

**NSF Standard 223 Draft (11/11/09)**  
**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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**Forward**.....Insert background document on development of these requirements.

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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 the ISO standard.

## 1.2 Scope

This standard contains supplemental minimum requirements for certification bodies that provide certification that a product meets NSF/ANSI 60: . The scope of the supplemental requirements includes, but is not limited to, the following: documentation reviews, product testing, and facility inspections conducted during an ISO 17020 or ISO/IEC Guide 65, section 13, surveillance.

## 1.3 Normative References

ISO/IEC Guide 65:1996 *General requirements for bodies operating product certification systems*

### ISO/IEC Guide 17020

NSF/ANSI Standard 60 (2009), *Drinking Water Treatment Chemicals – Health Effects*

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## 2 Definitions

**2.1 Blender** – A supplier that produces a product consisting 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 Bulk Transfer Facilities** – A facility/location where a bulk product is transferred from one bulk vessel to another, with or without intermediate product storage.

**2.3 Chemical Stock** - a store or supply of a chemical, accumulated or available for manufacturing a product.

**2.4 Diluter** – A supplier of a product composed of a single original product that is diluted with water to a specific concentration.

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

**2.6 Product Manufacturer** – The original chemical manufacturer of a product used as a drinking water treatment chemical.

**2.7 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.

**2.8 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.

**2.9 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.

**2.10 Re-labeller** – A company that places a new product label on an original product without opening the original packaging.

**2.11 Original Product** – The original product that is repackaged, relabeled, or diluted by a chemical distributor to produce a new finished product. An NSF/ANSI 60 certified product prior to being re-packaged, re-labeled, or diluted?

**2.12 Storage** – space or a place for storing a water treatment chemical.

**2.13 Unannounced Facility Inspection** – An audit of a chemical 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. Note: A delay of 1-2 hr between arrival time of the inspector and before the onset of the inspection due to security, safety, and personnel availability issues is acceptable.

2.14 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.

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### 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]

**3.2** Formal certification documents (ISO/IEC Guide 17020 and ISO/IEC Guide 65 section 12.3) 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.*

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## 4 Product Testing

### 4.1 Product Testing During Surveillance

As part of surveillance (ISO/IEC Guide 17020 and ISO/IEC Guide 65 Section 13), 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, blended, or re-packaged certified product, a minimum of one product per facility shall be tested annually. Products that have not been tested by a certification body for more than three years from the last test date cannot be considered compliant with this standard.

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## 5 Facility Inspections

### 5.1 Facility Inspections During Surveillance

As part of surveillance (ISO/IEC Guide 17020 and ISO/IEC Guide 65 Section 13), except as noted, suppliers producing certified products shall receive an unannounced inspection at least once per calendar year. The inspection frequency may be increased in cases of non-compliance. Such inspections shall include (but not be limited to):

- visual inspection of production;
- sample collection pursuant to 3.3 of NSF/ANSI 60;
- formulation validation;
- analytical procedures and methods review;
- records review related to formulation control per Section 3.6 of NSF/ANSI 60; and
- records review of chemical stock control and product traceability per Section 3.7 of NSF/ANSI 60.

Announced inspections can be authorized in lieu of unannounced inspections for the initial inspection, because of security concerns, when a facility is intermittently-staffed, and during accreditation reviews.

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## Annex A Informational Examples of Conformity Assessment Categories

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