Inspection Frequency Pursuant to NSF/ANSI 223

This document will describe the UL Follow-up Services default inspection frequency for products certified under the Drinking Water Treatment Chemicals category, and the conditions of NSF/ANSI 223 where a decreased inspection frequency is suitable or an increased inspection frequency is warranted.

Scope

The products covered under this category are certified using a product certification program that includes the Conformity Assessment Requirements in NSF/ANSI 223, Conformity Assessment Requirements for Certification Bodies that Certify Products Pursuant to NSF/ANSI/CAN 60: Drinking Water Treatment Chemicals – Health Effects. This standard specifically defines inspection activities at manufacturing facilities, as well as the frequency of surveillance audits and product testing. The standard also contains criteria for consideration of a decreased inspection frequency or an increased inspection frequency in cases where specific program deficiencies are identified.

Default Inspection Frequency

UL Global Field Services will audit manufacturers in this category twice per calendar year. These Conformity Assessment Requirements allow for decreased or increased inspection frequencies in accordance with the parameters stated in NSF/ANSI 223 and described as follows.

Decreased Inspection Frequency

The following criteria could result in decreased inspection frequencies under this standard. The decreased inspection frequency shall be a minimum of one inspection per calendar year. Please note, the terms manufacturer and manufacturing facility are intended to represent the location and process covered by the FUS Procedure. For example, for a FUS Procedure covering a repackaging process, the term manufacturer applies to the repackager.

- The manufacturer is not currently under an increased inspection frequency.
- The manufacturing facility is located in a country with a Transparency International Corruption Perceptions Index (TI CPI) score of greater than or equal to 50.
- If the manufacturing facility is located in a country with a TI CPI score less than 50 or lacks a score, the manufacturer must have been free of Variation Notices for the previous 36 months 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 that is registered by an external certification authority. The applicable quality management plans are as follows:
  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 relabelers and distributors).
- For manufacturing facilities that blend, dilute, dissolve, re-label, repackage, or trans-load non-certified products that are supplied by a facility located in a country with a TI CPI score less than 50 or lacks a score, one of the following criteria must be met:
  1. The supplier operates under a quality management plan that is registered by an external certification authority as listed in items 1 through 4 above.
  2. The manufacturing facility has an acceptable mechanism to verify that no changes have been made to the supplied product.

Subscribers whose manufacturing facilities meet the criteria above may elect to reduce the inspection frequency to once per calendar year by submitting the “Request for Reduced Inspection Form”. The form may be obtained by emailing waterquote@ul.com. UL will review the information submitted to confirm that the manufacturing facility meets the criteria.

Transparency International’s Corruption Perceptions Index (TI CPI) can be found at http://www.transparency.org/research/cpi/overview. The most recent CPI shall be utilized. The CPI is updated annually at the end of each year. UL will conduct an annual review of the CPI to determine countries that may have fallen below 50. An increase in inspection frequency (from once to twice per calendar year) may result for manufacturers in the affected countries or for manufacturers using suppliers in the affected countries.

Increased Inspection Frequency

Pursuant to NSF/ANSI 223, one or more of the following deficiencies shall be cause for increased inspection frequency:

- The manufacturing facility significantly or repeatedly deviates from its authorized formulation, including unauthorized changes to raw materials or suppliers. Severity and frequency will be judged by review of Variation Notice history.
- The facility's manufacturing processes, materials storage, labeling, handling, or shipping processes are in such a state that the efficacy or purity of the certified product is jeopardized.
- The manufacturer demonstrates a sustained lack of willingness or ability to meet administrative requirements for compliance to the UL FUS Procedure including failure to meet the product labeling, formulation and quality control, contamination prevention, or product traceability requirements.
- It becomes evident, as a result of complaints related to certified products, a product recall, or information from regulatory authorities, for example, that the manufacturing facility's ability to produce a product meeting NSF/ANSI/CAN 60 is in question.

The increased inspection frequency is a minimum of four inspections per calendar year and will continue for at least 36 months after all corrective actions have been implemented. Administrative deficiencies (e.g., supplier name changes due to mergers and acquisitions, editorial corrections of procedures and policies) or other minor changes shall not require the increased inspection frequency specified above, unless the administrative deficiencies have the potential to adversely affect a product's ability to meet NSF/ANSI/CAN 60.

Specific examples of deficiencies that would typically require increased inspection are presented below. This list is not comprehensive of all deficiencies which would result in increased inspection frequency.

- Lack of in-house measuring capabilities and/or manufacturing practices that would assure ongoing compliance with a products' ability to meet NSF/ANSI/CAN 60.
- 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 60.
- 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 60. 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 have 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 UL.
- Determination that the facility has had a significant test failure prompting a public notice and/or recall request from UL.

Facilities on an increased inspection frequency shall demonstrate the ability to meet the Conformity Assessment Requirements, without deficiencies that result in increased inspection, for no less than 36 months before reverting to the default inspection frequency.

For additional questions or assistance please visit UL.com/water or contact us at WaterInfo@UL.com

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