About NSF International
NSF’s Mission, Capabilities, and Services

NSF/ANSI Standard 60
Health Effects for Drinking Water Treatment Chemicals

NSF/ANSI Standard 61
Health Effects for Drinking Water System Components

NSF/ANSI Standard 372
Lead Content for Drinking Water System Components
Our Mission

NSF International is dedicated to being the leading global provider of public health and safety-based risk management solutions while serving the interests of all stakeholders, namely the public, the business community and government agencies.

NSF International is a global, independent, public health and safety organization.

Our mission and focus has always been protecting and improving human health.
NSF helps people live safer.

We carry out this human health and safety mission by:

**STANDARDS**
Writing standards to promote food, drinking water, indoor air, dietary supplements, consumer products and environmental safety

**TESTING**
Testing products to these and other standards

**CERTIFICATION**
Certifying products to these standards

**AUDITING**
Conducting safety audits for the food, water and consumer goods industries

**CONSULTING**
Providing strategic and technical consulting for the dietary supplement, pharmaceutical, medical device, food and beverage industries

**TRAINING**
Developing training and education programs
Bringing Industry, Regulatory and Consumers Together

Industry

Regulators
USDA, EPA, FDA, CPHC, HC, and International, National, State, Local Government Agencies

Consumers
Educators and Consumer Groups
In 1944, NSF was founded as the National Sanitation Foundation in the University of Michigan’s School of Public Health.

Today, we are now NSF International, with corporate headquarters in Ann Arbor, MI, USA, and 51 office and lab locations worldwide.
Today, NSF is a Global Leader in Public Health and Safety

Developer of over **90** national consensus standards

**Steadfast ties** with key associations and government agencies.
NSF works closely with international, federal, state and local regulators: FDA, USDA, EPA, U.S. Government & Legislature

Pan American Health Organization/World Health Organization Collaborating Center on Food Safety, Water Quality and Indoor Environment

Service provider to thousands of organizations in **168 countries**
NSF provides services in 168 countries with 51 office and laboratory locations.
NSF International Accreditations and Certifications

United States
Canada
Europe
China
ISO 17025
ISO 14001
NSF Standards Process
## Development of NSF 60 & 61

<table>
<thead>
<tr>
<th>Year</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>1972-1990</td>
<td>EPA operates registration program for some treatment and distribution products.</td>
</tr>
<tr>
<td>1984</td>
<td>EPA issues a RFP to develop product standards and a certification program.</td>
</tr>
<tr>
<td>1985</td>
<td>NSF led consortium (AWWA, AwwaRF, ASDWA, COSHEM) is awarded contract.</td>
</tr>
<tr>
<td>1988</td>
<td>NSF Standards 60 &amp; 61 are published.</td>
</tr>
<tr>
<td>1989</td>
<td>NSF begins certifying products to NSF-60 and NSF-61.</td>
</tr>
</tbody>
</table>
Joint Committee on Drinking Water Additives

- Developed in 1988
- One committee oversees 61 and a separate committee oversees 60
- Meets regularly to revise standard
- Functions via equal 3-part voting and consists of 33 members

**Manufacturers**
- Producers
- Trade Associations

**Public Health**
- EPA
- CDC
- Health Canada
- Academia
- State
- Local

**Users**
- Consumers
- Water Utilities
- Specifiers
- Certifiers
- Testing Labs
- Retailers
- NGOs

**EPA**

**CDC**

**Health Canada**

**Academia**

**State**

**Local**

**Consumers**

**Water Utilities**

**Specifiers**

**Certifiers**

**Testing Labs**

**Retailers**

**NGOs**
Council of Public Health Consultants

- NSF advisory body for standards development and program implementation
- Ensure public health issues addressed
- Review & ballot all standards or revisions
- Elects its own membership of 50 Regulators and User Representatives
  - Leaders in public health, environment and academics
- Technical Committee Role
  - Conduct review of proposed revisions utilizing technical expertise in the field or area covered by the ballot
ANSI

• American National Standards Institute

• Approves Standards
  – NSF/ANSI Standard 60
  – NSF/ANSI Standard 61

• ANSI accredits certification organizations
NSF developed many public health standards adopted by the U.S. EPA to protect drinking water; and standards promoting pool/spa safety. NSF tests and certifies products to these and other industry standards.

### Plumbing Products
- NSF/ANSI 14 and 61-Section 9;
- NSF/ANSI 372; UPC®; IPC®; ICC;
- ASTM; ASSE; ASME

### Filtration Products
- NSF/ANSI 42, 44, 53, 55, 58, 62, 177, 401 and 419; NSF Protocols P231, P248 and P477

### Municipal Water Products
- NSF/ANSI 60, 61, 372 and 419

### Onsite Wastewater Treatment and Reuse Devices
- NSF/ANSI 40, 41, 46, 245 and 350

### Recreational Water Safety
- NSF/ANSI 50: *Pumps, drains, pool covers, filters and pool chemicals*
NSF/ANSI 60 for Drinking Water Treatment Chemicals
Purpose of NSF/ANSI 60

Establishes minimum health effects requirements for the chemicals, the chemical contaminants, and the impurities that are directly added to drinking water from drinking water treatment chemicals
Scope of NSF/ANSI 60

• Applies to drinking water treatment chemicals that are directly added to water and intended to be present in the finished drinking water. (Example: chlorine, fluoride)

• Also applies to chemical products that are directly added to water but not intended to be present in the finished water. (Example: Reverse Osmosis Antiscalants)
Parameters excluded from NSF/ANSI 60

- Taste and Odor
- Performance
- Contaminants produced as by-products through reaction of the treatment chemical with a constituent of the treated water or surface water
What contaminants can enter the water through dosing of the treatment chemical?

Are they below the maximum allowable level?
NSF/ANSI 60 Requirements

- Exact ingredients and suppliers
- A proposed maximum use level for the product
- The manufacturing process
- A list of known or suspected impurities
- A Certificate of Analysis
- Product Use Instructions
NSF/ANSI 60 Requirements

Product is typically dosed into water at 10X maximum use level, and then analyzed for contaminants of concern.

Contaminants of concern

• Metals

• Organics
  • Formulation specific and usually will include scans for VOCs, residual monomers, and others.
Technical Evaluation

- Normalization
  - Contaminant concentrations are calculated to reflect in-the-field (at-the-tap) exposure levels. Normalized concentration is compared to pass/fail criteria of the standard.

- Normalized contaminant concentrations are compared to Single Product Allowable Concentrations (SPACs).
  - SPACs=1/10 of Total Allowable Concentration (TAC) of a contaminant in drinking water.
60 Requirements

Manufacturing Facility Inspection

- Inspection typically includes:
  - Production Area Walk Through
  - Verification of ingredients and sources used
  - Review of batch sheets for blended products
  - Review of production quality control processes
  - Identification of possible sources of contamination
  - Review product labeling (traceability) and packaging
Once all requirements are met:

- Products are Certified by NSF and entitled to bear the NSF Mark
- Certified Products appear in NSF listings
- Listings may include restrictions on use of the product in the field
Chemicals Certified to NSF 60 are retested and audited on an annual basis in order to ensure continued compliance to the standard.
If NSF Certified products fail monitoring tests, production is put on hold.

NSF retests the product.

Non-compliant product is destroyed.

If public health concern, product can be recalled and public notice can be given.

In some cases, compliance may be achieved by reduction of the affected product’s maximum use level.
NSF/ANSI 61 for Municipal Water Products
Scope of NSF/ANSI Standard 61

- Covers all products with drinking water contact from source to tap.

- Scope of NSF/ANSI 61 does not include performance, taste and odor, microbial growth support requirements, or point of use drinking water treatment devices.

Standard 61 establishes minimum health effects requirements for the chemical contaminants and impurities that are directly imparted to drinking water from products, components, and materials used in drinking water systems.
What contaminants migrate or extract into water?
Are they below the maximum allowable level?
Product manufacturer is required to disclose exact materials and suppliers used for each wetted component of their product.

NSF reviews material formulations and determines appropriate analytical testing to perform:

- May include metals testing and/or organics testing.
61 Requirements

- Product is flushed according to manufacturer’s instructions
- Product is exposed to formulated water for a number of days specified by the standard
  - Most municipal products are “conditioned” with water for 17 days
  - Water storage tanks are conditioned with water for 5 days
61 Requirements

- Product exposed to formulated exposure waters
  - pH 5
  - pH 6.5
  - pH 8
  - pH 10

- Water Contact Temperatures
  - Cold (23C)
  - Domestic Hot (60C)
  - Commercial Hot (82C)

- Exposure Sequence Varies based on Product Type
  - 1 hour for process media
  - 5 days for water storage tanks and tank coatings
  - 17 days for most products
  - 19 days for faucets and endpoint devices
61 Requirements

- Example in-vessel exposure
61 Requirements

- Example in-product exposure
61 Requirements

Extraction water is analyzed for contaminants
**Analytical Testing is Formulation Dependent**

Examples:

<table>
<thead>
<tr>
<th>Material Type</th>
<th>Typical Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Portland and Hydraulic Cements</td>
<td>Regulated metals, dioxins and furans, radionuclides, glycols and ethanolamines (or specific grinding aid used), BNA GC/MS organics analysis</td>
</tr>
<tr>
<td>EPDM</td>
<td>BNA GC/MS organics analysis, VOCs, phenolics, phthalates, nitrosamines</td>
</tr>
<tr>
<td>Epoxy Coatings</td>
<td>BNA GC/MS organics analysis, VOCs, bisphenol A and derivatives, epichlorohydrin, solvent and reactant additives</td>
</tr>
<tr>
<td>Brass</td>
<td>Regulated Metals (Al, Sb, As, Ba, Be, Bi, Cd, Cr, Cu, Pb, Hg, Ni, Se, Ag, Ti, Sn, Zn)</td>
</tr>
</tbody>
</table>
Toxicology evaluation is performed to compare results to acceptable limits.
61 Requirements

Technical evaluation is performed to compare results to acceptable limits

- Normalization: Contaminant concentrations are calculated to reflect in-the-field (at-the-tap) exposure levels based on field use assumptions using one of two end use conditions:
  - Static conditions: typically worst-case for service line and residential products.
  - Flowing conditions: typically worst-case for water treatment and distribution (water main) products.

- Normalized concentration is compared to pass/fail criteria of the standard
61 Requirements

Technical evaluation is performed to compare results to acceptable limits

Normalization Assumptions

- Some are identified in the Standard
  - Amount of piping in an average house
  - Amount of water used per day per home
  - Surface area to volume ratios of water storage tanks

- Some are identified by manufacturer
  - Size of products
  - Reservoir volumes
  - Surface area of elastomers
Technical evaluation is performed to compare results to acceptable limits

\[
\text{Normalized Result} = \text{Laboratory Result} \times \text{Normalization Factor}
\]
61 Requirements

Acceptance Criteria

Regulated contaminants:
- Includes USEPA and Health Canada regulated contaminants and EPA’s health advisories.

Non-regulated contaminants:
- More than 600 risk values have been set by NSF to address leaching of chemicals from materials that contact drinking water utilizing procedures outlined in Annex A of NSF 60 and 61.
Manufacturing Facility Inspection

- Inspection typically includes:
  - Production Area Walk Through
  - Review of production processes and quality control program
  - Identification of possible sources of contamination
  - Verification of materials and sources used in product
61 Requirements

Once all requirements are met:

- Products are Certified by NSF an entitled to bear the NSF Mark
- Certified Products appear in NSF listings
- Listings may include restrictions on use of the product in the field (e.g. municipal filters are typically listed with a minimum daily permeate flow)
- NSF Listings are available on the Internet at: http://www.nsf.org/certified-products-systems
Products Certified to NSF 61 are retested and audited on an annual basis in order to ensure continued compliance to the standard.
Product Failures under NSF/ANSI 61

- If NSF Certified products fail monitoring tests, production is put on hold
- Manufacturer must find and correct the root cause of the failure
- Non-compliant product is destroyed
- If public health concern, product can be recalled and public notice can be given
NSF/ANSI 372 for Municipal Water Products
This standard applies to any drinking water system component that conveys or dispenses water for human consumption through drinking or cooking.

Contains calculation and testing requirements.

NSF 61 recently updated to include requirement for testing to 372, unless product type specifically excluded by law

Standard 372 establishes procedures for the determination of lead content based on the wetted surface area of products.
Core Requirement is Lead Content Calculation

\[
WLC = \sum_{c=1}^{n} \left( LC_c \times \left[ \frac{\sum_{t=1}^{n} WSA_t}{WSA_c} \right] \right)
\]

where;

- \( WLC \) = weighted average lead content of product
- \( LC \) = percentage lead content of component
- \( WSA \) = wetted surface area of component
- \( n \) = number of wetted components in product
Lead content calculation is performed based on information provided by the product manufacturer and their suppliers.
372 Requirements

- Qualification Testing
- Auditing
- Certification and Listing
- Monitor Testing

Example faucet
## Example weighted average lead content calculation

<table>
<thead>
<tr>
<th>Component No.</th>
<th>Wetted surface area (total = 61.94 in²)</th>
<th>% wetted surface area (total = 100%)</th>
<th>% lead content</th>
<th>Contributing % lead</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>17.31</td>
<td>27.95</td>
<td>0.05</td>
<td>0.01</td>
</tr>
<tr>
<td>2</td>
<td>1.15</td>
<td>1.85</td>
<td>2.86</td>
<td>0.05</td>
</tr>
<tr>
<td>3</td>
<td>4.99</td>
<td>8.05</td>
<td>0.23</td>
<td>0.02</td>
</tr>
<tr>
<td>4</td>
<td>16.25</td>
<td>29.46</td>
<td>0.05</td>
<td>0.01</td>
</tr>
<tr>
<td>5</td>
<td>11.14</td>
<td>17.98</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>6</td>
<td>4.02</td>
<td>6.49</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>7</td>
<td>1.09</td>
<td>1.75</td>
<td>1.30</td>
<td>0.02</td>
</tr>
<tr>
<td>8</td>
<td>0.54</td>
<td>0.87</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>9</td>
<td>0.91</td>
<td>1.48</td>
<td>2.54</td>
<td>0.04</td>
</tr>
<tr>
<td>10</td>
<td>0.76</td>
<td>1.23</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>11</td>
<td>1.02</td>
<td>1.64</td>
<td>2.54</td>
<td>0.04</td>
</tr>
<tr>
<td>12</td>
<td>0.35</td>
<td>0.56</td>
<td>2.54</td>
<td>0.01</td>
</tr>
<tr>
<td>13</td>
<td>0.43</td>
<td>0.69</td>
<td>2.54</td>
<td>0.02</td>
</tr>
</tbody>
</table>

Weighted average lead content = 0.23% (in compliance)
372 Requirements

How are coatings and acid washed products handled?

- When coatings are used, evaluate the lead content of the substrate
- Coatings themselves are not allowed to contain lead as an intentional ingredient
- For acid washed products, the evaluation is based on untreated substrate
Lead Content Screening by XRF

- A “gun” is used to determine the lead content of each individual wetted component
372 Requirements

Material dissolution and lead content by ICP-MS

- Sample of the part is acquired by coring
- Material is dissolved in acid and diluted to a known mass/volume ratio
- Lead content of solution is determined by ICP-MS
Manufacturing Facility Inspection

- Inspection typically includes:
  - Production Area Walk Through
  - Review of production processes and quality control program
  - Identification of possible sources of contamination
  - Verification of materials and sources used in product
372 Requirements

Once all requirements are met:

- Products are Certified by NSF and entitled to bear the NSF Mark
- Certified Products appear in NSF listings
- NSF Listings are available on the Internet at: http://www.nsf.org/certified-products-systems
Products Certified to NSF 372 are retested and audited on an annual basis in order to ensure continued compliance to the standard.
Product Failures under NSF/ANSI 372

- If NSF Certified products fail monitoring tests, production is put on hold
- Manufacturer must find and correct the root cause of the failure
- Non-compliant product is destroyed
- If public health concern, product can be recalled and public notice can be given
Questions?

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