



NSF/ANSI 61: Drinking Water System Components – Health Effects Standard Overview

NSF/ANSI 61 is the only American National Standard addressing the human health effects of drinking water system components. As an approved standard of the American National Standards Institute, NSF/ANSI 61 is the legally recognized national standard in the United States for the human health effects assessment of drinking water contact materials, components and devices. This standard forms the basis of the regulatory framework and of public health protection for controlling the health effects of drinking water contact materials across the USA and Canada. It has also been used as a specification by water utilities around the world including South Korea, Saudi Arabia and the United Arab Emirates. Forty-eight U.S. states currently require municipal drinking water system components to comply with the requirements of the NSF/ANSI 61 standard.

NSF/ANSI 61 is a performance-based standard that evaluates the amount of contaminants that leach from the products into drinking water, rather than setting prescriptive limits on content. This differs from U.S. Food and Drug Administration requirements and some international standards that are based only on prescriptive content requirements.

NSF/ANSI 61 requires analysis for any chemicals that leach from a material into drinking water and a toxicological evaluation of concentrations leached to ensure that they are below levels that may cause potential adverse human health effects. The toxicological evaluation criteria are based on lifetime exposure to the concentration of contaminants in drinking water.

Background

Prior to 1988, the U.S. Environmental Protection Agency's Additives Advisory Program for drinking water system components provided the regulatory framework and approval processes for inclusion of products and components into the water distribution systems across the United States. In 1984 the U.S. EPA published an RFP for the purpose of privatizing the processes. A consortium led by NSF International and including 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 was awarded the contract to develop the standard.

Based on the cooperative work of this consortium, NSF/ANSI 61: *Drinking Water System Components — Health Effects* was published in 1988 to establish minimum requirements for the control of potential adverse human health effects from products that contact drinking water. The standard has been updated regularly since then to add testing criteria for additional contaminants and product types.

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Scope

NSF/ANSI 61 is intended for voluntary use by certifying organizations, utilities, regulatory agencies, and/or manufacturers as a basis for providing assurances that adequate health protection exists for products covered by this standard, which include:

- Pipes and related products (pipe, hose and fittings)
- Protective and barrier materials (cements/coatings)
- Joining and sealing materials (gaskets, adhesives and lubricants)
- Process media (filter media)
- Mechanical devices (water meters, valves and filters)
- Mechanical plumbing devices (faucets, drinking fountains and components)
- Potable water materials (non-metallic materials)

Requirements

NSF/ANSI 61 requires a complete formulation disclosure from product manufacturers and their component, material and ingredient suppliers. The standard requires a formulation review of all ingredients in each water contact material and development of a test battery to detect any chemical that may leach from water contact materials. The standard specifies formulated exposure waters of pH 5, 6.5, 8 and 10. Products are tested with the formulated test waters for various periods of time from 1 hour for water treatment process media to 19 days for faucets. Exposure water samples are then analyzed for all potential chemical contaminants that were identified in the formulation review. The chemical analyses include broad-based scans for metallic and organic chemicals which have the ability to identify trace quantities of contaminants or reaction by-products that may not be in the formulations of the materials.

Contaminant leachate concentrations detected in the laboratory tests are mathematically normalized to expected at-the tap concentrations. These normalized concentrations are then compared to the pass/fail criteria in the standard.

The process for establishing pass/fail criteria for drinking water contaminants is defined in NSF/ANSI 61, Annex A. For regulated contaminants with either a U.S. EPA maximum contaminant level (MCL) or a Health Canada maximum allowable concentration (MAC) value, these values are adopted by NSF/ANSI 61. Drinking water or

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other risk assessments from governmental or international agencies may also be used as sources for pass/fail criteria. If a published and peer-reviewed risk assessment is not already available, Annex A sets forth both quantitative and qualitative risk assessment approaches by which to establish criteria. Whether a qualitative or quantitative risk assessment approach is used is dependent on the quality and quantity of the available toxicity data for chemical.

External peer review is required under Annex A for all quantitative risk assessments (and certain qualitative assessments). External peer review is provided by the NSF Health Advisory Board (HAB), which consists of expert toxicologists from the U.S. EPA, U.S. state regulatory agencies and Health Canada, as well as academics, consultants and chemical manufacturers. Once finalized, all new pass/fail criteria (whether or not peer review was required) must be submitted to and approved by the NSF/ANSI 61 Joint Committee whose membership is comprised of equal representation from manufacturers, regulators and users. Additionally, the acceptance of the criteria by the NSF/ANSI 61 Joint Committee must also be reviewed and approved by the NSF Council of Public Health Consultants (CPHC) which consists of public health officials from the U.S. and Canadian federal government, states and provinces. Following CPHC approval, the criteria are then published in Annex D of NSF/ANSI 61. The current 2017 edition of NSF/ANSI 61 contains health effects criteria for over 2,000 drinking water contaminants.

NSF Certification of Products to NSF/ANSI 61

NSF offers product certification services for all product types covered by NSF/ANSI 61. NSF has established policies governing the associated product evaluation, listing services, follow-up and enforcement activities that include unannounced inspections of the production locations and the collection of representative samples of listed products for evaluation against the appropriate standards. Certified products may bear the NSF mark which is widely valued by consumers, manufacturers, retailers and regulatory agencies worldwide. Certified products also appear in NSF's online listings which are updated daily and available at <http://www.nsf.org/certified-products-systems>.

NSF International is accredited by the American National Standards Institute (ANSI-Accredited Product Certification Body - Accreditation #0216) and the Standards Council of Canada to the requirements of ISO/IEC 17065 as a product certification organization for NSF/ANSI 61.

The NSF certification process requires a disclosure by the manufacturer of all water contact materials in the product, and a disclosure by the manufacturer's material suppliers of all chemical ingredients in the materials. NSF staff perform a formulation review of each water contact material to determine any possible ingredients, contaminants or reaction by-products that may potentially leach from the material into drinking water. This

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formulation review then determines the types of chemical analyses that will be performed on a particular material.

NSF then conducts an inspection of the production facility to verify the product formulation and production process and to ensure adequate quality control procedures are in place to prevent the use of unauthorized materials. Product samples are collected and sent to NSF laboratories to be tested to the appropriate exposure protocol of the NSF/ANSI 61 standard.

Contaminant concentrations are determined from chemical analyses of the exposure water samples and then evaluated by NSF staff to the pass/fail criteria of NSF/ANSI 61. Products that meet the requirements of the standard are then certified and appear in NSF's online listings. Listed production facilities are then subjected to unannounced annual inspections by NSF auditors to ensure that NSF certified products are made according to the authorized formulations and processes. Products are collected on a routine basis (typically once annually) for retesting.

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