NSF/ANSI Standard
for Drinking Water Additives –

Conformity Assessment Requirements
for Certification Bodies that Certify Pool Chemicals Products Pursuant to NSF/ANSI/CAN 5060:
Drinking Water Treatment Chemicals – Health Effects – Equipment and Chemicals for Swimming Pools, Spas, Hot Tubs and Other Recreational Water Facilities

1 General

1.1 Purpose

This Standard establishes minimum requirements for certification bodies to be used when certifying recreational water treatment chemicals products to NSF/ANSI/CAN 5060: Drinking Water Treatment Chemicals – Health Effects. These requirements are supplemental to those contained in ISO/IEC 17065 or ISO/IEC 17020 and do not replace the requirements of either ISO Standard. By specifying this Standard, users of product certifications can communicate their expectation that certification activities addressed herein are performed in the particular manner described.

1.2 Scope

This Standard establishes requirements for activities to be performed when certification bodies certify products to NSF/ANSI/CAN 5060, including documentation reviews, product testing, and facility audits conducted during surveillance.

2 Normative references

The following documents contain provisions that, through reference, constitute provisions of this Standard. At the time this Standard was balloted, the editions listed below were valid. All documents are subject to revision, and parties are encouraged to investigate the possibility of applying the recent editions of the documents indicated below. The most recent published edition of the document shall be used for undated references.

ISO/IEC 17020:1998, General Criteria for the Operation of Various Types of Bodies Performing Inspection

ISO/IEC 17065, Conformity Assessment – Requirements for Bodies Certifying Products, Processes and Services

1 International Organization for Standardization. Chemin de Blandonnet 8, Case Postale 401, 1214 Vernier, Geneva, Switzerland. <www.iso.org>
3 Definitions

3.1 audit: An on-site, systematic and documented process that identifies any variances from the established requirements of NSF/ANSI/CAN 50 60 and this Standard.

3.2 authorized registered formulation: A copy of the formulation of the certified product registered by the certification organization.

3.3 blender: A company that produces a product comprised of a physical mixture of two or more ingredients. The mixture may be further diluted with treated water or another nonreactive substance.

   NOTE — The definition of blender pertains to physical mixtures of ingredients, and not to chemical products that are produced by a chemical reaction in blended processes.

3.4 certification system: The rules, policies, operations, and procedures of a certification body (CB) used for the purpose of ensuring certification of products to which the scope of NSF/ANSI/CAN 50 60 applies.

3.5 certified product: A single product or trade designation that appears in the public listings of an NSF/ANSI/CAN 50 60 certification body (CB) as an NSF/ANSI/CAN 50 60-certified product.

3.6 chemical stock: A store or supply of a chemical, accumulated or available for manufacturing a product.

3.7 diluter: A company that produces a product composed of a single source product, diluted with treated water to a specific concentration.

3.8 dissolver: A company that produces a liquid product composed of a single source product, dissolved with treated water to a specific concentration.

3.9 facility: A place (building, room, etc.) that is used to serve a specific manufacturing function related to the production of a certified product including a blended, diluted, dissolved, relabeled, or repackaged certified product.

3.10 original product: A NSF/ANSI/CAN 50 60 certified product prior to being blended, dissolved, diluted, relabeled, or repackaged.

3.11 product family: A group of products, under the same chemical category, for which a NSF/ANSI/CAN 50 60 certification body (CB) has designated a single product (one of the products in the group) as being representative of the group of products for the purposes of NSF/ANSI/CAN 60-50 certification testing for that group of products.

3.12 product manufacturer: The original chemical manufacturer of a product used as a drinking water treatment chemical.

3.13 relabeler: A company that places a new product label over the original label or replaces the original label on a product without opening the original packaging, provided that the new product label provides the same information on the product’s chemical nature and characteristics.

---

2 Transparency International. Alt-Moabit 96, 10559 Berlin, Germany. <www.transparency.org>
3.14 **repackager**: A company that opens the packaging of a product, places it into another container or package, seals the container or package, and labels the product.

3.15 **storage**: A space or a place for storing a water treatment product.

3.16 **transfer facility**: A location that is used by the NSF/ANSI/CAN 50 60-certified product supplier or manufacturer to transfer their bulk NSF/ANSI/CAN 50 60-certified products or materials from storage or initial transport vessels directly into other shipping vessels or packagings without further adjustments except for dilution with treated water.

3.17 **treated water**: Deionized water, distilled water, recirculated water within a plant originating from a potable water source, water treated on-site to potable water quality with the exception of disinfection, potable well water, well water treated on-site to potable water quality or a higher purity grade, demineralized water, condensate water originating from a potable water source.

3.18 **unannounced facility audit**: A site audit of a facility as part of surveillance of a product manufacturer, a blender, a diluter, a dissolver, a relabeler, a repackager or a transfer facility without prior notice, that includes a written record of the determination of compliance with NSF/ANSI/CAN 50 60 in conjunction with this Standard.

4 **General requirements**

ISO/IEC 17065 and ISO/IEC 17020 have no detailed requirements for certification systems, schemes or programs – only for certification bodies. This Standard is setting requirements for certification programs in which products shall be certified to NSF/ANSI/CAN 50 60.

Formal certification documents (ISO/IEC 17065, Section 7.8, and ISO/IEC 17020) shall indicate that the certification system utilized fulfills this Standard, by noting:

"Products certified via a product certification program in accordance with the NSF Pool Chemicals Conformity Assessment Standard NSF/ANSI-223."

5 **Product testing (during initial certification and on-going surveillance)**

As part of initial certification and on-going surveillance (ISO/IEC 17065, Section 7.9, and ISO/IEC 17020), except as noted below, a product shall be sampled and tested at least once per calendar year for the chemistry-specific analytes contained in Normative Annex 12 (Toxicology Review and Evaluation Procedures for Swimming Pool Treatment Chemicals) Tables 4.1, 5.1, 6.1 & 7.1 of NSF/ANSI/CAN 50 60 and other parameters identified in the product analytical summary from the formulation review. The product with the highest concentration may be tested as the representative of a series of analogous lower concentration products. For a blended, diluted, dissolved, repackaged or transferred certified product, a minimum of one product sample per facility shall be tested annually. If a certification body (CB) has been unable to sample and test a product for three years since the last test date, it shall delist the product.

6 **Facility audits**

6.1 **Facility audit requirements**

Facility audits shall include, but not be limited to the:

— on-site review of a facility’s Quality Management or Product Stewardship Program;
— visual inspection of production, process and equipment;
— collection of samples pursuant to Section 4;
— validation of formulations;
— validation of approved suppliers;
— review of analytical procedures and methods (if applicable);
— review of records related to formulation control; and
— review of chemical stock control records.

NOTE — Audit items noted above shall be conducted on-site at the facility; desk or remote audits shall not be allowed.

6.2 Facility audits during surveillance

6.2.1 Except as allowed pursuant to Section 5.2.2 or required pursuant to Sections 5.2.3 and 5.2.4, an organization certifying a facility’s product(s) shall audit the facility at least once per calendar year.

NOTE — Examples of a facility includes a product manufacturer, blender, diluter, dissolver, repackager, relabeler, or transfer facility.

6.2.2 If a facility has one or more of the deficiencies listed below, upon knowledge of such a deficiency(ies), a certifying organization shall begin auditing the facility at a frequency of at least four times per calendar year and shall not revert to the audit frequency in Section 5.2.1 for at least 36 months after all deficiencies have been resolved. Administrative deficiencies (e.g., supplier name changes due to mergers and acquisitions, editorial corrections of procedures and policies) or other minor changes that do not impact a product’s ability to meet the NSF/ANSI/CAN 50 60 single product allowable concentration limits for contaminants, shall not require the increased frequency of audits specified above, unless the administrative deficiencies have the potential to adversely affect a product’s ability to meet NSF/ANSI/CAN 50 60:

— the facility has significantly or repeatedly deviated from its authorized registered formulation (including changes to approved constituent chemicals, or blending with products from unauthorized suppliers);

— the facility’s / company’s manufacturing processes, materials storage and handling systems and/or shipment processes are in such state – that assurance of efficacy or purity of the certified product are negatively compromised or in a condition that product compliance with NSF/ANSI/CAN 50 60 is likely to be negatively affected;

— the facility has demonstrated a sustained lack of willingness or ability to meet administrative requirements for compliance with NSF/ANSI/CAN 50 60 under Section 3 General Requirements, including specifically and particularly failure to meet the Product Labeling provisions of Subsection 3.5, the Formulation Control requirements of Subsection 3.6, or the Product Traceability requirements of Subsection 3.7; or

— the certifying organization has received and verified information indicating that the facility’s ability to produce a product meeting NSF/ANSI/CAN 60 50 is in question; including, but not limited to, complaints related to certified products, a product recall, or information from regulatory authorities.

If a CB determines that a facility requires an increased audit frequency pursuant to Section 5.2.2 (including the results of an initial audit), and the facility severs relations with the CB and applies to a subsequent CB, the subsequent CB shall audit the facility at least four times per calendar year for a minimum of 36 months, pursuant to Section 5.2.2. The client, at the time of application to a CB, must contractually agree that they have not terminated a certification contract for the company, production facility(s), product(s), or families of products with another certifier, while under the increased audit frequencies in this Standard.
6.2.3 If the country in which the manufacturing, blending, diluting, dissolving, repackaging, relabeling, or product transferring facility is located has a score less than 50 or lacks a Corruption Perceptions Index (CPI) on Transparency International’s most recent CPI, then the audit frequency for a facility shall be increased to at least twice per calendar year. The facility shall, however, attain the audit frequency in Section 5.2.1, if:

— the facility engages in the audit regimen of Section 5.1 and if the facility demonstrates and maintains 36 months of continuous freedom from the deficiencies listed in Section 5.2.2, or

— the facility is part of a wholly owned global business entity, or joint venture where all parties are operating under a quality management plan as described as in c) below.

— the facility’s Quality or Environmental Management or Product Stewardship program includes one or more of the programs listed below and is capable of supporting and demonstrating the consistent fulfillment of the product requirements in NSF/ANSI/CAN 60. Registration by an external certification authority shall be the means to demonstrate the implementation of the quality or Environmental Management systems or Product Stewardship program. For programs 1, 2, and 3, the external certification authority shall be accredited by an International Accreditation Forum signatory. The CB shall assess whether the facility’s Quality or Environmental Management or Product Stewardship program is capable of supporting and demonstrating the consistent fulfillment of the product requirements in NSF/ANSI/CAN 60.

Demonstration of implementation of program 4 shall be by an external certification authority, which, if available, shall be accredited by an International Accreditation Forum signatory.

1. ISO 9001 registration (Quality Management Systems);

2. ISO 14000/1 registration (Environmental Management);

3. ACC (American Chemical Council) - RCMS (Responsible Care Management System);

4. NACD (National Association of Chemical Distributors) Code of Management Practice (for re-labelers and distributors); or

NOTE — Other certification systems shall be included as accepted by the NSF Joint Committee on Drinking Water Additives – Treatment Chemicals.

6.2.4 Facilities that blend, dilute, dissolve, relabel, repackage, or transfer noncertified products that are supplied by a facility that is located in a country with a TI CPI < 50 shall have an audit frequency of twice per calendar year. The CB has the option to reduce the inspection frequency to once every 12 months if the supplying facility meets one of the following criteria:

— the supplier to the facility also receives audits from a CB that is accredited by an International Accreditation Forum signatory, according to the requirements of this Standard; or

— the blender, diluter, dissolver, relabeler, repackager, or transfer facility has an alternate method that is acceptable to the CB, which provides a mechanism to verify that no changes have been made to the supplied product and continues to be provided identical product.

6.2.5 If a CB determines that a facility requires an increased audit frequency pursuant to Section 5.2.2 (including the results of an initial audit), and the facility severs relations with the CB and applies to a subsequent CB, the subsequent CB shall audit the facility at least four times per calendar year for a minimum of 36 months, pursuant to Section 5.2.2. The client, at the time of application to a CB, must contractually agree that they have not terminated a certification contract for the company, production facility(s), product(s), or families of products with another certifier, while under the increased audit frequencies in this Standard.
6.2.6 Change to 5.2.3: Announced audits may be allowed in lieu of unannounced facility audits for subsequent audits, where:

— there are verifiable security concerns;
— a facility is intermittently staffed; or
— the audit is being witnessed or assessed for accreditation surveillance purposes.

NOTE — A delay of up to two hours between arrival of the auditor and the onset of the audit is acceptable if there are security or safety concerns that are verified, or if there is a demonstrated lack of available personnel to accompany the inspectors.

6.2.7 Change to 5.2.4: If a manufacturing, blending, diluting, dissolving, repackaging, relabeling, or product transferring facility is located in a country where the security of the certification agency employees or contractors is in question, certifiers have the option to suspend on-site audits for a period of up to three consecutive years, if the conditions are sufficiently severe.

Certain countries have a prohibition for firms to conduct business activities in other countries. For example, the US Department of the Treasury enforces sanctions which sometimes include trade embargos with specific countries\(^3\). No audits shall be attempted, nor certifications given, when this is prohibited by law.

In addition, certain countries issue periodic travel advisories to their citizens of varying severity. For example, the US State Department issues Travel Warnings for regions of countries with descriptions of the types of hazards that are commonly encountered\(^4\).

A warning to “defer nonessential travel” is not sufficient to trigger suspension of on-site audits. However, warnings that identify violence, kidnappings, inability to protect citizens, lack of diplomatic or consular services, and/or homicides are of sufficient severity to consider suspension of on-site audits.

In such cases the certification agency shall determine if its employees / contractors should perform on-site audits. If on-site audits are suspended, the certification agency shall collect and analyze certified product samples a minimum of two times per year from the distribution channels (e.g., manufacturing, blending, diluting, dissolving, repackaging, relabeling, product transfer, or water treatment facilities), and perform a remote audit of the facility.

When the on-site audit is deferred and certification is performed via alternative means, the following footnote shall accompany the listing:

“[Certification Agency] has not conducted production control audits at this facility due to travel warnings from the [Source; e.g., US State Department]. Certification is based on testing of product samples from distribution channels and remote desk audits of records.”

The maximum deferral period for an unannounced, on-site audit is three consecutive years, after which time, the facility shall be delisted.

---

\(^3\) Examples of US Treasury Department prohibitions for business transactions with specific countries are located at: <www.treasury.gov>.

\(^4\) Examples of US State Department travel warnings are located at: <travel.state.gov>.
Informative Annex 1

Examples of Conformity Assessment Activities

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.

I-1.1 Examples of selecting test sample representatives for a product family

— A 12.5% solution of NaOCl will represent a family of 12.5%, 7.0%, 5.0% solutions that utilize the same chemical and dilution water source;

— A CaO(s) sample will represent a family of CaO(s) and Ca(OH)\(_2\)(aq) where the Ca(OH)\(_2\)(aq) is produced with potable water; and

— One sample of a group of repackaged, blended, diluted, dissolved, or transferred products, where all products are previously certified.

I-1.2 Examples of audit activities

— Inspecting production records to ensure batch sheets or continuous process control parameters conform to the requirements of the authorized formulation;

— Inspecting production records to ensure only authorized ingredients, reactants, and process aids from authorized suppliers are being used in certified products;

— Verifying that finished product identifiers (date code / lot numbers) can be traced back to specific lots of ingredients;

— Verifying that contamination control activities including storage, tamper evident packaging, and reusable container washouts are being conducted according to written procedures;

— Witnessing the selection, packaging, and traceability identification of product test samples; and

— Reviewing analytical procedures and records if analysis is conducted on ingredients or finished product.

I-1.3 Examples of deficiencies that would typically require an increase in the frequency of surveillance audits

— Lack of in-house measuring capabilities and/or manufacturing practices that would assure ongoing compliance with a products’ ability to meet NSF/ANSI/CAN 50;

— Detection of significant deviations from authorized formulations using unauthorized ingredients and/or suppliers with potential public health implications;

— Lack of a standardized system or detection of an existing system that is incapable of meeting the certification mark requirements of NSF/ANSI/CAN 50;

— Determination that the facility does not have or is systematically not following appropriate contamination control procedures that would assure sustainable product efficacy and purity and conformance with...
NSF/ANSI/CAN 50. This would apply to raw materials, intermediates and finished products. Other points of interest would include procedures, the vessels used in logistics, storage and reactions and other facility material transport systems;

— determination that there has been mislabeling violations that are other than editorial (spelling or grammar) errors that indicate a deficit of sustainable controls and ability to meet NSF/ANSI/CAN 60;

— determination that the facility has had a contamination complaint from a customer or regulatory agency due to an adverse event for a customer verified by the certification organization; and

— determination that the facility has had a significant test failure prompting a public notice and/or recall request from the certification organization.

I-1.4 Examples of administrative deficiencies identified during facility audits that would not necessarily require a change in the frequency of surveillance inspections

— supplier name changes due to mergers and acquisitions;

— minor and nonsystematic discrepancies in Authorized Registered Formulations that would not have an effect on public health; and

— readily detectable editorial errors such as spelling, grammar, etc., in labels, procedures, policies that do not affect the comprehension of the label, procedures or policies.

I-1.5 Example of an alternate method that would be acceptable to the certification body to provide verification that noncertified suppliers do not make unauthorized changes to the product

A repackaging firm located in Country 1 (TI CPI < 50), is certified by Certification Agency A, and has three suppliers. One supplier is in Country 1 and is certified by Certification Agency B. Another supplier is located in Country 2, and is certified by Certification Agency C. The third supplier is located in Country 3, and is not certified. The third supplier has each batch of material sent to the repackaging firm tested for the substances prescribed in NSF/ANSI/CAN 60 by a third-party testing organization located in Country 4 (TI CPI > 50). The testing organization is accredited by an international oversight agency, has a sound reputation, and its ownership is independent of the Country 3 supplier.

I-1.6 Example of an alternate method that would not be acceptable to the certification body to provide verification that noncertified suppliers do not make unauthorized changes to the product

A blender, diluter, dissolver, relabeler, repackager or a transfer facility located in Country 5 (TI CPI < 50), is certified by Certification Agency A, and has two suppliers. One supplier is in Country 6 and is certified by Certification Agency B. The second supplier is located in Country 7, and is not certified. The second supplier has each batch of material sent to the blender, diluter, dissolver, relabeler, repackager, or the transfer facility tested for the substances prescribed in NSF/ANSI/CAN 60 by a third-party testing organization located in Country 8. The testing organization is not accredited by any international oversight agency, it has been noted in the press for lapses in quality, and it does not have other multi-national clients. It is determined later that the testing organization’s ownership is related by marriage to the owners of the blender, diluter, dissolver, relabeler, repackager, or transfer facility’s firm.