The following is submitted by Richard Sakaji, East Bay Municipal Utility District on 13 February 2008

The following discussion argues for placing Annex G in NSF/ANSI Standard 61 as an **optional** step that plumbing supplies must pass through before they can be sold in the state of California. Since plumbing supplies sold in California must meet a lead content standard, those manufacturers wishing to sell their supplies in California would need to comply with the extra steps outlined in Annex G in order to receive certification under NSF/ANSI Standard 61(herein after referred to as Standard 61). At the Drinking Water Additives Joint Committee (DWAJC) meeting, at which the Annex G issue paper was presented, several DWAJC members expressed concern about amending Annex G to Standard 61. Two of these concerns seem to focus on whether Standard 61 could or should be modified to suit the needs of a single state and whether Standard 61 was the appropriate location for Annex G.

Based on a review of Standard 61 and the "NSF International Standards development and maintenance policies," neither document appears to contain specific language restricting or prohibiting Standard 61 from acting to address one state's specific needs. However, realistically, if Standard 61 attempted to respond to every individual local government (state, county, or city) need, the standard could become overtaxed and would run the risk of becoming too convoluted or burdensome to implement.

While the statement in Section 1 of the "NSF International Standards development and maintenance policies" document appears to encourage Standard 61 to be consistent with state and local government codes.

> "NSF Standards are intended to be consistent with government regulations and codes, when they exist."

This statement is made in the context of the American National Standards Institute (ANSI) and federal government policies (OMB A-119 is a policy document and is not part of the Code of Federal Regulations) used to guide the development of voluntary consensus standards. This statement provides additional guidance to ensure Standard 61 development is consistent with state and local government regulations and codes pertaining to voluntary consensus standards and should not be taken as encouraging the standard to be responsive to state and local government requirements outside the rules governing the use of voluntary consensus standards.

It is important to keep in mind that Standard 61 is a "voluntary consensus standard" and is not a national standard as defined by federal statute or code. States are not bound or required to participate in Standard 61 although a majority do utilize the standard by citation. In fact, not all states cite Standard 61 in state code or statute (as is necessary in many cases to establish an enforceable standard); hence, not all states provide an equal level of enforcement when it comes to the provisions of Standard 61. Historically Standards 60 and 61 grew from the combined needs of the individual state regulatory programs, none of whom had a regulatory requirement for using only certified chemicals

or materials at the time, always deferring to the USEPA Water Additives Advisory Program for guidance.

When the USEPA reduced their advisory role to the states by closing the Water Additives Advisory Program, the individual states and utilities were left without a means to determine which chemicals or materials could be used to treat and deliver water to consumers. So while there was an identified need that existed in each individual state, Standard 61 was developed in the absence of any state statute or regulatory requirement specifically calling for such a standard; true, at the time, the need for Standard 61 was greater than the need for the Standard to adopt Annex G, still the fact remains that the need for the standard was driven by the individual states and water utilities in the absence of state or federal standards. As pointed out previously, to this day, not all states cite Standard 61 as part of their enforceable standards. By responding to individual state needs and addressing those needs in Standard 61 will increase the dependence of the state programs on the standard. Over time this will reinforce the position of the standard and strengthen the program. Part of the focus in deciding whether to incorporate Annex G into Standard 61 should be on potential consequences of not being responsive to state needs.

By citing Standard 61 in the California plumbing code (January 1, 2008) and in the proposed California Waterworks standards (approved by the Office of Administrative Law and filed with Secretary of State; anticipated effective date March 9, 2008 or sooner), California has sent a message of support for the voluntary consensus standard program. Placing Annex G in another Standard or developing an independent standard for it would undermine California support of the Standard 61 process. Since Standard 61 has already been cited in the preceding documents, it would be necessary to revise the regulations and plumbing code which is both time consuming and a burden to state administrators whose staffs are resource limited.

Any state would probably look unfavorably at the prospect of rewriting state regulations when the mechanism for amending Annex G to Standard 61appears to be consistent with the intent and purpose of the Standard. While the State would not withdraw support for this initiative based on this one incident, failure to incorporated Annex G into Standard 61 could make them think twice about referencing any NSF/ANSI Standard in future legislation, code, or regulation undermining the purpose of voluntary consensus standards such as Standard 61.

The concern regarding overtaxing or burdening the standard can be abated by the manner in which the standard is modified. By restricting the development of an individual state requirement to a single topic that does not conflict with any of the other provisions in the standard and ensuring that Standard 61 users and testing organizations understand that an individual state's requirements are not applicable to other states, should be sufficient to avoid the issues that would prevent Annex G from becoming a part of Standard 61.

As proposed, Annex G is setup to operate and function in this exact manner. The introduction clearly states that the annex should only be used in States with a lead content standard effectively isolating it from the main body of the standard. References to Annex

G in the main body of the standard are careful to point out that Annex G only applies to those plumbing supplies that wish to conform to a lead content standard. The introductory paragraph to Annex G also states that the performance standard parts of Standard 61 must be complied with in order to receive certification, even if the part qualifies under the proposed lead content portion of Standard 61.

Based on the preceding discussion, there does not appear to be a compelling reason within the scope of the Standard not to act in a manner that addresses one state's specifics needs, especially if the added section does so in a "generic" manner. This would allow other states to cite Standard 61 if they chose to adopt a lead content standard. There is already movement outside of California to establish lead content standards for plumbing supplies, e.g., legislation in the House of Representatives (HR 2076, the Lead Free Drinking Water Act 2007) and in the Vermont Senate (S 152, 2007).

Requirements specific only to a single state have been addressed in previous revisions to Standard 61. As Standard 61 now stands, the q statistic will change in 2012. While there was a lot of research and development that was incorporated in changing the q statistic, one driver for the change was the settlement that resulted from California's Proposition 65 litigation. USEPA Lead/Copper workshop documents from 2005 indicate the former q statistic used in Standard 61 (11 μg) was too high and that under the Prop 65 (which pertains only to California) litigation settlement, the q statistic needed to be lowered to 5 μg. Standard 61 was revised with informative content this past November (2007) showing how the q statistic in the standard will change in 2012. Incorporating Annex G into Standard 61 for the State of California to cover the provisions of AB 1953 would be no different.

Up to this point the discussion as to whether or not the Standard should be responsive to an individual state's statutory requirements has been separated from the discussion regarding placement of the Annex within Standard 61. While the two issues are linked, they are also independent of each other. Since the issue paper was referred to the Drinking Water Additives Joint Committee on NSF's recommendation, this should be taken as an indication that NSF feel the proposed Annex G belongs in Standard 61. Otherwise, Annex G would have been submitted to NSF as a Draft Standard for Trial Use.

The intent behind submitting the proposal as an annex was to ensure the document would be a part of Standard 61 because, by definition, an annex is considered part of a document and the state could make use of citations already in statute. The annex extends or adds on to a document by setting forth the route or mechanism(s) through which the standard will be implemented. There is no need to cite annexes because they are considered part of the standard.

As it exists currently, Standard 61 is a performance based standard whose expressed purpose is to prevent adverse human health impacts from products that come into contact with drinking water.

> "NSF/ANSI 61 was developed to establish minimum requirements for the control of potential adverse human health effects from products that contact drinking water."

The adverse health effects from lead exposure are well documented and the lead content standard establishes a minimum content standard for plumbing supplies in direct contact with drinking water. Hence, the placement of Annex G in Standard 61 is appropriate.

At present, the standard meets the Standard 61 objective by testing a sampling of products under conditions that simulate product use. The contaminants that migrate from the product or are released from the product during the testing period are then measured in the water collected from the test rig. As proposed, Annex G takes a different tact to meeting the purpose of the standard, i.e., it restricts the contaminant content in the product. Some view this as a fundamental shift away from the current performance based standard; a standard that has been vetted through experimentation and experience. Component evaluation is the key requirement under Annex G. Since the basic procedure and requirements are established in Section 3 of Standard 61, it would make sense to draw upon these established requirements and protocol rather than develop a new standard. However, it should be reiterated that Annex G, as proposed, does not replace the current performance testing requirement and is an additional requirement for those states that have a lead content standard.

As stated earlier, Annex G separates the performance standard and the lead content standard, creating two requirements for those manufacturers qualifying their materials for sale in states with a lead content standard. It is important to recognize that Annex G still requires the component meet the performance standard by physical testing and does not excuse a manufacturer from performance testing simply because the content standard is met.

A lead content standard and a performance standard are not mutually exclusive. Given the variability in performance testing results due to between lot variation (limited sample size tested), raw material quality, and test conditions not simulating the full range of conditions in actual application, restricting the lead content reduces one source of variability. Because of the content restriction, items meeting the lead content standard will also have a greater likelihood of passing the performance standard, but simply meeting the lead content standard would not provide a guarantee that the items would pass the performance test.

Standard 61 has not confined itself to federal and state regulatory needs. There is precedence for Standard 61 to be responsive to public health and water quality issues in the absence of federal or state (limited) standards, as is case for the N-nitrosamines. There are no federal maximum contaminant levels (MCLs) for the N-nitrosamines, but several of these compounds are listed in Annex D Table D3 of Standard 61 with a Total Allowable Concentration (TAC) and Single Product Allowable Concentration (SPAC). While the presence of this listing does not in itself demonstrate the fulfillment of an individual state's requirement, it is an example of the standard taking action when there are limited or no statutory requirements driving the need for such action. Hence,

fulfilling the need of an individual state demonstrates the standard to be responsive to the regulatory body that needs it.

Given the purpose of Standard 61, there do not appear to be any technical, procedural or policy arguments that would preclude placing Annex G in Standard 61. While arguments have been expressed for developing a separate standard or placing the annex in another Standard, the simplest argument against either of these two options is that given the purpose and intent of Standard 61, it is unnecessary to exercise either of these options. Further, Annex G is appropriate given that NSF already applies a lead content standard for products under consideration in Standard 61 by prohibiting the intentional addition of lead to any products with very limited exceptions. This practice has been formalized in new draft language for Standard 61.

Separate issue:

Coatings and acid washing to meet the lead content standard. At present, Annex G does not address coatings or acid washing. These are not prohibited by the Standard, but the Task Group was unable to gather and assemble sufficient reference materials on which to base a standard. The testing must show the material:

1. does not leach lead over the lifetime of the fixture.

2. and that the expected life of the unit is accurately defined.

Both of these objectives are very difficult to demonstrate and while they are excellent objectives, the technical detail needed to meet these objectives could not be assembled and vetted in a timely manner for this revision. Both subject areas were purposefully left out of the proposed standard, at this time, but both or either can be added to the standard in the future through the submission of a white paper.