NSF Standard 223 Draft (10/20/10)
Conformity Assessment Requirements for Certification Bodies that Certify Products pursuant to NSF/ANSI Standard 60: Drinking Water Treatment Chemicals – Health Effects

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1 Purpose, scope, and normative references

1.1 Purpose

This standard establishes minimum requirements for certification bodies to be used when certifying products to NSF/ANSI Standard 60: Drinking Water Treatment Chemicals – Health Effects (NSF/ANSI 60). These requirements are supplemental to those contained in ISO Guide 65 or ISO 17020 and do not replace the requirements in 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 Standard 60, including documentation reviews, product testing, and facility inspections conducted during surveillance.

1.3 Normative references

- ISO/IEC Guide 65: 1996 *General requirements for bodies operating product certification systems*[1]
- ISO/IEC Guide 17020: 1998 *General criteria for the operation of various types of bodies performing inspection*[1]
- NSF/ANSI Standard 60 (2010), *Drinking Water Treatment Chemicals – Health Effects*[2]
- Transparency International *Corruption Perception Index*, 2009[3]

2 Definitions

2.1 Blender – A supplier that produces a product comprised of a physical mixture of two or more ingredients. The mixture may be further diluted with water or another non-reactive 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.

2.2 Certification system – The rules, policies, operations, and procedures of a certification body used for the purpose of ensuring certification of products to which the scope of NSF/ANSI 60 applies. At a minimum, a certification body's certification system shall include the annual recertification requirements included in this standard.

2.3 Certified product – A single product or trade designation that appears in the public listings of an NSF/ANSI 60 certification body as an NSF/ANSI 60 certified product.

2.4 Chemical stock - a store or supply of a chemical, accumulated or available for manufacturing a product.

2.5 Facility - a place (building, room, etc.) that is used to serve a specific manufacturing function.

[1] International Standardization Organization, 1 ch. De la Voie-Creuse, Case postale 56, CH 1211 Geneva, 20 Switzerland, www.iso.org
[2] NSF International, 789 North Dixboro Road, Ann Arbor, MI, USA 48105, www.nsf.org
[3] Transparency International, Alt-Moablt 961, 10559 Berlin, Germany, www.transparency.org

2.6 Original product –An NSF/ANSI 60 certified product prior to being blended, dissolved, re-packaged, re-labeled, or diluted.

2.7 Product family – A group of products, under the same chemical category, for which an NSF/ANSI 60 certification body 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 60 certification testing for the group of products.

2.8 Product manufacturer – The original chemical manufacturer of a product used as a drinking water treatment chemical.

2.9 Re-labeler – A company that places a new product label over the original label or replaces the original label on product without opening the original packaging.

2.10 Re-packager – A supplier, other than the original product supplier or the same production facility, that opens the packaging of a product, places it into another container or package, seals the container or package, and labels the product.

2.11 Storage – space or a place for storing a water treatment product.

2.12 Unannounced facility inspection – An audit of a product supplier's facility, without prior notice, that includes a determination of compliance with NSF/ANSI 60 in conjunction with the certification body's certification system.

3 General requirements

ISO Guide 65 and ISO Guide 17020 have no requirements for certification systems, schemes or programs – only for certification bodies. This standard is setting requirements for certification programs in which products will be certified to NSF/ANSI 60.

3.1 Formal certification documents (ISO/IEC Guide 65, section 12.3, and ISO/IEC Guide 17020) shall indicate that the certification system utilized fulfills this standard, by noting: "*Products certified via a product certification program in accordance with NSF Standard 223.*"

4 Product testing

4.1 Product testing during initial certification and on-going surveillance

As part of initial certification and on-going surveillance (ISO/IEC Guide 65, Section 13, and ISO/IEC Guide 17020), except as noted, a product shall be sampled and tested at least once per calendar year for the chemistry-specific analytes contained in Tables 4.1, 5.1, 6.1 & 7.1 of NSF/ANSI 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 diluted, dissolved, blended, or re-packaged certified product, a minimum of one product per facility shall be tested

annually. If a certification body is unable to sample and test a product for 3 years since the last test date, it shall delist the product.

5 Facility inspections

5.1 Facility inspection requirements

Facility inspections shall include, but not be limited to:

- visual inspection of production, process and equipment;
- sample collection pursuant to 4.1;
- formulation validation;
- analytical procedures and methods review (if applicable);
- review of records related to formulation control;
- review of chemical stock control records; and
- review of customer complaints related to certified products (if any).

5.2 Facility inspections during surveillance

5.2.1 Except as allowed pursuant to Section 5.2.2 or required pursuant to Section 5.2.3, beginning *[insert effective date]* an organization certifying a facility's product(s) shall audit the facility, including a product manufacturer, blender, diluter, dissolver, re-packager, and re-labeler, at least once every six months.

5.2.2 The audit frequency for a facility specified in Section 5.2.1 may be reduced to once every twelve months if:

A. For a least the most recent two consecutive years, the facility implements and complies with a Quality Management or Product Stewardship program that, at a minimum, includes procedures for;

1. ensuring conformity to approved formulations,
2. the sourcing and validation of raw materials,
3. the periodic review of quality control policies and quality control testing (if applicable), and
4. the periodic review of analytical procedures and methods (if applicable);

B. The Quality Management or Product Stewardship program in A includes one or more of the five programs listed below. For programs 1, 2, and 3, registration by an external certification authority shall be the means to demonstrate the implementation of the quality or environmental management systems. The certification authority shall be accredited by an International Accreditation Forum signatory. Demonstration of implementation of programs 4 and 5 shall also 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. ACS (American Chemical Society) RCMS (Responsible Care Management System),
4. CMA (Chemical Manufacturers Association) Audit, or
5. NACD (National Association of Chemical Distributors) Code of Management Practice (for re-labelers and distributors);

C. The facility has had no violations of NSF/ANSI Standard 60, except those having no potential impact on a product's certification (e.g., administrative deficiencies), during the most recent three consecutive years of audits, including audits performed prior to the effective date of this standard; and

D. The country in which the facility is located has a score greater than 5.0 on Transparency International's most recent Corruption Perceptions Index.

5.2.3 If a facility has one or more deficiency listed below, upon knowledge of such a deficiency, a certifying organization shall begin auditing the facility at a frequency of at least once every three months 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) shall not require the increased frequency of audits noted above, unless the administrative deficiencies have the potential to adversely affect a product's ability to meet NSF/ANSI Standard 60.

A. The facility has deviated from authorized formulations (including changes to, or blending with unauthorized suppliers);

B. The facility's manufacturing process or product storage or shipment process, including washout procedures on storage and shipping containers, has deviated such that product compliance with NSF/ANSI Standard 60 may be affected;

C. The facility has had two or more mislabeling violations; or

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

5.2.4 If a certification body determines that a facility requires an increased audit frequency pursuant to Section 5.2.3, and the facility severs relations with the certification body and applies to a subsequent certification body, the subsequent certification body shall audit the facility at least every three months for a minimum of 36 months, pursuant to Section 5.2.3. The client, at the time of application, must contractually agree that they have not terminated certification for the company, production facility(s), product(s), or families of products with another certifier, while under the increased inspection frequencies in NSF 223.

5.2.5 Announced inspections may be allowed in lieu of unannounced facility inspections for the initial inspection, because of security concerns, when a facility is intermittently-staffed, and during accreditation reviews. (Note: A delay up to two hours between arrival of the inspector and the onset of the inspection due to security, safety, and personnel availability is acceptable.)

Annex A
Examples of Conformity Assessment Activities
(Informative)

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

Examples of audit activities:

- Inspect production records to ensure batch sheets or continuous process control parameters conform to the requirements of the authorized formulation.
- Inspect production records to ensure only authorized ingredients, reactants, and process aids from authorized suppliers are being used in certified products.
- Verify that finished product identifiers (date code/lot numbers) can be traced back to specific lots of ingredients.
- Verify that contamination control activities including storage, tamper evident packaging, and re-useable container washout are being conducted according to written procedures.
- Witness the selection, packaging, and traceability identification of product test samples.
- Review analytical procedures and records if analysis is conducted on ingredients or finished product.

Examples of deficiencies that would typically require an increase in the frequency of surveillance inspections:

- The facility has deviated from authorized formulations using unauthorized ingredients and/or suppliers.
- The facility is placing the certification mark on product that is not certified.
- The facility is not following proper washout or other contamination control procedures.
- The facility has had two or more mislabeling violations that are other than editorial (spelling or grammar) errors.
- The facility has had a contamination complaint from a customer or regulatory agency verified by the certification organization.
- The facility has had a significant test failure prompting a public notice and/or recall request from the certification organization.

Examples of administrative deficiencies identified during facility inspections that would not necessarily require a change in the frequency of surveillance inspections:

- Supplier name changes due to mergers and acquisitions.
- Editorial errors such as spelling, grammar, etc. in labels, procedures, policies.