The Sum of all Parts - Drinking Water System Component Certification

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It is a common misconception that a final product can be considered certified without additional evaluation if all or most components making up the product are certified. Similarly, some product manufacturers believe that it is acceptable to market a product as being "made with certified components" when the final product has not been evaluated for certification. Believing in this misconception and marketing it as true can lead to hazardous or unhealthy consequences.

This question often arises regarding products intended for use with drinking water. The majority of US states require that municipal water treatment and distribution components be certified to NSF/ANSI 61: *Drinking Water System Components – Health Effects*. Therefore, it is important that state and local water system administrators have an understanding of how to verify certification and why "made with certified components" does not meet the criteria for final product certification.

First and foremost, if the final product trade designation does not appear in the public listings of an ANSI accredited certifier, specifically listed for standard NSF/ANSI 61, then the product is not considered certified. A certifier must assess all materials, suppliers, processes, and contamination risks at each factory location and determine the necessary test protocol for the final product. In addition to the initial evaluation by the certifier, certified products and each covered manufacturing location must be under the ongoing surveillance and testing protocols of the certification agency. Manufacturers who claim compliance for a product but do not have a listing and are not subject to surveillance testing and inspections by a certifier, may change components and suppliers freely and without warning. Even if the entire bill of materials for a product is originally composed of individually certified components and materials, there is no guarantee the product will be constructed of the same components at a later time. Therefore, if the final assembled product itself is not listed, then it should not be considered certified.

To understand why, one must have a basic understanding of the evaluation criteria under NSF/ANSI 61. The standard is not simply a review of products and the components or ingredients making up these products to determine whether a material or ingredient may or may not be used. Instead, the standard requires testing to determine chemical contaminants and impurities that are indirectly imparted to drinking water from products, components, and materials used in drinking water systems. With the exception of specific forms of stainless steel alloys previously evaluated per Annex C, all materials that will be in contact with water in the field must undergo extraction testing in the laboratory for material-specific, and possibly process related, analytes of interest. Compliance is determined by comparing the concentrations of chemical compounds that leach into the exposure waters to established drinking water contaminant limits.

A complete finished product is to be evaluated via laboratory testing, unless size, weight, volume, location, etc. make this impractical. This is to predict as closely as possible the total concentrations of contaminants that will leach into drinking water in the field. NSF/ANSI 61 specifically states those exceptions where surrogate samples may be tested in lieu of the finished product, and this must be carefully considered by the laboratory during the evaluation. This is because one or more contaminants may leach out from multiple materials in the final product, and the final concentration(s) are then the result of additive effects in the completed product. To provide an actual example, a check valve made entirely of certified components was noncompliant as a finished device because

the total concentration for 2-phenyl-2-propanol was above the allowable level. The compound was leaching from both the rubber components and the valve coating, and the combination of the two components together in the final device was not acceptable.

Components used in assembled products or devices may have undergone additional processing during the construction of the final device; processing that altered the water contact surface and changed the leaching characteristics of the materials or added unintended contaminants, not present before. These processes may be mechanical, such as machining, molding, stamping, fastening, etc., or chemical, such as acid washing, plating, coating, bonding, etc. For example, fasteners made of brass or bronze used to interconnect components within an assembled product, will contribute to lead leaching from the finished device. Similarly, welding or brazing will not only affect the water contact surface of a component, but also deposit additional materials that will need to be considered by the certifier and evaluated by test. Product certifications are supplier and manufacturing location specific because of the potential for contamination on the parts per billion level that cannot necessarily be perceived without testing and may pose a human health risk. It is not uncommon to detect contaminants from tools, cleaning fluids, processes such as abrasive blasting, or even packaging materials.

Another consideration is the temperature rating for certified components verses the temperature rating for the final product. As NSF/ANSI 61 requires extraction testing with exposure water, the temperature of the water can have a large effect. The typical exposure water temperatures are: cold [23 ± 2 °C (73 ± 4 °F)], domestic hot [60 ± 2 °C (140 ± 4 °F)], and commercial hot [82 ± 2 °C (180 ± 4 °F)]. The majority of materials will leach contaminants in greater amounts when exposed to hot water compared to cold water. However, there are some exceptions to be considered, such as volatile organic compounds, which will come out of solution at higher temperatures. If a final product is to be used in the field with hot water, either continuously or intermittently, it will need to be evaluated in the laboratory with the same hot water temperature or hotter, in order to be certified with the appropriate maximum temperature rating. A component which has only been certified with a cold water rating should be expected to leach more contaminants when exposed to hot water, possibly at noncompliant levels in the finished device.

In addition to water temperature, there are other conditions which may be different between component and final product. The certified components may not have undergone the same rigorous conditioning and exposure as required for the particular end product. The various product sections of NSF/ANSI 61 have different evaluation conditions. Products undergo both "conditioning," a period during which water sits in contact with the product and is discarded and refilled for a prescribed amount of hours or days, and "exposure," periods between 12 and 24 hours, when the final water sits in contact with the product before being collected for analysis. The conditioning period allows time for contaminants to seep out into water that will be discarded. The most rigorous evaluations are typically associated with shorter conditioning periods and longer exposure periods. However, it is not always possible, even for an experienced certifier, to determine which protocol is worst case without conducting the testing.

In the same way conditioning and exposure sequence can affect compliance of a final product, the section of the standard, normalization assumptions, and associated pass/fail criteria have a significant impact on compliance. Normalization is "the process of adjusting laboratory extraction results by accounting for differences between laboratory and field surface area-to-volume ratios to reflect the contaminant concentration at the tap" (NSF/ANSI 61 – 2017, Clause 2.16). Each section of the standard has different assumptions for how the product data should be normalized based on the intended use. In addition, normalized contaminant concentrations will either be compared to the Total Allowable Concentration (TAC), Single Product Allowable Concentration (SPAC), or even the STEL (Short-Term Exposure Limit), three different pass/fail criteria for the same contaminant based on where the product is used in the field.

For instance, a ½-inch valve evaluated for use anywhere within a residence, except in the last liter of plumbing, is considered an in-line mechanical device (Section 8). The same ½-inch valve evaluated for use in the last liter of plumbing, is considered a mechanical plumbing device or endpoint device (Section 9). For this example, the ½-inch valve is being evaluated for regulated metals "in-product", meaning the valve is to be filled with water. The exposed surface area in the field will be equal to the exposed surface area in the lab (SAF / SAL = 1). Assume the valve capacity is 180 milliliters. Section 8 requires that the valve, with a capacity less than 1 liter, be extended to a volume of 1 liter for the conditioning and exposure. The volume in the field is also to be considered 1 liter (NSF/ANSI 61 – 2017, Clause B.8.3.1). For Section 9 however, there is no requirement to extend the lab volume to 1 liter. The prescribed volume in the lab is the volume of the valve, or 180 milliliters. As previously mentioned, the volume in the field for a mechanical plumbing device is the last 1 liter of plumbing (Clause B.8.8.2). When evaluated to Section 8, contaminants from the valve are normalized with 1L / 1L = 1, times a dispersion factor of 0.33 (Clause B.8.4.2) and a time factor of 12hr / 16hr = 0.75 (Clause B.8.4.4 – a 16-hour final exposure is often more convenient for the lab to manage than the required 12-hour final exposure). The normalized concentrations are compared to the TAC. When evaluated to Section 9, metals contaminants from the valve (with the exception of lead) are normalized with 0.18L / 1L = 0.18, and the normalized concentrations are compared to the SPAC. For reference, the SPAC is typically one tenth of the TAC.

In the example of the ½-inch valve exposure, arsenic, a federally regulated metal, was detected at a level of 20 ppb in the laboratory extraction waters:

Normalized as an Inline Mechanical Device (Section 8)	**Normalized as a Mechanical Plumbing Device (Section 9)**
20 ppb X 0.2475 = 4.95 ppb	20 ppb X 0.18 = 3.6 ppb
TAC for Arsenic = 10 ppb	SPAC for Arsenic = 1 ppb
Compliant	Noncompliant

This is just one example of many situations where the section of the standard, normalization assumptions, and associated pass/fail criteria can have a significant impact on the compliance of a component that may have multiple end uses.

Chemical feeders and generators are another example of systems which may be constructed largely of certified components, but will need special evaluation and testing in order to be considered certified as a whole for the intended purpose. NSF/ANSI 61 – 2017, Clause B.8.5 states, "Chemical feeders and generators, feeder components, and the materials used therein present a special case because the materials are in contact with a concentrated chemical, which is then diluted at the prescribed feed rate, rather than in direct contact with water." The components and materials comprising chemical feeders and generators, if certified to NSF/ANSI 61 for other end uses, were conditioned and tested using water only, not the chemicals intended to be dosed in the field. It should be expected that different contaminant profiles and even contaminant by-products will be detected from materials when exposed to harsh chemicals as opposed to water. Thus, the test protocol for chemical feeders and generators includes conditioning per the manufacturer's instructions for field use, and the exposure involves operating the completed device until target dose levels are achieved, allowing the device to sit in contact with the chemical contents for a minimum of four hours at the normal temperature of operation, and then collecting the extractant for analysis of contaminants.

To summarize, the use of components which have been certified individually is always a good place to start for manufacturers seeking certification of a final product or assembly constructed of multiple components, but it does not necessarily mean testing will be waived or the final product will prove to be compliant. Most importantly, it does not mean that the final product can be considered certified, and marketed as such, without having been submitted to an ANSI accredited certifier for evaluation, certification, and listing. It is important to have a knowledgeable certifier evaluate all the complexities of the final product and its intended use in the water treatment or distribution system.

To ensure compliance, water systems administrators should locate final products on the online listing of the certifier and look for the authorized certification mark on the product or accompanying documentation where required by the certifier. This also means verifying that the supplied products originated from the manufacturing location(s) listed in the certification directory. Also take note of any associated use ratings and footnotes accompanying the product listing or certification marking. This information should be strictly followed so as not to void the certification and cause the product to leach differently in the field than expected from lab analysis. Whenever there are doubts or questions about certification status or proper end use for a final product in the field, always contact the applicable certifier for assistance and clarification.

About the author

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