BEHIND THE MARK

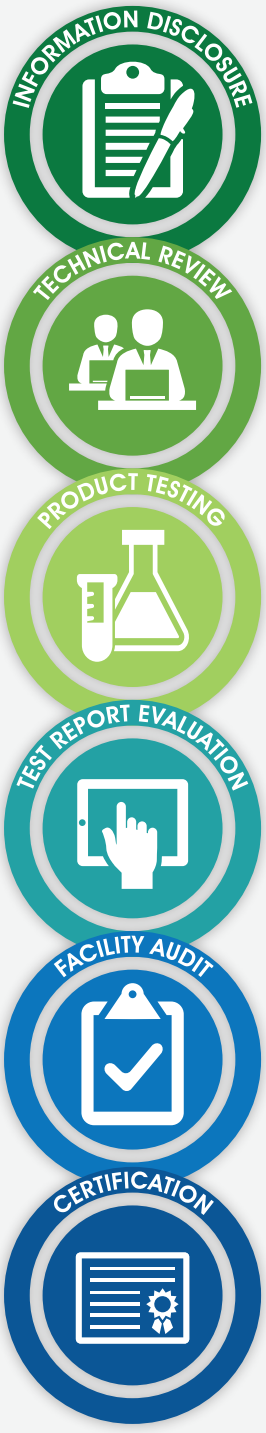
An in-depth look at the path to product certification

STANDARDS NSF/ANSI 60 AND 61

NSF/ANSI 60 and 61 are North America's flagship health effects standards for drinking water treatment chemicals and drinking water system components. The scope of NSF/ANSI 60 includes any chemical directly or indirectly added to treat drinking water, whether or not the chemical is intended to be present in finished water, whereas the scope of NSF/ANSI 61 includes any material or product that comes into contact with drinking water or drinking water treatment chemicals, from source to tap. Certification to these standards ensures that treatment chemicals and components of potable water distribution systems do not impart harmful contaminants into potable water.

Certification requires a rigorous evaluation process that includes complete information disclosure from the manufacturer, a thorough technical review of the product, laboratory testing and a complete audit of all manufacturing facilities producing the product. All requirements must be met with satisfactory results before a product is entitled to bear the NSF certification mark.

The NSF mark, signifying a product's compliance to NSF/ANSI 60 and/or 61, is widely recognized and specified worldwide. In fact, 49 U.S. states and the majority of Canadian provinces/territories have requirements for water treatment chemicals or water system components to comply with NSF/ANSI 60 and 61. However, there is not a widespread understanding among water utilities and project specifiers of exactly what certification to these standards entails. In this article, we go "behind the mark" to highlight the key requirements for certification to these widely specified standards.



1 INFORMATION DISCLOSURE

A manufacturer of a water treatment chemical or a water system component seeking certification of its product must first submit a detailed set of product information to NSF International. The manufacturer must also provide fundamental information related to the manufacturing location(s) for the product. Products are certified individually at each production location: Certification of a product at one manufacturing facility does not authorize the manufacturer to use the NSF mark on the same product produced at other locations unless NSF has specifically evaluated and listed those locations.

Manufacturers must also supply information regarding the function and end use of the product in the field. This information allows NSF to determine the amount of product that will come into contact with potable water, such as field surface area to volume ratios of a component or maximum use levels of a water treatment chemical. Product function can also impact the type of evaluation the product receives, as tank components are evaluated differently from pipe materials, and distribution system corrosion control chemicals are evaluated differently from reverse osmosis antiscalants and membrane cleaners.

Crucially, clients must also disclose detailed compositional and supply chain information for all water contact materials used in their product. For products that are comprised of multiple materials, the manufacturer must provide the trade name and disclose all sources of supply for each wetted material or ingredient used in the product. In some cases, additional formulary information will be required from individual material suppliers. In this case, NSF contacts material suppliers all the way down the supply chain to obtain full formulation of each wetted material, down to the individual chemical level. Similarly, manufacturers seeking certification of chemicals and single-material products must provide NSF with complete formulary information for the chemical or material they manufacture, for 100 percent of the formulation.

Manufacturers must also disclose coatings, platings, wash procedures or any other specialized processing steps used in the manufacture of their product, as these types of processes may have a health effects impact and therefore must be taken into account when evaluating the product to the applicable standard.

2 TECHNICAL REVIEW

Once NSF has received complete product information, our team of technical experts conducts a comprehensive review. The purpose of this review is to evaluate products for health effects, select the test representatives and create a customized test procedure specific to the product.

During the technical review, the product's ingredient or material formulations are reviewed individually and used to design a customized analytical test battery for the product. This test battery always includes, at a minimum, all material-specific analyses required by the applicable standard in addition to more specialized analyses designed to detect compounds unique to the formulations being evaluated. In many cases, the design of this test battery requires a line-by-line review of every individual chemical compound used in the treatment chemical, ingredient, material or assembly. This incredibly detailed review of the materials that comprise the product results in a highly specialized test battery designed to detect chemical contaminants that may be unintentionally added to the drinking water supply. NSF/ANSI 60 technical reviews include an additional step in which the safety and health effects of the intentional ingredients to be added to drinking water are assessed. If the intentional ingredients, such as phosphates or fluoride, exceed their safety requirements, then the maximum use level of the product or ingredient must be lowered.

If the certification request includes multiple versions of the same product (e.g. different formulations, models or sizes), the technical review team next determines the versions of the product that will require testing. When a family of products shares similar ingredients, materials, processing and field end uses, a set of worst-

case formulations, models and/or sizes can often be established, where the testing of these worst-case test cases can represent the entire range of products in laboratory testing.

Once the test sample(s) have been selected, the technical team summarizes the required testing in a customized plan, which is used to direct laboratory testing of the product. For NSF/ANSI 61, the test plan includes a complete set of directions to the laboratory regarding the appropriate field use normalization, required analyses, exposure water temperature, exposure duration and other details necessary to complete chemical leachate testing of the product. For NSF/ANSI 60, the test plan includes the maximum use level, a preparation method based on the type of chemical product, and the required analyses for contaminant testing.

Upon completion of the technical review, the manufacturer is issued an Unauthorized Registered Formulation (URF) that documents all relevant details about the products evaluated, including all wetted materials/ingredients reviewed under the request. This is an "unauthorized formulation" because the product cannot yet be represented as certified. The URF document will be used during the facility audit for verification against the manufacturing facility's production records.

3 PRODUCT TESTING

At this point in the process, the manufacturer is requested to submit samples of the specific products identified for testing during the technical review. Once the requested samples are received at NSF International's laboratories, our team tests them according to the custom test plan that was designed during the technical review based on standard requirements and the individual characteristics of the products under test.

For products being evaluated to NSF/ANSI 61, the exposure test is the first phase of product testing. Generally, the product is exposed to various buffered exposure waters depending on the analyses required for the test. Products are either filled with the exposure

water for an in-product exposure, or the wetted components of the product are submerged in exposure water for an in-vessel exposure. The samples undergo a sequence of water changes particular to the type of product being tested, with the length of the total exposure sequence ranging from one to 19 days. Products intended for use downstream of a domestic or commercial hot water heater will be exposed to hot water during this sequence, while all other products are exposed to water at ambient temperature. At the end of the exposure sequence, the water, along with any leachates that may have leached from the product, is collected from the product and preserved for analysis. Product exposures are always accompanied by a control exposure, which is used to subtract any background compounds that may have been present in the exposure water or in the components of the test assembly.

For products being evaluated to NSF/ANSI 60, chemical samples may be prepared for analysis by dosing them into a solution of deionized water and other reagents specific for the type of chemical being evaluated; this solution is then preserved for analysis. Alternatively, some chemicals, such as dry polymers, are directly extracted using solvents without first dissolving them into water. The solvent extraction is then analyzed for monomer contaminants.

Analytical testing is the next step of the testing process for samples being evaluated to either standard. The prepared and preserved samples are sent for analytical

testing using the test battery determined during the technical review of the product. A typical test battery will include analysis for regulated and non-regulated metals as well as a wide range of semi-volatile and volatile organic compounds using ICP-MS, GC-MS, HPLC, LC-MS, and a number of other quantitative analytical methods. Contaminants are identified either by use of authentic analytical standards, or by comparison to libraries containing the spectra of hundreds of thousands of compounds. The level of each compound detected in the sample water is quantified, control subtracted and summarized in a test report. Following peer review and final sign off by chemistry lab personnel, this test report is sent to NSF's technical team for toxicological evaluation of the results.

4 TEST REPORT EVALUATION

NSF technical staff review the data in the test report and confirm correct testing of the product. Next, the test results are normalized to accurately reflect field use conditions of the product, as testing in the laboratory setting does not always yield contaminant levels that are directly representative of real-world conditions. For example, plastic materials for use in manufacturing potable water storage tanks are tested by submerging small, rectangular plaques of the material in a glass jar filled with exposure water, typically at a surface area to volume ratio of 500 in2/L, whereas the actual surface area to volume ratio of a tank does not typically exceed 50 in2/L. Because chemical leaching tends to increase in proportion to the surface area to volume ratio being exposed, this overexposure of the plastic material would be expected to yield chemical leachates at a concentration ten times higher than would be seen in an actual tank in the field. Therefore, in scenarios where the exposure in the lab does not accurately represent its use in the field, the technical team mathematically adjusts the laboratory results to account for this difference in surface area to volume ratio.

In the example of the plastic tank material, the test results would be mathematically adjusted by a factor of 0.1. Similarly, water treatment chemicals are typically dosed into the test water at ten times their maximum use, with the resulting contaminant levels normalized back to the maximum use level of the chemical before evaluation. For both NSF/ANSI 60 and 61, the practice of overexposure increases the sensitivity of the analysis for low concentration contaminants. The field use assumptions used to determine the correct normalization of laboratory results are determined either by fixed requirements set forth in the standard, or based on the specific end use requested by the client. Given the significant impact of normalization on the evaluation of the product, the end use criteria used to generate these normalization assumptions always appear in the public listing for the product.

After the analytical test data is properly normalized, the test report is evaluated for compliance to the standard. All compounds detected in the test must be compared against the appropriate pass/fail criteria. If a regulatory criterion set by the United States Environmental Protection Agency (U.S. EPA) or Health Canada exists for a detected compound, this level is preferentially used to evaluate the contaminant. In the absence of regulatory criteria, pass/fail levels may be set by utilizing existing risk assessments published by other entities such as the World Health Organization (WHO) or the International Programme on Chemical Safety (IPCS). Alternately, with sufficient toxicological data available, NSF toxicologists may set pass/fail levels by performing a risk assessment according to requirements outlined in NSF/ANSI 60 and 61. These risk assessments must be

IMPORTANT ACRONYMS TO REMEMBER

URF: Unauthorized Registered Formulation

HAB: Health Advisory Board

WHO: World Health Organization

IPCS: International Programme on Chemical Safety

TOE: Threshold of Evaluation

ARF: Authorized Registered Formulation

peer-reviewed by a panel of external toxicologists on the Health Advisory Board (HAB) before the new criteria may be incorporated into the standards. Compounds for which no peer-reviewed criteria exist are often evaluated to the threshold of evaluation (TOE), a very conservative default level that may be used when no toxicological risk assessment has been performed on a given compound. Compounds without established criteria that have the potential for adverse health effects at very low levels (based on available toxicity data and structure activity relationships) may be assigned a criteria of zero, where no detectable level of that compound is allowable.

After comparing the level of each compound detected against the appropriate criterion, the technical review team issues the test report to the product manufacturer with a final status of pass or fail. Test reports are only issued with a passing status when the normalized levels of all detected contaminants are less than or equal to their individual evaluation criteria.

5 FACILITY AUDIT

The facility audit, another requirement for product certification, typically occurs in parallel with the laboratory testing of the product. Each facility seeking to manufacture certified product must undergo an initial audit where an NSF auditor visits the facility and performs a comprehensive inspection. Audits typically include a walk-through of the production area and a review of the facility's production processes and quality control program. The auditor looks to identify sources of potential product contamination via visual inspection and a review of the manufacturer's record system and key records. Additionally, the NSF auditor will compare the facility's records for product composition and material sources against the official record of materials evaluated during the product's technical review as documented in the URF. Any discrepancies between this document and the actual production records at the facility must be resolved prior to certification of the product, as formulary and supply chain differences have the potential to affect compliance of the product to the standard and, consequently, to have an impact on public health.

At the conclusion of the audit, the NSF auditor completes an audit report summarizing the results of the audit and identifying any items of non-compliance. All non-compliances must be resolved before certification can be granted.

6 LISTING, CERTIFICATION AND MONITORING

Once all requirements have been met with satisfactory results, the manufacturer is notified that products are officially certified and thus entitled to bear the NSF certification mark. The manufacturer is also issued an Authorized Registered Formulation (ARF) that lists the range of products covered by the certification and includes the full list of materials, ingredients and suppliers approved for use in manufacturing the certified product. This document will be used in future monitoring audits to verify continued compliance to the standard and to NSF policies.

The product's trade name(s), manufacturer and production location are made public in NSF's online listings of certified products (**http://www.nsf.org/certified-products-systems**), along with any end use parameters relevant to the manner in which the product was evaluated during the chemical extraction testing. These parameters may include size ranges, surface area to volume ratios, strengths, flow rates or other criteria critical to the evaluation of the product, as well as the certification temperature (cold, domestic hot or commercial hot) to which the product was tested. Any use of the product outside the listed parameters is considered outside of the scope of the certification of that product.

Once certified, the product enters the monitoring phase of certification, in which the product and its listed manufacturing facilities are subject to regularly recurring audits and monitoring tests, typically on an annual basis. Products that do not comply with these monitoring audits or tests are subject to removal from NSF listings and loss of their right to use the NSF certification mark. In extreme cases of non-compliance, NSF may take additional action such as requesting a product recall and issuing a public notice.

NSF International provides full-day training courses on NSF/ANSI 60 and 61 for those interested in a more in-depth understanding of these standards and the certification process. Please see the article titled, "Master the Standards" on page 18 of the *Municipal Water Matters: Special Edition* for more details.

Manufacturers of certified products must notify NSF prior to making any change to the product as documented in the product's ARF. The modification must be reviewed and approved by NSF's technical team before it can be implemented in products being represented as certified. Depending on the type of change requested, NSF may require chemical extraction testing of the modification prior to approval to verify that the modification does not negatively impact compliance to the standard or to public health.

Backed by this rigorous certification process and NSF International's team of experts, the NSF mark thus provides a high level of assurance that a chemical additive or water distribution component will not impart harmful contaminants into public water supplies. From source to tap, the NSF mark is an instrumental tool for helping regulators and water utilities to keep water clean, safe and available for all.