



SURVEILLANCE REQUIREMENTS FOR THIRD-PARTY CERTIFIERS OF DRINKING WATER TREATMENT CHEMICALS





Surveillance Requirements for Third-Party Certifiers of Drinking Water Treatment Chemicals

Nearly every state and jurisdiction in the U.S. requires that chemicals and additives used to treat public drinking water supplies be certified to NSF/ANSI 60: Drinking Water Treatment Chemicals—Health Effects. Products certified to NSF 60 have been independently evaluated for contaminants that can potentially cause adverse effects to human health. However, NSF/ANSI 60 defines neither the frequency of ongoing surveillance required for manufacturing facilities, nor the retesting frequency of certified products. As a result, there have been variations in the manner in which certification bodies have determined continuing compliance for certified products.

Published in 2012, NSF/ANSI 223: Conformity Assessment Requirements for Certification Bodies that Certify Products Pursuant to NSF/ANSI 60: Drinking Water Treatment Chemicals—Health Effects, provides surveillance requirements for certification bodies that test and certify chemicals and additives to NSF/ANSI 60. NSF/ANSI 223 specifically defines the inspection activities at a manufacturer’s facilities, including a review of the facility’s quality management system and other documentation. In detailing these specific requirements, NSF/ANSI 223 gives third-party certification bodies clear guidance regarding surveillance activities, and assures manufacturers of equivalent surveillance practices between various certifiers using NSF/ANSI 223.

This UL white paper presents detailed information on surveillance requirements now mandated under NSF/ANSI 223. The paper begins by providing information on current practices to control contamination of public drinking water supplies, and reviews the certification requirements of NSF/ANSI 60. The white paper then discusses the key inspection requirements in NSF/ANSI 223, with particular attention to the frequency of surveillance as detailed in the standard. The paper concludes with some considerations and recommendations for manufacturers seeking to utilize certification bodies accredited to NSF/ANSI 223 requirements.





General Requirements for U.S. Public Drinking Water Systems

The U.S. Environmental Protection Agency (EPA) estimates that Americans drink more than 1 billion glasses of tap water per day.¹ Although the safety of drinking water is mostly taken for granted, there are a number of natural and man-made factors that can affect water quality. These factors range from naturally occurring chemicals and animal waste to pesticides, chemical by-products of manufacturing processes, and improper chemical disposal. In addition, improperly treated or disinfected water, or water passing through a distribution system that has not been sufficiently maintained can pose potential health risks to humans.

The 1974 federal Safe Drinking Water Act (SDWA), mandates that the EPA set enforceable maximum contaminant levels (MCLs) for contaminants. The EPA's National Primary Drinking Water Regulations currently set maximum levels for 90 separate contaminants. Regulated contaminants have been identified through a rigorous process that evaluates potential health risks from exposure and determines an MCL that is below the level of potential risk. In addition to currently regulated drinking water contaminants, the EPA maintains a Contaminant Candidate List (CCL) comprised of other contaminants that may be subject to future regulation.

Public water supplies (PWSs) are required to verify that concentrations of regulated contaminants in their water supplies comply with the EPA's established MCLs. In addition to periodic sampling, PWSs also use suitable technologies to treat

the water and to minimize the risk of contaminants. The EPA may also require PWSs to treat water supplies in cases when a reliable detection method for a particular contaminant does not exist, or when it is not technically or economically feasible to set an applicable MCL.²

National drinking water regulations and standards apply to the more than 170,000 separate PWSs operating in the U.S., including approximately 54,000 individual community water systems. The regulations and standards are legally enforceable by both the EPA and individual state water authorities. PWSs that fail to monitor concentrations of regulated contaminants or treat water supplies as required are subject to administrative penalties, monetary forfeitures and other legal action.³

Drinking Water Treatment Chemical Certification Requirements—NSF/ANSI 60

There are a number of treatment methods available to PWS operators that can be used to achieve EPA-prescribed MCLs. Physical treatment processes can include sedimentation, in which impurities are allowed to naturally separate from water supplies, and filtration techniques, which actively remove suspended particles. Chemical treatments include flocculation, in which inorganic substances are added to aid in the coagulation of particle contaminants that can be more easily removed with physical treatment processes, and chlorination, which is frequently used to eliminate pathogens during and after the treatment process.

Although EPA regulations establish MCLs for regulated contaminants, it does not generally specify the methods of treatment to be used to achieve specified levels. In some jurisdictions, treatment methods may be prescribed by state or local statutes or regulations. In many cases, individual PWSs determine the treatment method, or combination of methods, to be used, consistent with the nature and condition of their respective water supplies.

Whether treatment methods are dictated by statute or based on the informed judgment of PWS operators, industry standards provide an important technical foundation for the treatment methods employed. Indeed, the requirements found in applicable industry standards are frequently incorporated by reference in state and local regulations or codes, or are contained in PWS procurement requirements.

Drafted and published in the 1980s at the request of the EPA's Office of Water, NSF/ANSI 60, Drinking Water Treatment Chemicals—Health Effects, details requirements designed to control potential adverse human health effects from contaminants in water treatment chemicals and other additives added to drinking water during its treatment, storage and distribution. NSF/ANSI 60 addresses only the potential health effects of many contaminants that may be present in drinking water treatment chemicals, and does not establish performance or taste and odor requirements for treatment products. Water treatment products included under the scope of NSF/ANSI 60 include



coagulation and flocculation chemicals, disinfectants and oxidation chemicals, chemicals used for corrosion and scale control, and other miscellaneous water supply chemicals.

Certification to NSF/ANSI 60 requires manufacturers to submit their products for evaluation against a variety of analytical methods, and to conduct a comprehensive risk assessment in certain cases. In addition, surveillance requirements have been added to effectively implement changes required by the California Code of Regulations that specifies annual recertification of drinking water treatment chemicals to NSF/ANSI 60.

Packaging and/or documentation for NSF/ANSI 60-certified products must also display the certification mark of an ANSI-accredited third-party certification organization, and provide information on the maximum use level, the lot number or date code of the production batch, and the location where the product was produced.

The Limits of Production Surveillance Under NSF/ANSI 60

In addition to product-specific packaging and labeling requirements, NSF/ANSI 60 also mandates annual, unannounced inspections of manufacturing and production facilities, as detailed in Section 3.8.2 of the standard. These inspections include a visual inspection of chemical production, product sampling, a validation of product formulation, a review of analytical procedures and methods, and a review of records related to formulation and chemical stock control.

In contrast with typical product standards, NSF/ANSI 60 outlines surveillance requirements that are limited in scope and general in nature. Surveillance requirements for a certification program are more appropriately placed in a certification scheme rather than a product standard. This limited scope of NSF/ANSI 60 surveillance requirements creates the potential for deviations from the original intent of the content currently in the product standard.

The general approach embodied in the surveillance requirements under NSF/ANSI 60 can also lead to differing interpretations of the requirements by third-party certifiers. Such differences can result in far less robust surveillance for some producers, creating a potential advantage in a competitive marketplace. In addition, producers who are held to a less strict interpretation of the surveillance requirements are likely to invest less in systems and controls, which could have a direct impact on product quality.

For these reasons, it was determined that incorporating surveillance requirements into a separate conformity assessment standard would bring more uniformity and focus to conformity assessment procedures conducted by accreditation bodies, hence the justification for the creation of NSF/ANSI 223.

Key Facility Inspection Requirements of NSF/ANSI 223

First published in 2012, NSF/ANSI 223 addresses a number of issues related to the surveillance requirements in NSF/ANSI 60. First, NSF/ANSI 223 is directed

not to chemical producers but to third-party certification bodies that test and certify water treatment chemicals to the requirements of NSF/ANSI 60. The standard's primary intent is to not to duplicate NSF/ANSI 60 product requirements, but rather to establish robust surveillance protocols to be applied to producers seeking to obtain and maintain NSF/ANSI 60 product certification. This approach solidifies NSF/ANSI 60 as a product standard, and will eventually separate the product requirements applicable to producers from surveillance procedures and processes required of certification bodies.

NSF/ANSI 223 requires certification bodies to conduct unannounced inspections of facilities producing water treatment chemicals certified to NSF/ANSI 60 at least once per calendar year. The requirements of NSF/ANSI 223 apply not just to manufacturing facilities, but also to facilities that blend, dilute, dissolve, repackage, re-label or transfer water treatment chemicals. In addition, inspections to verify compliance with the requirements of NSF/ANSI 223 must be conducted at the site of the facility. So-called desk audits or remotely conducted audits are not permitted under the standard.

NSF/ANSI 223 can also subject producers to increased inspection frequency under specific circumstances, as detailed in the following sections.

Production Deficiencies Identified Through Inspections

The frequency of inspections required under NSF/ANSI 223 is increased to four



times per calendar year when one or more of the following deficiencies are identified:

- Significant or repeated deviations from approved product formulations, including changes to constituent chemicals or the use of products from unauthorized suppliers
- The condition of a facility's manufacturing processes, materials storage and handling systems and/or shipment processes is such that the purity or efficacy of an NSF/ANSI 60-certified product is compromised
- Facility personnel have failed to demonstrate an ability or willingness to meet NSF/ANSI 60 requirements for formulation control or product labeling
- Receipt and verification by the certification body of adverse information about a NSF/ANSI 60-certified product or production facility, such as product complaints, product recalls or adverse regulatory action

In the above cases, the increased inspection frequency must be maintained until any and all deficiencies have been resolved and for an additional 36 months thereafter.

Production in Countries Viewed as Susceptible to Corrupt Practices

The frequency of inspection under NSF/ANSI 223 is increased to two times per calendar year in cases where a facility is located in a country viewed as susceptible

to corrupt practices. The standard has adopted by reference Transparency International's Corruption Perceptions Index (CPI),⁴ and mandates twice yearly inspections when a facility is located in a country that has a CPI score of less than 50. However, inspection frequency is reduced to once per calendar year when a facility has:

- Operated for a period of 36 months without any identified production deficiencies
- Maintained a certified quality or environmental management or product stewardship program, such as ISO 9001, ISO 14000/1 or others specified in the standard; or

- Is wholly owned by a global business entity operating under a certified quality or environmental management or product stewardship program specified in the standard

Under NSF/ANSI 223, the certification of a quality or environmental management or product stewardship program must be issued by a qualified third-party certification authority.

Manufacturers of Certified Products Using Products from Suppliers Located in Countries Viewed as Susceptible to Corrupt Practices

Facilities that are involved in the blending, diluting, dissolving, re-labeling,





repackaging or transfer of products to be certified to NSF/ANSI 60 which have received supplies from countries with a CPI of less than 50 are also subject to inspection twice per calendar year. However, inspection frequency may be reduced to once per calendar year if the supplying facility complies with either of the following:

- It also maintains a certified quality or environmental management or product stewardship program specified in the standard; or
- The facility can demonstrate suitable mechanisms or controls that assure the quality and consistency of a supplied product

It is important to note that the increased inspection frequencies detailed in NSF/ANSI 223 are maintained even when

a facility ends its relationship with a certification body and applies to another entity for certification. Under the standard's requirements, a certification body must require applicants for

NSF/ANSI 60 certification to affirm that they have not terminated their relationship with another certifier while operating under any of the increased inspection frequencies identified above.

Considerations for Producers of Water Treatment Chemicals and Additives

As previously noted, PWS operators generally rely on industry standards to identify and procure chemicals and additives that are safe to use in the treatment of public drinking water supplies. For these reasons, compliance

with the requirements of NSF/ANSI 60 is essentially mandatory for producers seeking to meet the procurement requirements of PWSs for water treatment chemicals and additives.

Producers of drinking water treatment chemicals and additives can expect individual PWS procurement policies to require certification to NSF/ANSI 60 by a certification body that is accredited to the requirements of NSF/ANSI 223 as a condition of product acceptance. Therefore, producers should prepare now by using accredited certification bodies that are evaluating chemicals using the requirements of NSF/ANSI 223 and NSF/ANSI 60 to avoid having their products disqualified from consideration by PWS authorities.





Summary and Conclusion

NSF/ANSI 223 significantly clarifies the scope of inspection requirements contained in NSF/ANSI 60. As NSF/ANSI 223 becomes incorporated by reference in PWS procurement policies, producers of drinking water treatment chemicals may need to prepare for more thorough and rigorous review of their facilities by accredited certification bodies. Reference to NSF/ANSI 223 in PWS procurement policies will eliminate discrepancies between certification bodies in the inspection of production facilities, thereby establishing a fair and equitable certification and surveillance process for all producers.

UL's current NSF/ANSI 60 certification program for drinking water treatment chemicals incorporates the requirements of NSF/ANSI 223 addressing the inspection of production facilities. UL also has a dedicated team of toxicologists, chemists and engineers specializing in water product certification, with more than 400 years of combined experience in testing to NSF/ANSI standards. And the UL Mark for water quality is recognized by the U.S. Environmental Protection Agency and accepted in all 50 states.

For more information about UL's program for the certification of drinking water treatment chemicals, contact Amanda Fisher, Business Development Manager, at amanda.fisher@ul.com

¹ "Water Facts," U.S. Environmental Protection Agency, Office of Water. June 2004. Web. 16 July 2013.
http://water.epa.gov/lawsregs/guidance/sdwa/upload/2009_08_28_sdwa_fs_30ann_waterfacts_web.pdf

² "Understanding the Safe Drinking Water Act," U.S. Environmental Protection Agency, Office of Water. June 2004. Web. 16 July 2013
http://water.epa.gov/lawsregs/guidance/sdwa/upload/2009_08_28_sdwa_fs_30ann_sdwa_web.pdf

³ "SDWA Statute, Regulations and Enforcement," U.S. Environmental Protection Agency. Web. 16 July 2013.
<http://www.epa.gov/compliance/civil/sdwa/sdwaenfstareq.html>

⁴ More information about Transparency International's Corruption Practice Index is available at
http://www.transparency.org/cpi2012/in_detail.