average daily drinking water consumption per day (generally 1 L for a child and 2 L for an adult).

NOTE 1 – In the absence of data to determine the drinking water contribution of a substance, a default drinking water contribution of 20% shall be applied (USEPA, 1991).

NOTE 2 – If calculation of the non-drinking water contribution of a substance exceeds the value of the (RfD x BW), verify that all potential exposures to the substance in the critical study have been accounted, e. g., whether the substance present as a contaminant in the feed as well as dosed into the drinking water.

A.7.3.1.2 Benchmark dose approach

The benchmark dose level (BMDL) for the substance shall be calculated by modeling the substance's dose response curve for the critical effect in the region of observed responses. The benchmark response (BMR) concentration shall be determined by whether the critical response is a continuous endpoint measurement or a quantal endpoint measurement. The BMR shall be calculated at the 10% response level.

The general procedure for calculating the TAC using the BMDL is as follows:

- a) Calculate the reference dose (RfD) according to the following equation:

$$\text{RfD (mg/kg/d)} = \frac{\text{BMDL (mg/kg/d)}}{\text{UF}} \times \frac{\text{number of days dosed per week}}{7 \text{ d}}$$

NOTE – When other than daily dosing was used in the critical study, the RfD calculation shall be adjusted to reflect a daily dosing schedule.

- b) Calculate the TAC based on the RfD with adjustment for significant contribution(s) of the substance from sources other than water according to the following equation:

$$\text{TAC (mg/L)} = \frac{[\text{RfD (mg/kg/d)} \times \text{BW (kg)}] - [\text{total contribution of other sources (mg/d)}]}{\text{DWI (L/d)}}$$

where:

BMDL = The lower confidence limit on the dose that produces a specified magnitude of change (10%) in a specified adverse response (BMD₁₀);

BW = Assumed body weight of individual to be protected in kg (generally 10 kg for a child, and 70 kg for an adult);

UF = Uncertainty factor (total) based upon the applicability of the test data in extrapolating to actual conditions of human exposure (see annex A, table A4). These are often referred to as safety factors; and

DWI = Drinking Water Intake: the assumed average daily drinking water consumption per day (generally 1 L for a child and 2 L for an adult).

NOTE 1 – In the absence of data to determine the drinking water contribution of a substance, a default drinking water contribution of 20% shall be applied (USEPA, 1991).

NOTE 2 – If calculation of the non-drinking water contribution of a substance exceeds the value of the (RfD x BW), verify that all potential exposures to the substance in the critical study have been accounted, e. g., whether the substance is present as a contaminant in the feed as well as dosed into the drinking water.

A.7.3.1.3 Selection of uncertainty factors (UFs)

Uncertainty factors used for the risk estimation shall include consideration of the areas of uncertainty listed in annex A, table A4. A default value of 10 shall be used for individual areas of uncertainty when adequate data are not available to support a data-derived uncertainty factor. Selection of the values of each uncertainty factor shall consider the following criteria (adapted from Dourson et al., 1996¹⁶):

A.7.3.1.3.1 Human variability

Selection of the human variability factor shall be based on the availability of data that identify sensitive subpopulations of humans. If sufficient data are available to quantitate the toxicokinetic and toxicodynamic variability of humans (see annex A, sections A.2.22 and A.2.23), factor values of 3, 1, or a value determined from the data shall be considered. In the absence of these data, the default value of 10 shall be used.

A.7.3.1.3.2 Interspecies variability

Selection of the interspecies variability factor shall be based on the availability of data that allow for a quantitative extrapolation of animal dose to the equivalent human dose for effects of similar magnitude or for an NOAEL. This includes scientifically documented differences or similarities in physiology, metabolism and toxic response(s) between experimental animals and humans. If sufficient data are available to quantitate the toxicokinetic and toxicodynamic variabilities between experimental animals and humans (see annex A, sections A.2.22 and A.2.23), factor values of 3, 1, or a value determined from the data shall be considered. In the absence of these data, the default value of 10 shall be used.

¹⁶The Food Quality Protection Act (FQPA) of 1996 re-emphasized the review and evaluation of toxicity data for the protection of children's health. USEPA has been very responsive to this initiative and published a draft document outlining the use of an uncertainty factor for children's protection and other database deficiencies (USEPA, 1999). Currently this factor is applied to pesticide evaluations only. In addition, publications by Renwick (1993) and the International Programme for Chemical Safety (IPCS) (1994) suggest the use of specific data in lieu of default values for uncertainty factors. This suggestion has been actively discussed at subsequent IPCS meetings and several individual chemical examples have been published (IPCS, 1999). The use of data-derived uncertainty factors, or judgment, as replacements to default values of 10 for each area of uncertainty is encouraged by several federal and international agencies and organizations (Meek, 1994; and Dourson, 1994).

A.7.3.1.3.3 Subchronic to chronic extrapolation

Selection of the factor for subchronic to chronic extrapolation shall be based on the availability of data that allow for quantitative extrapolation of the critical effect after subchronic exposure to that after chronic exposure. Selection shall also consider whether NOAELs differ quantitatively when different critical effects are observed after subchronic and chronic exposure to the compound. When the critical effect is identified from a study of chronic exposure, the factor value shall be 1. When sufficient data are available to quantitate the difference in the critical effect after subchronic and chronic exposure, or when the principal studies do not suggest that duration of exposure is a determinant of the critical effects, a factor value of 3 or a value determined from the data shall be considered. In the absence of these data, the default value of 10 shall be used.

A.7.3.1.3.4 Database sufficiency

Selection of the factor for database sufficiency shall be based on the ability of the existing data to support a scientific judgment of the likely critical effect of exposure to the compound. When data exist from a minimum of five core studies (two chronic bioassays in different species, one two-generation reproductive study, and two developmental toxicity studies in different species), a factor value of 1 shall be considered. When several, but not all, of the core studies are available, a factor value of 3 shall be considered. When several of the core studies are unavailable, the default value of 10 shall be used.

A.7.3.1.3.5 LOAEL to NOAEL extrapolation

Selection of the factor for LOAEL to NOAEL extrapolation shall be based on the ability of the existing data to allow the use of a LOAEL rather than an NOAEL for non-cancer risk estimation. If a well-defined NOAEL is identified, the factor value shall be 1. When the identified LOAEL is for a reversible or minimally adverse toxic effect, a factor value of 3 shall be considered. When the identified LOAEL is for a severe or irreversible toxic effect, a factor value of 10 shall be used.

A.7.3.2 Assessment of carcinogenic endpoints

Risk assessment for carcinogenic endpoints shall be performed using the linear approach, the non-linear approach, or both, consistent with the USEPA Carcinogen Risk Assessment Guidelines (USEPA, 2005). For substances that have been identified as known or likely human carcinogens (as defined by these Guidelines), a dose response assessment shall be performed. This dose response assessment shall include analysis of dose both in the range of observation (animal and human studies) and in the range of extrapolation to lower doses.

A.7.3.2.1 Analysis in the range of observation

Curve-fitting models shall be selected based on the characteristics of the response data in the observed range. The model shall be selected, to the extent possible, based on the biological mode of action of the substance taken together in a weight-of-evidence evaluation of the available toxicological and biological data. The selected model shall be used to determine the LED₁₀, which will either be the point of departure (see annex A, section A.2.14) for linear low dose extrapolation or the basis of the margin of exposure (MOE) analysis (see annex A, section A.2.9) for a non-linear assessment.

NOTE – See annex A, figure A2 for a graphical representation of this analysis.

The following types of models shall be considered, as appropriate to the mode of action of the substance under evaluation, the availability of adequate data, and the current state of risk assessment approaches:

- statistical or distribution models:
 - log-probit;

- logit; or
- Weibull.

- mechanistic models:
 - one-hit;
 - multihit;
 - multistage; or
 - cell kinetic multistage.

- model enhancement and dose scaling:
 - time to tumor response;
 - physiologically based toxicokinetic models;
 - biologically based dose-response models; or
 - surface area conversion.

If none of the available models provide a reasonable fit to the dataset, the following shall be considered to see if lack of fit can be resolved (USEPA, 1995):

- interference at higher dose concentrations from competing mechanisms of toxicity that are a progressive form of the response of interest;

- saturation of metabolic or delivery systems for the ultimate toxicant at higher dose concentrations; and

- interference at higher dose concentrations due to toxic effects unrelated to the response of interest.

NOTE – When adjusting for these possibilities does not provide a reasonable fit, one suggested approach is to delete the high dose data and refit the models based on the lower dose concentrations since these doses are the most informative of the exposure concentrations anticipated to be encountered by humans.

A.7.3.2.2 Analysis in the range of extrapolation

The choice of procedure for low dose extrapolation shall be based on the biological mode of action of the substance. Depending upon the quantity and quality of the data, and upon the conclusion of the weight-of-evidence evaluation, one of the following types of analysis shall be used: linear, non-linear, or linear and non-linear.

A.7.3.2.2.1 Linear analysis

The linear default assumption shall be used when the toxicological data support a mode of action due to DNA reactivity or another mode of action that is anticipated to be linear in nature. It shall also be used when no data are available to justify an alternate approach. For linear extrapolation, a straight line is constructed from the point of departure on the dose response curve to the zero dose/zero response point.

A.7.3.2.2.2 Non-linear analysis

The non-linear default assumption shall be used when the toxicological data are sufficient to support the assumption of a non-linear mechanism of action and no evidence for linearity is available. A margin of exposure (MOE) analysis shall be used for non-linear assessment. The margin of exposure shall be calculated by dividing the point of departure by the human exposure concentration of interest.

A.7.3.2.2.3 Linear and non-linear analysis

Linear and non-linear assessments shall be provided when the weight of evidence or the mode of action analysis indicates differing modes of action for different target tissues or to evaluate the implications of complex dose response relationships. Where the results of linear and non-linear evaluations differ, the range of estimates shall be discussed, along with a justification for the estimate used in evaluation of the substance.

A.7.3.3 Determination of the TAC for carcinogenic endpoints

The selected model shall be used to determine the dose equivalent to the LED₁₀. For linear analyses, the TAC shall be determined by linear extrapolation of the LED₁₀ to the origin of the dose response curve for the selected level of risk. For non-linear analyses, the TAC shall be equal to the human exposure concentration of interest that represents the selected MOE (LED₁₀/exposure of interest). For both types of analysis, the level of risk or margin of exposure shall be selected in accordance with the USEPA Carcinogen Risk Assessment Guidelines (USEPA, 2005).

A.7.4 Single Product Allowable Concentration (SPAC) calculation for new or updated risk assessments

Calculation of the SPAC is intended to account for potential contribution of a single substance by multiple products or materials in the drinking water treatment and distribution system. In any given drinking water treatment and distribution system, a variety of products and materials may be added to, or may contact, the treated water prior to ingestion. The SPAC calculation is intended to ensure that the total contribution of a single substance from all potential sources in the drinking water treatment and distribution system does not exceed its acceptable concentration.

A.7.4.1 SPAC determination for qualitative risk assessment

The SPAC for qualitative risk assessments shall be equal to the value of the TAC.

A.7.4.2 SPAC determination for quantitative risk assessment

To calculate the SPAC, an estimate of the number of potential sources of the substance from all products in the drinking water treatment and distribution system shall be determined. The SPAC shall be calculated as follows:

$$\text{SPAC (mg/L)} = \frac{\text{TAC (mg/L)}}{\text{estimated number of drinking water sources}}$$

In the absence of specific data regarding the number of potential sources of the substance in the drinking water treatment and distribution system, the SPAC shall be calculated as 10% of the TAC.

A.8 Risk estimation for short-term exposure (STEL calculation)

The STEL shall be calculated using the following equation:

$$\text{STEL (mg/L)} = \frac{\text{NOAEL or LOAEL (mg/kg/d)}}{\text{UF}} \times \frac{\text{BW (kg)}}{\text{DWI (L/d)}} = \frac{\text{number of days dosed per week}}{7 \text{ d}}$$

NOTE – When other than daily dosing was used in the critical study, the STEL calculation shall be adjusted to reflect the dosing schedule.

where:

NOAEL = Highest NOAEL for the critical effect in a study of less than or equal to 90 d duration (see annex A, section A.5); if an NOAEL is not defined, the LOAEL shall be used with a corresponding adjustment to the uncertainty factor (see annex A, table A4);

BW = Assumed body weight of the individual to be protected (in kg), generally 10 kg for a child and 70 kg for an adult. The default body weight shall reflect that of a child, in the absence of data that demonstrate that adults are more sensitive than children;

UF = Uncertainty factor based upon the applicability of the test data in extrapolating to actual conditions of human exposure (see annex A, table A4). These are often referred to as safety factors; and

DWI = Drinking Water Intake: the assumed average daily drinking water consumption in L/d, generally 1 L for a child and 2 L for an adult. The default water consumption shall reflect that of a child, in the absence of data that demonstrate that adults are more sensitive than children.

A.9 Development of chemical class-based evaluation criteria

A.9.1 Identification of the need for chemical class-based evaluation criteria

Annex A provides a threshold of evaluation to be utilized when the required toxicity data to perform qualitative or quantitative risk assessment (see annex A, section A.4) are unavailable, or when the required data are available, but the normalized contaminant concentrations do not exceed the threshold of evaluation concentrations (see annex A, section A.7.1). However, normalized contaminant concentrations for chemicals that do not meet minimum data requirements may exceed the threshold of evaluation concentrations. In this case, it may be possible to determine chemical class-based evaluation criteria for the substance on the basis of the known toxicities of other chemicals of similar structure and functionality. Those criteria can then be used as surrogates to the TAC and SPAC established on the basis of chemical-specific information.

Class-based evaluation criteria shall not be used for any substance for which adequate data exist to perform a chemical-specific risk assessment.

A.9.2 Procedure for defining class-based evaluation criteria

A.9.2.1 Establishment of the chemical class

The chemical class for which the class-based evaluation criteria are to be established shall consist of a clearly defined and closely related group of substances, and shall be defined according to chemical structure (e. g., aliphatic or aromatic), primary chemical functional group(s) (e. g., alcohol, aldehyde, or ketone), and molecular weight or weight range.

A.9.2.2 Review of chemical class toxicity information

Once the chemical class has been defined according to annex A, section A.9.2.1, information on chemicals of known toxicity that are included in the defined chemical class shall be reviewed. An appropriate number of chemicals of known toxicity shall be reviewed to establish class-based evaluation criteria. Sources of data for chemicals of known toxicity shall include, but not be limited to, the following:

- USEPA risk assessments, including Maximum Contaminant Levels (MCL), Health Advisories, and Integrated Risk Information System (IRIS¹⁷) entries;
- Health Canada risk assessments;

¹⁷ <http://www.epa.gov/iris/>

- risk assessments previously performed to the requirements of annex A;
- state or provincial drinking water standards and guidelines; and
- World Health Organization (WHO) or other international drinking water standards and guidelines.

An MCL and SPAC (for regulated contaminants) or a TAC and SPAC (for non-regulated contaminants) shall be identified for each chemical of known toxicity that is being used to determine the class-based evaluation criteria. Carcinogenic potential shall be evaluated using a quantitative structure-activity relationship program (e. g., OncoLogic^{®18} or equivalent) to verify that the carcinogenic potential of the chemical of unknown toxicity is no greater than that of the chemicals being used to define the class-based evaluation criteria.

A.9.2.3 Determination of the class-based evaluation criteria

After review of the available toxicity information specified in annex A, section A.9.2.2, the class-based evaluation criteria shall not exceed the lowest MCL or TAC and SPAC identified for the chemicals of known toxicity in the defined chemical class. These evaluation criteria shall be used as surrogates for the TAC and SPAC for each chemical of unknown toxicity that meets the specifications of the defined chemical class (see annex A, section A.9.2.1), until such time as sufficient toxicity data are available to determine chemical-specific evaluation criteria.

The class-based evaluation criteria shall not be applied to any substance for which available data and sound scientific judgment, such as structure-activity relationship considerations, indicate that adverse health effects may result at the established class-based evaluation criteria concentrations. If, after a chemical class is defined and its evaluation criteria established, a substance of greater toxicological significance is identified within the class, the class-based evaluation criteria shall be re-evaluated and revised to the acceptable concentrations of the new substance.

NOTE – It is recommended that documentation supporting class-based evaluation criteria be subject to the external peer-review requirements of annex A, section A.10.15.

A.10 Key elements of a risk assessment for drinking water additive chemicals

This section establishes the minimum criteria for the documentation of the data review performed on each drinking water additive chemical that requires a new or updated assessment. The assessment shall include, but not be limited to, evaluation of the elements detailed in this section.

A.10.1 Abstract

A summary shall be provided of the following:

- overview of the key toxicology studies;
- rationale for the selection of the critical effect and the corresponding NOAEL or other endpoint for calculation;
- major assumptions used in the assessment and areas of uncertainty; and
- presentation of the RfD, TAC, SPAC, and STEL values.

¹⁸ Logichem, Inc. P. O. Box 357, Boyertown, PA 19512

A.10.2 Physical and chemical properties

The assessment shall define the following parameters for the substance, as applicable:

- chemical formula, structure, CAS number, and molecular weight;
- physical state and appearance;
- melting point or boiling point;
- vapor pressure;
- solubility in water;
- density;
- organoleptic properties (taste and odor thresholds);
- dissociation constant (pKa); and
- partition coefficients (octanol/water, air/water).

A.10.3 Production and use

The assessment shall review the method(s) of production of the substance, whether it is a synthetic or a naturally occurring substance, and the principal uses of the chemical. This includes any use as a water treatment chemical or a food additive (direct or indirect) and its presence in such products as medicines, personal care products, or cosmetics.

A.10.4 Analytical methods

For each identified analytical method for the substance, the following shall be summarized:

- analytical matrix;
- sample preparation, if applicable;
- method of analysis;
- type of detector or the wavelength for spectroscopic methods; and
- detection limit.

A.10.5 Sources of human and environmental exposure

The assessment shall describe the substance's natural occurrence, if any, and its presence in food or other media. Human exposure from drinking water, food, and air shall be described, including occupational exposures. The major source(s) and route(s) of human exposure shall be identified.

A.10.6 Comparative kinetics and metabolism

All references describing the absorption, distribution, metabolism, and excretion of the substance shall be reviewed. Both human data (when available) and animal data shall be included.

A.10.7 Effects on humans

A summary of each relevant reference documenting human exposure to the substance that is used in the hazard assessment shall be provided. These exposures can include both case reports of incidental human exposure to the substance and epidemiological studies that explore the association between human exposure and specific toxic endpoints. Primary literature references shall be reviewed whenever possible.

Supporting data or other studies not utilized in the hazard assessment can be summarized in tabular form.

A.10.8 Effects on laboratory animals and *in vitro* test systems

A summary of each key study of the substance in experimental animals or *in vitro* test systems that is used in the hazard assessment shall be provided. The references used shall meet established toxicity study guidelines, as defined in annex A, section A.4.1, or any deficiencies shall be clearly identified. Studies shall include, but are not limited to, the following: single exposure, short-term exposure (repeated dose study of < 28 d), long-term and chronic exposure (repeated dose study of ≥ 28 d), genotoxicity, reproduction and developmental toxicity, immunotoxicity, and neurotoxicity. Primary literature references shall be reviewed whenever possible.

Supporting data or other studies not utilized in the hazard assessment can be summarized in tabular form.

A.10.9 Effects evaluation

The effects evaluation is intended to provide an overall summary of the data reviewed for the substance and describe its mode/mechanism of action, if possible. This evaluation also serves to define the level of hazard represented by exposure to the substance at relevant human concentrations. The evaluation shall contain three major elements: hazard identification (assessment), dose-response assessment, and exposure characterization.

A.10.9.1 Hazard identification

The hazard identification (assessment) shall identify and discuss the following issues:

- the key data that define the basis of the concern to human health;
- the characterization of the substance as carcinogenic or non-carcinogenic, the basis for this characterization, and the critical effect(s);
- the extent to which this characterization is a function of study design (e. g., adequate number of doses used, effects noted only at highest dose, study performed at the maximum tolerated dose);
- the conclusions of the key study(ies) and whether they are supported or conflicted by other data;
- the significant data gaps for the substance and any relevant non-positive data;
- the available human data (case reports or epidemiological studies) and how they support or do not support the conclusions from the key study(ies);
- the mechanism by which the substance produces the adverse effect(s) noted in the key study and whether this mechanism is relevant to humans; and
- the summary of the hazard assessment including confidence in the conclusions, alternate conclusions that may also be supported by the data, significant data gaps, and the major assumptions used in the assessment.

A.10.9.2 Dose-response assessment

The dose-response assessment shall identify and discuss the following issues:

- the data used to define the dose-response curve and in which species the data were generated;

- if animal data were used, whether the most sensitive species was evaluated;
- if human data were used, whether positive and negative data were reported;
- whether the critical data were from the same route of exposure as the expected human exposure (drinking water), and if not, whether pharmacokinetic data are available to extrapolate between routes of exposure;
- for non-carcinogens, the methodology employed to calculate the RfD and the selection of the uncertainty factors that were used;
- for carcinogens, the dose-response model selected to calculate the LED₁₀ and the rationale supporting its selection; and
- the RfD calculation (see annex A, section A.7.3).

A.10.9.3 Exposure characterization

The exposure characterization shall identify and discuss the following issues:

- the most significant source(s) of environmental exposure to the substance and the relative source contribution of each;
- the population(s) most at risk of exposure and the subpopulations that are highly exposed or sensitive; and
- any issues related to cumulative or multiple exposures to the substance.

A.10.10 Risk characterization

A.10.10.1 TAC derivation

The TAC derivation shall contain an explanation of all factors contributing to the TAC calculation, including adjustment for sources of the substance other than water. The TAC calculation shall be based on the oral RfD calculated during the dose response assessment in annex A, section A.10.9.2. The TAC calculation shall include adjustment for significant contributions of the substance from sources other than water (e. g., food and air). In the absence of data to determine the drinking water contribution of a substance, a default drinking water contribution of 20% shall be applied.

A.10.10.2 STEL derivation

When a short-term exposure level is calculated for a substance, the calculation shall be based on the NOAEL or LOAEL of the selected study (as defined in annex A, section A.5) with adjustment for body weight and daily water consumption of the protected individual, including any sensitive subpopulations. The default body weight and water consumption shall reflect that of a child, in the absence of data that demonstrate that adults are more sensitive to the substance than children. A rationale for the selection of uncertainty factors used in the calculation shall also be provided.

A.10.11 Risk management (SPAC derivation)

The TAC calculation shall form the basis of the SPAC calculation. The SPAC is equal to the TAC for qualitative risk assessments. For quantitative risk assessments, the SPAC shall be calculated as a percentage of the TAC value, based on the estimated total number of sources of the substance in the drinking water treatment and distribution system. In the absence of these data, the SPAC shall be calculated as 10% of the TAC value (with a default multiple source factor of 10 to account for other sources of the substance in drinking water).

A.10.12 Risk comparisons and conclusions

A review of other evaluations of the substance performed by other organizations (international, national, state, or provincial agencies, or other entities) shall be provided. Consistencies and differences between evaluations shall be noted. Any uncertainties in these evaluations shall be discussed. A summary of the overall risk of the substance shall be made, including a discussion about compounds of comparable risk (e. g., similar structure, chemical class) when possible.

A.10.13 References

An alphabetized list of all reviewed citations (both cited and not cited in the assessment) shall be provided in an established format such as that described in *The Chicago Manual of Style*.

A.10.14 Appendices

Supporting documents, complex calculations, data summary tables, unique definitions, and other pertinent information shall be included in appendices to the document.

A.10.15 Peer review

Risk assessments performed to the requirements of this annex shall undergo external peer review (USEPA, 1998) by an independent group of individuals representing toxicological expertise in the regulatory, academic, and industrial sectors, with the exception of the following:

- substances evaluated using the threshold of evaluation (see annex A, section A.7.1);
- substances evaluated to a TAC of 10 µg/L using the qualitative approach and concluded to be non-genotoxic (see annex A, sections A.4.2 and A.7.2); and
- non-regulatory criteria that have already undergone peer review such as USEPA IRIS assessments.

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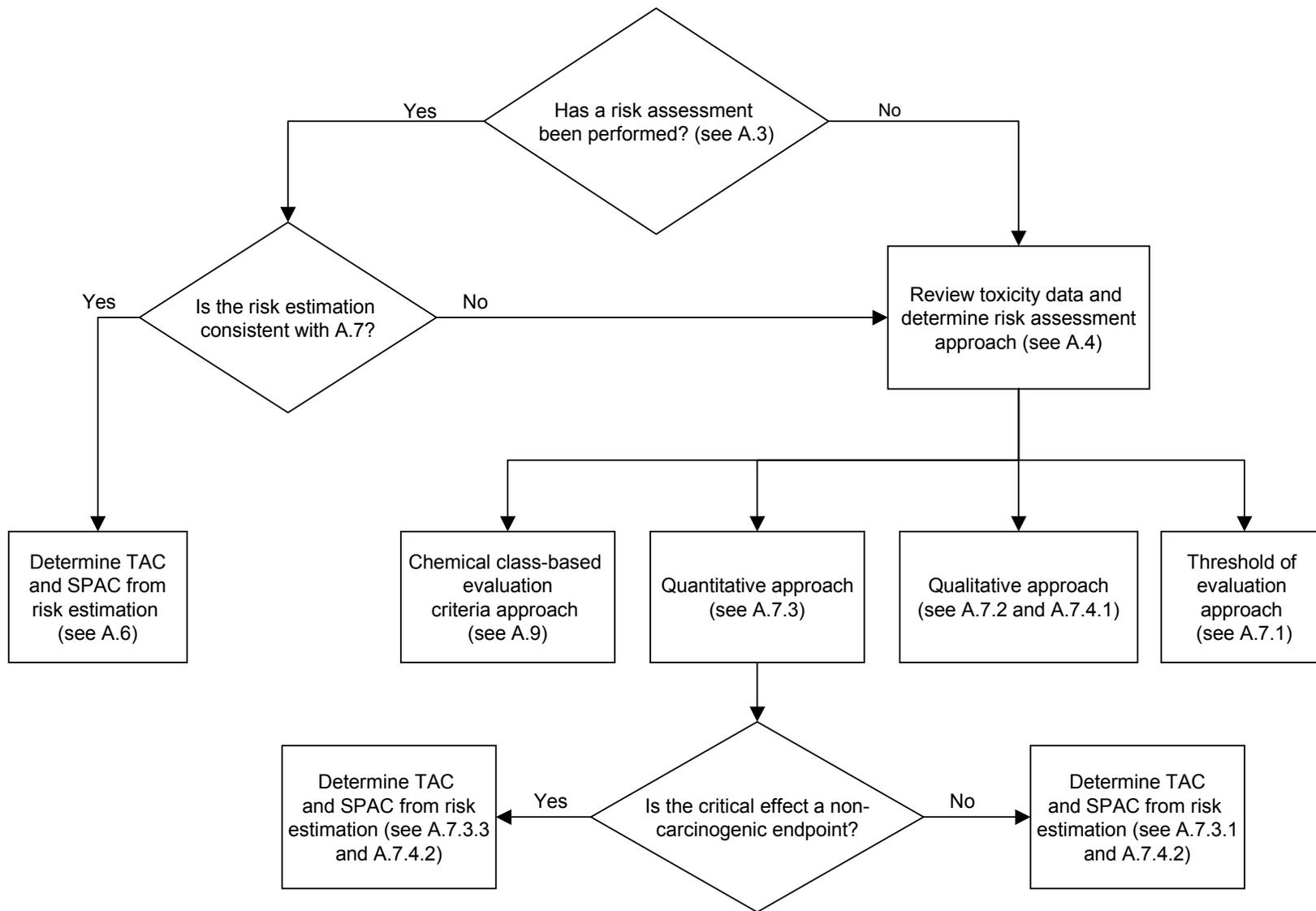


Figure A1 - Annex A toxicity data review process

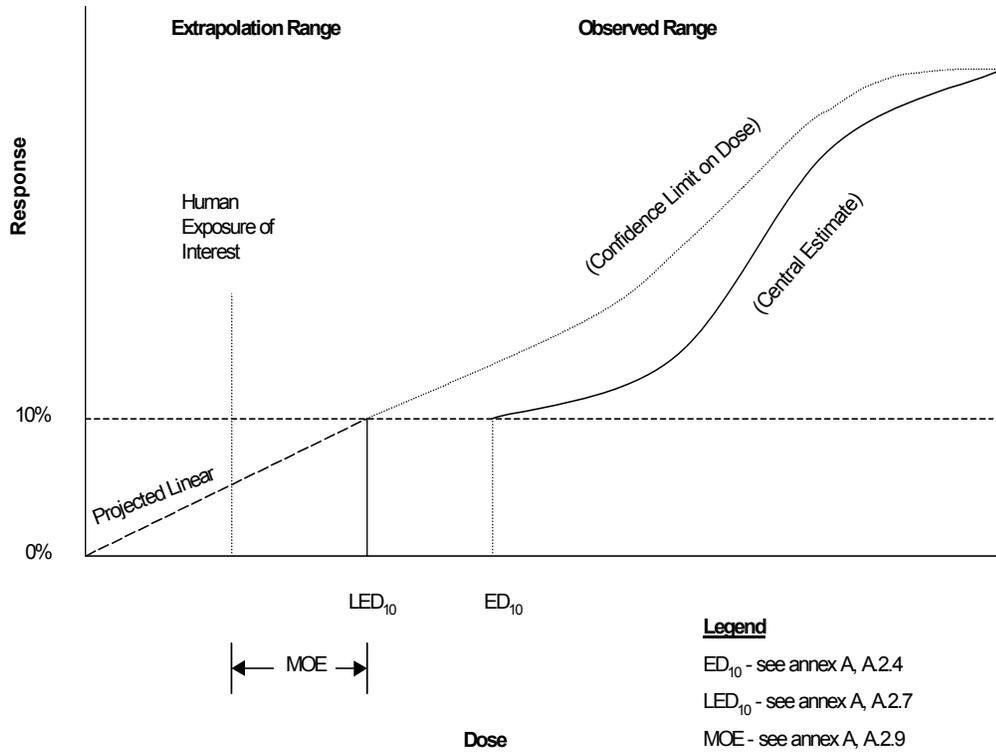


Figure A2 – Graphical presentation of data and extrapolations (USEPA, 1996a)

Table A1 – Qualitative risk assessment data requirements

Study type	Preferred criteria
Required studies	
gene mutation assay ¹	bacterial reverse mutation assay performed with and without exogenous metabolic activation using <i>Salmonella typhimurium</i> (preferred strains are TA97, TA98, TA100, TA102, TA1535, and TA1537) or <i>Escherichia coli</i> (preferred strains are WP2 <i>uvrA</i> or WP2 <i>uvrA</i> (pKM101)
chromosomal aberration assay ¹ (<i>in vitro</i> preferred)	metaphase analysis in mammalian cells and without exogenous metabolic activation
(<i>in vivo</i>)	metaphase analysis or micronucleus assay in mammalian species
Supplemental studies	
supplemental genotoxicity studies	mouse lymphoma assay, SCE ² , UDS ³ , HGPRT ⁴ , DNA binding (post labeling assay)
bioaccumulation potential	octanol/water partition coefficient
pharmacokinetics	absorption, distribution, metabolism, and excretion data in humans, other mammalian species, or both
structural/functional assessment	structure/activity relationship analysis
acute or short-term toxicity ⁵	1- to 14-d study or 14- to 28-d study using oral exposure route
cell proliferation/cell cycle assays	proliferating cell nuclear antigen (PCNA)
sensitization	guinea pig intradermal injection
<i>in vivo</i> gene mutation assay	transgenic gene mutation assays
endocrine disruption assays	receptor binding/transcriptional activation assays, frog metamorphosis assay, steroidogenesis assay
human data	epidemiological, occupational, or clinical studies
<p>¹ The gene mutation assay and the chromosomal aberration assay (<i>in vitro</i> or <i>in vivo</i>) shall constitute the minimum data set required to perform a qualitative risk assessment. When one or both <i>in vitro</i> genotoxicity studies are positive, the <i>in vivo</i> assay shall be required to be reviewed.</p> <p>² Sister chromatid exchange assay; SCEs are not considered to be mutagenic effects because the exchange is assumed to be reciprocal with no gain, loss, or change of genetic material. However, they do indicate that the test material has interacted with the DNA in a way that may lead to chromosome damage. In <i>in vitro</i> studies, SCEs do not provide adequate evidence of mutagenicity, but do identify the need for definitive chromosomal aberration studies. When evidence of <i>in vitro</i> clastogenicity exists, the induction of SCEs is often used as evidence of likely <i>in vivo</i> clastogenic activity because the <i>in vitro</i> aberration data demonstrate the clastogenic activity of the compound and the <i>in vivo</i> SCE data demonstrate that the compound interacted with the DNA in the target tissue.</p> <p>³ Unscheduled DNA synthesis assay</p> <p>⁴ Hypoxanthine guanine phosphoribosyl transferase assay</p> <p>⁵ Minimum reported parameters shall include clinical observations, hematology and clinical chemistry, and gross pathology.</p>	

Table A2 – Quantitative risk assessment data requirements

Study type	Preferred criteria
Required studies	
gene mutation assay ¹	bacterial reverse mutation assay performed with and without exogenous metabolic activation using <i>Salmonella typhimurium</i> (preferred strains are TA97, TA98, TA100, TA102, TA1535, and TA1537) or <i>Escherichia coli</i> (preferred strains are WP2 <i>uvrA</i> or WP2 <i>uvrA</i> (pKM101)
chromosomal aberration assay ¹ (<i>in vitro</i> preferred)	metaphase analysis in mammalian cells and without exogenous metabolic activation
(<i>in vivo</i>)	metaphase analysis or micronucleus assay in mammalian species
subchronic toxicity ¹	90-d assay in rodent species by oral route of exposure
Additional studies (required as indicated)	
reproduction assay ²	two generation reproductive assay in a rodent species
developmental assay ²	teratology study (two species, one rodent and one non-rodent, are preferred)
chronic study ³	2-yr bioassay in rodent species by oral route of exposure
Supplemental studies	
supplemental genotoxicity studies	mouse lymphoma, SCE ⁴ , UDS ⁵ , HGPRT ⁶ , DNA binding (post labeling assay)
bioaccumulation potential	octanol/water partition coefficient
pharmacokinetics	absorption, distribution, metabolism, and excretion data in humans, other mammalian species, or both
structural/functional assessment	structure/activity relationship analysis
acute or short-term toxicity ⁷	1- to 14-d or 14- to 28-d study using oral exposure
cell proliferation/cell cycle assays	proliferating cell nuclear antigen (PCNA)
sensitization	guinea pig intradermal injection
<i>in vivo</i> gene mutation assay	transgenic gene mutation assays
endocrine disruption assays	receptor binding/transcriptional activation assays, frog metamorphosis assay, steroidogenesis assay
human data	epidemiological, occupational, or clinical studies
<p>¹ The gene mutation assay, the chromosomal aberration assay (<i>in vitro</i> or <i>in vivo</i>), and the subchronic toxicity study shall constitute the minimum data set required to perform a quantitative risk assessment. When one or both <i>in vitro</i> genotoxicity studies are positive, the <i>in vivo</i> assay shall be required to be reviewed.</p> <p>² It is recommended that results of a screening assay, such as OECD No. 422, <i>Combined repeated dose toxicity study with reproduction/developmental toxicity screening test</i>, or data from other repeated dose assays that include histopathological examination of the reproductive tissues of each sex be reviewed prior to a determination that these assays are required for evaluation.</p> <p>³ A chronic study with evaluation of carcinogenic endpoints is required when review of the minimum data set concludes that the substance is likely to be a human health hazard at exposures of 10 µg/L or less.</p> <p>⁴ Sister chromatid exchange assay; SCEs are not considered to be mutagenic effects because the exchange is assumed to be reciprocal with no gain, loss, or change of genetic material. However, they do indicate that the test material has interacted with the DNA in a way that may lead to chromosome damage. In <i>in vitro</i> studies, SCEs do not provide adequate evidence of mutagenicity, but do identify the need for definitive chromosomal aberration studies. When evidence of <i>in vitro</i> clastogenicity exists, the induction of SCEs is often used as evidence of likely <i>in vivo</i> clastogenic activity because the <i>in vitro</i> aberration data demonstrate the clastogenic activity of the compound and the <i>in vivo</i> SCE data demonstrate that the compound interacted with the DNA in the target tissue.</p> <p>⁵ Unscheduled DNA synthesis assay</p> <p>⁶ Hypoxanthine guanine phosphoribosyl transferase assay</p> <p>⁷ Minimum reported parameters include clinical observations, hematology and clinical chemistry, and gross pathology.</p>	

Table A3 – TACs for qualitative risk assessment

Conclusion of data review	TAC
The weight of evidence review of the required genotoxicity studies and all other relevant data concludes that the substance is not a hazard at exposures of 10 µg/L or less.	10 µg/L
The weight of evidence review of the required genotoxicity studies, a repeated dose study of less than 90 d duration ¹ , and all other relevant data concludes that the substance is not a human health hazard at exposures of 50 µg/L or less.	≤ 50 µg/L
The weight of evidence review of the required genotoxicity studies and all other relevant data concludes that the data are insufficient to determine the potential human health hazard of the substance at exposures of 10 µg/L or less.	Supplemental studies or chronic toxicity and carcinogenesis bioassay required for review
The weight of evidence review of the required genotoxicity studies and all other relevant data concludes that the substance is likely to be a human health hazard at exposures of 10 µg/L or less.	Chronic toxicity and carcinogenesis bioassay required for review
¹ Required study parameters include organ and body weights, clinical chemistry and hematology, gross pathology, and histopathology.	

Table A4 – Uncertainty factors

Areas of uncertainty	Factor
Intraspecies extrapolation (species variation): This factor accounts for variations in chemical sensitivity among individuals in a species including toxicokinetic and toxicodynamic parameters.	1, 3, or 10
Interspecies extrapolation (animal to human): This factor accounts for variations in chemical sensitivity between experimental animals and humans, including toxicokinetic and toxicodynamic parameters.	1, 3, or 10
Less than lifetime duration of exposure: This factor is intended to extrapolate experimental results from subchronic to chronic exposure.	1, 3, or 10
Use of LOAEL rather than NOAEL ¹ : This factor addresses the uncertainty in developing a reference dose from a LOAEL rather than an NOAEL.	1, 3, or 10
Lack of database completeness: This factor accounts for the absence of data for specific toxic endpoints.	1, 3, or 10
¹ This adjustment is not required for BMD calculations.	
NOTE – When uncertainties exist in four areas, a 3000-fold composite uncertainty factor is appropriate. When uncertainties exist in five areas, a 10,000-fold composite uncertainty factor is appropriate. This consolidation of individual factors recognizes that each individual factor is conservative, and multiplication of four or five uncertainty factors is likely to result in an overly conservative RfD. Datasets that would result in a composite uncertainty factor of greater than 10,000-fold are considered too weak for quantitative risk assessment (see annex A, section A.4.2 for qualitative risk assessment requirements) (Dourson, 1994).	

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Annex B (normative)

Product/material evaluation

B.1 Background

Products/materials to be evaluated shall be prepared and exposed, and the extraction medium (e. g., water or chemical) analyzed, as described in this annex. Examples of products/materials covered by this annex are shown in annex B, table B1.

Table B2 in this annex outlines the various preparation and exposure methods for the products/materials covered by the annex.

The analytical methods included are based on contaminants that are likely to be present when established methods of production are used and the materials are derived from known sources. Modifications to the analytical procedures shall be permitted when products/materials are created with alternate methods or have originated from alternate sources.

B.2 General evaluation requirements

B.2.1 General

The requirements described in this section are general requirements and apply to all products/materials covered by NSF/ANSI 61, annex B. Sections B.3 to B.5 describe specific preparation, conditioning, and exposure sequences unique to individual product/material categories.

B.2.2 QA/QC and safety

The methods included in annex B, sections B.3 to B.5 have been written for trained chemical laboratory personnel. Appropriate quality assurance procedures and safety precautions shall be followed.

B.2.3 Samples

B.2.3.1 Material evaluation

A representative sample of the material (in either material sample or finished product form) shall be exposed.

B.2.3.2 Finished product evaluation

Samples of the finished product (e. g., pipe, fitting, or device) shall be exposed except in the following specific instances:

- concrete cylinders, cubes, or other concrete surrogate samples shall be permitted to be evaluated on behalf of concrete lined pipes and other concrete-based products;
- coatings, applied to an appropriate substrate, shall be permitted to be evaluated on behalf of products whose entire water contact surface is covered by the coating; and
- finished products shall be permitted to be evaluated using material samples if finished product evaluation is impractical for one or more of the following reasons:
 - an internal volume greater than 20 L (5.3 gal);

- a weight greater than 34 kg (75 lbs); or
- *in situ* manufacture of the finished product.

Material samples shall be permitted to be evaluated on behalf of a finished product if, and only if, no chemical or physical difference exists between the material sample and the material as represented in the finished product. All material samples shall be produced using all the same manufacturing processes as the finished product.

B.2.4 Washing

To remove any extraneous debris or contamination that occurred during shipping and handling, samples shall be rinsed with cold tap water prior to testing, followed by a rinse with reagent water meeting the requirements of annex B, section B.9.2.1, unless the manufacturer's instructions direct otherwise. If the exterior of a product is exposed, any printed markings (e. g., ink markings) shall be removed.

B.2.5 Extraction waters

Samples shall be exposed, based on a formulation review and determination of the most severe condition(s), to the required extraction waters as detailed in annex B, table B3, except for mechanical plumbing devices (annex B, section B.5.5). The characteristics and preparation of the waters are described in annex B, section B.9.

B.2.5.1 Exceptions

The manufacturer shall have the option specifically to request a change in the extraction water used, based on the intended application or the materials used in the device/product, provided that the manufacturer's use instructions indicate the use limitations.

B.2.5.2 Mechanical devices used in contact with drinking water treatment chemicals

These devices and materials shall be exposed to the chemicals and chemical mixtures that have been specified by the manufacturer.

B.2.5.3 Copper and copper alloys

Pipe and tubing manufactured from copper alloy C12200 shall be exposed in the pH 6.5 (annex B, section B.9.4) and in the pH 10 (annex B, 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.2.6 Product exposure

Samples shall be evaluated either "in-the-product/device" or in an exposure vessel.

B.2.6.1 Exposure in the product/device

When practical, products/devices shall be evaluated so that only the (exposed) wetted surface is exposed to extraction medium.

B.2.6.2 Exposure in vessels

Samples that are not evaluated as described in annex B, section B.2.6.1 shall be exposed to the extraction medium in containers composed of a material that is inert to the exposure water and with PTFE (polytetrafluoroethylene) lined lids, with no headspace.

Products exposed in vessels shall be exposed so that the surface-area-to-volume ratio described in the appropriate section (annex B, sections B.3 to B.5) shall be maintained.

B.2.6.3 Residual vinyl chloride monomer (RVCM)

Polyvinyl chloride (PVC) and chlorinated polyvinyl chloride (CPVC) pipe products/materials shall be evaluated for RVCM. RVCM shall be determined in the product wall, rather than by extraction, in accordance with annex B, section B.7.

B.2.7 Material exposure

Materials shall be exposed according to the protocol outlined for the materials' specified end use(s). If a material is intended for use in the manufacture of products covered under more than one section of this standard, the most stringent exposure condition shall be followed (e. g., temperature or surface-area-to-volume ratio). Materials intended to be processed by more than one method (e. g., injection molding, extrusion, or stamping) shall be tested in each of the processed forms.

B.2.7.1 Exposure of a material sample

A materials manufacturer shall have the option to request that a material be tested as a material sample (e. g., plaque, sheet) if, and only if, there is no chemical or physical difference in the material characteristics between the material sample and the material as it is used in covered applications. If the material is intended to be used only for the manufacture of products falling under the scope of a single section of this standard, the material shall be exposed under the conditions set forth in the corresponding section of annex B. The normalized contaminant concentrations shall meet the requirements of annex A.

B.2.7.2 Exposure in product form

A materials manufacturer shall have the option to request that a material be tested in the form of a finished product according to the protocol set forth in the appropriate section(s) of annex B.

B.2.7.3 Surface-area-to-volume ratio (s/v)

When a material is tested in the form of a material sample or in product form, the dimensions of the material or the product sample tested, and the extraction medium volume, shall be recorded and the laboratory tested surface-area-to-volume ratio calculated. When necessary, laboratory extraction results shall be adjusted to reflect the difference between laboratory and field surface-to-area volume ratios.

B.2.8 Exposure conditions

Exposure begins immediately after washing or the appropriate conditioning.

B.2.8.1 Method blanks

Method blanks shall be prepared using the same reagent and in the same manner as product samples, but no product shall be added. An uncoated substrate, as applicable, shall be included. Method blanks shall be processed with all samples.

B.2.8.2 Method standards

Method standards shall be prepared along with all samples. Method standards are prepared in the same manner as method blanks, except that a known amount of the expected contaminant is added.

B.2.8.3 Sequential exposure

Tests for evaluation shall be conducted using a sequential exposure procedure. There shall be no significant time interval between exposures (decant, discard, fill, continue exposure). The products shall be exposed depending on the intended end-use application, as described in the appropriate section (annex B, sections B.3 to B.5). Analyses shall be performed only on the final extraction medium, unless otherwise noted.

B.3 Joining and sealing materials

B.3.1 Sample requirements

Test samples of joining and sealing materials shall be prepared so that, upon exposure, a minimum surface-area-to-volume ratio of 15 cm²/L (8.8 in²/gal) is obtained. Materials used at higher surface-to-volume ratios in the field shall be exposed at or above the actual use ratio. Test samples for the various types of joining and sealing materials are described in annex B, table B4.

B.3.2 Preparation

Samples shall be prepared so that the entire surface to be exposed is covered by extraction water. Products (as appropriate) shall be applied to a glass panel in a manner consistent with the manufacturer's published instructions. Products requiring a reactive substrate (i. e., where glass is inappropriate), shall be applied to an appropriate alternate substrate.

B.3.2.1 Gasket materials

Gasket materials shall be cut to the appropriate size as described in annex B, section B.3.1.

B.3.2.2 Caulks, greases, lubricants, and sealants

Caulks, greases, lubricants, and sealants shall be applied to a glass panel in such a manner that an even film, consistent with end use, is exposed and the surface-area-to-volume ratio described in annex B, section B.3.1 is maintained. The slides shall be allowed to air dry or cure according to the manufacturer's published instructions.

B.3.2.3 Adhesives and cements

B.3.2.3.1 Adhesives and cements intended for joining pipe and fittings shall be prepared as pipe and fittings joints assembled in accordance with the manufacturer's use instructions. The joints shall be produced using ½-in nominal diameter pipe (or tubing) and fittings, or the minimum size specified by the manufacturer, if that size is greater. Unless the manufacturer's use instructions state otherwise, PVC pipe and fitting joints shall be assembled per ASTM D2855 and CPVC pipe and fitting joints assembled per appendix XI of ASTM F493. If the manufacturer's use instructions recommend the use of a primer, testing shall incorporate the use of a primer. Unless the manufacturer's use instructions state otherwise, joints shall be allowed to air cure for 48 ± 2 h at room temperature prior to washing, conditioning, and exposure in-product.

B.3.2.3.2 Adhesives and cements not intended for joining pipes and fittings shall be prepared in a manner consistent with the manufacturer's use instructions. These products shall be applied to glass panels (or the manufacturer's intended substrate) so that an even film, consistent with end use, is

exposed at a field surface-area-to-volume ratio greater than or equal to that of a typical installation. Unless the manufacturer's use instructions indicate otherwise, the slides shall be allowed to air cure for 48 ± 2 h at room temperature prior to washing, conditioning, and exposure in-vessel.

B.3.2.4 Solders

These products shall be prepared by placing the solder in a ceramic combustion boat (96 x 12 x 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.

The boat (with solder) shall be placed in the oven and allowed to heat until the solder has melted (approximately 1 – 2 min). The boat shall be allowed to cool and the solder piece removed.

B.3.2.5 Fluxes

Fluxes shall be prepared by applying a thin film to a copper sheet of the appropriate size as described in annex B, section B.3.1. The copper sheet shall then be placed in a muffle furnace that has been set to 300 °C (572 °F). The copper sheet (with flux) shall be allowed to heat until the flux flows (approximately 30 to 60 sec). The copper sheet shall be allowed to cool prior to exposure.

B.3.3 Conditioning for joining and sealing materials intended for joining pipe and fittings

After washing (annex B, section B.2.4), and prior to exposure, product/material samples shall be conditioned to simulate pre-use flushing and disinfection procedures. The samples shall be exposed for evaluation immediately after conditioning. Joining and sealing materials shall be conditioned at the temperature appropriate for the intended end use. The product samples shall be conditioned in accordance with 4.5.5 for single time point evaluations and 4.5.7 for multiple time point evaluations.

B.3.4 Conditioning for all other joining and sealing materials

After preparation, the test samples shall be washed as described in annex B, section B.2.4.

B.3.5 Exposure for joining and sealing materials intended for joining pipe and fittings

Exposure shall begin immediately after conditioning. The samples shall be exposed to the appropriate extraction water according to annex B, section B.2.5, based on end use or application. The product samples shall be exposed in accordance with 4.5.6 for single time point evaluations or in accordance with 4.5.7 for multiple time point evaluations. The extraction water shall be collected for analysis as described in annex B, section B.6.

B.3.6 Exposure for all other joining and sealing materials

After conditioning, these materials shall be exposed in the appropriate extraction water (annex B, section B.2.5) in accordance with the intended end-use application as described below. The extraction water samples shall be collected as described in annex B, section B.6.

B.3.6.1 Cold application

Products to be evaluated for cold applications shall be exposed using the sequence in table B5.

B.3.6.2 Hot application samples

Products to be evaluated for hot applications shall be exposed using the sequence in table B6.

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.

B.4 Mechanical devices

B.4.1 Samples

Samples shall consist of the entire device, portion(s)/ component(s) of the device, or a specimen of the material(s). The manufacturer shall have the option to request that the samples represent a product line of varying sizes, as described below. When it is necessary to calculate normalization factor(s), the wetted exposed surface area of the sample shall be calculated and recorded prior to testing.

B.4.1.1 Entire device

A single device shall represent a product line of varying sizes when:

- materials are of the same alloy, composition, or formulation;
- materials have undergone the same manufacturing process, e. g., casting or extrusion;
- designs are analogous; and
- it has the greatest exposed wetted surface-area-to-volume ratio.

The wetted surface-area-to-volume ratio shall be calculated as $SA_F/V_{F(\text{static})}$, with SA_F equal to the surface area exposed in the field, and $V_{F(\text{static})}$ equal to the volume of water to which the device is exposed under the static condition. The surface-area-to-volume ratio for a device with an internal volume of less than 1 L (0.26 gal) shall be calculated with the assumption that $V_{F(\text{static})}$ is equal to 1 L (0.26 gal).

NOTE 1 – For a product line of varying sizes with volumes of less than 1 L (0.26 gal), the device with the largest wetted surface area will be the device with the greatest exposed surface-area-to-volume ratio.

NOTE 2 – Design differences such as external and internal threaded outlets shall not be considered analogous.

NOTE 3 – For internal threaded products, SA_F shall be equal to the normally wetted surface area of the product including 25% of the threaded area(s). The capacity of the product shall be equal to the volume of water contacted by the wetted surface area of the product including the volume contained within 25% of the threaded area(s). When the product capacity is less than 1 L (0.26 gal), $V_{F(\text{static})}$ shall equal 1 L (0.26 gal). When the product capacity is equal to or greater than 1 L (0.26 gal), $V_{F(\text{static})}$ shall be equal to the capacity.

B.4.1.2 Component

A component shall represent a product line of varying sizes when:

- materials are of the same alloy, composition, or formulation; and
- materials have undergone the same manufacturing process, e. g., casting or extrusion; and
- designs are analogous; and
- it has the greatest exposed wetted surface-area-to-volume ratio.

The wetted surface-area-to-volume ratio shall be calculated as $SA_F/V_{F(\text{static})}$, with SA_F equal to the surface area exposed in the field, and $V_{F(\text{static})}$ equal to the volume of water to which the component is exposed under the static condition. The surface-area-to-volume ratio for a component with an internal volume of less than 1 L (0.26 gal) shall be calculated with the assumption that $V_{F(\text{static})}$ is equal to 1 L (0.26 gal).

NOTE 1 – For a product line of varying sizes with volumes of less than 1 L (0.26 gal), the component with the largest wetted surface area will be the component with the greatest exposed surface-area-to-volume ratio.

NOTE 2 – Design differences such as external and internal threaded outlets shall not be considered analogous.

NOTE 3 – For internal threaded products, SA_F shall be equal to the normally wetted surface area of the product including 25% of the threaded area(s). The capacity of the product shall be equal to the volume of water contacted by the wetted surface area of the product including the volume contained within 25% of the threaded area(s). When the product capacity is less than 1 L (0.26 gal), $V_{F(\text{static})}$ shall equal 1 L (0.26 gal). When the product capacity is equal to or greater than 1 L (0.26 gal), $V_{F(\text{static})}$ shall be equal to the capacity.

B.4.1.3 Material

The material shall be representative of that used in the component or device.

Materials shall be evaluated using a minimum surface-area-to-volume ratio of 50 cm²/L.

B.4.2 Sample preparation

Prior to conditioning and exposure, the samples shall be washed as described in annex B, section B.2.4, unless the manufacturer's instructions direct otherwise. When required, the device shall be properly prepared per the manufacturer's recommendations.

When the test sample contains internal threaded outlets, 75% of the threaded surface area(s) shall be covered by insertion of a threaded component of the appropriate diameter to produce a watertight seal. The threaded component shall also be present in the method blank (see Annex B, section B.2.8.1).

NOTE – To facilitate the exposure of product samples that are connected to pipe or tubing products under normal installation conditions (e. g., valves), the samples may be attached to lengths of pipe or tubing of the appropriate nominal diameter. When a test sample is prepared in this manner, the assembly shall be designed so that the volume of the test sample plus the attached pipe or tubing is equal to the $V_{F(\text{static})}$ for the product. The pipe or tubing material shall also be present in the method blank as required in annex B, section B.2.8.1.

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 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). 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 extraction media shall be collected as described in annex B, section B.6.

B.4.4.2 Point-of-entry systems and system components requiring exposure under pressure

B.4.4.2.1 The system or component(s) of a system shall be installed and flushed in accordance with the manufacturer's instructions using the exposure water specified in B.2.5 at an initial inlet static pressure of 340 kPa (50 psig).

B.4.4.2.2 After flushing, the system or component(s) shall be conditioned in accordance with the times and temperatures specified in B.4.3 and exposed in accordance with the times and temperatures specified in B.4.4.1, each using the exposure water specified in B.2.5 at an initial inlet static pressure of 340 kPa (50 psig).

B.4.4.2.3 A minimum sample volume of 2 L shall be collected at each sample point. If the water holding volume of the product is greater than 2 L, the entire volume shall be collected in a suitable collection vessel, and subsamples for analysis obtained from this volume. If the water holding volume of the product is less than 2 L, sufficient products shall be exposed to provide the required 2 L volume of extractant water (up to a maximum of eight).

B.4.4.2.5 Systems with adsorptive or absorptive media shall be tested with and without the media. Testing without media shall include removal of the adsorptive or absorptive media from the system, as well as the removal of any non-media materials or ingredients that cannot be dissociated from the media or materials that would be released into the effluent of the system in the absence of the physical barrier provided by the media.

NOTE – An example is the binder used to produce carbon blocks. Normalization for changes in wetted surface area from the normal configuration should be taken into account. Carbon block end caps, for example, will have more wetted surface area exposed without the carbon block attached, and an appropriate adjustment in the end caps included in the exposure shall be made.

When these units are evaluated with the media removed, the evaluation shall be as specified in B.2.4.4.1 through B.4.4.2.3. When these units are evaluated with the media, the evaluation shall be as specified in 7.5.5.4.

B.4.4.3 Chemical feeder and generator exposure

The samples shall be exposed to the appropriate drinking water treatment chemical or chemical mixture for a minimum of 4 h (or for a longer period as recommended by the manufacturer) at 23 ± 2 °C (73 ± 4 °F). For devices that normally operate at lower or higher temperatures, the exposure shall be at the normal operating temperature. The extractant shall be collected in a vessel appropriate for shipping and storage. For chemical feeders, a sample of the chemical prior to feeding shall be collected if possible. For chemical generators, samples of the raw chemicals shall be collected. For all devices where the extractant is a mixture of water and the chemical(s), a sample of the influent water shall be collected and

preserved as described in annex B, section B.6. Analysis of the extractant shall be in accordance with the requirements of NSF/ANSI 60. Samples of the chemicals prior to feeding samples of raw materials, and influent water samples, shall be analyzed for background levels of contaminants only if, after normalization, the concentration of a contaminant(s) exceeds the SPAC (annex B, section B.8.6).

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. 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 extraction media shall be collected as described in annex B, section B.6.

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.

B.5 Mechanical plumbing devices

B.5.1 Samples

Samples shall consist of the entire device, portion(s)/component(s) of the device, or a specimen of the materials(s) of the device. The samples shall be permitted to represent a product line of varying sizes, as described in annex B, sections B.5.1.1 and B.5.1.2. When it is necessary to calculate normalization factor(s), the wetted surface area of the sample shall be determined. When materials and components are tested using in-vessel exposure, the actual wetted surface area and the volume of water in the extraction vessel shall be determined.

B.5.1.1 Device

A single device shall represent a product line of varying sizes when the following requirements are met:

- materials are of the same alloy, composition, or formulation;
- design and manufacturing processes are analogous; and
- it has the greatest wetted surface-area-to-volume ratio.

The surface-area-to-volume ratio for an endpoint device, other than a commercial kitchen device, shall be calculated with the assumption that the device volume is 1 L (0.26 gal). The surface-area-to-volume ratio for a commercial kitchen device shall be calculated with the assumption that the device volume is 18.9 L (5 gal).

B.5.1.2 Component

A component shall represent a product line of varying sizes when the following requirements are met:

- materials are of the same alloy, composition, or formulation;
- design and manufacturing processes are analogous; and
- it has the greatest wetted surface-area-to-volume ratio.

The surface-area-to-volume ratio for a regular endpoint component shall be calculated with the assumption that the component volume is 1 L (0.26 gal).

B.5.1.3 Material

The material shall be representative of that used in the component or device. Material samples not related to a specific component or device can also be evaluated.

B.5.2 Washing

The device shall be flushed for 15 min with tap water under pressure, then rinsed with three volumes of reagent water that meets the requirements of annex B, section B.9.2. Alternate preparation of the device shall be performed when required by published manufacturer's instructions. Components and materials shall be washed according to annex B, section B.2.4.

B.5.3 Conditioning

Conditioning of the sample shall be performed in the sample or in a vessel. Endpoint devices, components, and materials shall be conditioned by rinsing with three volumes of extraction water (specified in annex B, section B.5.5) at room temperature 23 ± 2 °C (73 ± 4 °F). The units or exposure vessels shall be filled with extractant water and held until the start of the exposure sequence for a period not to exceed 72 h.

B.5.4 Exposure

NOTE – Revisions to lead requirements of this section have been made and are located in Annex F of this Standard. Please refer to that annex for additional details. The revisions contained in Annex F are informational at this time and are scheduled to be incorporated into this section July 1, 2012.

After conditioning, the sample shall be exposed to extraction water according to the applicable scheme detailed in annex B, sections B.5.4.1 through B.5.4.3. Reflecting the sample's intended use, samples shall be exposed to extraction waters at the specified temperatures for the entire duration of the exposure. Exposure shall be limited to 23 ± 2 °C (73 ± 4 °F) except for instant hot water dispensers, in which case the manufacturer's specified thermostat setting shall be used.

Evaluation of endpoint devices, components, and materials for contaminants other than lead shall require exposure of at least one sample according to the timetable of figure B1. The number of products to be tested shall be specified by the manufacturer. When one sample is tested at a single time point, the normalized contaminant concentrations from exposure on Day 19 shall be compared to their respective SPACs. If more than one sample is tested at a single time point, the geometric mean of normalized contaminant concentrations from exposure on Day 19 shall be compared to their respective SPACs.

Evaluation of endpoint devices, components and materials for the contaminant lead shall require exposure of at least three devices (more if specified by the manufacturer), according to the timetable of figure B1. It is recommended that product lines thought to be marginally acceptable, and those that leach levels of lead approaching the maximum allowable level, should be tested for more than the minimum number of products. The rationale for selecting a number greater than three products is provided in annex B, section B.8.9. On Days 3, 4, 5, 10, 11, 12, 17, 18, and 19, the 16 h dwell extractant water shall be collected. The lead test statistic Q shall be determined as described in annex B, section B.8.9, and compared to 11 µg.

When additional extraction water is needed to complete all analyses, additional samples shall be exposed.

B.5.4.1 Exposure sequence for endpoint devices

The device shall be inverted and filled with extraction water and held according to figure B1 during the exposure sequence. Hot water dispensers shall be heated to operating temperature, then exposed following the sequence in figure B1 at the elevated temperature.

The final exposure water shall be collected and preserved in accordance with applicable analytical methods. When tested at a single time point, only the contaminant levels present in the 16 h dwell samples shall be used to evaluate the product's leaching characteristics.

For endpoint devices, the exposure sequence in figure B1 shall be conducted and the Days 3, 4, 5, 10, 11, 12, 17, 18, and 19 lead dosages shall be determined.

B.5.4.2 Exposure sequence for components and materials

The exposure procedures provided in annex B, section B.5.4.1 shall be followed. Samples shall be tested at a surface area-to-volume ratio at least as high as the ratio that exists in the device.

B.5.4.3 Method blanks

Method blanks are prepared using the same reagents and in the same manner as samples, but no sample is added. An uncoated substrate, as applicable, shall be included. Method blanks shall be processed with all samples.

B.5.4.4 Method standards

Method standards shall be prepared along with all samples. Method standards are prepared in the same manner as method blanks, except a known amount of the expected contaminants is added.

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 chlorine.

All exposure water that is being used to determine conformance to this Standard shall be prepared fresh daily and stored in a closed container.

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.

B.6 Collection and preservation of extraction media after exposure

Immediately after the exposure period, the extraction media shall be poured into sample bottles previously prepared as detailed in annex B, table B10 for storage until analysis. The procedures described in annex B, table B10 are based on collection methods included in "Manual For The Certification of Laboratories Analyzing Drinking Water," (EPA-570/9-82-002) and *Standard Methods For The Examination of Water and Wastewater* (most recent edition).

B.7 Analysis methods

B.7.1 General

This section is divided into five parts: metals, organics ([t]her than residual vinyl chloride monomer (RVCM) and solvent], radionuclides, RVCM, and solvents analyses. The specific analyses performed shall be formulation-dependent.

Each testing organization shall periodically review the analytical methods it uses to ensure that applicable advances in analytical methodologies are instituted.

B.7.2 Definitions

B.7.2.1 identified compound with standard: A compound identification made based on the daily analysis (initial or continuing calibration) of an authentic standard of an analyte. Retention time and mass spectrum are used for qualitative determination of the analyte. A calibration curve is used for quantitative determination of the analyte.

B.7.2.2 identified compound without standard: A compound identification based on mass spectral matches between the analyte and mass spectral libraries (commercial or private), or on spectral interpretation by a qualified chemist, or both. The quantitative determination is made through direct correlation between the analyte response and the nearest internal standard response.

B.7.2.3 matrix spike: An aliquot of a sample matrix fortified with a known quantity of analyte.

B.7.2.4 method detection limit (MDL): As defined in 40 CFR Part 136, Appendix B, the minimum concentration of a substance that can be measured and reported with 99% confidence that the substance concentration is greater than zero. The MDL is determined from analysis of a minimum of seven aliquots of standard (known quantity of analyte in reagent matrix) at concentrations that are in the range of the estimated detection limit.

B.7.2.5 method validation: Verification of an analytical procedure performed by determining the method detection limit (see annex B, section B.7.2.4).

B.7.2.6 reporting limit (RL): The lowest concentration of analyte that can be reliably reported.

B.7.2.7 unknown: An analyte for which an identification cannot be determined. Information on chemical class, functional group(s), and chemical structure may be determined by spectral interpretation.

B.7.3 Metals analysis

Analyses for metals shall be performed, except as otherwise provided for herein, in accordance with currently accepted U. S. Environmental Protection Agency (EPA) Methods (see 40 CFR Part 141 and Methods for Chemical Analysis of Water and Wastes, EPA 600/4-79-020). When no EPA method is provided, analyses shall be performed in accordance with *Standard Methods for the Examination of Water and Wastewater* (most current edition). If neither of these two documents addresses the required parameters and matrix, or if an alternate method is desired, method validation shall be completed prior to the application of the method (see annex B, section B.7.2.5).

B.7.4 Organics analysis

B.7.4.1 General requirements for analysis of organics

Analyses for organics shall be performed, except as otherwise provided for herein, in accordance with currently accepted EPA methods (see 40 CFR Part 141 and Methods for Chemical Analysis of Water and Wastes, EPA 600/4-79-020). When no EPA method is provided, analyses shall be performed in accordance with *Standard Methods for the Examination of Water and Wastewater* (most current edition). If neither of these two documents addresses the required parameters and matrix, or if an alternate method is desired, method validation shall be completed prior to the application of the method (see annex B, section B.7.2.5).

B.7.4.2 Gas chromatography/mass spectroscopy (GC/MS) analysis

B.7.4.2.1 General requirements for GC/MS analysis

The minimum instrument operation requirements for GC/MS analysis shall be in accordance with USEPA Method 625 (USEPA-600/4-84-053. *Methods for Organic Chemical Analysis of Municipal and Industrial Wastewater*, June 1984¹⁹) with the following modifications:

- The average chromatographic peak area of each internal standard in the calibration curve shall be determined. The chromatographic peak area of each internal standard in the continuing calibration shall be greater than 50% and not more than 200% of that average;
- While a continuing calibration check (CCC) is performed, concentrations of 10% of the target compounds for each analysis (e. g., base/neutral, base/neutral/acid, or acid) shall be allowed to fall outside the range of 70% to 130% (outlier) of the true value. None of the concentrations shall be allowed to fall below 50% or above 200% of the true value. If a positive sample analyte result

¹⁹ USEPA, Environmental Monitoring and Support Laboratory, Cincinnati, OH 45268

is identified for any outlier, a second CCC shall be performed. If the second CCC determines the sample analyte result no longer to be an outlier, the sample shall be reanalyzed. However, if the second CCC also determines the analyte to be an outlier, a new calibration curve shall be determined and the sample shall be reanalyzed;

- If commercially available mass spectral libraries are utilized, a minimum size of 100,000 compounds shall be required; and
- The testing laboratory shall report the compounds detected during GC/MS analysis as one of the following:
 - identified compound with standard (see annex B, section B.7.2.1);
 - identified compound without standard (see annex B, section B.7.2.2); or
 - unknown (see annex B, section B.7.2.7).

B.7.4.2.2 Requirements for identified compounds with standards via GC/MS analysis

Contaminants that have been identified and quantified by comparison to authentic standards shall be normalized in accordance with the requirements of this Standard (see annex B, section B.8). The normalized contaminant concentration shall be compared to the acceptable exposure concentration as determined in accordance with annex A of this Standard.

B.7.4.2.3 Requirements for identified compounds without standards via GC/MS analysis

Contaminants that have been identified and quantified by comparison to a known mass spectrum, or by spectral interpretation by a qualified chemist, or both, shall be normalized in accordance with the requirements of this Standard (see annex B, section B.8). The normalized contaminant concentration shall be compared to the acceptable exposure concentration as determined in accordance with annex A of this Standard. In addition, the product manufacturer shall assist the testing laboratory in the identification of an authentic standard for the compound and an appropriate analytical method, if applicable, so that confirmatory identification and quantification can be performed.

B.7.4.2.4 Requirements for unknowns via GC/MS analysis

Contaminants that are detected by GC/MS analysis, but are not identified and quantified against a known mass spectrum or authentic standard, shall be evaluated as follows:

- a) The product material formulation(s) shall be reviewed for potential identification of the unknown contaminant(s) as an ingredient or byproduct;
- b) The manufacturer shall be notified and requested to provide supporting information that enables identification of the unknown contaminant(s);
- c) Structure activity relationships (SAR) shall be utilized when sufficient structural identification of the unknown contaminant(s) can be made; and
- d) Alternative methods of analysis that may identify the unknown contaminant(s) shall be considered.

Contaminants that can be identified after performing one or more of the above steps shall be normalized in accordance with the requirements of this Standard (see annex B, section B.8). The normalized contaminant concentration shall be compared to the acceptable exposure concentration as determined in accordance with annex A of this standard. In addition, the product manufacturer shall assist the testing laboratory in the identification of an authentic standard for the compound and an appropriate analytical method, if applicable, so that confirmatory identification and quantification can be performed.

Contaminants detected by GC/MS analysis for which no identification can be made after performing the above steps shall not be considered in the determination of product compliance to this Standard. When unknown contaminants are detected in the extractant water, the testing laboratory shall report the analytical results to the product manufacturer.

NOTE – The product manufacturer should assist the testing laboratory in a continuing effort to identify the unknown contaminant(s) until specific identification is achieved.

B.7.4.3 Polynuclear aromatic hydrocarbon (PNA) analysis

Analysis for polynuclear aromatic hydrocarbons (PNAs) shall be in accordance with EPA Method 525.2 (USEPA-600/4-79-020, *Methods for the Chemical Analysis of Water and Wastes*, March 1983).

B.7.4.4 Phenol and minimally substituted phenols

Analysis for phenol and minimally substituted phenols shall be in accordance with EPA Method 420.2 (USEPA-600/4-79-020, *Methods for the Chemical Analysis of Water and Wastes*, March 1983). Analysis for maximally substituted phenols shall be performed by GC/MS base/acid scan (see annex B, section B.7.4.2).

B.7.5 Radionuclides analysis

Analyses for radionuclides shall be performed in accordance with Prescribed Procedures for Measurement of Radioactivity in Drinking Water, EPA-600/4-80-032. When no EPA method is provided, analyses shall be performed in accordance with *Standard Methods for the Examination of Water and Wastewater* (most current edition). If neither of these two documents addresses the required parameters and matrix, or if an alternate method is desired, method validation shall be completed prior to the application of the method (see annex B, section B.7.2.5).

B.7.6 RVCM analysis

B.7.6.1 General requirements for RVCM analysis

This method covers the analysis of residual vinyl chloride monomer (RVCM) in PVC and CPVC potable water products using gas chromatography. Method sensitivity is 0.5 ppm (mg/kg) when analyzing 0.5 g of plastic material, using flame ionization detector (FID).

B.7.6.2 Extraction of samples for RVCM analysis

Polyvinyl chloride (PVC) and chlorinated polyvinyl chloride (CPVC) products shall be evaluated for RVCM in the product wall. The RVCM concentration shall be determined in the wall, rather than in the extraction water, because very low levels of vinyl chloride cannot be as reliably detected in the extraction water.

B.7.6.2.1 Sample preparation for RVCM analysis

PVC and CPVC samples shall be prepared as described in the following procedure. All samples shall be prepared in duplicate.

- a) Chop a section of PVC or CPVC product sample into coarse pieces.
- b) Weigh 0.500 ± 0.005 g of chopped sample pieces into a 20-mL glass vial.

NOTE – The weights of the sample and the duplicate should not differ by more than 0.005 g.

- c) Add 10 mL of N,N-dimethylacetamide (distilled in glass) to the sample bottle, seal and cap.

- d) Shake sample bottle at least 30 min on a reciprocating shaker.

B.7.6.2.2 Standards for RVCM analysis

Both a standard stock solution and a secondary dilution standard shall be prepared for the RVCM analysis, using vinyl chloride gas (99.9%) and N,N-dimethylacetamide (DMAC).

B.7.6.2.3 Standard stock solution for RVCM

The standard stock solution shall be prepared as follows:

- a) Pipette approximately 9.8 mL of DMAC into a 10-mL volumetric flask.
- b) Allow the flask to stand unstoppered until the wetted surface has dried.
- c) Weigh the flask and stopper to the nearest 0.1 mg and record the weight.
- d) Fill a 50-mL valved gas-tight syringe with vinyl chloride gas to the 50-mL mark.
- e) Lower the needle to 5 mm above the meniscus of the DMAC and slowly introduce the standard above the surface.
- f) Immediately reweigh the flask and contents and record the weight.
- g) Dilute to volume with DMAC, stopper, and mix.
- h) Transfer the solution into a PTFE sealed screw-cap vial.
- i) Store at -10 °C to -20 °C (14 °F to -4 °F)
- j) Calculate stock standard solution with respect to a 0.500 g sample as follows:

$$\frac{(\text{gram of vinyl chloride}) (1 \times 10^6)}{0.500 \text{ g}} = \text{ppm (mg/kg) (mg/d)}$$

B.7.6.2.4 Secondary dilution standard for RVCM analysis

Using the stock standard solution, a secondary dilution in DMAC shall be prepared that is representative of a concentration suitable for making calibration standards and spikes.

B.7.6.3 Apparatus for RVCM analysis

The following apparatus shall be used for RVCM analysis:

- Gas Chromatograph (GC) equipped with a mL headspace sampling system, 80 °C (176 °F) oil bath, FID, data recording system, and autosampler;
- Column: 6 ft x 2 mm ID glass column packed with 1% SP-1000 on Carbopack B 60/80 mesh. Equivalent columns shall be permitted as long as the column provides maximum separation from interferences and the ability to meet established accuracy and precision;
- GC Conditions: The analysis shall be performed using an oven temperature program whereby the initial temperature of approximately 70 °C (158 °F) is held for 5 min, increased at 70°C/min (158°F/min) to approximately 220 °C (428 °F), and held until DMAC elutes (total run time about 16 min);

- The injector, detector, and sample loop temperature shall be held at approximately 200 °C, 275 °C, and 80 °C, (392 °F, 527 °F, and 176 °F) respectively; and
- The helium carrier gas shall have a flow rate of 20 mL/min. The headspace shall have a flow rate of 5 mL/min. The hydrogen and air flows for the flame shall be approximately 30 and 400 mL/min, respectively.

NOTE – All of these flow rates will vary somewhat between GCs to optimize separation and response. The above are given only as guidelines.

B.7.6.4 RVCM analysis

The sample and standards prepared in annex B, sections B.7.6.2.1 and B.7.6.2.2 shall be loaded into an auto sampler and equilibrated to 80 °C (176 °F) for 10 min prior to analysis.

B.7.6.5 Quality control for RVCM analysis

Duplicate analysis shall be performed on each sample. Duplicate spiked samples shall be run at the rate of one set per ten samples. An instrument standard shall be run with every ten analyses (fifth sample), and a reagent blank is required for each sample set. Quality control charts shall be developed and maintained and used as a check on the analytical system.

B.7.6.6 Evaluation and pass/fail criteria for RVCM analysis

PVC and CPVC products with an RVCM concentration of less than or equal to 3.2 mg/kg shall be considered acceptable. This acceptance criterion was determined using the equation described below:

$$M_W = 4/r [D/\pi]^{0.5} [(t + t_0)^{0.5} - t^{0.5}]M_P,$$

where:

M_W = RVCM diffused into water (mg/L);
 M_P = RVCM concentration in the PVC wall (mg/kg);

NOTE – A factor of 1.4 corrects for the ratio of density of water to PVC.

R = pipe radius (cm);
 D = diffusivity constant,

where:

D = $D_0 \times e^{(-17,000/RT)}$;
 R = gas constant 1.987°K⁻¹;
 T = temperature (°K);
 D_0 = 3.7 cm²/sec (319680 cm²/d);
 t_0 = diffusion time period (d);
 t = product age at beginning of the diffusion time (d); and
 30 °C = 303 °K.

The calculations shall be as follows:

$$M_W = 4/r [D/\pi]^{0.5} [(t + t_0)^{0.5} - t^{0.5}](M_P \times 1.4 \text{ kg/L})$$

$$M_P = \frac{M_W}{4/r [D/\pi]^{0.5} [(t + t_0)^{0.5} - t^{0.5}] (1.4 \text{ kg/L})}$$

$$M_p = \frac{0.0002 \text{ mg/L}}{(3.15)(0.000235)(0.061)(1.4 \text{ kg/L})}$$

$$M_p = 3.2 \text{ mg/kg}$$

NOTE – The following assumptions were used in the preceding calculations:

- 30-d-old product is tested equivalent to 1 in inner pipe diameter;
- $t_0 = 16 \text{ h}$ (0.67 d); and
- $M_w = 0.2 \text{ } \mu\text{g/L}$ (0.0002 mg/L).²⁰

B.7.7 Solvent analysis

This section outlines the general procedure for determining solvent levels in the extraction water. The method described below is based on direct injection gas chromatography with flame ionization detection (FID). In some instances, an enhancement step (e. g., purge and trap [cold or heated] or headspace analysis) shall be required to complete the analysis. The choice of enhancement shall be dependent on the desired detection levels of the solvent of interest. The method sensitivity for direct injection is approximately 100 $\mu\text{g/L}$ (0.1 mg/L) for selected solvents.¹⁵⁾

B.7.7.1 General requirements for solvent-containing materials

These products shall be evaluated to determine the solvent leaching rates over time, if applicable. The relationship between contaminant concentration and time shall be determined by plotting a minimum of five points. In many instances, direct injection shall be sufficient only for the early testing period. When direct injection is no longer adequate for determining a concentration, a more sensitive method shall be required (i. e., purge and trap).

B.7.7.2 Apparatus for solvent analysis

The recommended apparatus shall be a gas chromatograph (GC) equipped with an FID, temperature programming, data recording system, and an autosampler. A purge and trap (with and without heat) system and headspace sampling system shall also be available.

NOTE – The analysis conditions may require adjustment relative to the specific solvent or solvent system being evaluated.

B.7.7.3 Quality control for solvent analysis

Duplicate matrix spike samples shall be run at the rate of one set per ten samples or fewer. An instrument standard shall be run with every ten samples, and a reagent blank shall be required for each daily analysis. Quality control charts shall be developed, maintained, and used as a check on the analytical system.

B.8 Normalization

B.8.1 General

This section provides the calculations used to determine the level of contaminants projected "at the tap" based on the level of contaminants identified during laboratory analysis. The normalized contaminant concentration shall be compared to the requirements established in annex A.

²⁰ This concentration is based on the USEPA MCL for vinyl chloride (2 $\mu\text{g/L}$ or 0.002 mg/L), and since the SPAC = 1/10 MCL, the SPAC = 0.2 $\mu\text{g/L}$, or 0.0002 mg/L.

B.8.2 Definitions

B.8.2.1 residential products: Products used in buildings.

B.8.2.2 service line products: Products used from the water main to building plumbing systems.

B.8.2.3 multiple user service line products: Products used between the water main and multiple family residences or commercial buildings.

B.8.2.4 water main (distribution) products: Products used in locations other than buildings or service lines.

B.8.2.5 multiple-installation products: Products present in the drinking water system at regularly repeating intervals.

B.8.3 Normalization factor

To account for any differences in surface-area-to-volume ratios between laboratory and actual field use conditions, an adjustment or conversion using the equation below may be needed:

$$\begin{aligned}
 NF &= N1 \times N2 \\
 N1 &= \frac{SA_F}{SA_L} \times \frac{V_L}{V_{F(\text{static})}} \\
 N2 &= \frac{V_{F(\text{static})}}{V_{F(\text{flowing})}}
 \end{aligned}$$

where:

SA_F = surface area exposed in the field;

SA_L = surface area exposed in the laboratory;

V_L = volume of extraction water used in the laboratory;

$V_{F(\text{static})}$ = volume of water to which the product is exposed in the field for the static condition; and

$V_{F(\text{flow})}$ = volume of water to which the product is exposed in the field under flow conditions during a period of time equivalent to the laboratory test.

B.8.3.1 Static condition

The contaminant concentration shall be adjusted to reflect differences in surface-area-to-volume relationships between laboratory and field exposures under static conditions. This calculation shall use the N1 term defined in annex B, section B.8.3. The N2 term shall always equal one when calculating normalized static concentrations.

For multiple-installation products (e. g., pipes, fittings, and joining and sealing products used with pipes and fittings), the $V_{F(\text{static})}$ component of the N1 term shall be the volume of water contained within 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).

For valves, water meters, service saddles, backflow preventers and other products not present in the system at regularly repeating intervals, the $V_{F(\text{static})}$ component of the N1 term shall be the volume of water

a product holds (on its own) when filled to capacity; $V_{F(\text{static})}$ shall equal 1 L (0.26 gal) for all products that, when filled to capacity, hold (on their own) less than 1 L (0.26 gal) of water.

NOTE 1 – Annex B, table B11 details the assumptions and resulting N1 factors for typical product categories.

NOTE 2 – For internal threaded products, SA_F shall be equal to the normally wetted surface area of the product including 25% of the threaded area(s). The capacity of the product shall be equal to the volume of water contacted by the wetted surface area of the product including the volume contained within 25% of the threaded area(s). When the product capacity is less than 1 L (0.26 gal), $V_{F(\text{static})}$ shall equal 1 L (0.26 gal). When the product capacity is equal to or greater than 1 L (0.26 gal), $V_{F(\text{static})}$ shall be equal to the capacity.

B.8.3.2 Flowing conditions

In addition to the static condition, the contaminant concentration shall also be adjusted to reflect differences between laboratory and field exposures under flowing conditions. For this calculation, N2 will vary depending on use. For those products not having specific flowing N2 factors outlined in table B11, product literature or operational procedures shall be consulted.

NOTE – Annex B, table B11 details the assumptions and resulting N2 values for typical product categories.

B.8.4 Normalization of service line and residential products

B.8.4.1 For all service line and residential products, with the exception of mechanical plumbing devices covered under 9, a single normalized static concentration shall be determined for each contaminant.

NOTE – For residential and service line products, the static condition is the most conservative normalization, since the N2 values for these products are ≤ 0.1 .

B.8.4.2 For in-line devices, with the exception of expansion tanks, pressure tanks, and point-of-entry components, media, or systems, the static normalized contaminant concentration shall be multiplied by an additional normalization factor, N3. The factor $N3 = 1/DF$, where DF is equal to the ratio of the contaminant concentration in the device to the contaminant concentration at the tap. The value of N3 for in-line devices shall be 0.33.

B.8.4.3 For all in-line devices, normalized contaminant concentrations shall be adjusted to a 12-h exposure when the final exposure is other than 12 h in length.

NOTE – For example, when the final exposure for an in-line device is 16 h, the normalized contaminant concentrations shall be multiplied by a factor of $^{12}/_{16}$.

B.8.4.4 For point-of-entry systems, $V_{F(\text{static})}$ shall be equal to system void volume.

B.8.4.5 For point-of-entry components, $V_{F(\text{static})}$ shall be equal to $^{1}/_{3}$ the volume of the smallest tank for which the component is being evaluated for use, plus the volume of the component.

NOTE – Point-of-entry system tanks hold media displacing much of the tanks' void volume. The $^{1}/_{3}$ is to account for a common design difference between a system's "unit void volume" and "void volume" (volume with and without media respectively) that provides "freeboard" or open space to allow the media to expand during the regeneration cycles of media use.

B.8.5 Normalization for chemical feeders and generators

Chemical feeders and generators, feeder components, and the materials used therein present a special case because the materials are in contact with a concentrated chemical, which is then diluted at the prescribed feed rate, rather than in direct contact with water.

In addition to the equation in annex B, section B.8.3, the following normalization factor shall be used to estimate the normalized concentration of a contaminant in the finished drinking water:

$$NF = N1 \times N2 \times N4$$

where:

$$N4 = V_{TC}/V_{WT}$$

V_{TC} = volume of concentrated treatment chemical contacted or generated by the device 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 period of time equivalent to the laboratory test

B.8.6 Normalization for other products

The normalization factors described below shall be applied to products and materials not covered in annex B, sections B.8.4 and B.8.5. For these products, a single normalized concentration (either static condition or flowing condition, whichever is most conservative) shall be determined for each contaminant. For products that have a flowing $N2$ value ≤ 0.1 , the static condition shall be the most conservative condition. For products that have a flowing $N2$ value > 0.1 , the flowing condition shall be the most conservative condition. Normalization factors that are not included in annex B, table B11 shall be determined on a case-by-case basis using the equation in annex B, section B.8.3. Where a product is available in various sizes, the product with the highest surface-area-to-volume ratio (typically the smallest diameter) shall be evaluated. For products, components, or materials that may be used in any of the four end use categories in annex B, table B11, qualifying by use of the largest normalization factor shall qualify other use categories. Table B11 in this annex details the assumptions and resulting $N1$ and $N2$ values for various product categories.

B.8.7 Normalized concentration

The concentration of a contaminant in the finished drinking water shall be estimated using the following calculation:

$$\text{Normalized Concentration} = (\text{Laboratory Concentration}) \times (\text{Normalization Factor})$$

B.8.7.1 Static condition

The normalized contaminant concentration under static conditions shall be compared to the EPA MCL or the calculated TAC (as specified in annex A), and shall be less than or equal to the MCL or TAC.

B.8.7.2 Flowing condition

The normalized contaminant concentration under flowing conditions shall be compared to the Single Product Allowable Concentration (SPAC) (as specified in annex A), and shall be less than or equal to the SPAC.

B.8.7.3 Barrier materials containing solvents

Products/materials containing solvents shall be exposed so that the solvent leaching rates over time are determined. The relationship between normalized contaminant concentrations and time shall be determined and plotted with a minimum of five points. The normalized contaminant concentrations shall be compared to the STEL as specified in annex A, section A.5.

B.8.7.4 Joining and sealing materials containing solvents

The manufacturer shall have the option of initiating additional exposure testing to determine contaminant concentrations over time for solvent-containing materials. The relationship between contaminant concentrations and time shall be determined, and plotted with a minimum of 5 points. The normalized contaminant concentrations shall be calculated and then compared to the STEL as specified in annex A, section A.5.

B.8.8 Normalization for endpoint devices, components, and materials

B.8.8.1 Normalization for lead

For endpoint products other than commercial kitchen products, each laboratory concentration shall be normalized using the equation in annex B, section B.8.3 where: $V_{F(\text{static})} = 1 \text{ L (0.26 gal)}$ when the volume of the device is less than 1 L (0.26 gal), and $N_2 = 1$, and shall be multiplied by the cold mix volume adjustment factor (see 9.2.1).

For commercial kitchen products, each laboratory concentration shall be normalized using the equation in annex B, section B.8.3 where $V_{F(\text{static})} = 18.9 \text{ L (5 gal)}$ and $N_2 = 1$ and shall be multiplied by the CMV adjustment factor (see 9.2.1).

A parametric data evaluation (annex B, section B.8.9) shall be used to evaluate the test results for lead.

When a device or component has been tested for lead through separate exposure of two or more components or materials, the values of the test statistic Q for each exposure shall be summed. The summed test statistic Q shall be evaluated against the criteria in annex B, section B.8.9.

B.8.8.2 Normalization for all analytes except lead

For endpoint products other than commercial kitchen products, the laboratory concentration shall be normalized using the equation in annex B, section B.8.3 where: $V_{F(\text{static})} = 1 \text{ L (0.26 gal)}$ when the volume of the device is less than 1 L (0.26 gal), and $N_2 = 1$, and shall be multiplied by the CMV adjustment factor (see 9.2.1).

For commercial kitchen products, each laboratory concentration shall be normalized with the equation in annex B, section B.8.3 where: $V_{F(\text{static})} = 18.9 \text{ L (5 gal)}$ and $N_2 = 1$, and shall be multiplied by the CMV adjustment factor (see 9.2.1).

When one sample is tested, the normalized contaminant concentrations from exposure on Day 19 shall be compared to their respective SPACs. If more than one sample is tested, the geometric mean of normalized contaminant concentrations from exposure at Day 19 shall be compared to their respective SPACs.

B.8.9 Parametric data evaluation

The term "product" connotes "endpoint devices, components, and materials." The procedure for the evaluation of lead leaching from these products is based on testing a sampling of products to determine the lead leaching dosage of the product line. A derived test statistic determines whether the product line is acceptable under this Standard. The calculations assume that the lead dosage leached from the product is lognormally distributed.

The number of products to be tested shall be specified by the manufacturer, though a minimum of three is required. It is recommended that product lines thought to be marginally acceptable (those that leach higher, but acceptable, dosages of lead) be tested for more than the minimum number of products. For each of the products tested, the "product dosage" D_i is derived from the test data as detailed in annex B, section B.8.9.2. These dosages are used to calculate the test statistic Q, which determines whether the

product line is acceptable. Q is an exact 90% upper confidence bound on the 75th percentile product dosage.

In the event of a product failure, there is provision for a single retest. Retest results shall be combined with those from the initial test. The accumulated product dosages shall be used to calculate the retest statistic, R, which determines whether the product line is acceptable. R is an exact 99% upper confidence bound on the 75th percentile product dosage.

B.8.9.1 Test data

The analytical protocol described in annex B, section B.5.4 generates nine measured lead dosages (on Days 3, 4, 5, 10, 11, 12, 17, 18, and 19) leached from each of the products sampled from a particular product line. The number of products tested is defined as "n." The test data are described as (9 x n) data values of x_{ij} (ith product measured on the jth day) and are shown in annex B, table B12. These are used to calculate the product dosage D_i , for each of the tested products.

These data are used to calculate the statistics Q and R for the initial test and retest, respectively.

B.8.9.2 Calculations

$$D_i = e^{Y_i}$$

and

$$Y_i = \frac{(Y_{i3} + Y_{i4} + Y_{i5} + Y_{i10} + Y_{i11} + Y_{i12} + Y_{i17} + Y_{i18} + Y_{i19})}{9}$$

Calculate the log-dosage mean of Y_i and the log-dosage standard deviation of Y_i for each product, where:

$$\text{Log - dosage mean} = \bar{Y} = \frac{\sum_{i=1}^n Y_i}{n}$$

and

Log-dosage standard deviation =

$$S = \sqrt{\frac{\sum_{i=1}^n (Y_i - \bar{Y})^2}{(n-1)}}$$

B.8.9.3 Initial test statistic

NOTE – Revisions to lead requirements of this section have been made and are located in Annex F of this Standard. Please refer to that annex for additional details. The revisions contained in Annex F are informational at this time and are scheduled to be incorporated into this section July 1, 2012.

The test statistic Q shall be determined as:

$$Q = e^{\bar{Y}} \cdot e^{k_1 S}$$

where the log-dosage mean, \bar{Y} , and the log-dosage standard deviation, S, are determined using the procedures described in annex B, section B.8.9.2. The value of k_1 depends upon the sample size. Table

B13 in this annex presents the value of k_1 for a range of sample sizes. The acceptability of the product line depends upon the value of the test statistic, where:

- Case I: If $Q \leq 11 \mu\text{g}$, the product line has tested as acceptable; or
- Case II: If $Q > 11 \mu\text{g}$, the product line has tested as unacceptable.

When a device or component has been tested for lead through separate exposure of two or more components or materials, the summed value of the test statistic Q shall be compared to the preceding criteria.

B.8.9.4 Retest statistic

NOTE – Revisions to lead requirements of this section have been made and are located in Annex F of this Standard. Please refer to that annex for additional details. The revisions contained in Annex F are informational at this time and are scheduled to be incorporated into this section July 1, 2012.

The retest statistic R shall be determined as:

$$R = e^{\bar{Y}} \cdot e^{k_2 \cdot S}$$

where the log-dosage mean, \bar{Y} and the log-dosage standard deviation, S are determined using the procedures described in annex B, section B.8.9.2. The value of k_2 depends upon the sample size. Annex B, table B14 presents the value of k_2 for a range of sample sizes. The acceptability of the product line depends upon the values of the retest statistic, where:

- Case I: If $R \leq 11 \mu\text{g}$, the product line has tested as acceptable; or
- Case II: If $R > 11 \mu\text{g}$, the product line has tested as unacceptable.

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

All exposure water that is used to determine compliance to this Standard shall be prepared fresh daily and stored in a closed container.

B.9.2 Reagents

B.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 M Ω -cm at 25° C (77 °F); and
- total organic carbon (TOC) maximum 100 $\mu\text{g/L}$.

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.

B.9.2.2 Phosphate buffer stock solutions (0.1M)

Phosphate buffer stock solutions shall be prepared as follows: Dissolve 13.89 g sodium dihydrogen phosphate monohydrate in reagent water, dilute to 1.0 L (0.26 gal), and mix thoroughly. Prepare fresh weekly. This buffer shall be used with only the magnesium hardness reagent.

B.9.2.3 Magnesium hardness stock solution (0.04M)

Magnesium hardness stock solution shall be prepared by dissolving 8.13 g magnesium chloride hexahydrate in reagent water, diluting to 1.0 L (0.26 gal), and mixing thoroughly. The solution shall be prepared fresh weekly.

B.9.2.4 Chlorine stock solution (0.025M)

Chlorine stock solution shall be prepared as follows: Dilute 7.3 mL reagent grade sodium hypochlorite (5% NaOCl) to 200 mL with reagent water. Store in tightly stoppered amber reagent bottle protected from light and stored at 20 °C (68 °F). Prepare fresh weekly.

B.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 chlorine. This determination shall be referred to as "A."

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 chlorine residual, the following formula shall be used:

$$\text{mL stock solution} = \frac{2.0 \times B}{A}$$

where:

A = chlorine equivalent per mL of chlorine stock solution (determined above); and
B = liters of extraction water.

B.9.2.5 Calcium hardness stock solution (0.04M)

Calcium hardness stock solution shall be prepared by dissolving 4.44 g anhydrous calcium chloride in reagent water, diluting to 1.0 L (0.26 gal), and mixing thoroughly. The solution shall be prepared fresh weekly.

B.9.2.6 Sodium bicarbonate buffer (0.04M)

Sodium bicarbonate buffer shall be prepared by dissolving 3.36 g sodium bicarbonate in reagent water and diluting to 1.0 L (0.26 gal), mixing thoroughly. The solution shall be prepared fresh weekly.

B.9.2.7 Sodium hydroxide solution (0.1M)

Sodium hydroxide solution shall be prepared by dissolving 4.0 g of sodium hydroxide in reagent water, diluting to 1.0 L (0.26 gal), and mixing well.

B.9.2.8 Sodium borate solution (0.05M)

Sodium borate solution shall be prepared by dissolving 19.07 g of sodium borate decahydrate ($\text{Na}_2\text{B}_4\text{O}_7 \cdot 10 \text{H}_2\text{O}$) in reagent water, diluting to 1.0 L (0.26 gal), and mixing well.

B.9.3 pH 5 water

pH 5 extraction water shall be prepared to contain 100 mg/L hardness and 2 mg/L 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 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.

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 pH 8 water (conditioning)

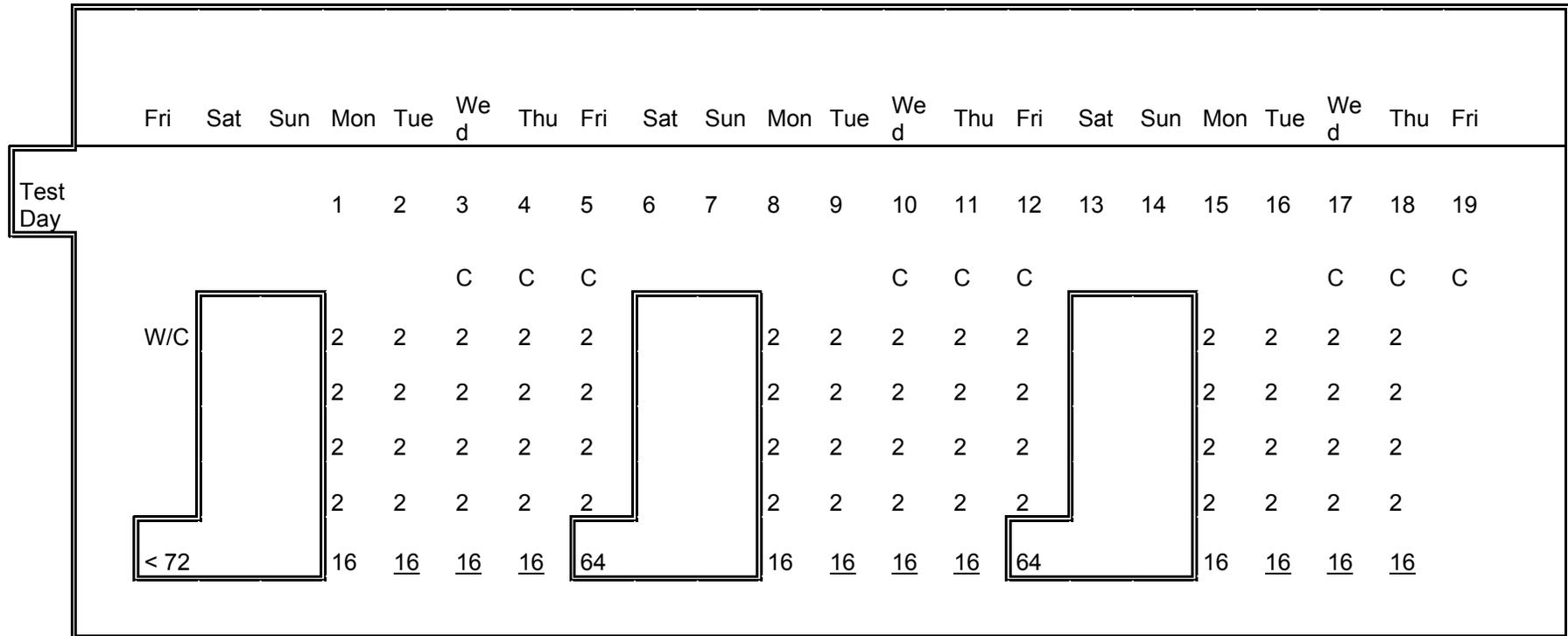
pH 8 conditioning water shall be prepared to contain 100 mg/L hardness and 2 mg/L available chlorine. Stock reagent solutions in the amounts shown in annex B, table B15 shall be diluted to the desired water volume with reagent water.

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 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 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.



Key

W/C = washing and conditioning
 < 72 = dwell between conditioning and exposure sequence (Maximum: 72 h)
 2 = dump and fill 2 h intervals
 16 = 16 h dwell (overnight)
16 = 16 h dwell for data
 C = collect prior day's 16 h dwell
 64 = 64 h dwell (weekend)

Figure B1 – Exposure sequence for mechanical plumbing device

Table B1 – NSF/ANSI 61 products

Joining and sealing materials	Mechanical devices
adhesives brazing materials fluxes solders caulks gaskets grouts lubricants o-rings packing primers sealants	chemical feeders dry feeders (e. g., pellet droppers) pressure gas injection systems pumps vacuum injection systems disinfection/generators chlorine dioxide hypochlorite ozone ultraviolet electrical wire submersible well pumps pumps switches and sensors (e. g., water level, flow, pressure, temperature) valves and related fittings (transmission/distribution system) water process treatment devices aeration equipment clarifiers electro dialysis microfiltration mixers reverse osmosis screens strainers ultrafiltration

Table B2 – Exposure summary

Category	Annex B reference section	Type of samples (surface area)	Required preparation	Product exposure
joining and sealing materials	4	15 cm ² /L	Some products applied to an appropriate substrate. Some products cut to appropriate size. Washed to remove debris accumulated during shipping and handling.	cold exposure = 24, 24, 24 h at 23 °C (73 °F) hot exposure = 1, 1, 1 h at 82 °C (180 °F)
mechanical devices	5	entire device, component, or material specimen ¹	Wash to remove debris accumulated during shipping.	conditioning period prior to exposure (2 wk maximum) cold exposure = 24, 24, 24 h at 23 °C (73 °F)

¹ A material specimen shall be exposed using a minimum surface-area-to-volume ratio of 50 cm²/L.

Table B3 – Extraction water selection

Analytes of interest	pH		
	5	8	10
metals	X		X
organics		X	
KEY X = Required extraction water selection.			

Table B4 – Test samples joining and sealing materials

Material	Typical form
adhesives and cements intended for joining pipe and fittings	applied to assembled pipe and fitting joints
adhesives and cements not intended for joining pipe and fittings	applied to glass panels
caulks, greases, lubricants, sealants	applied to glass panels
flux	applied to copper sheet and heated
gasket materials	ASTM D3182 tensile sheets or finished product
solders and solder/flux combinations	product heated in ceramic combustion boats

Table B5 – Exposure sequence for cold applications

Exposure temperature	Exposure time	Elapsed time	Comment
23 ± 1 °C (73 ± 2 °F)	24 ± 1 h	1 d	Extraction water is decanted and discarded; the exposure vessel or product is refilled with exposure water and exposure is continued.
23 ± 1 °C (73 ± 2 °F)	24 ± 1 h	2 d	Extraction water is decanted and discarded; the exposure vessel or product is refilled with exposure water and exposure is continued.
23 ± 1 °C (73 ± 2 °F)	24 ± 1 h	3 d	Extraction water is collected for analysis.

Table B6 – Exposure sequence for hot applications

Exposure temperature	Exposure time	Elapsed time	Comment
60 ± 1 °C (140 ± 2 °F) or 82 ± 1 °C (180 ± 2 °F)	60 ± 5 min	1 h	Extraction water is decanted and discarded; the exposure vessel or product is refilled with exposure water and exposure is continued.
60 ± 1 °C (140 ± 2 °F) or 82 ± 1 °C (180 ± 2 °F)	60 ± 5 min	2 h	Extraction water is decanted and discarded; the exposure vessel or product is refilled with exposure water and exposure is continued.
60 ± 1 °C (140 ± 2 °F) or 82 ± 1 °C (180 ± 2 °F)	60 ± 5 min	3 h	Extraction water is collected for analysis.

Table B7 – Product exposure¹

Product	In-the-product	In-a-vessel	Other
aeration equipment	x		material exposed in a vessel
chemical feeders	x		material exposed in a vessel
clarifiers			material exposed in a vessel
disinfection equipment			material exposed in a vessel
electrical wire		x	
in-line devices	x		
membranes/cartridges	x		
mixers			materials exposed in a vessel
pumps	x		
reverse osmosis			
screens		x	
strainers	x		
switches/sensors	x		
valves	x		

¹ For the purposes of this table, product may represent either the entire device or a component. These are the typical exposure conditions. However, products may be exposed in any fashion provided that the exposure is consistent with requirements in annex B, section B.2.

Table B8 – In-line device exposure sequence

Temperature	In-line device exposure time	Elapsed time ¹ in-line devices
23 ± 2 °C (73 ± 4 °F)	24 h	24 h
23 ± 2 °C (73 ± 4 °F)	24 h	48 h
23 ± 2 °C (73 ± 4 °F)	12 to 16 h	60 to 64 h

¹ Elapsed time does not include the initial 14-d conditioning period.

Table B9 – Other mechanical device exposure sequence

Temperature	Exposure time other mechanical devices	Elapsed time ¹ other mechanical devices
23 ± 2 °C (73 ± 4 °F)	24 h	24 h
23 ± 2 °C (73 ± 4 °F)	24 h	48 h
23 ± 2 °C (73 ± 4 °F)	24 h	72 h

¹ Elapsed time does not include the initial 14-d conditioning period.

Table B10 – Extractant water collection and preservation

Contaminant	Preservative	Container	Storage
herbicide	none	1 L (32 oz) amberglass bottles with PTFE lid	4 °C (39 °F)
metals, including mercury	Conc. HNO ₃ to pH < 2 (1.25 mL)	125 mL (4 oz) HDPE bottles with PTFE lid	room temp.
miscellaneous organics	none	500 mL amber bottle with PTFE lid	4 °C (39 °F)
pesticides	none	500 mL (16 oz) amber glass bottle with PTFE lid	4 °C (39 °F)
phenols	H ₂ SO ₄ to pH < 2 (2.50 mL)	250 mL (8 oz) amber glass bottle with PTFE lid	4 °C (39 °F)
phthalate	none	1 L glass bottle with PTFE lid (in duplicate)	4 °C (39 °F)
polyaromatic hydrocarbon	none	1 L glass bottle (in duplicate)	4 °C (39 °F)
radionuclides	10.0 mL HNO ₃	1 L (32 oz) polyethylene bottle (in duplicate)	room temp.
solvents	none	125 mL (4 oz) amber bottle with PTFE lid	4 °C (39 °F)
total kjeldahl nitrogen	H ₂ SO ₄ to pH < 2	250 mL amber bottle with PTFE lid	4 °C (39 °F)
total organic carbon	none	250 mL amber bottle with PTFE lid	4 °C (39 °F)
non-section 9 exposure for volatile organic chemicals (VOCs)	HCl	40 mL amber glass vial with PTFE lid	4 °C (39 °F)
section 9 exposure for volatile organic chemicals (VOCs)	sodium thiosulfate (a few grains to neutralize the chlorine)	40 mL amber glass vial with PTFE lid	4 °C (39 °F)

Table B11 – Normalization factors, assumptions, and examples pertaining to – water main joining and sealing materials

Product nominal diameter (n. d.)	Exposure type	Probable end use ¹	Assumptions	N1	N2 (flowing normalization only)
n. d. > 4 in	in-the-vessel	water main	– water is exposed to the same material from the treatment plant to the service line.	calculated in accordance with annex B, section B.8.3	1
<p>EXAMPLE – IN-THE-VESSEL WATER MAIN JOINING AND SEALING MATERIAL:</p> <p><u>Assumptions:</u></p> <ul style="list-style-type: none"> • product is a joining and sealing material applied to a 6 in nominal diameter pipe and was exposed in a vessel; • 0.5 in joining and sealing material width is exposed to water; • 20 ft long pipe (used to derive $V_{F(\text{static})}$ and SA_F) and 1 joint per 20 ft length; and • the ratio of SA_L to V_L was recorded and reported by the laboratory. <p> $SA_F = 60.77 \text{ cm}^2 (9.42 \text{ in}^2)$ $SA_L = 15 \text{ cm}^2 (2.3 \text{ in}^2)$ $V_{F(\text{static})} = 111 \text{ L (29.3 gal)}$ $V_L = 1 \text{ L (0.26 gal)}$ </p> <p> $N1 = \frac{SA_F}{SA_L} \times \frac{V_L}{V_{F(\text{static})}} = \frac{9.42}{2.33} \times \frac{0.26}{29.4} = 0.036$ and $N2=1$ </p> <p><u>Comments:</u></p> <ul style="list-style-type: none"> • Concentrations reported by the laboratory would be multiplied by 0.036 to obtain a normalized static concentration. The resulting normalized static concentration would be multiplied by 1 ($N2 = 1$) to obtain the normalized flowing concentration. 					

¹ Probable end use and corresponding assumptions are related to the nominal diameter of the product.

Table B11 (cont.) – Normalization factors, assumptions, and examples pertaining to – *service line joining and sealing materials*

Product nominal diameter (n. d.)	Exposure type	Probable end use ¹	Assumptions	N1	N2 (flowing normalization only)
4 in > n. d. > 1 in	in-the-vessel	service line	– joining/sealing materials applied to 1 in nominal diameter pipe – 1 user connection per service line and 180 gal/d/user – distance from water main to residence = 100 ft and therefore $V_{fc} = 4.08$ gal – flow rate equals 180 gal/d and therefore $V_{F(flow)} = 180$ gal – 10 joints are present on the service line	calculated in accordance with annex B, section B.8.3	0.023
<p>EXAMPLE --IN-THE-VESSEL SERVICE LINE JOINING AND SEALING MATERIALS:</p> <p><u>Assumptions:</u></p> <ul style="list-style-type: none"> • an in-the-vessel exposure was conducted; • product is used to join 1 in nominal diameter pipe; • 0.5 in width of the joining and sealing material comes in direct contact with water; • 100 ft of the pipe is present in the service line and therefore $V_{F(static)} = 4.08$ gal; • 10 joints are present on the service line; and • the ratio of SA_L to V_L was recorded and reported by the laboratory. <p> $SA_F = 10.1 \text{ cm}^2 (1.57 \text{ in}^2) \times 10 = 101.3 \text{ cm}^2 (15.7 \text{ in}^2)$ $SA_L = 15 \text{ cm}^2 (2.3 \text{ in}^2)$ $V_{F(static)} = 15.44 \text{ L (4.08 gal)}$ $V_L = 1 \text{ L (0.26 gal)}$ </p> <p> $N1 = \frac{SA_F}{SA_L} \times \frac{V_L}{V_{F(static)}} = \frac{15.7}{2.3} \times \frac{0.26}{4.08} = 0.44$ </p> <p> $N2 = \frac{V_{F(static)}}{V_{F(flow)}} = \frac{4.08}{180} = 0.023$ </p> <p><u>Comments:</u></p> <ul style="list-style-type: none"> • Concentrations reported by the laboratory would be multiplied by 0.44 to obtain a normalized static concentration. The resulting normalized static concentration would be multiplied by 0.023 to obtain the normalized flowing concentration. 					

¹ Probable end use and corresponding assumptions are related to the nominal diameter of the product.

Table B11 (cont.) – Normalization factors, assumptions, and examples pertaining to – residential joining and sealing materials

Product nominal diameter (n. d.)	Exposure type	Probable end use ¹	Assumptions	N1	N2 (flowing normalization only)
1 in > n. d. ≥ 0.5 in	in-the-vessel	residential	– joining/sealing materials applied to 0.5 in nominal diameter pipe – length of pipe in the residence = 280 ft (140 ft cold side and 140 ft hot side) and therefore $V_{F(\text{static})}=2.86$ gal (1.43 gal hot and 1.43 gal cold) – flow rate equals 180 gal/d and therefore $V_{F(\text{flow})} = 180$ gal – 200 joints are present in the residential system	calculated in accordance with annex B, section B.8.3	0.016
<p>EXAMPLE--IN-THE-VESSEL RESIDENTIAL JOINING AND SEALING MATERIAL:</p> <p>Assumptions:</p> <ul style="list-style-type: none"> • an in-the-vessel exposure was conducted; • product is a joining and sealing material used to join ½ in nominal diameter pipe; • 0.25 in width of the joining and sealing material comes in direct contact with water; • 280 ft of pipe is present in the residence (used to derive $V_{F(\text{static})}$ and SA_F); • the ratio of SA_L to V_L was recorded and reported by the laboratory; and • 200 joints are present in the residential system. <p> $SA_F = 2.54 \text{ cm}^2 (0.393 \text{ in}^2) \times 200 = 507 \text{ cm}^2 (78.6 \text{ in}^2)$ $SA_L = 65 \text{ cm}^2 (10 \text{ in}^2)$ $V_{F(\text{static})} = 10.83 \text{ L (2.86 gal)}$ $V_L = 1 \text{ L (0.26 gal)}$ </p> <p> $N1 = \frac{SA_F}{SA_L} \times \frac{V_L}{V_{F(\text{static})}} = \frac{78.6}{10} \times \frac{0.26}{2.86} = 0.73$ </p> <p> $N2 = \frac{V_{F(\text{static})}}{V_{F(\text{flow})}} = \frac{2.86}{180} = 0.016$ </p> <p><u>Comments:</u></p> <ul style="list-style-type: none"> • Concentrations reported by the laboratory would be multiplied by 0.73 to obtain a normalized static concentration. The resulting normalized static concentration would be multiplied by 0.016 to obtain the normalized flowing concentration. 					

¹ Probable end use and corresponding assumptions are related to the nominal diameter of the product.

Table B11 (cont.) – Normalization factors, assumptions, and examples pertaining to – water main valves

Product nominal diameter (n. d.)	Exposure type	Probable end use ¹	Assumptions	N1	N2 (flowing normalization only)
n. d. ≥ 4 in	in-the-product	water main	– twenty 4-in valves per mile (5,280 ft) – a width of 6 in is exposed for each valve	1	0.002
<p>EXAMPLE – IN-THE-PRODUCT WATER MAIN VALVE:</p> <p>Assumptions:</p> <ul style="list-style-type: none"> • product is a 4-in nominal diameter valve used on pipe with a nominal diameter of 4 in; • an in-the-product exposure was conducted; and • for each valve, a width of 6 in comes in direct contact with water. <p> $SA_F = 484 \text{ cm}^2 (75 \text{ in}^2)$ $SA_L = 484 \text{ cm}^2 (75 \text{ in}^2)$ $V_{F(\text{static})} = 1.24 \text{ L (0.327 gal)}$ $V_L = 1.24 \text{ L (0.327 gal)}$ </p> <p> $N1 = \frac{SA_F}{SA_L} \times \frac{V_L}{V_{F(\text{static})}} = \frac{75}{75} \times \frac{0.327}{0.327} = 1$ </p> <p> $N2 = \frac{\text{volume of 20 valves}}{\text{volume of 1 mi of pipe}} = \frac{6.52}{3,447} = 0.002$ </p> <p><u>Comments:</u></p> <ul style="list-style-type: none"> • Laboratory concentrations would be multiplied by 0.002 and compared to the SPAC. 					

¹ Probable end use and corresponding assumptions are related to the nominal diameter of the product.

Table B11 (cont.) – Normalization factors, assumptions, and examples pertaining to – residential and service line valves (including multiple user)

Product nominal diameter (n. d.)	Exposure type	Probable end use ¹	Assumptions	N1	N2 (flowing normalization only)	N3
4 in > n. d. ≥ 0.5 in	in-the-product	service line or residential	– when product holds less than 1 L (0.26 gal) under static conditions, $V_{F(\text{static})} = 1 \text{ L} = 0.26 \text{ gal}$ – $V_{F(\text{flow})} = 180 \text{ gal}$	calculated in accordance with annex B, section B.8.3	0.0015	0.33
<p>EXAMPLE – IN-THE-PRODUCT SERVICE LINE VALVE:</p> <p><u>Assumptions:</u></p> <ul style="list-style-type: none"> • product is a 0.5-in nominal diameter valve with a length of 2 in; • an in-the-product exposure was conducted; and • $V_{F(\text{static})} = 1 \text{ L}$ because the valve holds less than 1 L of water when filled to capacity under static conditions. <p> $SA_F = 20.26 \text{ cm}^2 (3.14 \text{ in}^2)$ $SA_L = 20.26 \text{ cm}^2 (3.14 \text{ in}^2)$ $V_{F(\text{static})} = 1 \text{ L} (0.26 \text{ gal})$ $V_L = 0.0064 \text{ L} (0.0017 \text{ gal})$ </p> <p> $N1 = \frac{SA_F}{SA_L} \times \frac{V_L}{V_{F(\text{static})}} \times \text{dispersion factor (N3)} = \frac{3.14}{3.14} \times \frac{0.0017}{0.26} \times 0.33 = 0.0021$ </p> <p> $N2 = \frac{V_{F(\text{static})}}{V_{F(\text{flow})}} = \frac{0.26}{180} = 0.0015$ </p> <p><u>Comments:</u></p> <ul style="list-style-type: none"> • Laboratory concentrations would be multiplied by 0.0021 to obtain the normalized static concentration. The resulting normalized static concentration would be multiplied by 0.0015 to obtain the normalized flowing concentration. 						

¹ Probable end use and corresponding assumptions are related to the nominal diameter of the product.

Table B12 – Data available for determination of lead test statistic

Product#	Measured lead dosage on day								
	3	4	5	10	11	12	17	18	19
1	X_{13}	X_{14}	X_{15}	X_{110}	X_{111}	X_{112}	X_{117}	X_{118}	X_{119}
2	X_{23}	X_{24}	X_{25}	X_{210}	X_{211}	X_{212}	X_{217}	X_{218}	X_{219}
3	X_{33}	X_{34}	X_{35}	X_{310}	X_{311}	X_{312}	X_{317}	X_{318}	X_{319}
•	•	•	•	•	•	•	•	•	•
•	•	•	•	•	•	•	•	•	•
•	•	•	•	•	•	•	•	•	•
n	X_{n3}	X_{n4}	X_{n5}	X_{n10}	X_{n11}	X_{n12}	X_{n17}	X_{n18}	X_{n19}

Table B13 – Values of k_1 for determining test statistic Q

Sample size	k_1	Sample size	k_1	Sample size	k_1
3	2.60281	19	1.05769	35	0.94208
4	1.97224	20	1.04590	36	0.93783
5	1.69779	21	1.03510	37	0.93377
6	1.53987	22	1.02517	38	0.92990
7	1.43526	23	1.01598	39	0.92618
8	1.35984	24	1.00747	40	0.92262
9	1.30234	25	0.99954	41	0.91921
10	1.25672	26	0.99213	42	0.91592
11	1.21943	27	0.98520	43	0.91277
12	1.18824	28	0.97869	44	0.90973
13	1.16167	29	0.97256	45	0.90680
14	1.13870	30	0.96677	46	0.90397
15	1.11859	31	0.96130	47	0.90125
16	1.10080	32	0.95612	48	0.89861
17	1.08491	33	0.95120	49	0.89607
18	1.07063	34	0.94653	50	0.89361

Table B14 – Values of k_2 for determining retest statistic R

Sample size	k_2	Sample size	k_2	Sample size	k_2
6	2.84809	21	1.39862	36	1.18574
7	2.49072	22	1.37611	37	1.17721
8	2.25337	23	1.35548	38	1.16907
9	2.08314	24	1.33647	39	1.16130
10	1.95433	25	1.31889	40	1.15387
11	1.85297	26	1.30257	41	1.14676
12	1.77079	27	1.28738	42	1.13994
13	1.70259	28	1.27319	43	1.13340
14	1.64491	29	1.25989	44	1.12711
15	1.59536	30	1.24740	45	1.12107
16	1.55224	31	1.23565	46	1.11526
17	1.51431	32	1.22455	47	1.10966
18	1.48063	33	1.21407	48	1.10425
19	1.45048	34	1.20413	49	1.09904
20	1.42329	35	1.19470	50	1.09401

Table B15 – 1-L volume of extraction water

pH	Solution #1	Solution #2	Chlorine stock solution
5	25 mL of 0.1 M NaH ₂ PO ₄	25 mL of 0.04 M MgCl ₂	annex B, section B.9.2.4
6.5	25 mL of 0.04 M NaHCO ₃	25 mL of 0.04 M CaCl ₂	annex B, section B.9.2.4
8 (conditioning)	25 mL of 0.04 M NaHCO ₃	25 mL of 0.04 M CaCl ₂	annex B, section B.9.2.4
8 (organic)	25 mL of 0.04 M NaHCO ₃	25 mL of 0.04 M CaCl ₂	none
10	50 mL of 0.1 M NaOH	50 mL of 0.05 M Na ₂ B ₄ O ₇	annex B, section B.9.2.4

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Annex C (normative)

Acceptable materials

C.1 Purpose

This annex defines the evaluation process for materials that have been submitted for qualification as acceptable materials.

C.2 Evaluation of acceptable materials

A material shall be designated as an “acceptable material” in table C1 if it has a standard material formulation or specification (e. g., ASTM); has undergone extraction testing that demonstrates that the material does not contribute any contaminant in excess of its acceptable level as determined by this Standard (see annex C, section C.3); and is accompanied by adequate documentation (see 3.4).

C.3 Extraction testing

Thirty randomly selected samples from a variety of manufacturers of the material, in a specific form (e. g., pipe or tube), shall undergo extraction testing. All the samples shall have been manufactured using the same production process. Selection of analytical testing shall be performed in accordance with 3.3. The samples shall be exposed at the maximum surface-area-to-volume ratio for which acceptance is being sought. Depending on the specific form of the material, the samples shall be evaluated with the extraction protocol, normalization formulas and assumptions, and evaluation criteria contained in the applicable sections of this Standard.

C.4 Documentation

The material’s evaluation shall be supported by the following documentation:

- the published material formulation or specification to which the material is fabricated;
- literature that comprehensively addresses the production process, raw material sources, and all other factors that could potentially affect the composition and variability of the material; and
- information and data that summarize the results from the laboratory extraction of the thirty randomly selected samples, including data from a detection limit study, quality control data run concurrently with the samples, a description of the methods and instrumentation used, and a verification that the laboratory in which the extraction testing was conducted is certified for drinking water analysis by the regulatory agency having authority.

A final report that outlines the manner in which these requirements have been met shall be prepared.

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 (0.040 max.), sulfur (0.030 max.), silicon (0.75 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 (0.040 max.), sulfur (0.030 max.), silicon (0.75 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 (0.040 max.), sulfur (0.030 max.), silicon (0.75 max.), nickel (11.00-14.0), 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 (0.040 max.), sulfur (0.030 max.), silicon (0.75 max.), nickel (10.0-15.0), chromium (16.0-18.0), molybdenum (2.0-3.0), iron (balance)
stainless steel	UNS S32205 (Type 2205)	ASTM A 240 ASTM A 789 ASTM A 790 ASTM A 815	3,484 cm ² /L (540 in ² /L)	23°C (73°F)	percent composition: carbon (0.030 max.), manganese (2.00 max.), phosphorus (0.030 max.), sulfur (0.020 max.), silicon (1.0 max.), nickel (4.5-6.5), chromium (22.0-23.0), molybdenum (3.0-3.5), nitrogen (0.14-0.20)

Table C1 – Acceptable materials

Material	Specific designation	Standard (product) reference	Surface-area-to-volume ratio	End-use temperature	Composition
stainless steel	UNS S32003 (Type 2203)	ASTM A 240 ASTM A 789 ASTM A 790 ASTM A 815	3,484 cm ² /L (540 in ² /L)	23°C (73°F)	percent composition: carbon (0.03 max.), manganese (2.0 max.), phosphorus (0.03 max.), sulfur (0.02 max.), silicon (1.00 max.), nickel (3.0-4.0), chromium (19.5-22.5), molybdenum (1.5-2.0), nitrogen (0.14-0.20) iron (balance)
stainless steel	UNS S32101 (Type 2101)	ASTM A 240 ASTM A 789 ASTM A 790 ASTM A 815	3,484 cm ² /L (540 in ² /L)	23°C (73°F)	percent composition: carbon (0.040 max.), manganese (4.0-6.0 max.), phosphorus (0.04 max.), sulfur (0.03 max.), silicon (1.0 max.), nickel (1.35 – 1.70), chromium (21.0 -22.0), molybdenum (0.1-0.8), nitrogen (0.2-0.25); copper (0.10- 0.80)
stainless steel	UNS S32304 (Type 2304)	ASTM A 240 ASTM A 789 ASTM A 790 ASTM A 815	3,484 cm ² /L (540 in ² /L)	23°C (73°F)	percent composition: carbon (0.030 max.), manganese (2.50 max.), phosphorus (0.040 max.), sulfur (0.030 max.), silicon (1.00 max.), nickel (3.0 – 5.5), chromium (21.5 -24.5), molybdenum (0.05 -0.60), nitrogen (0.05-0.20); copper (0.05- 0.60)

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Annex D (normative)

Normative drinking water criteria

D.1 General

The drinking water criteria in this annex shall be used as normative evaluation criteria for the determination of product compliance with the health effects requirements of this Standard. The values in these tables include the consensus USEPA and Health Canada drinking water criteria for contaminants evaluated by these two agencies. They also include criteria for non-regulated contaminants that have been developed according to the toxicity data requirements of annex A, and that have been externally peer-reviewed. Non-regulatory USEPA guidance values that have been reviewed and found to satisfy annex A toxicity data requirements are also included, as well as chemicals that have been evaluated using the threshold of evaluation approach.

The drinking water criteria in this annex have not been evaluated for taste and odor considerations at the concentration limits indicated.

The substances listed in annex D, tables D1, D2, D3, and D4 are not intended to encompass all the potential analytes of interest that need to be considered in evaluating products to the requirements of this Standard. The user is cautioned that each product may have formulation-dependent analytes of interest for which acceptable concentration limits have not been determined. In these cases, the user is required to develop acceptable concentration limits based on the requirements of annex A in order to determine full compliance with the Standard.

These tables are specific to NSF/ANSI 61. While the tables may be used for evaluation of impurities in drinking water treatment chemicals, the substances listed in these tables may not have been evaluated for use as direct additive drinking water treatment chemicals under NSF/ANSI 60. Use as direct additive drinking water treatment chemicals may require the consideration of different exposure parameters from those used for NSF/ANSI 61 evaluation.

D.2 USEPA and Health Canada drinking water criteria

Table D1 contains drinking water criteria for contaminants regulated by the USEPA and established by Health Canada. Values for each contaminant have been agreed upon by representatives of both agencies for the purpose of evaluating products against the health effects requirements of this Standard. For each substance, the values in the table represent a consensus decision regarding the selection of the most appropriate assessment upon which to base NSF/ANSI 61 evaluation.

At the time of publication, the indicated values were valid. These values are subject to change, however, and the user is encouraged to contact USEPA or Health Canada for the most current values. Some of these values have been developed using a linear multistage model to predict theoretical excess carcinogenic risk at low exposure concentrations. Where the database is sufficient and the compound mode of action can be determined, the USEPA is replacing the default linear multistage model with either a biologically based cell kinetic multistage model or a margin of exposure analysis. Cancer potency (q1*) values developed using the linear multistage model may be re-evaluated in the future.

D.3 NSF International peer-reviewed drinking water criteria

Table D2 contains drinking water criteria for unregulated substances for which NSF International has determined Total Allowable Concentrations (TAC) and Single Product Allowable Concentrations (SPAC) in accordance with annex A of this Standard. These criteria have been externally peer-reviewed.

At the time of publication, the indicated values were valid. These values are subject to change, however, and the user is encouraged to contact NSF International for the most current values.

D.4 Drinking water criteria based on USEPA guidance concentrations

Table D3 contains drinking water criteria for unregulated contaminants for which the acceptable drinking water concentrations are based on USEPA guidance values, including those in the USEPA Health Advisory and Integrated Risk Information System (IRIS) databases. A relative source contribution factor has been applied to calculation of the drinking water criteria when such a factor was not applied as part of the USEPA risk assessment. In the absence of sufficient information to determine a data-derived relative source contribution factor, a default 20% drinking water contribution is assumed.

At the time of publication, the indicated values were valid. These values are subject to change, however, and the user is encouraged to contact USEPA for the most current values. Some of these values have been developed using a linear multistage model to predict risk at low exposure concentrations and may be re-evaluated in the future.

D.5 Threshold of evaluation (TOE) chemical list

Table D4 contains the list of chemicals that have been evaluated under the threshold of evaluation because of the lack of the minimum data to determine chemical specific concentrations in accordance with the requirements of annex A (see annex A, section A.7.1). Qualification to the threshold of evaluation category includes a comprehensive literature search for the particular substance and consideration of structure-activity relationships.

**Table D1 – U. S. Environmental Protection Agency and Health Canada
NSF/ANSI 61 drinking water criteria**

Contaminant (Reference)¹	Drinking water regulatory level (MCL/MAC) (mg/L)	Single product allowable concentration (SPAC) (mg/L)
Organics/pesticides		
alachlor (40 CFR §141.60, §141.61)	0.002	0.0002
aldicarb aldicarb sulphone aldicarb sulphoxide (40 CFR §141.60, §141.61)	0.007	0.0007
aldrin / dieldrin issue date: 10/94	0.0007	0.00007
atrazine issue date: 04/93	0.003	0.0003
atrazine and metabolites Issue date: 04/93	0.005	0.0005
azinphos-methyl Issue date: 02/86	0.02	0.002
bendiocarb Issue date: 02/86	0.04	0.004
benzene (40 CFR §141.60, §141.61)	0.005	0.0005
benzo(a)pyrene (PAH) (40 CFR §141.60, §141.61)	0.0002	0.00002
bromodichloromethane — see trihalomethanes (total)	N/A	N/A
bromoform — see trihalomethanes (total)	N/A	N/A
bromoxynil Issue date: 03/87	0.005	0.0005
carbaryl issue date: 02/86	0.09	0.009
carbofuran (40 CFR §141.60, §141.61)	0.04	0.004
carbon tetrachloride (40 CFR §141.60, §141.61)	0.005	0.0005
chlordane (40 CFR §141.60, §141.61)	0.002	0.0002
chlorodibromomethane — see trihalomethanes (total)	N/A	N/A
chloroform — see trihalomethanes (total)	N/A	N/A
chlorpyrifos issue date: 02/86	0.09	0.009
cyanazine issue date: 02/86	0.01	0.001
cyanobacterial toxin (microcystin-LR) issue date: 04/02	0.0015	0.00015
2,4-D (40 CFR §141.60, §141.61)	0.07	0.007

**Table D1 – U. S. Environmental Protection Agency and Health Canada
NSF/ANSI 61 drinking water criteria**

Contaminant (Reference)¹	Drinking water regulatory level (MCL/MAC) (mg/L)	Single product allowable concentration (SPAC) (mg/L)
Organics/pesticides		
dalapon (40 CFR §141.60, §141.61)	0.2	0.02
diazinon issue date: 02/86	0.02	0.002
dibromo-3-chloropropane (1,2-) (40 CFR §141.60, §141.61)	0.0002	0.00002
dicamba issue date: 03/87	0.12	0.012
dichlorobenzene o- (40 CFR §141.60, §141.61)	0.6	0.06
dichlorobenzene m- (see o-dichlorobenzene)	0.6	0.06
dichlorobenzene p- (40 CFR §141.60, §141.61)	0.075	0.0075
dichloroethane (1,2-) (40 CFR §141.60, §141.61)	0.005	0.0005
dichloroethylene (1,1-) (40 CFR §141.60, §141.61)	0.007	0.0007
dichloroethylene (cis-1,2-) (40 CFR §141.60, §141.61)	0.07	0.007
dichloroethylene (trans-1,2) (40 CFR §141.60, §141.61)	0.1	0.01
dichloromethane (40 CFR §141.60, §141.61)	0.005	0.0005
dichloropropane (1,2-) (40 CFR §141.60, §141.61)	0.005	0.0005
diclofop-methyl Issue date: 03/87	0.009	0.0009
di(2-ethylhexyl)adipate (40 CFR §141.60, §141.61)	0.4	0.04
di(2-ethylhexyl)phthalate (PAE) (40 CFR §141.60, §141.61)	0.006	0.0006
dimethoate Issue date: 02/86	0.020	0.002
dinoseb (40 CFR §141.60, §141.61)	0.007	0.0007
diquat (40 CFR §141.60, §141.61)	0.02	0.002
diuron issue date: 03/87	0.15	0.015
endothall (40 CFR §141.60, §141.61)	0.1	0.01
endrin (40 CFR §141.60, §141.61)	0.002	0.0002
ethylbenzene (40 CFR §141.60, §141.61)	0.7	0.07

**Table D1 – U. S. Environmental Protection Agency and Health Canada
NSF/ANSI 61 drinking water criteria**

Contaminant (Reference)¹	Drinking water regulatory level (MCL/MAC) (mg/L)	Single product allowable concentration (SPAC) (mg/L)
Organics/pesticides		
ethylene dibromide (EDB) (40 CFR §141.60, §141.61)	0.00005	0.000005
glyphosate (40 CFR §141.60, §141.61)	0.7	0.07
heptachlor (40 CFR §141.60, §141.61)	0.0004	0.00004
heptachlor epoxide (40 CFR §141.60, §141.61)	0.0002	0.00002
hexachlorobenzene (40 CFR §141.60, §141.61)	0.001	0.0001
hexachlorocyclopentadiene (40 CFR §141.60, §141.61)	0.05	0.005
lindane (40 CFR §141.60, §141.61)	0.0002	0.00002
malathion issue date: 02/86	0.19	0.019
methoxychlor (40 CFR §141.60, §141.61)	0.04	0.004
metolachlor Issue date: 02/86	0.05	0.005
metribuzin issue date: 02/86	0.08	0.008
monochlorobenzene (40 CFR §141.60, §141.61)	0.1	0.01
nitrilotriacetic acid Issue date: 01/90	0.4	0.04
oxamyl (vydate) (40 CFR §141.60, §141.61)	0.2	0.02
paraquat (as dichloride) issue date: 02/86	0.01	0.001
parathion Issue date: 02/86	0.05	0.005
pentachlorophenol (40 CFR §141.60, §141.61)	0.001	0.0001
phorate Issue date: 02/86	0.002	0.0002
picloram (Issue date 06/88)	0.19	0.019
polychlorinated biphenyls (PCB) (40 CFR §141.60, §141.61)	0.0005	0.00005
simazine (40 CFR §141.60, §141.61)	0.004	0.0004
styrene (40 CFR §141.60, §141.61)	0.1	0.01
2,3,7,8-TCDD (Dioxin) (40 CFR §141.60, §141.61)	3E-08	3E-09

**Table D1 – U. S. Environmental Protection Agency and Health Canada
NSF/ANSI 61 drinking water criteria**

Contaminant (Reference)¹	Drinking water regulatory level (MCL/MAC) (mg/L)	Single product allowable concentration (SPAC) (mg/L)
Organics/pesticides		
terbufos issue date: 01/87	0.001	0.0001
tetrachloroethylene (40 CFR §141.60, §141.61)	0.005	0.0005
2,3,4,6-tetrachlorophenol issue date: 02/87	0.1	0.01
toluene (40 CFR §141.60, §141.61)	1	0.1
toxaphene (40 CFR §141.60, §141.61)	0.003	0.0003
2,4,5-TP (40 CFR §141.60, §141.61)	0.05	0.005
trichlorobenzene (1,2,4-) (40 CFR §141.60, §141.61)	0.07	0.007
trichloroethane (1,1,1-) (40 CFR §141.60, §141.61)	0.2	0.02
trichloroethane (1,1,2-) (40 CFR §141.60, §141.61)	0.005	0.0005
trichloroethylene (40 CFR §141.60, §141.61)	0.005	0.0005
2,4,6-trichlorophenol issue date: 02/87	0.005	0.0005
trifluralin issue date: 02/89	0.045	0.0045
trihalomethanes (total)	0.08	0.008
bromodichloromethane	—	—
bromoform	—	—
chlorodibromomethane	—	—
chloroform	—	—
(40 CFR §141.64)		
vinyl chloride (40 CFR §141.60, §141.61)	0.002	0.0002
xlenes (total) (40 CFR §141.60, §141.61)	10	1
Regulated metals		
antimony (40 CFR §141.60, §141.62)	0.006	0.0006
arsenic Issue date: 10/01	0.010	0.001
barium (40 CFR §141.60, §141.62)	2	0.2
beryllium (40 CFR §141.60, §141.62)	0.004	0.0004
boron issue date: 09/90	5	0.5
cadmium (40 CFR §141.60, §141.62)	0.005	0.0005

**Table D1 – U. S. Environmental Protection Agency and Health Canada
NSF/ANSI 61 drinking water criteria**

Contaminant (Reference)¹	Drinking water regulatory level (MCL/MAC) (mg/L)	Single product allowable concentration (SPAC) (mg/L)
Regulated metals		
chromium (total) (40 CFR §141.60, §141.62)	0.1	0.01
copper (40 CFR §141.80; 65 FR 1950)	TT ² (action level 1.3 mg/L)	0.13
lead (at tap) (40 CFR §141.80; 65 FR 1950)	TT ^{2,3,8} (action level 0.015 mg/L)	0.0015 ⁸
mercury (inorganic) (40 CFR §141.60, §141.62)	0.002	0.0002
selenium (40 CFR §141.60, §141.62)	0.05	0.005
thallium (40 CFR §141.60, §141.62)	0.002	0.0002
Other inorganics		
asbestos (40 CFR §141.60, §141.62)	7 ⁴ MFL	0.7 MFL
bromate (40 CFR §141.64)	0.01	0.005 ⁵
chloramines (total as Cl ₂) (40 CFR §141.65)	4 ⁶	0.4
chlorine (free as Cl ₂) (40 CFR §141.65)	4 ⁶	0.4
chlorine dioxide (as ClO ₂) (40 CFR §141.65)	0.8 ⁶	0.08
chlorite (40 CFR §141.64)	1	0.1
cyanide (as free cyanide) (40 CFR §141.60, §141.62)	0.2	0.02
fluoride (40 CFR §141.60, §141.62)	1.2 ⁷	0.12
haloacetic acids (total) (40 CFR §141.64)	0.06	0.006
nitrate (as N) (40 CFR §141.60, §141.62)	10	1
nitrite (as N) (40 CFR §141.60, §141.62)	1	0.1
nitrate + nitrite (both as N) (40 CFR §141.60, §141.62)	10	1
Radionuclides		
beta particle and photon activity (40 CFR §141.16)	4 mrem/y	0.4 mrem/y
gross alpha particle activity (40 CFR §141.15)	15 pCi/L	1.5 pCi/L
combined radium 226 and 228 (40 CFR §141.15)	5 pCi/L	0.5 pCi/L
uranium	0.02 mg/L 13 pCi/L	0.002 mg/L 1.3 pCi/L

**Table D1 – U. S. Environmental Protection Agency and Health Canada
NSF/ANSI 61 drinking water criteria**

Contaminant (Reference)¹	Drinking water regulatory level (MCL/MAC) (mg/L)	Single product allowable concentration (SPAC) (mg/L)
<p>¹ The references for criteria based on U. S. primary drinking water regulations are from the U. S. Code of Federal Regulations, Title 40 (Protection of Environment), revised as of July 1, 1999. This document is available on-line at http://www.access.gpo.gov/nara/cfr/cfr-table-search.html. Issue dates are given for criteria based on Health Canada guidelines. Additional information on the guidelines for these chemicals is available at http://www.hc-sc.gc.ca/ehp/ehd/bch/water_quality.html.</p> <p>² TT = treatment technique</p> <p>³ For section 9 products, a Q statistic value of 11 µg lead for a 1 L (0.26 gal) draw is used as the evaluation criteria. This is based on the assumption that sources other than the Section 9 device contribute 4 µg for a 1 L (0.26 gal) draw, resulting in a total limit of 15 µg lead for a 1 L (0.26 gal) draw.</p> <p>⁴ MFL = Million Fibers per liter, with fiber length > 10 microns</p> <p>⁵ Beginning January 2005, the Single Product Acceptable Concentration (SPAC) for bromate will be lowered to 0.003 mg/L, unless it is demonstrated to the Joint Committee on Drinking Water Additives by the manufacturers of hypochlorite treatment chemicals that the drinking water industry demand for hypochlorite chemicals cannot be adequately met unless the SPAC remains at 0.005 mg/L.</p> <p>⁶ Value represents the maximum residual disinfectant level (MRDL)</p> <p>⁷ "Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States," August 17, 2001 / Morbidity & Mortality Weekly Report 50 (RR14); 1-42</p> <p>⁸ Revisions to lead requirements of this section have been made and are located in Annex F of this Standard. Please refer to that annex for additional details. The revisions contained in Annex F are informational at this time and are scheduled to be incorporated into this section July 1, 2012.</p>		

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Table D2 – NSF International peer-reviewed drinking water criteria

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Short term exposure level (STEL) mg/L	Source of supporting documentation
Inorganics					
iodine	7553-56-2	0.3	0.1	0.3	NSF action level ¹ External peer review date: 04/25/2002
thiocyanate potassium salt sodium salt ammonium salt	333-20-0 540-72-7 1762-95-4	0.2 (total as SCN)	0.02 (total as SCN)	0.9 (total as SCN)	NSF action level ¹ External peer review date: 09/03/2003
titanium and titanium dioxide	7440-32-6 13463-67-7	90 (total as Ti)	9 (total as Ti)	90 (total as Ti)	NSF action level ¹ External peer review date: 09/04/2003
tungsten	7440-33-7	0.01	0.01	0.01	NSF action level ¹ External peer review date: 04/06/2005

Table D2 – NSF International peer-reviewed drinking water criteria

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Short term exposure level (STEL) mg/L	Source of supporting documentation
Organics					
acetophenone	98-86-2	0.2	0.02	1	NSF action level ¹ External peer review date: 09/03/2003
adipic acid	124-04-9	30	3	100	NSF action level ¹ External peer review date: 04/06/2005
benzyl alcohol	100-51-6	3	0.3	10	NSF action level ¹ External peer review date: 04/26/2002
benzaldehyde	100-52-7	0.9	0.09	40	NSF action level ¹ External peer review date: 04/15/1999
bisphenol A diglycidyl ether	1675-54-3	1 (total)	0.1 (total)	5	NSF action level ¹ External peer review date: 10/03/2002
bisphenol A diglycideryl ether	5581-32-8				
t-butanol	75-65-0	9	0.9	40	NSF action level ¹ External peer review date: 10/03/2002
di-t-butyl peroxide	110-05-4	0.01	0.01	0.01	NSF action level ¹ External peer review date: 10/03/2002
n-butyl acetate	123-86-4	1	0.1	20	NSF action level ¹ External peer review date: 04/25/2002
γ-butyrolactone	96-48-0	4	0.4	4	NSF action level ¹ External peer review date: 10/04/2002
2-chloro-1,4-benzenediamine	615-66-7	0.3	0.03	0.5	NSF action level ¹ External peer review date: 04/20/2004
4-chloro-1,2-benzenediamine	95-83-0	0.2	0.02	0.2	NSF action level ¹ External peer review date: 04/20/2004
4-chloro-1,3-benzenediamine	5131-60-2	0.3	0.03	0.3	NSF action level ¹ External peer review date: 04/06/2005
4-chlorobenzo-trifluoride	98-56-6	0.3	0.03	2	NSF action level ¹ External peer review date: 04/07/2006
p-chloro-m-cresol	59-50-7	0.7	0.07	1	NSF action level ¹ External peer review date: 04/25/2002
cyclohexanone	108-94-1	30	3	40	NSF action level ¹ External peer review date: 04/26/2002

Table D2 – NSF International peer-reviewed drinking water criteria

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Short term exposure level (STEL) mg/L	Source of supporting documentation
2,2-dibromo-3-nitrilopropionamide	10222-01-2	0.4	0.09		NSF action level ¹ External peer review date: 04/20/2004
2,4-dichlorobenzoic acid	50-84-0	0.1	0.01	0.5	NSF action level ¹ External peer review date: 04/21/2004
dodecanedioic acid	693-23-2	30	30	30	NSF action level ¹ External peer review date: 10/07/2005
ethylenediamine	107-15-3	10	2	40	NSF action level ¹ External peer review date: 04/06/2005
2-ethylhexanoic acid	149-57-5	0.7	0.07	10	NSF action level ¹ External peer review date: 04/06/2005
furfural	98-01-1	0.2	0.02	3	NSF action level ¹ External peer review date: 09/03/2003
hexamethylenediamine	124-09-4	10	1	20	NSF action level ¹ External peer review date: 04/06/2006
1(3H)-isobenzofuranone	87-41-2	0.01	0.01	0.01	NSF action level ¹ External peer review date: 04/06/2006
melamine	108-78-1	3.0	0.3	3.0	NSF action level ¹ External peer review date: 04/14/1999
methanol	67-56-1	20	2	20	NSF action level ¹ External peer review date: 04/06/2006
methyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate and 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionic acid	6386-38-5 20170-32-5	0.02 (total)	0.002 (total)	0.1	NSF action level ¹ External peer review date: 04/20/04
methyl isoamyl ketone (MIAK)	110-12-3	0.06	0.006	0.8	NSF action level ¹ External peer review date: 04/25/2002
methyl isobutyl ketone (MIBK)	108-10-1	7	0.7	100	NSF action level ¹ External peer review date: 10/06/2005

Table D2 – NSF International peer-reviewed drinking water criteria

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Short term exposure level (STEL) mg/L	Source of supporting documentation
oligomeric cyclic ethers CBEL (total OCE 3-6) OCE-3: 1,6,11-trioxacyclopentadecane OCE-4: 1,6,11,16-tetraoxacyclopentadecane OCE-5: 1,6,11,16,21-pentaoxacyclopentadecane OCE-6: 1,6,11,16,21,26-hexaoxacyclopentadecane	295-63-6 17043-02-6 56890-57-4 64001-05-4	3	0.4	3	NSF action level ¹ External peer review date: 10/04/2002
phenyl glycidyl ether	122-60-1	0.006	0.0006	0.1	NSF action level ¹ External peer review date: 10/03/2002
di-propylene glycol n-butyl ether	29911-28-2	2	0.2	30	NSF action level ¹ External peer review date: 10/03/2002
propylene glycol n-butyl ether	5131-66-8	2	0.2	30	NSF action level ¹ External peer review date: 10/03/2002
2,4,4'-trichloro-2'-hydroxydiphenyl ether	3380-34-5	0.5	0.05	8	NSF action level ¹ External peer review date: 10/19/2000
triethyl citrate	77-93-0	4	0.4	20	NSF action level ¹ External peer review date: 11/05/2004
1,3,5-trioxane	110-88-3	0.7	0.07	3	NSF action level ¹ External peer review date: 04/20/04
¹ NSF action levels have been derived according to the requirements of NSF/ANSI 61 – 2000 or 2003e, annex A.					

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Table D3 – Drinking water criteria based on USEPA guidance concentrations

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation ^{1, 2, 3}
Inorganics				
chromium III	16065-83-1	10	1	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency consensus date: 04/28/1998
chromium VI	18540-29-9	0.02	0.002	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency consensus date: 04/28/1998
manganese	7439-96-5	0.3	0.03	Derived from the oral RfD on the USEPA IRIS database, with a 3x modifying factor because of the large contribution from food sources and a default 20% relative source contribution for drinking water. Verification date: 05/12/1995
molybdenum	7439-98-7	0.04	0.004	USEPA Draft Health Advisory issue date: 1993
silver	7440-22-4	0.1	0.01	USEPA Lifetime Drinking Water Health Advisory Issue date: 1992
strontium	7440-24-6	4	0.4	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 06/23/1992
acetone	67-64-1	6	0.6	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency consensus date: 05/29/03

Table D3 – Drinking water criteria based on USEPA guidance concentrations

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation ^{1, 2, 3}
Organics				
acrolein	107-02-8	0.004	0.0004	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency consensus date: 05/16/2003
acrylamide	79-06-1	0.0001	0.00001	USEPA Drinking Water Health Advisory 10 ⁻⁵ /10 ⁻⁶ cancer risk levels Issue date: 1987
acrylic acid	79-10-7	4	0.4	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. verification date: 02/17/1994
acrylonitrile	107-13-1	0.0006	0.00006	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. verification date: 02/11/1987
aniline	62-53-3	0.06	0.006	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 06/03/87
azobenzene	103-33-3	0.003	0.0003	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 02/03/88
benzidine	92-87-5	0.000002	0.0000002	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 12/17/86
benzoic acid	65-85-0	30	3	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 09/17/87
benzotrichloride	98-07-7	0.00003	0.000003	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 08/02/89
benzyl chloride	100-44-7	0.002	0.0002	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. verification date: 03/01/1989
bis(chloroethyl)ether	111-44-4	0.0003	0.00003	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 07/23/86

Table D3 – Drinking water criteria based on USEPA guidance concentrations

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation ^{1, 2, 3}
Organics				
bis(chloromethyl)ether	542-88-1	0.000002	0.0000002	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 05/04/88
bromochloromethane	74-97-5	0.09	0.009	USEPA Lifetime Drinking Water Health Advisory issue date: 1989
bromomethane	74-83-9	0.01	0.001	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 05/26/1988
butylbenzyl phthalate	85-68-7	1	0.1	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 06/15/1989
n-butanol	71-36-3	0.7	0.07	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 05/14/1986
caprolactam	105-60-2	4	0.4	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 03/24/88
carbon disulfide	75-15-0	0.7	0.07	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 08/05/1985
chloral hydrate	302-17-0	0.7	0.07	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency Consensus Date: 11/16/1999

Table D3 – Drinking water criteria based on USEPA guidance concentrations

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation ^{1, 2, 3}
Organics				
chlorobenzilate	510-15-6	0.1	0.01	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 05/17/89
cyclohexylamine	108-91-8	1	0.1	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 09/17/87
1,4-dibromobenzene	106-37-6	0.07	0.007	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency Consensus Date: 05/15/1986
1,2-dibromoethane	106-93-4	0.0002	0.00002	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Agency Completion Date: 07/26/2004
dichloroacetic acid	79-43-6	0.007	0.0007	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ upper bound risk levels. Agency Consensus Date: 08/20/2003
p,p'-dichlorodiphenyl dichloroethane (DDD)	72-54-8	0.001	0.0001	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 06/24/87
p,p'-dichlorodiphenyl dichloroethylene (DDE)	72-55-9	0.001	0.0001	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 06/24/87
p,p'-dichlorodiphenyl trichloroethane (DDT)	50-29-3	0.001	0.0001	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 06/24/87
1,3-dichloropropene mixed isomers cis- trans-	542-75-6 10061-01-5 10061-02-6	0.004	0.0004	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Agency Consensus Date: 04/20/2000
3,3'-dichlorobenzidine	91-94-1	0.0008	0.00008	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 11/30/88

Table D3 – Drinking water criteria based on USEPA guidance concentrations

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation ^{1, 2, 3}
Organics				
diethyl phthalate	84-66-2	6	0.6	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 07/16/1987
2,4-dimethylphenol	105-67-9	0.1	0.01	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 02/21/1990
2,6-dimethylphenol	576-26-1	0.004	0.0004	Derived from the oral RfD on the USEPA IRIS database with an default 20% relative source contribution for drinking water. verification date: 01/22/1986
3,4-dimethylphenol	95-65-8	0.007	0.0007	Derived from the oral RfD on the USEPA IRIS database with an default 20% relative source contribution for drinking water. verification date: 01/22/1986
dimethylterephthalate	120-61-6	0.7	0.07	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 10/09/1985
di-n-butyl phthalate	84-74-2	0.7	0.07	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 01/22/1986
2,4/2,6-dinitrotoluene mixture	N/A	0.0005	0.0005	USEPA IRIS $10^{-5}/10^{-6}$ cancer risk levels. Verification date: 05/03/89
diphenylamine	122-39-4	0.2	0.02	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 07/22/1986

Table D3 – Drinking water criteria based on USEPA guidance concentrations

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation ^{1, 2, 3}
Organics				
1,4-dioxane	123-91-1	0.03	0.003	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels Verification date: 02/03/88
1,2-diphenylhydrazine	122-66-7	0.0005	0.00005	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 10/29/86
1,4-dithiane	505-29-3	0.07	0.007	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 06/24/1992
epichlorohydrin	106-89-8	0.04	0.004	USEPA Drinking Water Health Advisory 10 ⁻⁵ /10 ⁻⁶ cancer risk levels Issue date: 1987
ethylene glycol	107-21-1	10	1	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. verification date: 03/19/1987
ethylene glycol monobutyl ether	111-76-2	4	0.4	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency Consensus Date: 11/16/1999
ethylene thiourea	96-45-7	0.0006	0.00006	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 02/20/91
formaldehyde	50-00-0	1	0.1	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. verification date: 06/20/1990
1,2,3,4,6,7,8-heptachlorodibenzo-p-dioxin	35822-46-9	0.000003	0.0000003	Toxic Equivalency Factor: 0.01
1,2,3,4,6,7,8-heptachlorodibenzofuran	67562-39-4	0.000003	0.0000003	Toxic Equivalency Factor: 0.01
1,2,3,4,7,8,9-heptachlorodibenzofuran	55673-89-7	0.000003	0.0000003	Toxic Equivalency Factor: 0.01

Table D3 – Drinking water criteria based on USEPA guidance concentrations

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation ^{1, 2, 3}
Organics				
hexabromobenzene	87-82-1	0.01	0.001	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. verification date: 11/06/1985
1,2,3,4,7,8-hexachloro-dibenzo-p-dioxin	39227-28-6	0.0000003	0.00000003	Toxic Equivalency Factor: 0.1
1,2,3,7,8,9-hexachloro-dibenzo-p-dioxin	19408-74-3	0.0000003	0.00000003	Toxic Equivalency Factor: 0.1
1,2,3,6,7,8-hexachloro-dibenzo-p-dioxin	57653-85-7	0.0000003	0.00000003	Toxic Equivalency Factor: 0.1
1,2,3,4,7,8-hexachloro-dibenzofuran	70648-26-9	0.0000003	0.00000003	Toxic Equivalency Factor: 0.1
1,2,3,7,8,9-hexachloro-dibenzofuran	72918-21-9	0.0000003	0.00000003	Toxic Equivalency Factor: 0.1
1,2,3,6,7,8-hexachloro-dibenzofuran	57117-44-9	0.0000003	0.00000003	Toxic Equivalency Factor: 0.1
2,3,4,6,7,8-hexachloro-dibenzofuran	60851-34-5	0.0000003	0.00000003	Toxic Equivalency Factor: 0.1
hydrazine/hydrazine sulfate	302-01-2	0.0001	0.00001	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 06/03/87
isophorone	78-59-1	0.4	0.04	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 08/05/92
isopropylbenzene (cumene)	98-82-8	0.7	0.07	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency Consensus Date: 06/06/1997
maleic anhydride	108-31-6	0.7	0.07	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 03/24/88
4,4'-methylene bis (N,N'-dimethyl)aniline	101-61-1	0.008	0.0008	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 04/05/89

Table D3 – Drinking water criteria based on USEPA guidance concentrations

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation ^{1, 2, 3}
Organics				
methyl ethyl ketone (MEK)	78-93-3	4	0.4	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency Consensus Date: 09/10/2003
methyl mercury	22967-92-6	0.0007	0.00007	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 06/19/2001
methyl methacrylate	80-62-6	10	1	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency Consensus Date: 11/25/1997
2-methyl naphthalene	91-57-6	0.03	0.003	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency Consensus Date: 12/11/2003
naphthalene	91-20-3	0.1	0.01	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency Consensus Date: 07/01/1998
nitrobenzene	98-95-3	0.004	0.0004	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 07/08/85
nitroguanidine	556-88-7	0.7	0.07	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 05/17/1989

Table D3 – Drinking water criteria based on USEPA guidance concentrations

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation ^{1, 2, 3}
Organics				
N-nitroso-di-n-butylamine	924-16-3	0.00006	0.000006	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 10/29/86
N-nitroso-N-methylethylamine	10595-95-6	0.00002	0.000002	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 02/11/87
N-nitroso-di-N-propylamine	621-64-7	0.00005	0.000005	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 02/11/87
N-nitrosodiethanolamine	1116-54-7	0.0001	0.00001	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 01/28/87
N-nitrosodiethylamine	55-18-5	0.000002	0.0000002	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 10/29/86
N-nitrosodimethylamine	62-75-9	0.000007	0.0000007	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 10/29/86
N-nitrosodiphenylamine	86-30-6	0.07	0.007	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 02/11/87
N-nitrosopyrrolidine	930-55-2	0.0002	0.00002	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 10/14/86
1,2,3,4,6,7,8,9-octa-chlorodibenzo-p-dioxin	3268-87-9	0.0003	0.00003	Toxic Equivalency Factor: 0.0001
1,2,3,4,6,7,8,9-octachlorodibenzofuran	39001-02-0	0.0003	0.00003	Toxic Equivalency Factor: 0.0001
1,2,3,7,8-penta-chlorodibenzo-p-dioxin	40321-76-4	0.00000003	0.000000003	Toxic Equivalency Factor: 1
1,2,3,7,8-penta-chlorodibenzofuran	57117-41-6	0.0000006	0.00000006	Toxic Equivalency Factor: 0.05
2,3,4,7,8- penta-chlorodibenzofuran	57117-31-4	0.00000006	0.000000006	Toxic Equivalency Factor: 0.5
pentachloronitrobenzene	82-68-8	0.02	0.002	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 04/15/1987

Table D3 – Drinking water criteria based on USEPA guidance concentrations

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation ^{1, 2, 3}
Organics				
phenol	108-95-2	2	0.2	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency Consensus Date: 08/28/2002
m-phenylenediamine	108-45-2	0.04	0.004	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 02/26/1986
phthalic anhydride	85-44-9	10	1	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 02/24/1988
propargite	2312-35-8	0.1	0.01	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 03/23/88
propylene oxide	75-56-9	0.001	0.0001	USEPA IRIS $10^{-5}/10^{-6}$ cancer risk levels. verification date: 04/05/1990
quinoline	91-22-5	0.0001	0.00001	USEPA IRIS $10^{-5}/10^{-6}$ cancer risk levels. Agency Consensus Date: 09/21/2001
sodium diethyldithiocarbamate	148-18-5	0.2	0.02	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 10/09/1985
2,3,7,8-tetra-chlorodibenzo-p-dioxin	1746-01-6	0.00000003	0.000000003	Toxic Equivalency Factor: 1
2,3,7,8-tetrachlorodibenzofuran	51207-31-9	0.00000003	0.000000003	Toxic Equivalency Factor: 0.1
1,1,1,2-tetrachloroethane	630-20-6	0.01	0.001	USEPA IRIS $10^{-5}/10^{-6}$ cancer risk levels. verification date: 05/04/1988

Table D3 – Drinking water criteria based on USEPA guidance concentrations

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation ^{1, 2, 3}
Organics				
1,1,2,2-tetrachloroethane	79-34-5	0.002	0.0002	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 06/26/86
1,2,4-tribromobenzene	615-54-3	0.04	0.004	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 05/15/1986
tributyltin oxide	56-35-9	0.002	0.0002	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Agency Consensus date: 07/02/1997
trichlorofluoromethane	75-69-4	2	0.2	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 05/31/1985
1,2,3-trichloropropane	96-18-4	0.04	0.004	USEPA Lifetime Drinking Water Health Advisory issue date: 1989
1,3,5-trinitrobenzene	99-35-4	0.2	0.02	Derived from the oral RfD on the USEPA IRIS database with a default 20% relative source contribution for drinking water. Verification date: 08/27/1997
2,4,6-trinitrotoluene	118-96-7	0.01	0.001	USEPA IRIS 10 ⁻⁵ /10 ⁻⁶ cancer risk levels. Verification date: 09/22/88

Table D3 – Drinking water criteria based on USEPA guidance concentrations

Substance	CAS #	Total allowable concentration (TAC) mg/L	Single product allowable concentration (SPAC) mg/L	Source of supporting documentation ^{1, 2, 3}
<p>¹ Criteria are derived from the oral RfD on the USEPA IRIS database as follows:</p> <p>Oral RfD (mg /kg-d) x (70 kg /2 L/d) x relative source contribution factor = TAC (mg/L)</p> <p>where:</p> <p>70 kg = assumed adult body weight 2 L/d = assumed adult water consumption relative source contribution factor = percentage of daily exposure to the substance represented by drinking water (default value is 20%)</p> <p>Other criteria have been used directly, unless otherwise noted.</p> <p>² The IRIS verification date represents the date the oral RfD or the cancer risk assessment was peer reviewed by the USEPA. Refer to the online IRIS database for the complete update and revision history of the IRIS files: (http://www.epa.gov/ngispgm3/iris/subst).</p> <p>³ Toxic Equivalency Factors (TEFs) have been established as a means to compare the potency of 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD) to individual congeners of polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), and polychlorinated biphenyls (PCBs). The USEPA uses an approach to dioxin risk assessment methodology in which levels of dioxins and furans are analytically determined, the concentration of each congener is multiplied by its respective TEF value, and all the products are totaled to a single 2,3,7,8-TCDD equivalent.</p> <p>Van den Berg et al. 1998. Toxic Equivalency Factors (TEFs) for PCBs, PCDDs, PCDFs for Humans and Wildlife. Environmental Health Perspectives 106(12):775:792.</p> <p>U. S. Environmental Protection Agency. 2000. Chapter 9: Toxic Equivalency Factors (TEFs) for Dioxin and Related Compounds. From Exposure and Human Health Risk Assessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds. Part II: Health Assessment for 2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD) and Related Compounds. NCEA-I-0386. September 2000. SAB Review Draft. http://www.epa.gov/ncea/pdfs/dioxin/part2/fm-chap9.pdf</p>				

– concluded –

Table D4 – Threshold of evaluation chemicals¹

Substance	CAS #
Inorganics	
gallium	007440-55-3
hafnium	007440-58-6
tantalum	007440-25-7
yttrium	007440-65-5
Organics	
acenaphthylene	000208-96-8
acetamide, 2,2-dibromo-	000598-70-9
acetic acid, propyl ester	000109-60-4
acetophenone, 2,2-dimethoxy-2-phenyl-	024650-42-8
acetophenone, p-isopropyl-	000645-13-6
acetophenone, 2'-methyl-	000577-16-2
acetophenone, 4-methyl	000122-00-9
acetophenone, alpha-hydroxy-	000582-24-1
acetophenone, 3'-methyl-	000585-74-0
acetophenone, 4'-isopropenyl	005359-04-6
acetophenone, 4'-hydroxy-	000099-93-4
acridine	000260-94-6
adipic acid, monomethyl ester	000627-91-8
alcohols, C12-C15, ethoxylated propoxylated	068551-13-3
allyl ether	000557-40-4
allyl phenol ether	001746-13-0
aminopiperidine, 4, 2,2,6,6-tetramethyl-	036768-62-4
aminoundecanoic acid, 12-	000693-57-2
ammonium chloride, octadecyldimethyl{3-(trimethoxysilyl)propyl}	027668-52-6
benzaldehyde azine	000588-68-1
benzaldehyde, 3,5-di-tert-butyl-4-hydroxy-	001620-98-0
benzaldehyde, 4-hydroxy-3-methoxy (Vanillin)	000121-33-5
benzaldehyde, 3,5-dimethoxy-4-hydroxy-	000134-96-3
benzaldehyde, 2-hydroxy-	000090-02-8
benzaldehyde, 2-hydroxy-4-methoxy	000673-22-3
benzaldehyde, hydroxymethoxy-	106799-60-4
benzaldehyde, 2-methyl-	000529-20-4
benzaldehyde, 3-methyl-	000620-23-5
benzaldehyde, 4-methyl-	000104-87-0
benzaldehyde, 2-, 3-, 4-methyl- mixed isomers	001334-78-7
benzaldehyde, tert-butylmethyl-	066949-23-3
benzeneacetic acid, alpha-oxo-, methyl ester	015206-55-0
benzene, 1-chloro-2-(trifluoromethyl)-	000088-16-4
benzene, 1-chloro-3-(trifluoromethyl)-	000098-15-7
benzene, 1,2,3-trichloro-	000087-61-6
benzene, (1,1-dimethylethoxy)-	006669-13-2
benzene, 1,1'-[(1-propenylthio)methylene]bis-, (Z)-	056195-66-5
benzene, 2-ethoxyethenyl-	017655-74-2
benzene, (2-methoxy-1-methylethyl)-	065738-46-7
benzene, divinyl-	001321-74-0
benzene, (1-methoxy-1-methylethyl)-	000935-67-1
benzene, 1,1-oxybis-	000101-84-8
benzene, 1,3-Dimethyl-5-isopropyl-	004706-90-5
benzene, 4,6-diisopropyl-1,3-dimethyl-	005186-68-5

Table D4 – Threshold of evaluation chemicals¹

Substance	CAS #
Organics	
benzeneacetaldehyde	000122-78-1
benzeneamine, 4-(1-methylethyl)-N-phenyl-	005650-10-2
benzenediamine, ar,ar-diethyl-ar-methyl	068479-98-1
benzenediamine, 5-chloro-1,3-	033786-89-9
benzenedimethanol, a,a,a',a'-tetramethyl-1,4-	002948-46-1
benzenedimethanol, a,a,a',a'-tetramethyl-1,3-	001999-85-5
benzenemethanamine, 1,3-	001477-55-0
benzenemethanamine, N-(phenylmethylene)-	000780-25-6
benzenemethanol, 4-(1-methylethyl)-	000536-60-7
benzenepropanoic acid, 3,5-bis(1,1-dimethylethyl)-4-hydroxy-	020170-32-5
benzenesulfonamide, 4-methyl-	000070-55-3
benzenesulfonyl isocyanate, 4-methyl	004083-64-1
benzenetricarboxylic acid, 1,2,4-	000528-44-9
benzimidazolone, 3-methyl-2-	001849-01-0
benzimidazolone, 4-methyl-	019190-68-2
benzothiazolin-3-one	002634-33-5
benzofuran, methyl-	025586-38-3
benzoic acid, 2-cyano-	003839-22-3
benzoic acid, 2,5-dichloro-	000050-79-3
benzoic acid, 3,4-dichloro-	000051-44-5
benzoic acid, mixed isomers (2,4- or 2,5-dichloro-)	035915-19-6
benzoic acid, m-methyl-	000099-04-7
benzoic acid, o-methyl-	000118-90-1
benzoic acid, p-methyl-	000099-94-5
benzoic acid, 4-tert-butyl-	000098-73-7
benzonitrile	000100-47-0
benzoquinone, 2,6-dimethyl-1,4-	000517-61-7
benzoquinone, 2,6-di-t-butyl-	000719-22-2
benzoquinone, 2,5-di-tert-pentyl-p-	004584-63-8
benzothiazole	000095-16-9
benzothiazole, 2-(cyclohexylamino)-	028291-75-0
benzothiazole, ethylamino-	028291-69-2
benzothiazole, 2-(methylmercapto)-	000615-22-5
benzothiazole, 2-methyl-	000120-75-2
benzothiazole, 2-(morpholiniothio)-	000102-77-2
benzothiazole-2-thione, N-methyl-	002254-94-6
benzotriazole, 2-(2-hydroxy-5-methyl-phenyl)-	002440-22-4
benzothiazolinone, 2-	000934-34-9
benzotropilidene, 3,4-	000264-09-5
benzoxazole, N-methyl-2-	019776-98-8
benzyl ethyl ether	000539-30-0
benzyl alcohol, 4-ethoxy	006214-44-4
benzyl alcohol, alpha, alpha, 4-trimethyl-	001197-01-9
benzyl alcohol, a,a-dimethyl-p-isopropyl-	003445-42-9
benzylamine	000100-46-9
benzylamine, N,N-dimethyl-	000103-83-3
benzylidiphenylphosphine oxide	002959-74-2
binaphthyl sulfone	032390-26-4
bisphenol A bis(polypropylene glycol) ether	037353-75-6

Table D4 – Threshold of evaluation chemicals¹

Substance	CAS #
Organics	
bisphenol F diglycidyl ether	002095-03-6
borneol	000507-70-0
bromobenzene	000108-86-1
bromophenol	032762-51-9
bromophenol, 2-	000095-56-7
bromophenol, 3-	000591-20-8
bromophenol, 4-	000106-41-2
1-butanamine,N,N-dibutyl-	000102-82-9
butanedioic acid	000110-15-6
butanediol diglycidyl ether, 1,4-	002425-79-8
butanediol dimethacrylate, 1,4-	002082-81-7
butanenitrile	000109-74-0
butanetricarboxylic acid, 2-phosphono-, 1,2,4-	037971-36-1
butanoic acid	000107-96-2
butanoic acid, 3,3-dimethyl-	001070-83-3
butanone, 1-phenyl-2-	001007-32-5
buten-1-ol, 2-methyl-2-	004675-87-0
buten-1-ol, 3-methyl-2-	000556-82-1
buten-1-ol, 3-methyl-3-	000763-32-6
butenal, methyl-	001115-11-3
butene, 2,3-dichloro-2-methyl-	000507-45-9
butenoic acid, trans-2-	000107-93-7
butenoic acid, 2-	003724-65-0
butenoic acid, 3-	000625-38-7
butyl isocyanate, n-	000111-36-4
butylamine, N-butyldiene	004853-56-9
carbodiimide, di-t-butyl-	000691-24-7
carbonic acid, diisopropyl ester	006482-34-4
chloroethane, 1-butoxy-2-	010503-96-5
chlorotoluene, p-	000106-43-4
cinnamate, 2-ethylhexyl-4-methoxy-	005466-77-3
cyanovaleic acid, 4-	unknown
cyclododecane	000294-62-2
cyclohexadecane	000295-65-8
cyclohexadiene-1-one, 2,6-(1,1-dimethylethyl)-4-methylene-2,5-	002607-52-5
cyclohexadiene-1-one, 2,6-di-tert-butyl-4-hydroxy-4-methyl-2,5-	010396-80-2
cyclohexanamine, 4,4'-methylene-bis-	001761-71-3
cyclohexanamine, N-methyl-	000100-60-7
cyclohexanamine, N-cyclohexyl-	000101-83-7
cyclohexanamine, N,N-dimethyl-	000098-94-2
cyclohexenecarbonitrile	027456-25-3
cyclohexanedimethanamine, 1,3-	002579-20-6
cyclohexane, cis-1-methyl-4-isopropyl-	006069-98-3
cyclohexane, 1-isopropyl-4-methyl-	000099-82-1
cyclohexanemethanol, trans-alpha,alpha,4-trimethyl-	005114-00-1
cyclohexane, methyl-	000108-87-2
cyclohexanol	000108-93-0
cyclohexanol, 3-methyl-	000591-23-1
cyclohexanol, trimethyl-	001321-60-4

Table D4 – Threshold of evaluation chemicals¹

Substance	CAS #
Organics	
cyclohexanol, 4-tert-butyl-	000098-52-2
cyclohexanone, 2-hydroxy	000533-60-8
cyclohexanone, 2-(1-hydroxycyclohexyl)-	028746-99-8
cyclohexen-1-one, 3-methyl-2-	001193-18-6
cyclohexene, 4-cyano also (1-cyano-3-cyclohexene)	000100-45-8
cyclohexyl isocyanate	003173-53-3
cyclohexylurea, dimethyl-	031468-12-9
cyclopentane, trimethyl	030498-64-7
cyclopentanol, 2-methyl-	024070-77-7
cyclopentanone	000120-92-3
cyclopentylcyclopentanone, 2-	004884-24-6
decadien-1-al, trans,trans-2,4-	025152-84-5
decadienal, 2,4-	002363-88-4
decamethylcyclopentasiloxane	000541-02-6
decanamide, N,N-dimethyl-	014433-76-2
decanedioic acid, bis(2,2,6,6-tetramethyl-4-piperidinyl)-	052829-07-9
decanedioic acid, dimethyl ester	000106-79-6
decanoic acid, methyl ester	000110-42-9
decylamine, n-	002016-57-1
dehydroabietic acid	001740-19-8
dehydroacetic acid	000520-45-6
di-o-tolylguanidine, 1,3-	000097-39-2
diazacyclotetradecane-2,9-dione, 1,8-	056403-09-9
dibenzylamine	000103-49-1
dibenzyl ether	000103-50-4
dibutyl cyanamide, N,N-	002050-54-6
1,3-dicyclohexylurea	002387-23-7
diethylene glycol monomethacrylate homopolymer	027598-43-2
diethyleneglycol monophenyl ether	000104-68-7
diethylurea, 1,3-	000623-76-7
diglycol chlorohydrin	000628-89-7
dihydro-5-pentyl-2(3H)-furanone	000104-61-0
dihydrobenzofuran, 2,3-	000496-16-2
dihydrofuran, 4-methyl-2,3-	034314-83-5
dihydromethoxymethyl oxopyridinecarbonitrile	000524-40-3
dihydromethyl benzimidazolone	005400-75-9
dimethyl ditallow ammonium chloride	068783-78-8
dimethyl glutarate	001119-40-0
dimethyl succinate	000106-65-0
dimethyl thioacetamide	000631-67-4
dimethyl-3,3'-thiobispropionate	004131-74-2
dimethyl-p-benzoquinone, 2,5-	000137-18-8
dimethylaminopyridine	001122-58-3
dimethylbenzaldehyde, 2,4-	015764-16-6
dimethylbenzaldehyde, 2,5	005779-94-2
dimethylbenzaldehyde, 3,4-	005973-71-7
dimethylcyanamide	001467-79-4
dimethyldiphenyl sulphone	005097-12-1
dimethyldithiocarbamate, methyl	003735-92-0

Table D4 – Threshold of evaluation chemicals¹

Substance	CAS #
Organics	
dimethyldodecanamide, N,N-	003007-53-2
dimethylhexane-2,5-diol, 2,5-	000110-03-2
dioctyldiphenylamine	026603-23-6
dioxacyclododecane-7,12-dione, 1,6-	000777-95-7
dioxadithionane, 1,3,6,7-	005980-67-6
dioxathiocane, 1,3,6-	002094-92-0
dioxolane-1,3, 4-ethyl	029921-38-8
diphenylamine, 4-hydroxy-	000122-37-2
diphenyl sulfide	000139-66-2
diphenylamine, 4-(diisopropylamino)	064092-29-1
diphenylethanedione, 1,2-	000134-81-6
dipropylamine, 3,3'-diamino-	000056-18-8
dithiolane-2-thione, 1,3-	000822-38-8
docosane	000629-97-0
docosenamide (erucamide)	000112-84-5
dodecamethylcyclohexasiloxane	000540-97-6
dodecanamide	001120-16-7
dodecanamine, 1-	000124-22-1
dodecylamine, N,N-dimethyl-	000112-18-5
dodecyl glycidyl ether	002461-18-9
ethane, 1,2-diphenoxy-	000104-66-5
ethan-1-one, 1-(methylphenyl)-	026444-19-9
ethane, 1-(3-hydroxyphenyl)-2-phenyl-	033675-75-1
ethanediamide, N-(2-ethoxyphenyl)-N'-(2-ethylphenyl)-	023949-66-8
ethanol, 2-[2-[2-[2[(1,1,3,3-tetramethylbutyl)phenoxy]ethoxy]ethoxy]-	049796-75-0
ethanol, 2-[2-[2-[(1,1,3,3-tetramethylbutyl)phenoxy]ethoxy]ethoxy]-	058705-51-4
ethanol, 2-[2-[4-(1,1,3,3-tetramethylbutyl)phenoxy]ethoxy]-	002315-61-9
ethanol, 2-(4-methoxyphenoxy) -	005394-57-0
ethanone, 1-[4-(ethoxymethyl)phenyl]-	093205-94-8
ethanone, 1-(4-hydroxy-3-methoxyphenyl)-	000498-02-2
ethanone, 1-(4-(1-hydroxy-1-methylethyl)phenyl)-	054549-72-3
ethanone, 1-[3-(methoxymethyl)phenyl]-	112766-37-7
ethanone, 1-[4-(methoxymethyl)phenyl]-	022072-50-0
ethyl hydroxyphthalide	000485-26-7
ethylbenzene acetate	000101-97-3
ethylcyclopentanone	004971-18-0
ethylene glycol dimethacrylate	000097-90-5
ethylene glycol monoethyl ether acetate	000111-15-9
fenchyl alcohol	001632-73-1
fenchyl alcohol, alpha-	000512-13-0
fenchyl alcohol, alpha-	014575-74-7
fluorenone	000486-25-9
formamide, N,N-diethyl-	000617-84-5
formamide, N-methyl-N-phenyl-	000093-61-8
formamide, N-cyclohexyl-	000766-93-8
formamide, N-(1,1-dimethylethyl)-	002425-74-3
formamide, N,N-dimethylthio-	000758-16-7
formamide, N,N-di-n-butyl-	000761-65-9
formamidine, N,N-dimethyl-N'-cyclohexyl-	003459-75-4

Table D4 – Threshold of evaluation chemicals¹

Substance	CAS #
Organics	
formylcyclopentene, 1-	006140-65-4
furan, tetrahydro-2,2,5,5-tetramethyl-	015045-43-9
furanic acid, bis(2-ethylhexyl) ester	000141-02-6
furfural, 5-methyl	000620-02-0
furylmethylketone, 5-methyl-2-	001193-79-9
geraniol	000106-24-1
gutaraldehyde	000111-30-8
glycidyl ether, 2-methylphenyl-	002210-79-9
guanidine, 1,2,3-triphenyl-	000101-01-9
heneicosane	000629-94-7
heptacosane	000593-49-7
heptadecanoic acid, 16-methyl-, methyl ester	005129-61-3
heptyl aldehyde, n-	000111-71-7
hexacosane	000630-01-3
hexanoic acid, 2-ethyl-, methyl ester	000816-19-3
hexanoic acid, methyl ester	000106-70-7
hex-1-ene, 2-ethyl-	001632-16-2
hex-2-en-1-ol, cis-	000928-94-9
hex-2-en-1-ol, trans-	000928-95-0
hex-5-en-1-ol	000821-41-0
hexadecanamide	000629-54-9
hexadecanamide, N,N-dimethyl-	003886-91-7
hexadecene-1	000629-73-2
hexamethylene oxide	000592-90-5
hexamethylene dibenzamide	005326-21-6
hexamethyleneimine, 1-ethyl-	006763-91-3
hexamethylene oxide	000592-90-5
hexanal, 2-ethyl-	000123-05-7
hexanal	000066-25-1
hexanamine, 2-	005329-79-3
hexane, 2,5-dimethyl-	000592-13-2
hexane-2,5-dione	000110-13-4
hexaoxacyclotriacontane, 1,6,11,16,21,26-	064001-05-4
hexen-2-one, 3-, 3,4-dimethyl-	020685-46-5
hexen-2-one, 4-, 3,4-dimethyl-	053252-21-4
hexen-2-one, 3-methyl-4-	072189-24-3
hexen-2-one, 5-methyl-3-	005166-53-0
hexen-2-one, 5-methyl-5-	003240-09-3
hexyne-2,5-diol, 2,5-dimethyl-3-	000142-30-3
hydrocinnamic acid	006386-38-5
hydroxydiphenylamine, 3-	000101-18-8
hydroxypropyl methacrylate, 2-	000923-26-2
icosane	000112-95-8
imidazole, methylphenyl-	000670-91-7
indan-1-ol	006351-10-6
indan-1-one	000083-33-0
indene, 1H-, 2,3-dihydro-1-methyl-	000767-58-8
indene, 1H-, 2,3-dihydro-4-methyl-	000824-22-6
indene, 1H-, 2,3-dihydro-5-methyl-	000874-35-1

Table D4 – Threshold of evaluation chemicals¹

Substance	CAS #
Organics	
indene, 2,3-dihydro- also (2,3-dihydro-1H-)	000496-11-7
indene	000095-13-6
isoalkanes, C9-C12	090622-57-4
isobutylene	000115-11-7
isobutyramide	000563-83-7
isobutyric acid	000079-31-2
isobutyronitrile	000078-82-0
isocrotonic acid	000503-64-0
isoindole, 2H-, 4,7-dione	056460-94-7
isophorone diamine	002855-13-2
Isovanillin	000621-59-0
laurolactam	000947-04-6
maleic anhydride, 2,3-dimethyl-	000766-39-2
mephenesin	000059-47-2
methacrylate, lauryl-	000142-90-5
methacrylic acid	000079-41-4
methacrylic acid, 2-hydroxyethyl ester	000868-77-9
methacrylic acid, 3-(trimethylsilyl)propyl ester	002530-85-0
methane, chlorodifluoro-	000075-45-6
methane, di-t-butoxy	002568-93-6
methane, di-t-butyl-	001070-87-7
methoxybenzene	000100-66-3
methyl anthranilate	000134-20-3
methylcarbamate, methyl N-butyl-N-	054644-60-9
methylcoumarin, 7-diethylamino-4-	000091-44-1
methyl palmitate	000112-39-0
methyl laurate	000111-82-0
methyl salicylate	000119-36-8
methyl stearate	000112-68-1
methyl-4-isopropyl cyclohexane, trans-1-	001678-82-6
methyldiethyl carbamate	004652-44-2
methylene bis(4-methyl-6-tertbutyl-phenol), 2,2'	000119-47-1
2,2'-methylenediphenol	002467-02-9
4,4'-methylenediphenol	000620-92-8
methylenephenethyl alcohol, beta-	006006-81-1
methylindene	029036-25-7
methylpiperidine, 1-	000626-67-5
methylthioacetone nitrile	035120-10-6
morpholine, methyl-	000109-02-4
morpholine, 4-dodecyl-	001541-81-7
morpholinecarbaldehyde, 4-	004394-85-8
morpholinecarboxamide, N-cyclohexyl-4-	003417-54-7
morpholinepropanenitrile, 4-	004542-47-6
N-butyl formamide	000871-71-6
N-isopropyl-2-methyl-2-propyl-1,3-propanediol dicarbamate	000078-44-4
naphthalene, dimethyl-	028804-88-8
naphthalene, 1,2-dimethyl-	000573-98-8
naphthalene, 1,3-dimethyl-	000575-41-7
naphthalene, 1,4-dimethyl-	000571-58-4

Table D4 – Threshold of evaluation chemicals¹

Substance	CAS #
Organics	
naphthalene, 1,5-dimethyl-	000571-61-9
naphthalene, 1,7-dimethyl-	000575-37-1
naphthalene, 1,8-dimethyl-	000569-41-5
naphthalene, 2,3-dimethyl-	000581-40-8
naphthalene, 2,6-dimethyl-	000581-42-0
naphthalene, 2,7-dimethyl-	000582-16-1
naphthalene, 1-ethyl-	001127-76-0
naphthalene, 2-ethyl-	000939-27-5
naphthalene, ethyl	027138-19-8
nonacosane	000630-03-5
nonanal	000124-19-6
nonanoic acid, 9-oxo-	002553-17-5
nonanoic acid, n-	000112-05-0
norbornene, 5-ethylidene-2-	016219-75-3
octacosane	000630-02-4
octadecadienoic acid, (Z,Z)-9,12-, butyl ester	002634-45-9
octadecane, n-	000593-45-3
octadecenoic acid, 6(Z), methyl ester	002777-58-4
octadecenoic acid, 6-, methyl ester	052355-31-4
octadecenoic acid, 7-, methyl ester	057396-98-2
octadecenoic acid, 9(E)-, methyl ester	001937-62-8
octadecenoic acid, 9(Z)-, methyl ester	000112-62-9
octadecenoic acid, 9-, methyl ester	002462-84-2
octadecenoic acid, 10-, methyl ester	013481-95-3
octadecanamide	000124-26-5
octadecenamide	000301-02-0
octadecene, 1-	000112-88-9
octadien-1-ol, 3,7-dimethyl-2,6-	000624-15-7
octadien-2-ol, 2,6-dimethyl-5,7-	005986-38-9
octadien-3-ol, 2,6-dimethyl-1,7-	022460-59-9
octadien-3-ol, 3,7-dimethyl-1,6-	000078-70-6
octadien-3-ol, 3,7-dimethyl-4,6-	018479-54-4
octanal	000124-13-0
octanoate, methyl-	000111-11-5
octaphenyl pentaethylene glycol ether, tert-	038621-31-7
octen-3-ol, 1-	003391-86-4
octylphenoxy-pentaethoxyethanol, tert-	037809-81-7
oleate, n-butyl-	000142-77-8
oxabicyclo (4.1.0) heptane-3-carboxylic acid, 7-	002386-87-0
oxamide, di-tert-butyl-	037486-48-9
oxaspirodecadienedione, di-(t-butyl)	082304-66-3
oxirane, [(dodecyloxy)methyl]-	002461-18-9
oxybis(propanenitrile)	001656-48-0
palmitate, isopropyl-	000142-91-6
palmitic acid, n-butyl ester	000111-06-8
pentacosane	000629-99-2
pentane, 1-amino	000110-58-7
pentanediol, 2,2,4-trimethyl-1,3-	000144-19-4
pentanenitrile	000110-59-8

Table D4 – Threshold of evaluation chemicals¹

Substance	CAS #
Organics	
pentaoxacyclopentacosane, 1,6,11,16,21-	056890-57-4
pentenal, trans-2-	001576-87-0
penten-2-ol, 3-	001569-50-2
penten-2-one, 3,4-dimethyl-3-	000684-94-6
peroxide, tert-butyl-	000110-05-4
phenanthrene	000085-01-8
phenol, 4-ethoxy-	000622-62-8
phenol, o-(1-phenylethyl)-	004237-44-9
phenol, (phenylethyl)-	051937-33-8
phenol, o-(alpha, alpha-dimethylbenzyl)-	018168-40-6
phenol, p-(alpha, alpha-dimethylbenzyl)-	000599-64-4
phenol, p-phenylethyl-	006335-83-7
phenol, 4-(2-propenyl)-	000501-92-8
phenol, 3,5-dibenzyl-2,4,6-trimethyl-	unknown
phenol, 2,6-di-t-butyl-4-methoxy-	000489-01-0
phenol, 2,2'-methylenebis (6-tert-butyl)-4-ethyl-	000088-24-4
phenol, 4-(1-phenylethyl)-	001988-89-2
phenol, 2-allyl-	001745-81-9
phenothiazine	000092-84-2
phenoxypropanol, 1- (or 2-)	041593-38-8
phenyl isothiocyanate	000103-72-0
phenyl-1-buten-4-ol, 4-	000936-58-3
phenylbutane, 2-	000135-98-8
phenylene) bis-ethanone, 1,1'-(1,4-	001009-61-6
phenylene) bis-ethanone, 1,1'-(1,3-	006781-42-6
phenylenediamine, N,N-bis(1,3-dimethylbutyl)-N'-phenyl-p-	019929-72-7
2,2'-p-phenylenedioxydiethanol	000104-38-1
phenylethanol, 2-	000060-12-8
(phenylimino) cyclohexadiene	002406-04-4
phenylindan, 1,1,3-trimethyl-3-	003910-35-8
phorone	000504-20-1
phosphate, diphenyl-2-ethylhexyl-	001241-94-7
phosphonic acid, (nitrilotris(methylene))tri-, pentasodium	002235-43-0
pinanol	000473-54-1
pinanol (or cis-2-pinanol)	004948-28-1
pinanol, trans-2-	004948-29-2
pinocampheol (also pinocamphone)	000547-60-4
piperazine, 1-(2-aminoethyl)-	000140-31-8
piperidine, 1-formyl	002591-86-8
piperidine, 2-propyl-	000458-88-8
piperidinol, 1,2,2,6,6-pentamethyl-4-	002403-89-6
piperidinol, 2,2,6,6-tetramethyl-4-	002403-88-5
piperidone, 2-	000675-20-7
poly(oxy-1,2-ethanediyl), a-isotridecyl-w-hydroxy-, phosphate	073038-25-2
propanal, 2,2-dimethyl-3-hydroxy-	000597-31-9
propanaminium chloride, N,N,N-trimethyl-3-((1-oxo-2-propenyl)amino)-1-	045021-77-0
propane, 1,1-dimethoxy-2-methyl	041632-89-7
propanediol, 2-ethyl-2-butyl-1,3-	000115-84-4
propanenitrile, 3-(diethylamino)-	005351-04-2

Table D4 – Threshold of evaluation chemicals¹

Substance	CAS #
Organics	
propanenitrile, 3,3'-oxybis-	001656-48-0
propanenitrile, 3,3'-thiobis-	000111-97-7
propanoic acid, 2-methyl-, 1-(1,1-dimethylethyl)-2-methyl-1, 3-propanediyl ester	074381-40-1
propanoic acid, 3-ethoxy-, ethyl ester	000763-69-9
propanoic acid, ethyl ester	000105-37-3
propanoic acid, 2,2-dimethyl-	000075-98-9
propanoic acid, 2-methyl-, 3-hydroxy-2,4,4-trimethylpentyl ester	000077-68-9
propanoic acid, 2-methyl-, 3-hydroxy-2,4,4-trimethylpentyl ester	074367-34-3
propanoic acid, 2-methyl, 2,2-dimethyl-1-(2-hydroxy-1-methylethyl) propyl ester	074367-33-2
propanol, 1-amino-2 -	000078-96-6
propanol, 1-[4-(1,1-dimethylethyl)phenoxy]-2-	002416-30-0
propanol, 1-phenoxy 2-	000770-35-4
propanol, phenyl-1-	001335-12-2
propanol, 1-propoxy-2-	001569-01-3
propanone, 1-phenyl-1-	000093-55-0
propanone, 1-, 2-hydroxy-2-methyl-1-phenyl-	007473-98-5
propenoic acid, 2-methyl-2-, polymer with octadecyl-2-methyl-2-propenoate	027401-06-5
propenone, (dihydroxy methoxyphenyl) phenyl-	018956-15-5
pyrazine, 2-methyl-	000109-08-0
pyrene	000129-00-0
pyridine, 2-methyl-	000109-06-8
pyridine, 2,4-dimethyl-	000108-47-4
pyridine, trimethyl-	029611-84-5
pyridine, 2,4,6-trimethyl-	000108-75-8
pyridine, 1,2,3,4-tetrahydro-1,2,2,6-tetramethyl-	063867-76-5
pyridine, 1,2,3,6-tetrahydro-1,2,3,4-tetramethyl-	090949-18-1
pyridine, 1,2,3,6-tetrahydro-1,2,4,5-tetramethyl-	090949-19-2
pyridine, 1,2,3,6-tetrahydro-1,2,4,6-tetramethyl-, cis-	023513-16-8
pyridine, 1,2,3,6-tetrahydro-1,3,3,6-tetramethyl-	122913-54-6
pyridine, 1,2,3,6-tetrahydro-1,4,5,6-tetramethyl-	090949-20-5
pyridine, 1,2,3,6-tetrahydro-2,2,2,6-tetramethyl-	001124-69-2
pyridine, 1,2,5,6-tetrahydro-2,2,5,5-tetramethyl-	155904-89-5
pyridine, 2,3,4,5-tetrahydro-2,2,4,6-tetramethyl-	200561-41-7
pyrrolidine	000123-75-1
pyrrolidinone, 1-decyl-2-	055257-88-0
quinoline, 3,4-dihydro-2,4,4-trimethyl-	063177-93-5
sodium p-sulfophenyl methallyl ether	001208-67-9
soya alkylamines, ethoxylated	061791-24-0
squalene	007683-64-9
stearic acid, butyl ester	000123-95-5
styrene, alpha-methyl-	000098-83-9
styrene, methyl- (mixed isomers)	025013-15-4
sulfonylbis(4-methyl)-benzene, 1,1'	000599-66-6
terephthalic acid, monomethyl ester	001679-64-7
terpineol, alpha-	000098-55-5
tert-butylamine	000075-64-9
tetracosane	000646-31-1

Table D4 – Threshold of evaluation chemicals¹

Substance	CAS #
Organics	
tetradecamethylcycloheptasiloxane	000107-50-6
tetradecanamide	000638-58-4
tetradecanamine, 1-	002016-42-4
tetradecane	001120-36-1
tetraethyleneglycol di-(2-ethylhexoate)	018268-70-7
tetraethyleneglycol dimethacrylate	000109-17-1
tetrahydrofuran, diphenyl-	050637-09-7
tetrahydrofurfuryl alcohol	000097-99-4
tetrahydropyridine, 2,3,4,5-	000505-18-0
tetramethyl urea	000632-22-4
tetramethyldec-5-yne-4,7-diol, 2,4,7,9-	000126-86-3
tetramethyldecynediol	001333-17-1
2,6,10,14-tetramethylhexadecane	000638-36-8
tetramethylpyrazine, 2,3,5,6-	001124-11-4
tetramethylsuccinonitrile	003333-52-6
tetraoxacycloeicosane, 1,6,11,16-	017043-02-6
tetrathiacyclooctadecane, 1,3,10,12-tetraoxa-6,7,15,16-	099634-55-6
4,4'-thiobis-(6-t-butyl-o-cresol)	000096-66-2
toluene, 2,6-diamino-	000823-40-5
toluenesulfonamide, N-ethyl-4-	000080-39-7
toluenesulfonic acid, p-, butyl ester	000778-28-9
toluidine, N,N-diethyl-p-	000613-48-9
triallyl cyanurate	000101-37-1
tributoxyethyl phosphate	000078-51-3
tributylphosphine oxide	000814-29-9
trichloroaniline, 2,4,5-	000636-30-6
trichloroaniline, 2,3,4-	000634-67-3
trichlorotrifluoroethane	026523-64-8
tricosane, also (n-tricosane)	000638-67-5
triethylamine	000121-44-8
triethyleneglycol dimethacrylate	000109-16-0
triethylsilanol	000597-52-4
trimethylcyclohexanone	050874-76-5
trimethylolpropane trimethacrylate	003290-92-4
trioxane, 1,3,5-trimethyl-	000123-63-7
trioxepane, 1,3,5-	005981-06-6
triphenylphosphate	000115-86-6
triphenylphosphine oxide	000791-28-6
tropic acid	000552-63-6
undecanoic acid	000112-37-8
urea, N,N-bis-(1,1-dimethylethyl)-	005336-24-3
urea, 1,1,3,3-tetrabutyl-	004559-86-8
urea, N,N',N'-trimethyl-	000623-14-4
valeronitrile, 2,4-dimethyl-	034372-09-3
¹ For the chemicals listed in this table, the evaluation criteria are 0.003 mg/L under static conditions, and 0.0003 mg/L under flowing conditions.	

Annex E²¹ (informative)

Informational drinking water criteria

E.1 General

The drinking water criteria in this annex have not undergone external peer review.

The drinking water criteria in this annex are intended to be used as guidance in the determination of evaluation criteria for those compounds that do not have normative evaluation criteria established. Some of these values, as noted in the tables, are currently under external peer review for inclusion as normative criteria. The values in these tables include criteria that have been developed according to the requirements of annex A, but have not been externally peer-reviewed. The tables also include non-regulatory USEPA values that have been reviewed but failed to satisfy annex A toxicity data requirements. Compounds that have been detected only at concentrations below the threshold of evaluation (see annex A, section A.2.7.1) to which the threshold of evaluation protocol has been applied are also listed here.

The drinking water criteria in this annex have not been evaluated for taste and odor considerations at the concentration limits indicated.

In the event that one of the chemicals listed in this annex is detected at concentrations exceeding the guidance evaluation criteria values, a complete toxicity data review should be conducted. The review should be performed according to annex A requirements prior to using the informational evaluation criteria values to determine product compliance to this Standard.

The substances listed in tables E1 and E2 are not intended to encompass all of the potential analytes of interest that need to be considered when evaluating products. The user is cautioned that each product may have formulation-dependent analytes of interest for which concentration limits have not been determined. In these cases, the user is required to develop acceptable concentration limits based on the requirements of annex A of NSF/ANSI 61 in order to determine full compliance with the Standard.

These tables are specific to NSF/ANSI 61. While the tables may be used for evaluation of impurities in drinking water treatment chemicals, the substances listed in these tables may have not been evaluated for use as direct additive drinking water treatment chemicals under NSF/ANSI 60. Use as direct additive drinking water treatment chemicals may require the consideration of different exposure parameters from those used for NSF/ANSI 61 evaluation.

E.2 NSF International drinking water criteria (not externally peer-reviewed)

Table E1 contains drinking water criteria for unregulated contaminants that have been identified as extractants from products covered by this Standard. For criteria set by NSF International, the TAC and SPAC criteria have been determined in accordance with annex A of NSF/ANSI 61. External peer review is in progress on these evaluation criteria, as noted in the table. As external peer review is completed, those criteria will be submitted for inclusion as normative evaluation criteria in this Standard.

In the absence of sufficient information to determine a data-derived relative source contribution factor, a default 20% drinking water contribution is assumed. Some of the SPAC values do not represent 10% of

²¹ The information contained in this Annex is not part of this American National Standard (ANS) and has not been processed in accordance with ANSI's requirements for an ANS. Therefore, this Annex may contain material that has not been subjected to public review or a consensus process. In addition, it does not contain requirements necessary for conformance to the Standard.

the corresponding TAC values; either a data deficiency precluded setting of the TAC at a higher value, or a data-derived multiple source factor other than the 10% default value was applied.

E.3 Informational threshold of evaluation chemicals

Table E2 contains chemicals that have been evaluated using the threshold of evaluation (see annex A, section A.7.1), but that may have sufficient toxicity data available that would enable chemical specific risk assessments to be performed if needed. To date, these chemicals have not been detected at concentrations exceeding the threshold of evaluation criteria. In the event that these chemicals are detected at concentrations exceeding the threshold of evaluation criteria, a toxicity data review should be conducted according to annex A prior to using the threshold of evaluation to determine product compliance to this Standard.

Table E1 – NSF International drinking water criteria (not externally peer reviewed)

Substance	CAS #	Total Allowable Concentration (TAC) mg/L	Single Product Allowable Concentration (SPAC) mg/L	Source of supporting documentation
Inorganics				
aluminum	7429-90-5	2	2	NSF action levels ¹ Issue date: 07/90
bismuth	7440-69-9	0.100	0.010 (non-section 9) 0.05 (section 9)	NSF action levels ¹ Issue date: 08/02/95
lithium	7439-93-2	1.0	0.3	NSF action levels ¹ Issue date: 09/27/99
nickel	7440-02-0	0.1	0.02	NSF action levels ¹ Issue date: 07/22/96
vanadium	7440-62-2	0.03	0.003	NSF action levels ¹ Issue date: 02/11/00
Organics				
acetaldehyde	75-07-0	0.01	0.01	NSF action levels ¹ Issue date: 04/24/96
11-aminoundecanoic acid	2432-99-7	0.05	0.05	NSF action levels ¹ In external peer review as of 04/15/99
bisphenol A	80-05-7	0.1	0.01	NSF action levels ¹ Issue date: 02/06/97
1,3-butadiene	106-99-0	0.0002	0.00002	NSF action levels ¹ Issue date: 1/12/96
butyl acrylate	141-32-2	0.01	0.01	NSF action levels ¹ Issue date: 12/13/95
<i>tert</i> - butyl hydroquinone	1948-33-0	0.01	0.01	NSF action levels ¹ Issue date: 11/03/95
butyltin compounds (mono- and di- only)	N/A	0.02 (total)	0.004 (total)	NSF action levels ¹ Issue date: 12/19/91
dibutylamine	111-92-2	0.01	0.01	NSF action levels ¹ Issue date: 08/19/95
dichloropropanol includes: 2,3-dichloro-1-propanol 1,3-dichloro-2-propanol	26545-73-3 616-23-9 96-23-1	0.03 (total)	0.009 (total)	NSF action levels ¹ Issue date: 5/97
diethylene triamine	111-40-0	0.01	0.01	NSF action levels ¹ Issue date: 11/14/97
diisononyl phthalate	28553-12-0	0.05	0.05	NSF action levels ¹ Issue date: 04/06/98
ethyl acrylate	140-88-5	0.01	0.001	NSF action levels ¹ Issue date: 01/28/92
ethyl-4-ethoxybenzoate	23676-09-7	0.05	0.05	NSF action levels ¹ Issue date: 11/17/99
2-ethyl-1-hexanol	104-76-7	0.05	0.05	NSF action levels ¹ Issue date: 03/29/95
hydroquinone	123-31-9	0.006	0.0006	NSF action levels ¹ Issue date: 04/16/92

Table E1 – NSF International drinking water criteria (not externally peer reviewed)

Substance	CAS #	Total Allowable Concentration (TAC) mg/L	Single Product Allowable Concentration (SPAC) mg/L	Source of supporting documentation
Organics				
isophthalic acid	121-91-5	0.01	0.01	NSF action levels ¹ Issue date: 12/18/95
maleic acid	110-16-7	0.05	0.05	NSF action levels ¹ Issue date: 05/26/95
2-mercaptobenzothiazole	149-30-4	0.04	0.004	NSF action levels ¹ Issue date: 11/05/93
4,4'-methylenedianiline	101-77-9	0.001	0.0001	NSF action levels ¹ Issue date: 06/90
1-methylnaphthalene	90-12-0	0.05	0.05	NSF action levels ¹ Issue date 09/16/96
N-methyl-2-pyrrolidone	872-50-4	1	0.1	NSF action levels ¹ Issue date: 06/17/93
methyltin compounds(mono- and di- only)	N/A	0.03 (total)	0.006 (total)	NSF action levels ¹ Issue date: 12/19/91
2-phenyl-2-propanol	617-94-7	0.05	0.01	NSF action levels ¹ In external peer review as of 04/15/99
propylene glycol monomethyl ether	107-98-2	0.05	0.05	NSF action levels ¹ Issue date: 2/04/94
terephthalic acid	100-21-0	0.01	0.01	NSF action levels ¹ Issue date: 01/10/97
tetrahydrofuran	109-99-9	1	0.37	NSF action levels ¹ Issue date: 01/26/96
tetramethylthiourea	2782-91-4	0.002	0.0002	NSF action levels ¹ Issue date: undated
toluene diisocyanate 2,4- (80%) and 2,6-(20%) (for specified mixture only)	26471-62-5	0.008	0.0008	NSF action levels ¹ Issue date: ~ 6/99
trimethylamine	75-50-3	0.01	0.001	NSF action levels ¹ Issue date: 11/11/96
vinyl acetate	108-05-4	0.02	0.002	NSF action levels ¹ Issue date: 05/03/91
¹ NSF action levels have been derived according to the requirements of ANSI/NSF 61 – 1999a, annex A. External peer review is in progress on some of these substances, as noted.				

– concluded –

Table E2 – Threshold of evaluation chemicals having datasets from which specific TAC/SPAC values, or CBEL values, could be set using Annex A¹

Substance	CAS#
Inorganics	
cobalt	007440-48-4
titanium	007440-32-6
Organics	
acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-	000137-58-6
benzalazine	064896-26-0
benzamide	000055-21-0
benzophenone	000119-61-9
benzoguanamine	000091-76-9
benzotriazole, 1,2,3-	000095-14-7
benzyl acetate	000140-11-4
benzyl alcohol, 3,5-di-tert-butyl-4-hydroxy-	000088-26-6
cyanoguanidine	000461-58-5
cyclohexene	000110-83-8
dichlorodifluoromethane	000075-71-8
dichlorophenol, 2,4-	000120-83-2
diethylaminoethanol	000100-37-8
dimethylacetamide, n,n-	000127-19-5
dimethyl adipate	000627-93-0
dimethylaminopropanenitrile	001738-25-6
dimethylformamide, n,n-	000068-12-2
dimethyl phthalate	000131-11-3
diphenyl guanidine, 1,3- (or n,n-)	000102-06-7
diphenyl-p-phenylenediamine, n,n'-	000074-31-7
ethanol, 2-diethylamino-	000100-37-8
ethanol, 2-(dimethylamino)-	000108-01-0
ethanol, 2-phenoxy-	000122-99-6
ethanol, 1-phenyl-	000098-85-1
fluoranthene	000206-44-0
fluorescein	002321-07-5
fluorescein, dipotassium salt	006417-85-2
furanmethanol, 2-	000098-00-0
heptanoic acid, n-	000111-14-8
hexamethylenetetramine	000100-97-0
hexanoic acid, n-	000142-62-1
isobutyl isobutyrate	000097-85-8
(isopropylamino)diphenylamine, 4-	000101-72-4
isopropyltoluene	000099-87-6
methyl acrylate	000096-33-3
methyldiethanolamine, n-	000105-59-9
methylene diphenyl diisocyanate	000101-68-8
methylene bis(n-iso-butylbenzenamine)	088990-59-4
phenylene diamine, n-(1,3-dimethylbutyl)-n'-phenyl-p-	000793-24-8
phenylenediamine, n-phenyl-p-	000101-54-2
phthalic acid, o-	000088-99-3
piperidine	000110-89-4
sebacate, bis(2-ethylhexyl)-	000122-62-3

Table E2 – Threshold of evaluation chemicals having datasets from which specific TAC/SPAC values, or CBEL values, could be set using Annex A¹

Substance	CAS#
Organics	
silane, gamma-aminopropyl triethoxy-	000919-30-2
tacrine	000321-64-2
tetramethylene sulfone	000126-33-0
tetramethyl piperidinone	000826-36-8
thiabendazole	000148-79-8
triallyl isocyanurate	001025-15-6
triethylene diamine	000280-57-9
tris(2-ethylhexyl) phosphate	000078-42-2
vanillin, o-	000148-53-8
¹ For the chemicals in this table, the evaluation criteria are 0.003 mg/L under static conditions and 0.0003 mg/L under flowing conditions. The chemicals that appear in this table have been detected only at concentrations not exceeding these threshold of evaluation concentrations as established in this standard (see annex A, A.7.1), and have not been evaluated for specific TAC and SPAC values. If any of these chemicals are detected at concentrations exceeding the threshold of evaluation, toxicity data shall be reviewed to determine whether specific TAC and SPAC values can be established, prior to using threshold of evaluation to determine compliance with the Standard.	

– concluded –

Annex F²² (informative)

Revisions to the evaluation of lead

F.1 Background

The Lead Task Group (LTG) was created by the Drinking Water Additives Joint Committee (DWA JC) to review questions posed about the evaluation of lead under NSF/ANSI 61 and to provide the committee recommendations should they be warranted. The LTG provided an interim report to the DWA JC in November 2005 detailing its discussions and findings, and continued to meet in 2006. Based on those discussions, the LTG developed proposed changes designed to increase the public health protection of the standard relative to the evaluation of lead leaching. Five key points leading to that decision were:

- There is no USEPA Maximum Contaminant Level (MCL) for lead. The USEPA maximum contaminant level goal (MCLG) is zero. There does not appear to be a lower threshold for the toxic effects of lead. Even small doses accumulate to a demonstrated toxic effect.
- The International Agency for Research on Cancer (IARC) has classified inorganic lead compounds as probable human carcinogens (Group 2A) (ATSDR 2005, IARC 2006).
- The USCDC states that efforts to eliminate lead exposures through primary prevention have the greatest potential for success in reducing blood lead levels (USCDC 2005).
- The lead and copper rule requirement that defines corrosion control optimization for large systems is based on the difference between the 90th percentile lead level and the source water lead concentration being less than the practical quantitation level of 5 ppb (Code of Federal Regulations 40 CFR – Part 141.81(b)(3)).
- NSF/ANSI-61-conformant products shouldn't cause LCR action level exceedances.

To increase the level of health effects protection provided by this Standard, the requirements for evaluation of lead leaching will be updated based on the revisions contained in this annex. The revisions address the following items related to reduction of the acceptance criteria for lead to be based on the 5 ug/L corrosion control optimization level for large systems:

- a) Reduction of the TAC for lead from 15 ug/L to 5 ug/L; and
- b) Reduction of the SPAC for lead from 1.5 ug/L to 0.5 ug/L; and
- c) Reduction of the Q (&R) Statistic criteria from 11 to 5 for all section 9 devices other than supply stops, flexible plumbing connectors, and miscellaneous components; and
- d) Reduction of the Q (&R) Statistic criteria from 11 to 3 for supply stops, flexible plumbing connectors, and miscellaneous components.

These revisions will be transferred to the main body of the Standard as normative requirements on the date identified in F.2.

²² The information contained in this Annex has been processed in accordance with ANSI requirements for public review and consensus ballot. The requirements were approved by the Drinking Water Additives Joint Committee for inclusion in the Standard as normative requirements effective July 1, 2012.

The LTG also investigated the N3 factor used during the normalization of in-line device results under Section 8 of this Standard. They concluded that although the dispersion of contaminants between an in-line device and a faucet is a real phenomenon, use of the N3 factor may not take into account the additive effect of additional extractions of the same contaminant from other in-line devices installed in close proximity. This potential was identified as most significant in residential applications with a nominal ID of less than 1½" where the number of devices installed in close proximity could exceed three, canceling $\frac{1}{3}$ (0.33) N3 factor. However, the LTG is not recommending removal of this factor at this time for the following reasons.

- The combined effect of reducing the acceptance criteria for lead that applies to these products (reduced from 15 ug/L to 5 ug/L) and the removal of the 0.33 N3 factor results in a nearly tenfold increase in the stringency of the standard for lead. At this level, even the occasional detection of lead from products produced using alloys with lead compositions less than 0.1% were found to occur and would lead to failures under the Section 8 evaluation protocol.
- At this lower level of extractions, it was identified that the Section 8 exposure protocol would need to be updated to account better for the normal variability in lead extraction rather than depending on the single-value approach used now.
- The American Water Works Association Research Foundation (AwwaRF) has several projects underway that may provide additional information on lead extraction from in-line devices to assist in determining the appropriate use of the N3 factor.
- The American Foundry Society is sponsoring a non-leaded copper casting consortium of manufacturers to study issues surrounding the use of non-leaded copper alloys.
- The reduction in acceptance criteria from 15 ug/L to 5 ug/L still makes the evaluation of these products three times more stringent.

The LTG is recommending that this decision be revisited on a regular basis as new information becomes available, including the additional experience that will be gained by manufacturers and certifiers as they evaluate products to these new criteria.

F.2 Incorporation of revisions into standard

The revisions in this annex shall be incorporated into the body of this Standard July 1, 2012.

NOTE – Due to the significant impact of these changes, the Drinking Water Additives Joint Committee (DWA JC) established an extended effective date for the new requirements. The 7/1/2012 effective date was selected to provide manufacturers a reasonable time to reengineer products to meet the new requirements, to have them tested, and to make them available in the marketplace. Manufacturers and certifiers are strongly encouraged actively to pursue conformance to the new requirements prior to 7/1/2012.

F.3 Revisions

F.3.1 Revisions to Annex D: Normative drinking water criteria

**Table D1 – U. S. Environmental Protection Agency and Health Canada
NSF/ANSI 61 drinking water criteria**

Contaminant (Reference) ¹	Drinking water regulatory level (MCL/MAC) (mg/L)	Single product allowable concentration (SPAC) (mg/L)
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lead (at tap) (40 CFR §141.80; 65 FR 1950)	TT ^{2,3} (action level 0.015 0.005 mg/L)	0.00150 0.0005
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¹ The references for criteria based on U. S. primary drinking water regulations are from the U. S. Code of Federal Regulations, Title 40 (Protection of Environment), revised July 1, 2001. This document is available online at <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>. Issue dates are given for criteria based on Health Canada guidelines. Additional information on the guidelines for these chemicals is available at http://www.hc-sc.gc.ca/ehp/ehd/bch/water_quality.html.

² TT = treatment technique. The lead and copper rule requirement that defines corrosion control optimization for large systems is based on the difference between the 90th percentile lead level and the source water lead concentration being less than the practical quantitation level of 5 ppb (Code of Federal Regulations 40 CFR – Part 141.81(b)(3)).

³ For section 9 products other than supply stops, flexible plumbing connectors, and miscellaneous components, a Q statistic value of 445 µg lead for a 1 L (0.26 gal) draw is used as the evaluation criterion. For supply stops, flexible plumbing connectors, and miscellaneous section 9 devices, a Q statistic value of 3 µg lead for a 1-L (0.26-gal) draw is used as the evaluation criterion. This is based on the assumption that sources other than the Section 9 device contribute 4 µg for a 1 L (0.26 gal) draw, resulting in a total limit of 15 µg lead for a 1 L (0.26 gal) draw.

⁴ MFL = Million Fibers per Liter, where fiber length > 10 microns

⁵ Beginning January 2005, the Single Product Acceptable Concentration (SPAC) for bromate will be lowered to 0.003 mg/L, unless it is demonstrated to the Joint Committee on Drinking Water Additives by the manufacturers of hypochlorite treatment chemicals that the drinking water industry demand for hypochlorite chemicals cannot be adequately met unless the SPAC remains at 0.005 mg/L.

⁶ Value represents the maximum residual disinfectant level (MRDL)

⁷ “Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States,” August 17, 2001 / Morbidity & Mortality Weekly Report 50 (RR14); 1-42

F.3.2 Revisions to Section 9: Mechanical plumbing devices

9.5.1 Evaluation of lead

For endpoint devices other than commercial kitchen devices, supply stops, flexible plumbing connectors, and miscellaneous components, the lead test statistic Q shall not exceed 445 µg when normalized for the 1-L (0.26-gal) first draw sample. For commercial kitchen devices, the lead test statistic Q shall not exceed 445 µg when normalized for the 18.9-L (5-gal) first draw sample. For supply stops, flexible plumbing

connectors, and miscellaneous components, the lead test statistic Q shall not exceed 3 µg when normalized for the 1-L (0.26-gal) first draw sample.

~~NOTE — The limit of 11 µg for lead is based on a limit of 15 µg total lead, including lead contributed from the device interior as well as from sources other than the device, which is assumed to be 4 µg.~~

F.3.3 Revisions to Annex B relative to the evaluation of Section 9 products

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B.5.4 Exposure

Following conditioning, the sample shall be exposed to extraction water according to the applicable scheme detailed in annex B, sections B.5.4.1 through B.5.4.3. Reflecting the sample's intended use, samples shall be exposed to extraction waters at the specified temperatures for the entire duration of the exposure. Exposure shall be limited to 23 ± 2 °C (73 ± 4 °F) except for instant hot water dispensers, in which case the manufacturer's specified thermostat setting shall be used.

Evaluation of endpoint devices, components, and materials for contaminants other than lead shall require exposure of at least one sample according to the timetable of figure B1. The number of products to be tested shall be specified by the manufacturer. When one sample is tested, the normalized contaminant concentrations from exposure on Day 19 shall be compared to their respective SPACs. If more than one sample is tested, the geometric mean of normalized contaminant concentrations from exposure on Day 19 shall be compared to their respective SPACs.

Evaluation of endpoint devices, components, and materials for the contaminant lead shall require exposure of at least three devices (more if specified by the manufacturer), according to the timetable of figure B1. It is recommended that product lines thought to be marginally acceptable, and those that leach levels of lead approaching the maximum allowable level, should be tested for more than the minimum number of products. The rationale for selecting a number of products greater than three is provided in annex B, section B.8.9. On Days 3, 4, 5, 10, 11, 12, 17, 18, and 19, the 16 h dwell extractant water shall be collected. The lead test statistic Q shall be determined as described in annex B, section B.8.9 and compared to 11 µg.

When additional extraction water is needed to complete all analyses, additional samples shall be exposed.

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B.8.9.3 Initial test statistic

The test statistic Q shall be determined as:

$$Q = e^{\bar{Y}} \cdot e^{k_1 S}$$

where the log-dosage mean, \bar{Y} , and the log-dosage standard deviation, S, are determined using the procedures described in annex B, section B.8.9.2. The value of k_1 depends upon the sample size. Table B13 in this annex presents the value of k_1 for a range of sample sizes. The acceptability of the product line depends upon the value of the test statistic and product type, where

For end-point devices other than supply stops, flexible plumbing connectors, and miscellaneous components:

- Case I: If $Q \leq 115$ µg, the product line has tested as acceptable; or
- Case II: If $Q > 115$ µg, the product line has tested as unacceptable.

For supply stops, flexible plumbing connectors, and miscellaneous components:

- Case I: If $Q \leq 3 \mu\text{g}$, the product line has tested as acceptable; or
- Case II: If $Q > 3 \mu\text{g}$, the product line has tested as unacceptable.

When a device or component has been tested for lead through separate exposure of two or more components or materials, the summed value of the test statistic Q shall be compared to the preceding criteria.

B.8.9.4 Retest statistic

The retest statistic R shall be determined as:

$$R = e^{\bar{Y}} \cdot e^{k_2 S^2}$$

where the log-dosage mean, \bar{Y} , and the log-dosage standard deviation, S , are determined using the procedures described in annex B, section B.8.9.2. The value of k_2 depends upon the sample size. Annex B, table B14 presents the value of k_2 for a range of sample sizes. The acceptability of the product line depends upon the values of the retest statistic and product type, where:

For end-point devices other than supply stops, flexible plumbing connectors, and miscellaneous components:

- Case I: If $R \leq 445 \mu\text{g}$, the product line has tested as acceptable; or
- Case II: If $R > 445 \mu\text{g}$, the product line has tested as unacceptable.

For supply stops, flexible plumbing connectors, and miscellaneous components:

- Case I: If $R \leq 3 \mu\text{g}$, the product line has tested as acceptable; or
- Case II: If $R > 3 \mu\text{g}$, the product line has tested as unacceptable.

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F.4 Additional information on lead

Lead is a heavy, bluish-gray metal that occurs naturally in the Earth's crust, usually associated with ores containing other elements. Because of its physical properties (corrosion resistance, malleability), lead and lead alloys have historically been used in plumbing applications. Elevated lead levels in drinking water generally occur due to corrosion of lead pipe used for service lines and of lead contained in household plumbing. Various health effects have been associated with lead exposure, including interference with red blood cell chemistry; delays in normal physical and mental development in babies and young children; slight deficits in the attention span, hearing, and learning abilities of children; and slight increases in the blood pressure of some adults. Long-term effects of lead exposure include stroke, kidney disease, and cancer (USEPA 2005).

Exposure to lead, especially in infants and young children, may cause permanent neurological damage leading to IQ reductions, attention deficit disorders, and aggressive behavior (Needleman and Gatsonis 1990, Schwartz 1994). Too much lead can also damage reproductive systems and the kidneys, and can cause high blood pressure and anemia (WHO 1993).

Kidney tumors have developed in rats and mice that had been given large doses of some kinds of lead compounds. The Department of Health and Human Services (DHHS) has determined that lead and lead compounds are reasonably anticipated to be human carcinogens based on limited evidence from studies

in humans and sufficient evidence from animal studies, and the USEPA has determined that lead is a probable human carcinogen. The International Agency for Research on Cancer (IARC) has determined that organic lead compounds are "not classifiable as to their carcinogenicity to humans (Group 3) based on inadequate evidence from studies in humans and in animals." IARC has classified inorganic lead compounds as probable human carcinogens (Group 2A). (ATSDR 2005, IARC 2006).

In light of these findings, the USEPA has set a MCLG of zero for lead. The LCR lead action level of 0.015 mg/L at the 90th percentile is not a health-based action level, but was derived based on the capabilities of corrosion control processes to control lead concentrations adequately at the tap (USEPA 2004). The WHO has established a health guideline for lead in drinking water at 0.1 mg/L (WHO 1993). The U. S. Center for Disease Control and Prevention has set a level of 10 µg of lead per deciliter (dL) of blood as the level above which a child is to be investigated for lead poisoning. The USCDC states that efforts to eliminate lead exposures through primary prevention have the greatest potential for success in reducing blood lead levels (USCDC 2005).

Recently published research has documented measurable childhood IQ deficits at a blood lead level as low as 2.5 µg/dL, a level previously believed to be well below the threshold for observable neurological damage (Hertz-Picciotto et al 2000, Lanphear et al 2000, Bellinger 2003). Canfield et al (2003) evaluated the relationship between blood lead levels and IQ in children using linear and nonlinear models, and concluded that children in the U. S. may be more adversely affected by environmental lead than previously thought. Their results indicated that each 10 µg/dL increase in the lifetime average blood lead concentration was associated with a 4.6-point decrease in IQ. However, for a sub-sample of children with blood lead levels below 10 µg, the change in IQ associated with a change in blood lead concentration from 1 to 10 µg /dL was greater (7.4 points).

Very recently published research (Menke et al 2006) demonstrated a link between blood lead levels below 10 µg/dL, and death by heart attack and stroke. The effects begin to appear at ~2 µg/dL, or one-fifth of the current USCDC blood lead intervention level. This relationship was previously unknown and, if confirmed, is likely to lead to a reduction in the USCDC blood lead intervention level. The Menke et al study resulted in an editorial in the journal in which it appeared (Nawrot and Staessen 2006), calling attention to the significance of the demonstrated effects. A proposal to reduce the current USCDC blood lead intervention level from 10 to 2 µg/dL has also been published (Gilbert and Weiss 2006). The change is justified by health effects research and present laboratory accuracy for blood lead determinations. Any reduction in the USCDC blood lead intervention level is likely to cause the USEPA to reexamine the Action Level for lead in drinking water.

F.5 References

Agency for Toxic Substances and Disease Registry. 2005. Public Health Statement for Lead. Atlanta, GA: U. S. Department of Health and Human Services, Public Health Service.

American Water Works Association Research Foundation (AwwaRF) projects including ongoing research on lead extraction from in-line devices:

– AwwaRF# 3018: Contribution of Service Line and Plumbing Fixtures to Lead and Copper Rule Compliance Issues

– AwwaRF# 3107: Effect of the Change in Disinfectants on Lead, Brass, and Copper Components in the Distribution System.

– AwwaRF# 3112: Performance and Metal Release of Non-Leaded Brass Meters, Components, and Fittings.

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Standards and Criteria²³

The following standards and criteria established and adopted by NSF as minimum voluntary consensus standards are used internationally:

- 2 Food equipment
- 3 Commercial warewashing equipment
- 4 Commercial cooking, rethermalization, and powered hot food holding and transport equipment
- 5 Water heaters, hot water supply boilers, and heat recovery equipment
- 6 Dispensing freezers
- 7 Commercial refrigerators and freezers
- 8 Commercial powered food preparation equipment
- 12 Automatic ice making equipment
- 13 Refuse processors and processing systems
- 14 Plastics piping system components and related materials
- 18 Manual food and beverage dispensing equipment
- 20 Commercial bulk milk dispensing equipment
- 21 Thermoplastic refuse containers
- 24 Plumbing system components for recreational vehicles
- 25 Vending machines for food and beverages
- 29 Detergent and chemical feeders for commercial spray-type dishwashing machines
- 35 High pressure decorative laminates (HPDL) for surfacing food service equipment
- 36 Dinnerware
- 37 Air curtains for entranceways in food and food service establishments
- 40 Residential wastewater treatment systems
- 41 Non-liquid saturated treatment systems
- 42 Drinking water treatment units – Aesthetic effects
- 44 Residential cation exchange water softeners
- 46 Evaluation of components and devices used in wastewater treatment systems
- 49 Class II (laminar flow) biosafety cabinetry
- 50 Circulation system components and related materials for swimming pools, spas/hot tubs
- 51 Food equipment materials
- 52 Supplemental flooring
- 53 Drinking water treatment units – Health effects
- 55 Ultraviolet microbiological water treatment systems
- 58 Reverse osmosis drinking water treatment systems
- 59 Mobile food carts
- 60 Drinking water treatment chemicals – Health effects
- 61 Drinking water system components – Health effects
- 62 Drinking water distillation systems
- 143 Environmentally preferable products – Hard surface cleaners
- 169 Special purpose food equipment and devices
- 170 Glossary of food equipment terminology
- 173 Dietary supplements
- 177 Shower filtration systems – Aesthetic effects
- 184 Residential dishwashers
- 222 Ozone generators
- 245 Wastewater treatment systems – Nitrogen reduction
- 14159-1 Hygiene requirements for the design of meat and poultry processing equipment
- 14159-2 Hygiene requirements for the design of hand held tools used in meat and poultry processing equipment
- 14159-3 Hygiene requirements for the design of mechanical belt conveyors used in meat and poultry processing equipment

²³ The information contained in this Standards and Criteria page is not part of this American National Standard (ANS) and has not been processed in accordance with ANSI's requirements for an ANS. Therefore, this Standards and Criteria page may contain material that has not been subjected to public review or a consensus process. In addition, it does not contain requirements necessary for conformance to the Standard.



THE HOPE OF MANKIND rests in the ability of man to define and seek out the environment which will permit him to live with fellow creatures of the earth, in health, in peace, and in mutual respect.