Annex F, NSF/ANSI 61 – 2007a

Revisions to the Evaluation of Lead

The attached copy of Annex F is an excerpt from NSF/ANSI Standard 61 - 2007a and is provided here for informational purposes. The standard in its entirety should be used when evaluating products for compliance.

789 N. Dixboro Road, Ann Arbor, Michigan 48105-9723 USA
1-800-NSF-MARK 734-769-8010
www.nsf.org

Annex F[22]

(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 90^{th} percentile lead level and the source water lead concentration being less that 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 $^{1}/_{3}$ (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)
•		
•		
•		
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
•		
•		
•		

[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 that 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 ~~11~~5 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 ~~11~~5 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~~5 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

•

•

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.

•

•

•

B.8.9.3 Initial test statistic

The test statistic Q shall be determined as:

$$Q = e^{\overline{Y}} \cdot e^{k_1 S}$$

where the log-dosage mean, $\overline{Y}$, 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 ≤ ~~11~~5 µg, the product line has tested as acceptable; or
– Case II: If Q >~~11~~5 µg, the product line has tested as unacceptable.

For supply stops, flexible plumbing connectors, and miscellaneous components:

- Case I: If Q ≤ 3 µg, the product line has tested as acceptable; or
- Case II: If Q > 3 µg, 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:

$$R = e^{\overline{Y}} \cdot e^{k_2 S}$$

where the log-dosage mean, $\overline{Y}$,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 ≤ ~~11~~5 µg, the product line has tested as acceptable; or
- Case II: If R > ~~11~~5 µg, the product line has tested as unacceptable.

For supply stops, flexible plumbing connectors, and miscellaneous components:

- Case I: If R ≤ 3 µg, the product line has tested as acceptable; or
- Case II: If R > 3 µg, the product line has tested as unacceptable.

•
•

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.

Bellinger, David C. 2003. "Lead". *Pediatrics*. Vol. 113(4):1016. Evanston, IL.

Canfield, R., Henderson, C., Cory-Slechta, D., Cox, C., Todd, J., and Lanphear, B. 2003. "Intellectual

Impairment in Children with Blood Lead Concentrations below 10 ug per deciliter." *N. Engl. J. Med*. 348:1517-26.

Gilbert, S. G. and Weiss, B. 2006. "A Rationale for Lowering the Blood Lead Action Level from 10 to 2 μg/dL." *NeuroToxicology* 27:693-701.

Hertz-Picciotto, I., Schramm, M., Watt-Morse, M., Chantala, K., Anderson, J., and Osterloh, J. 2000. "Patterns and Determinants of Blood Lead During Pregnancy." *Am. J. Epidemiol.* 152:829-837.

International Agency for Research on Cancer. 2006. Inorganic and Organic Lead Compounds. *IARC Monogr. Eval. Carcinogen. Risks Hum.*, 87 (In preparation). http://monographs.iarc.fr/ENG/Meetings/vol87.php

Lanphear, B. P., Dietrich, K., Auinger, P., and Cox, C. 2000. "Cognitive Deficits Associated with Blood Lead Concentrations <10 microg/dL in US children and Adolescents." *Public Health Rep* 115:521-9.

Menke, A., Muntner, P., Batuman, V., Silbergeld, E. and Guallar, E. 2006. "Blood Lead Below 0.48 μmol/L (10 μg/dL) and Mortality among US Adults." *Circulation* 114:1388-1394.

Nawrot, T. and Staessen, J. 2006. "Low-Level Environmental Exposure to Lead Unmasked as Silent Killer." [Editorial] *Circulation* 114:1347-49.

Needleman, H. L. and Gatsonis, C. A. 1990. "Low-Level Lead Exposure and the IQ of Children: A Meta-Analysis of Modern Studies." *J Am Med Assn*, 263(5):673-678.

Schwartz, J. 1994. "Low-Level Lead Exposure and Children's IQ: A Meta-Analysis and Search for a Threshold." *Environmental Research*, 65:42-45.

U. S. Centers for Disease Control and Prevention. 2005. Preventing Lead Poisoning in Young Children. Atlanta, GA http://www.cdc.gov/nceh/lead/ACCLPP/meetingMinutes/lessThan10MtgMAR04.pdf

U. S. Environmental Protection Agency. 2004. USEPA Lead and Copper Rule Workshop 2: Monitoring Protocols Summary. May 12-13, 2004. http://www.epa.gov/safewater/lcrmr/pdfs/summary_lcmr_review_monitoring_workshop_summary_05-04.pdf . Accessed 9/16/05.

U. S. Environmental Protection Agency. 2005. Office of Ground Water and Drinking Water. Consumer Fact Sheet – Lead. http://www.epa.gov/safewater/dwh/c-ioc/lead.html. Accessed 11-9-2005.

World Health Organization. 1993. Guidelines for Drinking Water Quality, 2nd Edition, Volume 1, pp. 49-50. Geneva, Switzerland: WHO. www.who.int/water_sanitation_health/diseases/lead/en