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SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

PEOPLE OF THE STATE OF CALIFORNIA ex. rel. DANIEL E. LUNGREN, Attorney General of the State of California, Plaintiffs, vs. AMERICAN STANDARD, INC.; et al., Defendant.	No. 948017 CONSENT JUDGMENT AS TO DEFENDANTS AMERICAN STANDARD, INC., ELKAY MANUFACTURING COMPANY, MASCO CORPORATION OF INDIANA, MOEN INCORPORATED, UNIVERSAL-RUNDLE CORPORATION; ELJER MANUFACTURING, INC.; UNITED STATES BRASS CORPORATION

1. Introduction

1.1. On December 15, 1992, the Attorney General of the State of California ("Attorney General"), on behalf of People of the State of California, ("People") filed a Complaint for Civil Penalties and Injunctive Relief

("Complaint") in San Francisco County Superior Court ("Action"). American Standard, Inc., Elkay Manufacturing Company, Masco Corporation of Indiana, Moen Incorporated, Universal-Rundle Corporation, Eljer Manufacturing, Inc. and United States Brass Corporation are among the defendants named in the Complaint, and are hereinafter referred to as "Settling Defendants."

1.2. Settling Defendants are corporations that employ more than ten persons and manufacture and/or sell faucets to persons in the State of California. For purposes of this Consent Judgment, the term "faucet" shall have the meaning set forth in section 15 hereof.

1.3. The People's Complaint alleges that Settling Defendants have sold faucets containing lead as a constituent of brass used in the manufacture of the faucets, that under certain conditions this lead leaches into water in the faucets, and that the resulting exposures and discharges from residential use of such faucets violates provisions of the Safe Drinking Water and Toxic Enforcement Act of 1986, Health and Safety Code sections 25249.5 and 25249.6. ("Proposition 65"), and Business and Professions Code sections 17200 et seq. ("Unfair Competition Act"), by knowingly and intentionally exposing persons to a chemical known to the State of California to cause reproductive toxicity and cancer, without first providing a clear and reasonable warning to such individuals, and by knowingly discharging or releasing such chemicals into a source of drinking water.

1.4. On December 15, 1992 the Natural Resources Defense Council and the Environmental Law Foundation ("Private Plaintiffs"), filed a complaint, which was subsequently amended, against Settling Defendants and certain other defendants, with similar material allegations of fact.

1.5. For purposes of this Consent Judgment only, the parties stipulate that this Court has jurisdiction over the allegations of violations contained in the Complaint and personal jurisdiction over each Settling Defendant as to the acts alleged in the Complaint, that venue is proper in the County of San Francisco, and that this Court has jurisdiction to enter this Consent Judgment as a resolution of all claims which were or could have been raised in the Complaint based on the facts alleged therein.

1.6. On May 5, 1994, the Superior Court sustained a demurrer filed by the Settling Defendants and certain other defendants who demurred to the first and second causes of action in the Complaint, on the ground that water standing in a faucet is not a "source of drinking water," such that there would be a discharge prohibited by Proposition 65. On June 12, 1995 the Court of Appeal denied the Attorney General's writ petition, issuing an opinion finding that faucets and the water within them are not a "source of drinking water" under Proposition 65. On July 24, 1995, the Attorney General and certain private parties including the Private Plaintiffs, who were granted leave to intervene, petitioned the California Supreme Court for review.

1.7. For the purpose of avoiding prolonged litigation, the parties enter into this Consent Judgment as a full settlement of all claims that were raised in the Complaint based on the facts alleged therein, or which could have been raised in the Complaint arising out of the facts alleged therein. By execution of this Consent Judgment, Settling Defendants do not admit any violations of Proposition 65 or the Unfair Competition Act or any other law and specifically deny that they have committed any such violations. Nothing in this Consent Judgment shall be construed as a decision by the Court on any issue of law or fact or as an admission by any party of any fact, issue of law or violation of law, nor shall compliance with the Consent Judgment constitute or be construed as an admission by any party of any fact, issue of law, or violation of law. Nothing in this Consent Judgment shall prejudice, waive or impair any right, remedy or defense the Attorney General and Settling Defendants may have as to each other in any other or future legal proceedings unrelated to these proceedings, the facts alleged in the Complaint, or matters covered by this Consent Judgment. However, this paragraph shall not diminish or otherwise affect the obligations, responsibilities and duties of the parties under this Consent Judgment.

1.8. The Attorney General, on behalf of the People, has filed a proof of claim in United States Brass Corporation's bankruptcy proceeding currently pending in Sherman, Texas ("U.S. Brass Bankruptcy Proceeding"), asserting $1 million in civil penalties and restitution (the "People's Claim").

2. Test Methods and Statistical Analysis

2.1. Covered Products manufactured by each Settling Defendant and shipped after December 31, 1996 for sale in California shall be tested in accordance with NSF International Standard 61, section 9 (the "NSF Protocol") as adopted by NSF and in effect on August 1, 1995. Such testing shall be completed as soon as reasonably possible, but not later than December 31, 1996. In applying the NSF Protocol to Covered Products, all provisions of the NSF Protocol shall be followed, including but not limited to the use of Test Statistic Q as defined in Appendix B, section 12.11 of the NSF Protocol (the "NSF Test Statistic Q"). In meeting the requirements of this Consent Judgment, any Settling Defendant may test product lines of Covered Products, as provided for in section 8.1 of Appendix B of the NSF Protocol, or test Covered Products which are of "Similar Application" as that term is used in section 9.2.2 of the NSF Protocol. A copy of the NSF Protocol is attached to this Consent Judgment as Exhibit A. For purposes of this Consent Judgment, the term "Covered Products" shall have the same meaning as set forth in Exhibit B to this Consent Judgment.

2.2. In the event that the NSF Protocol is amended in a manner that either yields the same or more stringent results (i.e., it produces a numerical result which is the same or greater than would be produced pursuant to the current version of the NSF Protocol), any Settling Defendant may, at its sole option, elect to use the revised version of the NSF

Protocol to demonstrate compliance with this Consent Judgment. Any Settling Defendant so electing shall provide written notice to the Attorney General as part of its next regular submission pursuant to Section 5 hereof.

2.3. The use of the NSF protocol, and the standards set forth in the Consent Judgment, are based on determinations concerning the nature of the laboratory test used and its relationship to actual and specific conditions of faucet use and consumption, including factors such as the length of time the water dwells in the faucet, the chemical properties of the water, the pattern of consumption of water from the faucet and other factors unique to faucets. This Consent Judgment, including but not limited to the warning standard set forth in section 3.1 and the lead reduction levels set forth in section 4.1, is accepted by the parties, including the Attorney General in the name of the People, solely for purposes of resolving issues disputed with respect to the Settling Defendants in this action, including future compliance by Settling Defendants with this Consent Judgment and shall not be used for any other purposes in the prosecution or defense of this Action.

3. Clear and Reasonable Warnings

3.1. Warning standard. Each Settling Defendant shall provide warnings in the manner set forth in this Consent Judgment for any Covered Product it manufactures or ships for sale for use in California, for which the intended uses include use in a residential kitchen (a "Residential Kitchen Faucet"), unless the NSF Test Statistic Q for that Covered

Product is less than or equal to 5 micrograms. Each Settling Defendant shall provide warnings in the manner set forth in this Consent Judgment for any Covered Product other than a Residential Kitchen Faucet for which the NSF Test Statistic Q exceeds 11 micrograms.

3.2. Form of Warning. For each Covered Product requiring a warning pursuant to this Consent Judgment, which is manufactured 30 or more days after the date of entry of this Consent Judgment, but prior to December 31, 1996, for sale in California by a Settling Defendant, each Settling Defendant shall provide a warning, where required by this Consent Judgment, in the form set forth in Exhibit D to the Modified Preliminary Injunction entered by the Court on September 9, 1994, which is set forth as Exhibit C to this Consent Judgment, or in the form set forth in Exhibit D to this Consent Judgment (including the incorporation of warnings anywhere in the instructions for installation, maintenance or use enclosed with individual packages of Covered Products), or in the form set forth in Exhibit E to this Consent Judgment. For any Covered Product requiring a warning pursuant to this Consent Judgment which is manufactured by a Settling Defendant on or after December 31, 1996 for sale in California, such Settling Defendant shall provide a "hang tag" warning, securely affixed to the Covered Product, with the form, size and content set forth in Exhibit E.

3.3. Alternative Warning Requirements. If, with respect to Covered Products, the People permit any other warning

standard (i.e., the NSF Test Statistic Q above which a warning is required by this Consent Judgment) or vary the permissible manner, form, size or content of warning by way of settlement or compromise with any other person in the course of doing business, or any other entity, or if another warning standard, manner, form, size or content of warning is incorporated by way of a final judgment as to any other person in the course of doing business, or any other entity, then any Settling Defendant may, at its sole option, give warnings on the same terms as provided in those settlements, compromises or judgments.

4. Lead Reduction

4.1. In lieu of making a payment in satisfaction of the People's claims for civil penalties, restitution or disgorgement, in the amount of $1.00 per Covered Product manufactured and shipped for sale in California by each Settling Defendant between February 27, 1988 and the date of entry of this Consent Judgment, Covered Products manufactured and shipped by Settling Defendants for sale or use within the State of California shall have an NSF Test Statistic Q that complies with the levels set forth below:

a) By no later than December 31, 1996, all Covered Products shipped for sale in California shall have an NSF Test Statistic Q less than or equal to 11 micrograms.

b) Covered Products shall have an NSF Test Statistic Q less than or equal to 5 micrograms according to the following schedule:

% meeting 5 microgram Q Test	Time
65	December 31, 1996
80	December 31, 1997
90	December 31, 1998
95	December 31, 1999 and thereafter

For purposes of section 5 of this Consent Judgment, each Settling Defendant shall calculate the percentage of Covered Product meeting the levels set forth above by aggregating the units of all Covered Products it manufactures and ships for sale or use in California in the calendar year following the dates set forth above and determining the percentage of the total units that have an NSF Test Statistic Q less than or equal to 5 micrograms.

c) Notwithstanding the levels set forth in section 4.1(a) and (b), bubblers manufactured and shipped by Elkay Manufacturing Company for sale or use within the State of California, on or after December 31, 1995 and listed in Exhibit B (Covered Products), shall have an NSF Test Statistic Q less than or equal to 1 microgram.

4.2. In the event that a Settling Defendant fails to meet the requirements of section 4.1, the Attorney General shall, upon motion brought to enforce this Consent Judgment, obtain from such Settling Defendant a stipulated penalty for each Covered Product shipped in violation of this Consent Judgment, in accordance with Section 12 hereof. Such penalties shall be in addition to, and not in lieu of, any

injunctive relief available to enforce this Consent Judgment.

5. Verification

5.1. First Report. On or before the ninetieth day following entry of this Consent Judgment, for each Covered Product which has been tested in accordance with the NSF Protocol, each Settling Defendant shall submit to the Attorney General a schedule identifying, by model number or by model series,

(a) each Covered Product it manufactures and ships for sale in California, and which is intended for use in a kitchen, for which the NSF Test Statistic Q is less than or equal to 5 micrograms; and

(b) each Covered Product it manufactures and ships for sale in California, and which is intended for use other than in a kitchen, for which the NSF Test Statistic Q is less than or equal to 11 micrograms.

5.2. Second Report. On or before March 31, 1997, each Settling Defendant shall submit to the Attorney General a schedule identifying all Covered Products, by model number or model series, it manufactured for sale or use in California, as of December 31, 1996, for which the NSF Test Statistic Q is greater than 11 micrograms.

5.3. Additional Reports. Each Settling Defendant shall provide to the Attorney General on or before March 31, 1998 a schedule showing, by model number or model series, all Covered Products it manufactures and ships for sale in California, for which the NSF Test Statistic Q is:

(a) for Covered Products intended for installation in a kitchen, less than or equal to 5 micrograms:

(b) for Covered Products intended for installation in a kitchen, greater than 5 micrograms, but less than or equal to 11 micrograms;

(c) any other Covered Product less than or equal to 5 micrograms; and

(d) any other Covered Product, greater than 5 micrograms, but less than or equal to 11 micrograms.

5.4. Each schedule required pursuant to this section 5 shall be certified by an independent third party, selected by each Settling Defendant, which has a drinking water additives certification program accredited by the American National Standards Institute ("ANSI"). For each category reported pursuant to section 5.3, each Settling Defendant shall also report the percentage of total Covered Product shipped to California in the preceding calendar year that falls within such category.

5.5. Each Settling Defendant shall make a submission as required under section 5.3 no later than March 31, 1998, and on or before March 31 of every year thereafter (for the preceding calendar year), until the submission establishes that at least 95% of Covered Products manufactured for sale in California by such Settling Defendant have an NSF Test Statistic Q less than or equal to 5 micrograms, as required by this Consent Judgment. One year following the date upon which a Settling Defendant makes a submission that establishes that at least 95% of Covered Products

manufactured for sale in California during the intervening twelve month period by such Settling Defendant have an NSF Test Statistic Q less than or equal to 5 micrograms, such Settling Defendant shall submit to the Attorney General a final report establishing that at least 95% of Covered Products manufactured for sale in California by such Settling Defendant have an NSF Test Statistic Q less than or equal to 5 micrograms, as required by this Consent Judgment.

5.6. Until a Settling Defendant's submission establishes that at least 95% of Covered Products manufactured for sale in California by such Settling Defendant have an NSF Test Statistic Q less than or equal to 5 micrograms, as required by this Consent Judgment, such Settling Defendant shall submit a schedule showing changes to the schedule required under section 5.3:

(a) each time it adds a new or different Covered Product to its product line manufactured for sale in California; and

(b) each time there is a change of design or manufacturing process where such change could reasonably be expected to produce a change in the NSF Test Statistic Q sufficient to cause the Covered Product to be classified in a different category in the schedule required by section 5.3.

For purposes of this Consent Judgment, a Covered Product is new, or different from existing Covered Products if such Covered Product does not qualify for inclusion as a representative member of a product line, as provided for in section 8.1 of Appendix B of the NSF Protocol or is not of

"Similar Application" as that term is used in section 9.2.2 of the NSF Protocol.

5.7. Any documents provided to the Attorney General under this section shall not, without the permission of the submitting party, be made available to the public unless required by the California Public Records Act or other laws, or except as part of presenting such records to a court as part of any proceeding. If a request for such records under the California Public Records Act or other law is made, the Attorney General shall respond to the request in the manner he determines is required by law. The Attorney General shall immediately notify the Settling Defendant whose Covered Product is at issue, of the receipt of any such request, and shall provide written notice to each such Settling Defendant 10 days prior to releasing any records pursuant to such a request. The Attorney General shall immediately notify the Settling Defendant of his intent to use such records in, or produce such records for, any court proceeding, other than a proceeding to enforce the terms of this Consent Judgment, and shall provide written notice to the Settling Defendant at least 10 days prior to such use, unless the time allotted by the subject court necessitates a more limited period of notice, in which case the Attorney General shall provide notice to the Settling Defendant by telephone at least 48 hours prior to the court proceeding giving rise to the claim of necessity.

5.8. The Attorney General may request additional information in support of the reports required pursuant to

this Consent Judgment at any time and may, upon a showing of good cause, move to obtain from each Settling Defendant, such additional information as is reasonable and necessary to verify the accuracy and truthfulness of the reports required pursuant to this section 5.

6. Duties Limited to California

This Consent Judgment shall have no effect on Covered Products sold by Settling Defendants for use outside the State of California.

7. Litigation Costs

No later than 30 days after entry of this Consent Judgment, Settling Defendants collectively, except U. S. Brass, shall pay the sum of $50,000 as reimbursement for the People's costs and fees in investigating and prosecuting this action. Said payment shall be made by delivery of certified funds payable to the California Public Health Foundation at 2001 Addison Street, Suite 210, Berkeley, California, (Attn: James Simpson, General Counsel), for deposit to the Environmental Health Account where it shall be used by the Attorney General to reimburse expenses incurred in this case or for investigating and prosecuting other matters concerning Proposition 65. The parties to this Consent Judgment also anticipate that this Fund may be used for the investigation and prosecution by the Attorney General of parties who are not defendants in this Action, but who may be manufacturing, importing, distributing or selling faucets in violation of Proposition 65. Except as specifically

provided in this Consent Judgment, each side shall bear its own costs and attorney's fees.

8. Lead Information Fund

8.1 Pursuant to this Consent Judgment and in consideration of the Consent Judgment that will concurrently be entered in the NRDC Action with respect to these Settling Defendants, Settling Defendants collectively shall pay $100,000 to a non-profit entity designated by the Attorney General to be used by agreement with the Attorney General, in consultation with Natural Resources Defense Council, the Environmental Law Foundation and the Settling Defendants, to fund activities relating to the education of the general public concerning lead in tapwater, which may include dissemination of information concerning leaching of lead from faucets, or free or reduced cost testing for lead in tapwater, or investigation of drinking water contamination that may violate Proposition 65. U.S. Brass shall make a payment of $30,000 of the $100,000 payment required by this section in accordance with section 8.2 hereof, and the other Settling Defendants shall collectively pay the remaining $70,000 by delivery of certified funds to the party designated by the Attorney General within 30 days after entry of this Consent Judgment as to Settling Defendants.

8.2 Within thirty (30) days after entry of this Consent Judgment, U.S. Brass shall file a motion with the Bankruptcy Court for the Eastern District of Texas, Sherman Division (the "Bankruptcy Court") seeking approval of a compromise and settlement of the People's Claim. In settlement of this

claim, the People shall have an Allowed General Unsecured Claim against U.S. Brass in the amount of $30,000 on which distributions shall be made in accordance with the plan of reorganization that is confirmed by the Bankruptcy Court. U.S. Brass will take all reasonable steps to secure approval of the compromise and settlement. The Attorney General shall reasonably cooperate with U.S. Brass in its efforts to secure such approval. The entry of an order by the Bankruptcy Court approving the compromise and settlement (the "Compromise Order") is a condition precedent to the Consent Judgment becoming effective as to U.S. Brass. Distributions on account of the People's Claim shall be made to the fund created pursuant to section 8.1 of this Consent Judgment. Upon entry of the Compromise Order, the Attorney General shall submit to the Bankruptcy Court an order withdrawing the People's Claim.

9. Action by Private Plaintiffs

This Consent Judgment is entered in conjunction with a Consent Judgment filed in Natural Resources Defense Council, et al. v. Price Pfister, Inc., et al., S.F. Superior Ct. No. 948024, as to Settling Defendants. In conjunction with said Consent Judgment, this Consent Judgment provides a complete resolution of all claims which were or could have been made against the Settling Defendants based on the facts alleged in the Private Plaintiffs' action.

10. Modification of Consent Judgment

This Consent Judgment may be modified by written agreement of the Attorney General and the Settling Defendant to whom

the modification applies, after noticed motion, and upon entry of a modified Consent Judgment by the Court thereon, or upon motion of the Attorney General or any Settling Defendant as provided by law and upon entry of a modified Consent Judgment by the Court.

11. Additional Enforcement Actions; Continuing Obligations

By entering into this Consent Judgment, the People do not waive any right to take further enforcement actions with respect to matters not addressed by section 15 of this Consent Judgment.

12. Enforcement of Consent Judgment

The Attorney General may, by motion or order to show cause before the Superior Court of San Francisco, enforce the terms and conditions contained in this Consent Judgment. In any such proceeding the Attorney General shall seek to enforce this Consent Judgment by seeking injunctive relief and/or stipulated penalties, which the Attorney General shall recover in the amount of $1.00 for each Covered Product sold for installation in a residential setting in violation of this Consent Judgment. In no event shall the same Covered Product be subject to more than one stipulated penalty, including but not limited to any stipulated penalty sought by the Private Plaintiffs pursuant to the Consent Judgment entered in NRDC et al v. Price-Pfister et al, S.F. Superior Court No. 948024.

13. Application of Consent Judgment

This Consent Judgment shall apply to and be binding upon the People and the Settling Defendants, their divisions, subdivisions, and the successors or assigns of any of them. For purposes of this Consent Judgment, the term "Settling Defendants" shall be deemed to include direct and indirect subsidiaries of Masco Corporation that manufacture faucets.

14. Authority to Stipulate to Consent Judgment

Each signatory to this Consent Judgment certifies that he or she is fully authorized by the party he or she represents to stipulate to this Consent Judgment and to enter into and execute the Consent Judgment on behalf of the party represented and legally to bind that party.

15. Claims Covered

This Consent Judgment is a final and binding resolution between the People and each Settling Defendant, of any violation of Proposition 65, Business and Professions Code Sections 17200 et seq., or any other statutory or common law claim that could have been asserted against any of them for failure to provide clear, reasonable, and lawful warnings of exposure to lead that leaches into water that passes through faucets, including but not limited to Covered Products manufactured, sold or distributed by each Settling Defendant, or from knowingly discharging lead into any source of drinking water in violation of Proposition 65 as a result of the use of each Settling Defendant's faucets, including but not limited to Covered Products, manufactured, sold or distributed by each Settling Defendant, or any other

claim based on the facts alleged in the Complaint, whether based on actions committed by any of the Settling Defendants, or by any entity within their chain of distribution, including, but not limited to, retail sellers and any other person in the course of doing business, with respect to faucets manufactured, sold or distributed by a Settling Defendant. As between the People and any Settling Defendant, compliance with the terms of this Consent Judgment resolves any issue, now and in the future, concerning compliance by any Settling Defendant, its parent, subsidiaries or affiliates, and its customers, distributors, wholesalers, retailers or any other person in the course of doing business who may use, maintain or sell faucets manufactured, sold or distributed by a Settling Defendant, with the requirements of Proposition 65 and the Unfair Competition Act with respect to lead in its faucets, including but not limited to Covered Products, and any resulting consumer exposure or discharge into drinking water. For purposes of this Consent Judgment, the term "faucet" shall mean a device from which water empties into a sink, tub or drain and which provides drinking water to the consuming public, including hot water dispensers and similar products, but excluding drinking water fountains other than bubblers listed in Exhibit B as Covered Products. Nothing in this section shall be construed to affect the liability of any defendant in this Action, other than the Settling Defendants.

16. Use of Documents

The Attorney General shall not use documents that any Settling Defendant has produced in the course of this Action or in settlement discussions during the course of this Action in a manner that would violate the Protective Order entered in this Action without first obtaining the written consent of the Settling Defendant that produced the document(s) in question. The Protective Order is hereby incorporated into this Consent Judgment as if fully set forth herein.

17. Retention of Jurisdiction

This Court shall retain jurisdiction of this matter to implement the Consent Judgment.

18. Provision of Notice

18.1. When any party is entitled to receive any notice or report under this Consent Judgment, the notice or report shall be sent by overnight courier service to the person and address set forth in this paragraph. Any party may modify the person and address to whom notice is to be sent by sending each other party notice by certified mail, return receipt requested. Said change shall take effect for any notice mailed at least five days after the date the return receipt is signed by the party receiving the change.

18.2. Notices or reports shall be sent to the following:

For the Attorney General:
Edward G. Weil
Deputy Attorney General
2101 Webster Street, 12th Floor
Oakland, CA 94612
Telephone: 510-286-1362
Telecopier: 510-286-4020

For American Standard, Inc.:
Office of the Secretary
American Standard Inc.
One Centennial Avenue
P.O. Box 6820
Piscataway, NJ 08855-6820
Telephone: 908-980-2300

For Elkay Manufacturing Company:
President, Elkay Division
Elkay Manufacturing Company
2222 Camden Court
Oak Brook, IL 60521
Telephone: 708-574-8484
Telecopier: 708-574-8629

For Masco Corporation of Indiana:

General Counsel
Masco Corporation
21001 Van Born Road
Taylor, MI 48180
Telephone: 313-374-6358
Telecopier: 313-374-6135

with a copy to:

Michele Corash, Esq.
Morrison and Foerster
345 California Street
San Francisco, CA 94104
Telephone: 415-677-7124
Telecopier: 415-677-6284

For Moen Incorporated:

Office of the President
Moen Incorporated
25300 Al Moen Drive
P.O. Box 8022
North Olmsted, OH 44070-8022
Telephone: 216-962-2000
Telecopier: 216-962-2725

with a copy to:

Office of the General Counsel
American Brands Inc.
PO Box 811
1700 East Putnam Avenue
Old Greenwich, CT 06870
Telephone: 203-698-5150
Telecopier: 203-698-5172

For Universal-Rundle Corporation:
Office of the General Counsel
NORTEK Inc.
50 Kennedy Plaza
Providence, RI 02903
Telephone: 401-751-9844

For Eljer Manufacturing, Inc.	with a copy to:
Vice President and General Counsel 17120 Dallas Parkway Dallas, TX 75248 Telephone: 214-407-2600 Telecopier: 214-407-7238	Kurt Weissmuller, Esq. McClintock, Weston, Benshoof, Rochefort, Rubalcava & MacCuish 444 South Flower Street Los Angeles, CA 90071 Telephone: 213-623-2322 Telecopier: 213-623-0824
For United States Brass Corporation:	with a copy to:
Vice President and General Counsel 17120 Dallas Parkway Dallas, TX 75248 Telephone: 214-407-2600 Telecopier: 214-407-7238	Kurt Weissmuller, Esq. McClintock, Weston, Benshoof, Rochefort, Rubalcava & MacCuish 444 South Flower Street Los Angeles, CA 90071 Telephone: 213-623-2322 Telecopier: 213-623-0824

19. Pending Proceedings

This Consent Judgment is in no way contingent on the outcome of the pending proceedings in People v. Superior Court (American Standard) (S.F. Superior Court No. 948017) or Natural Resources Defense Council, et al v. Price-Pfister, et al (S.F. Superior Court No. 948024). Upon entry of this Consent Judgment, the Attorney General shall advise the court before which that proceeding is pending, if any, of the entry of this Consent Judgment.

20. Individual Obligations

Except as set forth in sections 7 and 8 hereof, the obligations of the Settling Defendants pursuant to this Consent Judgment are individual to each of them and are in

_____ Dated: _____
For Elkay Manufacturing Company

_____ Dated: _____
For Masco Corporation of Indiana

_____ Dated: _____
For Moen Incorporated

_____ Dated: _____
For Universal-Rundle Corporation

VP-Gen. Counsel Dated: 8-25-95
For Eljer Manufacturing, Inc.

Mark Rendall VP-General Counsel Dated: 8/25/95
For United States Brass Corporation

IT IS SO ORDERED, ADJUDGED AND DECREED.

DATED: _____ _____
JUDGE OF THE SUPERIOR COURT

_____ Dated: _____
For Elkay Manufacturing Company

_____ Dated: _____
For Masco Corporation of Indiana

_____ Dated: _____
For Moen Incorporated

RJ Regel Dated: August 28, 1995
For Universal-Rundle Corporation

_____ Dated: _____
For Eljer Manufacturing, Inc.

_____ Dated: _____
For United States Brass Corporation

IT IS SO ORDERED, ADJUDGED AND DECREED.

DATED: _____ _____
JUDGE OF THE SUPERIOR COURT

_____ Dated: _____

For Elkay Manufacturing Company

_____ Dated: _____

For Masco Corporation of Indiana

_____ Dated: AUGUST 29, 1995

For Moen Incorporated

_____ Dated: _____

For Universal-Rundle Corporation

_____ Dated: _____

For Eljer Manufacturing, Inc.

_____ Dated: _____

For United States Brass Corporation

IT IS SO ORDERED, ADJUDGED AND DECREED.

DATED: _____ _____

JUDGE OF THE SUPERIOR COURT

_____ Dated: _____
For Elkay Manufacturing Company


_____ Dated: August 28, 1995
For Masco Corporation of Indiana

_____ Dated: _____
For Moen Incorporated

_____ Dated: _____
For Universal-Rundle Corporation

_____ Dated: _____
For Eljer Manufacturing, Inc.

_____ Dated: _____
For United States Brass Corporation

IT IS SO ORDERED, ADJUDGED AND DECREED.

DATED: _____ _____
JUDGE OF THE SUPERIOR COURT

Richard A Batchman
For Elkay Manufacturing Company Dated: 8-25-95

For Masco Corporation of Indiana Dated: _____

For Moen Incorporated Dated: _____

For Universal-Rundle Corporation Dated: _____

For Eljer Manufacturing, Inc. Dated: _____

For United States Brass Corporation Dated: _____

IT IS SO ORDERED, ADJUDGED AND DECREED.

DATED: _____ JUDGE OF THE SUPERIOR COURT

no way collective or joint. No Settling Defendant shall be held responsible for the failure of any other Settling Defendant to comply with the terms hereof.

21. Court Approval

If this Consent Judgment is not approved by the Court, it shall be of no force or effect and cannot be used in any proceeding for any purpose.

22. Execution in Counterparts

The stipulations to this Consent Judgment may be executed in counterparts and/or by facsimile, which taken together shall be deemed to constitute one document.

IT IS SO STIPULATED:

DATED: _____, 1995

DANIEL E. LUNGREN, Attorney General of the State of California
Chief Assistant Attorney General
THEODORA BERGER
Assistant Attorney General
CRAIG C. THOMPSON
EDWARD G. WEIL
SUSAN S. FIERING
Deputy Attorneys General

By: Edward G. Weil
Deputy Attorney General
Attorneys for People of the State of California

For American Standard, Inc.

Dated: 8/25/95

EXHIBIT A

Exhibit A

NSF Protocol as in effect on August 1, 1995

DRINKING WATER SYSTEM COMPONENTS - HEALTH EFFECTS

NSF *International* Standard

NSF 61, Section 9 - 1994

Developed by a consortium of:

- NSF *International* (lead)
- The American Water Works Association Research Foundation
- The Association of State Drinking Water Administrators
- The American Water Works Association

NSF

The mission of NSF is to provide clients and the general public with objective, high quality, timely, third-party services at acceptable cost. Services include development of consensus standards, voluntary product testing and certification with policies and practices which protect the integrity of registered Marks, education and training, and research and demonstration, all relating to public health and the environmental sciences.

This Standard is subject to revision.
Contact NSF to confirm this revision is current.

Users of this Standard may request clarifications and interpretations, or propose revisions by contacting:

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NSF *International*

STANDARD 61, SECTION 9 - 1994

DRINKING WATER SYSTEM COMPONENTS — HEALTH EFFECTS

As Prepared by

The NSF Joint Committee on Drinking Water Additives

and

Recommended for Adoption by

The NSF Council of Public Health Consultants

Adopted by

The NSF Board of Trustees

September 1994

PREFACE

In response to a competitive request for proposals from the U.S. Environmental Protection Agency (EPA), a Consortium led by NSF *International* (NSF) agreed to develop voluntary third-party consensus standards and a certification program for all direct and indirect drinking water additives. Other members of the Consortium include the American Water Works Association Research Foundation, the Association of State Drinking Water Administrators, the Conference of State Health and Environmental Managers, and the American Water Works Association. (COSHEM has since become inactive as an organization.) Each organization was represented on a steering committee with oversight responsibility for the administration of the cooperative agreement. The Steering Committee provides guidance on overall administration and management of the cooperative agreement. Currently, the member organizations remain active in an oversight role.

Two standards for additives products were developed. NSF Standard 60: Drinking Water Treatment Chemicals — Health Effects covers many of the water treatment chemicals, also known as direct additives. This standard, Standard 61: Drinking Water System Components — Health Effects, covers all indirect additives products and materials. Testing to determine the potential of a product to impart taste and/or odor to drinking water is not included in this standard.

Standard 61 was developed to establish minimum requirements for the control of potential adverse human health effects from products which contact drinking water. It does not attempt to include product performance requirements which are currently addressed in other voluntary consensus standards established by such organizations as the American Water Works Association, the American Society for Testing and Materials, and the American National Standards Institute. Because this Standard complements the performance standards of these organizations, it is recommended that products also meet the appropriate performance requirements specified in the standards of such organizations.

Standard 61, and subsequent product certification against it, has replaced the EPA Additives Advisory Program for drinking water system components. EPA terminated its advisory role in April of 1990. For more information with regard to EPA's actions, refer to the July 7, 1988 *Federal Register* (53FR25586).

The standard and the accompanying text are intended for voluntary use by certifying organizations, utilities, regulatory agencies, and/or manufacturers as a basis of providing assurances that adequate health protection exists for covered products. Product certification issues, including frequency of testing and requirements for follow-up testing, evaluation, enforcement, and other policy issues are not addressed by the standard.

NSF Standard 61 was initially adopted by ANSI in 1989, and most recently, in 1993. NSF and all stakeholders, have worked since 1988 to complete Standard 61, by the inclusion of mechanical plumbing products. Devices used within the final one liter of the distribution system are covered under Section 9, and include end-point devices such as faucets, glass fillers, water coolers, residential ice makers, and supply stops.

Section 9 was accepted by the NSF Joint Committee on Drinking Water Additives, and the NSF Council of Public Health Consultants. It was adopted by the NSF Board of Trustees on September 9, 1994, and is now finalized as NSF Standard 61, Section 9.

DISCLAIMERS

NSF *International* (NSF), in performing its functions in accordance with its objectives, does not assume or undertake to discharge any responsibility of the manufacturer or any other party. The opinions and findings of NSF represent its professional judgment. NSF shall not be responsible to anyone for the use of or reliance upon this standard by anyone. NSF shall not incur any obligations or liability for damages, including consequential damages, arising out of or in connection with the use, interpretation of, or reliance upon this standard.

Participation in NSF's standards development activities by a representative of a regulatory agency (Federal, state, local) shall not be construed as the agency's endorsement of NSF, its policies, or any of its standards.

NSF standards provide basic criteria to promote and protect public health. Provisions for safety have not been included in this standard because governmental agencies or other national standards-setting organizations provide safety requirements.

Unless otherwise referenced, the appendices are not considered an integral part of NSF standards. They are provided as general guidelines to the manufacturer, regulatory agency, user, or certifying organization.

CONSORTIUM ORGANIZATIONS

NSF *International*

Popularly referred to as NSF, NSF *International* is a noncommercial agency. It is incorporated under the laws of Michigan as a not-for-profit organization devoted to research, education, and service. It seeks to solve problems involving man and his environment. It wishes to promote health and enrich the quality of life through conserving and improving that environment. Its fundamental principle of operation is to serve as a neutral medium in which business and industry, official regulatory agencies, and the public come together to deal with problems involving products, equipment, procedures, and services related to health and the environment. It is conceived and administered as a public service organization.

NSF is perhaps best known for its role in developing standards and criteria for equipment, products, and services that bear upon health. NSF was the lead organization in the Consortium responsible for developing this Standard. NSF conducts research; tests and evaluates equipment, products, and services for compliance with standards and criteria; and grants and controls the use of NSF registered Marks.

NSF offers product certification (Listing Services) for all products covered by its standards. Each program has established policies governing the associated product evaluation, Listing Services, follow-up and enforcement activities. The NSF Listing Mark is widely recognized as a sign that the product or service to which it relates complies with the applicable NSF standard(s).

AWWA Research Foundation

The mission of the American Water Works Association Research Foundation (AWWARF) is to sponsor practical, applied research in behalf of the drinking water industry of North America. The scope of the research program embraces all aspects of water supply operation, from development and maintenance of water resources to treatment technologies and water quality issues, from storage and distribution system operations to health effects studies and utility planning and management activities. AWWARF serves as the centralized industry institution for planning, managing, and funding cooperative research and development in drinking water, including the subsequent transfer of technology and results for practical application by the water utility community.

AWWARF's purpose in this cooperative program is to provide a communication link with the water utilities throughout North America and serve as the focal point for identification of research needs of the water supply industry with respect to the additives program.

The Association of State Drinking Water Administrators

The Association of State Drinking Water Administrators (ASDWA) is a non-profit organization whose eligible membership is comprised of drinking water program administrators in each of the 50 states and 7 U.S. territories. Through the organization, representatives speak with a collective voice to Congressional committees, the United States Environmental Protection Agency (EPA), professional and trade associations, water utilities, and the general public on issues related to state drinking water programs. With its mission of protecting the public health through assurance of high quality drinking water, and promoting responsible, reasonable, and feasible drinking water programs at the state and federal levels, the Association is a valued contributor to the consortium, and to the program. It provides the link between the additives program and the state drinking water programs.

The Conference of State Health and Environmental Managers

The Conference of State Health and Environmental Managers (COSHEM), known formerly as the Conference of State Sanitary Engineers (CSSE), is currently inactive as an organization. It brought to the consortium expertise and involvement of state health and environmental program managers. The Conference was the focal point for health concerns of all state environmental programs, including drinking water, wastewater, air, solid and hazardous wastes, radiological, occupational, health, and food. A standing committee on water supply focused on drinking water issues and kept the membership informed. The Conference played an important role early in the program through two-way communication with state health and environmental program decision makers.

American Water Works Association

The purpose of the American Water Works Association (AWWA) is to promote public health, safety, and welfare by improving the quality and increasing the quantity of water delivered to the public, and to developing and furthering an understanding of the problems relating thereto by:

- advancing the knowledge of the design, construction, operation, water treatment and management of water utilities;
- developing standards for procedures, equipment, and materials used by public water supply systems;
- advancing the knowledge of problems involved in the development of resources, production, and distribution of safe and adequate water supplies;
- educating the public on the problems of water supply and promoting a spirit of cooperation between consumers and suppliers in solving these problems; and
- conducting research to determine the causes of problems of providing a safe and adequate water supply and proposing solutions thereto in an effort to improve the quality and quantity of the water supply provided to the public.

AWWA brings to the Consortium its established position as the largest public drinking water association in North America, with a broad membership that includes utilities, consultants, manufacturers/distributors/
agents, contractors, and other organizations with a direct interest in drinking water.

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APPENDICES

[1]This Appendix is not part of the Standard.

NSF STANDARD 61, SECTION 9

DRINKING WATER SYSTEM COMPONENTS — HEALTH EFFECTS

SECTION 1. GENERAL

1.0 SCOPE: This standard is intended to cover specific materials or products that come into contact with drinking water and/or in contact with drinking water treatment chemicals. The primary focus of the standard is on contaminants or impurities which may be imparted indirectly to drinking water. The products and/or materials covered include, but are not limited to process media (carbon, sand, etc.), protective materials (coatings, linings, liners, etc.), joining and sealing materials (solvent cements, adhesives, welding materials, gaskets, etc.), pipes and related products (pipes, tanks, fittings, etc.), and mechanical devices used in treatment/transmission/distribution systems (valves, chlorinators, separation membranes, etc.).

1.1 LIMITATIONS: The requirements of this standard are limited to addressing potential health effects, except where specific application and/or performance standards are referenced. The criteria set forth in this standard cover products produced by good manufacturing practices and generally recognized manufacturing processes. As the presence of unusual or unexpected impurities may be dependent upon the method of manufacture and the quality of raw material used, products prepared by other than recognized methods of manufacture or with unusual raw materials shall be fully evaluated in accordance with Section 3.0 of this standard (general requirements). Products that have been evaluated and found to meet other NSF standards having health requirements equivalent to this standard as indicated in each section shall be acceptable for drinking water applications without separate evaluation under this standard.[1]

1.2 ALTERNATE MATERIALS: Where specific materials are mentioned in this standard, it is understood that the use of alternate materials will be acceptable provided they are evaluated in a manner that is at least as stringent as specified by the standard for a similar use condition, and determined to be satisfactory. Products using specific materials not named in the appropriate section of this standard shall have these unnamed materials evaluated in a manner consistent with the appropriate requirements, based on end use, for the product.

1.3 STANDARD REVIEW: A complete review of this standard shall be conducted at least every five (5) years to keep requirements consistent with new technology. These reviews shall be conducted by representatives of industry, public health, and users on the Joint Committee for Drinking Water Additives.

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[1]Final acceptance of a product for drinking water application is the responsibility of the appropriate federal, state, and/or local regulatory agent.

SECTION 2. DEFINITIONS

2.0 CERTIFYING AGENCY: The organization which tests and evaluates the product and attests that the product meets the standard.

2.1 CHAIN-OF-CUSTODY: This is a procedure used to create a written record that can be used to trace the possession and handling of a sample from the point of collection through analysis. Refer to the EPA Manual For the Certification of Laboratories Analyzing Drinking Water (EPA 570/9-82-002) for more information.

2.2 CONTAMINANT: Any physical, chemical, biological, or radiological substance or matter in water. (This term is consistent with the definition in the Federal Safe Drinking Water Act. A contaminant under this definition may have a beneficial or detrimental effect on the potability of the water.)

2.3 DIRECT ADDITIVE: Contaminants added to water in the production of drinking water.

2.4 DISTRIBUTION SYSTEM: A system of conduits (e.g., pipes) by which a primary water supply is distributed to consumers. This term applies particularly to the network or pipelines in the streets in a domestic water system.

2.5 DRINKING WATER: Water intended for human consumption.

2.6 GOOD MANUFACTURING PRACTICE: The practice of maximizing the purity of the product by maintaining and practicing appropriate quality control and quality assurance procedures.

2.7 INDIRECT ADDITIVE: Contaminants that are introduced to drinking water through contact with surfaces of materials or products used for its treatment, storage, transmission, and/or distribution.

2.8 MANUFACTURER: A corporation, company, or individual that produces, formulates, packages or repackages products used in contact with drinking water.

2.9 MAXIMUM CONTAMINANT LEVEL (MCL): Maximum concentration of a contaminant allowed in a public drinking water supply as defined under the Federal Safe Drinking Water Act. (NOTE: If the manufacturer requests review relevant to Canadian requirements, the certifying agency may consider alternative regulatory levels; e.g., Canadian Maximum Acceptable Concentrations [MACs].)

2.10 MAXIMUM ALLOWABLE LEVEL (MAL): The maximum concentration of a contaminant in drinking water that a single product is allowed to contribute under this standard.

2.11 NORMALIZED CONCENTRATION: A value for contaminant concentration from a laboratory extraction test adjusted to reflect the contaminant concentration under field conditions.

2.12 NORMALIZATION: The process of adjusting laboratory extraction results to represent estimated exposure levels "at-the-tap."

2.13 TRANSMISSION SYSTEM: A system of conduits (e.g., pipes) by which a primary water supply is transmitted to the distribution system.

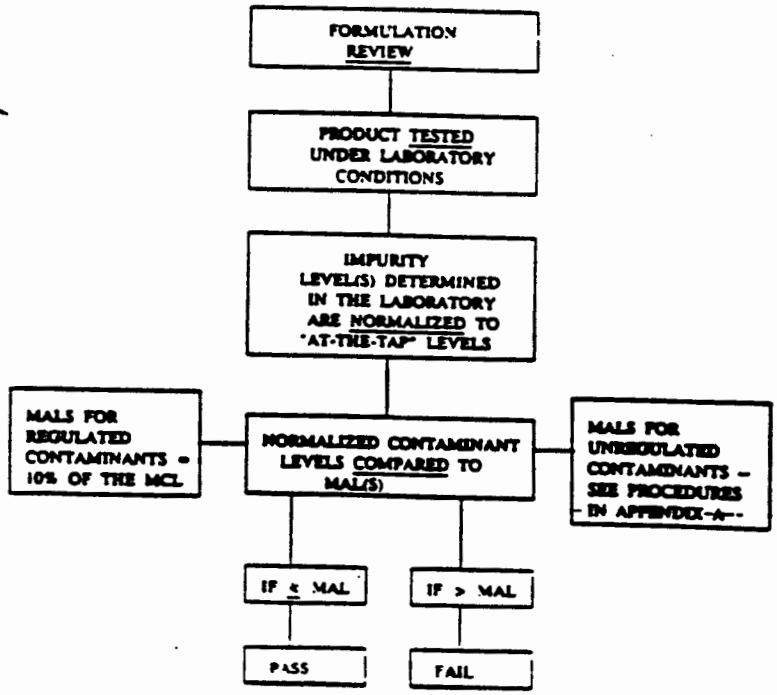
SECTION 3. GENERAL REQUIREMENTS

3.0 GENERAL: Indirect additives shall be evaluated and tested in accordance with Appendices A and B. The Maximum Allowable Level (MAL) of a contaminant and indirect additive shall be calculated as outlined in Appendix A and shall not be exceeded for acceptance of a product under this standard. Under the provisions of this standard, a product shall not contribute any contaminant to drinking water in excess of the contaminant's MAL.

Indirect additives under this standard shall be:

- The covered contaminants listed in each of the product sections of this standard; and,
- Other constituents and contaminants as identified in the formulation review under Appendix A.

The following diagram provides an overview of the evaluation procedure.



3.1 ACCEPTABLE MATERIALS: Materials shown in Appendix C shall not require additional testing to meet the requirements of this standard. Appendix C shall be subject to review as new toxicological data becomes available.

3.1.1 REQUIREMENTS: To be included in Appendix C, materials must meet all the following requirements and be accepted in accordance with NSF policies and procedures governing revisions to NSF standards.

3.1.1.1 Documentation shall be provided that addresses the production process(es), raw material sources, and other factors that may affect final product composition and variability.

3.1.1.2 The material shall conform to a published material formulation standard (e.g., ASTM, ANSI, ISO).[2]

3.1.1.3 Extraction data, using surface area to volume testing ratio proposed to be shown in Appendix C shall be provided. A minimum of 30 random samples for each type of production process shall be tested.[3] The normalized extractant concentrations shall not exceed MALs as established in accordance with the standard. The exposure and test methods used shall be described and detection limits provided. The following minimum information shall be provided:

- Supporting documentation for method detection limit study.
- Quality control data run concurrently with the samples.
- Description of method and instrumentation used.
- Verification that the laboratory is certified for drinking water analysis by the regulatory agency having authority.

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[2]American Society for Testing and Materials (ASTM), 1916 Race St., Philadelphia, PA 19103-1187.

American National Standards Institute (ANSI) 11 West 42nd Street, New York, NY 10036.

International Organization for Standardization (ISO), 1, Rue de Verembe, Case Postal 56, CH-1211 Geneve 20, SWITZERLAND/SUISSE.

[3]The sample number was chosen based on a power of 96% and p value of 0.10.

3.1.1.4 A complete report, with justification, as to how the requirements of Sections 3.1.1.1 through 3.1.1.3 have been met shall be provided to the NSF Joint Committee on Drinking Water Additives to use in its consideration of additions to Appendix C.

3.1.1.5 Materials accepted into Appendix C are subject to future reconsideration because of revised MALs, revised justification criteria presented in Section 3.1.1, or for other reasons determined to be appropriate by the Joint Committee.

SECTION 9. MECHANICAL PLUMBING DEVICES

9.0 COVERAGE: This section covers mechanical plumbing devices, components, and materials which are typically installed within the last liter of the distribution system (endpoint devices) and are intended by the manufacturer to dispense water for human ingestion. In-line devices are excluded from this section. Point-of-use and point-of-entry water treatment devices are excluded.

Endpoint devices specifically included in this section are:

1. Lavatory single and two handle faucets (for example: centersets, widespread, mini-spread, and basin cocks) without a hose end spout and which are not metering, self-closing, or electronic.
2. Residential two hole and single hole bar faucets.
3. Residential kitchen single and two handle faucets (for example: top mounts, concealed fittings, and wall mounts) without a hose end spout.
4. Hot and cold water dispensers.
5. Drinking fountains, drinking fountain bubblers, and water coolers.
6. Glass fillers.
7. Commercial and institutional kitchen and bar faucets.
8. Residential refrigerator ice-makers.
9. Supply stops and endpoint control valves.

Endpoint devices specifically excluded in this section are:

1. Bath and shower valves, shower heads of all types, and Roman tub valves.
2. All drains.
3. Residential laundry fittings, shampoo fittings, and faucets with a hose end spout.
4. All commercial, industrial, and institutional devices that are not specifically included in this section, such as:
   a. Self-closing, metering, or electronically activated faucets
   b. Utility, laundry, laboratory, bidet, and shampoo fittings
   c. Faucets with a hose end spout.
5. Backflow prevention devices

9.1 DEFINITIONS

9.1.1 WATER DISTRIBUTION SYSTEM (BUILDING): A continuous system of piping, devices and related fittings, beginning after the water meter and water meter setting equipment, which is intended to convey potable water in a building to points of usage.

9.1.2 IN-LINE DEVICE: Any device installed downstream of the water meter assembly and before the endpoint devices.

9.1.3 ENDPOINT DEVICE: Any single device typically installed within the last one liter of the water distribution system of a building.

9.2 DEVICE, COMPONENT, OR MATERIAL REQUIREMENTS:

9.2.1 GENERAL: Devices, components, or materials shall be considered to have met the requirements of this standard if at least one of the following conditions are met:

1. The devices, components, or materials covered under this section are tested and evaluated according to procedures specified in Appendix B, Sections 8 and 12; OR

2. The devices, components, or materials meet the requirements of another section of this standard for similar application.

Where all components and/or materials of a device meet the requirements of this standard, and are deemed to be of a similar application as the device, the device shall also meet the requirements of this standard. Where all materials of a component meet the requirements of this standard, and are deemed to be of a similar application as the component, the component shall also meet the requirements of this standard.

9.2.2 SIMILAR APPLICATION: Prior to making a determination that a device, component or material is of a similar application, the following shall have been evaluated and found to be true:

1. The device, component, or material sample used to qualify a device, component or material under Section 9.2.1 shall:

   a. be made of the same alloy(s), composition(s), or formula(s);

   b. have undergone analogous manufacturing processes;

c. have been tested at a temperature that meets or exceeds the required exposure temperature in Appendix B, Section 8;

d. have been conditioned and exposed for the same period of time in Appendix B, Section 8 or the concentration of the contaminant shall be normalized to reflect the exposure in Appendix B, Section 8;

e. have a surface area to volume ratio which meets or exceeds that of the device, component, or material to be qualified.

2. The combination of normalized concentrations, from components and/or materials, for specific contaminants shall not exceed the MALs specified in Appendix A when materials and components are used to qualify components or devices.

9.2.3 SUPPORT OF MICROBIOLOGICAL GROWTH: Devices, components, or materials which meet the microbiological growth support requirements of another section of this standard shall be exempt from further microbiological growth support testing. In addition, metallic devices, components, or materials shall also be exempt from microbiological growth support requirements. Other devices, components, or materials requiring evaluation (e.g., coatings, gaskets) shall be tested in accordance with Appendix D.

9.3 EXPOSURE AND NORMALIZATION: Samples for testing shall be prepared, exposed, and the extractant water analyzed as required in Appendix B, Section 8. The number of samples tested shall be determined as outlined in Appendix B, Section 8.4.

Exposure of endpoint devices, except for hot water dispensers, shall be limited to cold temperature. Materials and components shall be exposed at a surface area to volume ratio sufficiently rigorous to ensure that the required laboratory detection limits are achieved for all analytes after normalization.

The concentration of extracted contaminants shall be normalized to end use conditions according to the normalization procedure outlined in Appendix B, 12.0 for endpoint devices. Normalized concentrations of contaminants, except for lead, shall be no greater than the MALs specified in Appendix A.

The amount of lead from endpoint devices, except for commercial kitchen and bar faucets, shall not exceed 11 µg when normalized for the 1 liter first draw sample. (This is based on a limit of 15 µg total lead, including the lead contributed from the device interior as well as from sources other than the device, which shall be assumed to be 4 µg.) The amount of lead from commercial kitchen and bar faucets shall not exceed 11 µg when normalized for the first 5 gallon (18.9 liter) draw sample.

APPENDIX A

TOXICOLOGY REVIEW AND EVALUATION PROCEDURES

(This Appendix is part of the Standard)

1.0 General

2.0 Application and Evaluation Stage
- 2.0.1 Product Use
- 2.0.2 Formulation Information
- 2.0.3 Exposure Data
- 2.0.4 Regulatory, Codex, or Other Acceptances for Substances
- 2.0.5 Justification for Submitted Information
- 2.0.6 Selection of Substances for Testing
- 2.0.7 Toxicity Test Guidelines
- 2.0.8 Potential Exposure Resulting from Short-Term, High-Level Contaminants
- 2.0.9 Application Verification

3.0 Risk Estimation
- 3.0.1 Regulated Contaminants
- 3.0.2 Unregulated Contaminants

APPENDIX A
TOXICOLOGY REVIEW AND EVALUATION PROCEDURES

1.0 GENERAL: These product/material (referred to as product) review and test guidelines are to assist in establishing the toxicity, if any, of the products under anticipated use conditions. Prior to initiating new toxicity testing, the applicant is strongly encouraged to discuss information requirements and test protocols with the certifying agency. If an EPA Maximum Contaminant Level (MCL) is available, no new toxicity testing and evaluation (Sections 2.0.6 and 2.0.7) may be necessary, but a risk estimate (Maximum Allowable Level or MAL) must be calculated per Appendix A, Section 3.0.

2.0 APPLICATION AND EVALUATION STAGE:

2.0.1 PRODUCT USE: The applicant shall identify the function and physical properties of the product.

2.0.2 FORMULATION INFORMATION: The applicant shall submit formulation information for the product in the form prescribed by the certifying agency, including complete product formulation (e.g., constituents in parts-per-hundred) and method of manufacture. The following information shall be provided for each constituent, as applicable: Chemical Abstracts Registry Number, structural formula, molecular weight, and source. A list of known or suspected impurities/contaminants shall be provided and their concentrations in the product noted. Selected spectra (e.g., UV/visible, infrared) may also be required for some additive products or their principal constituent(s).

2.0.3 EXPOSURE DATA: Estimated exposure concentrations for substances being tested will be determined according to the protocols described in Appendix B.

2.0.4 REGULATORY, CODEX, OR OTHER ACCEPTANCES FOR SUBSTANCES: If the product contributes a substance to water which is listed in the current U.S. Code of Federal Regulations (CFR), Title 21 (Food and Drug Regulations) or other applicable references, the references shall be provided. The certifying agency will evaluate the relevance of the reference to the intended drinking water use.

2.0.5 JUSTIFICATION FOR SUBMITTED INFORMATION: All health and safety information relevant to the evaluation of the product shall be provided to the certifying agency as noted in Section 2.0.7. The manufacturer shall describe how the submitted data satisfy the toxicity testing guidelines outlined in Section 2.0.7. To the extent the information and justification provided by the manufacturer satisfy the certification agency requirements, further toxicity testing according to the guidelines presented in Sections 2.0.6 and 2.0.7 may not be required.

2.0.6 SELECTION OF SUBSTANCES FOR TESTING: Toxicity testing guidelines presented in Section 2.0.7 are designed to examine the health impact of contaminants contributed to drinking water. Substances for testing could include, but are not limited to, the product as formulated, product constituents, total extractants, and any other chemicals contributed to the water as a result of product use. Manufacturers shall provide a rationale to justify their selection of test substances.

2.0.7 TOXICITY TEST GUIDELINES: Minimum testing guidelines for an additive are based on the anticipated human exposure to the additive, calculated using estimates of the concentration(s) of the test substance at the tap (see Section 3.0 for regulated and unregulated contaminants and the calculations described in Appendix B, Section 11.0). Toxicity testing guidelines are described for each of the following four ranges normalized contaminant concentrations: Level I (<10 ppb), Level II (≥10 and <50 ppb), Level III (≥50 and <1000 ppb), Level IV (≥1000 ppb) in Figures A1, A2, A3, and A4 respectively. These guidelines are not intended to be a rigid set of requirements, and may be modified, based on best scientific judgment, to either exclude and/or include certain toxicity testing. Each testing level includes a Supplemental Studies category for additional studies, if indicated. Supplemental Studies could include metabolism, pharmacokinetics, immunotoxicity, neurotoxicity, and other endpoints as appropriate. In some instances a second test species may be required for a traditional toxicity test. Toxicity testing shall be done in accordance with the most recent version of toxicity testing protocols such as those described by the Organization For Economic Cooperation and Development (OECD, 1985), U.S. Environmental Protection Agency (EPA, 1982), and Food and Drug Administration (FDA, 1982). All studies initiated to comply with this standard shall be conducted in accordance with Good Laboratory Practice (21 CFR, Pt 58/40 CFR, Pt 792).

A. LEVEL I (POTENTIAL HUMAN EXPOSURE FROM DRINKING WATER AT NORMALIZED CONTAMINANT CONCENTRATIONS <10 PPB)

Level I toxicity test guidelines include genetic toxicity testing and, if indicated, Supplemental Studies. For indirect additives, if the total normalized contaminant concentration is <10 ppb and the analysis of individual components is technically impractical and/or the constituents cannot be synthesized in quantities sufficient for testing, then genetic toxicity testing of the extractants should be considered. Genetic toxicity testing includes one assay from each of the following categories of genotoxicity tests: gene mutation (preferably Ames Salmonella assay with and without activation), and chromosomal aberrations

(preferably in vivo mammalian chromosome aberration or micronucleus test). Results from these two tests shall be used to determine the need for further testing. If there is no demonstrable genetic toxicity, no further genetic toxicity testing shall be required. If results are positive, a long-term cancer bioassay shall be required. If mutagenic activity is observed in one genetic toxicity test, additional genetic toxicity testing or Supplemental Studies may be recommended. Results from additional genetic toxicity testing or Supplemental Studies will be used to determine whether a long-term cancer bioassay (preferably oral route) will be required.

B. LEVEL II (POTENTIAL HUMAN EXPOSURE FROM DRINKING WATER AT NORMALIZED CONTAMINANT CONCENTRATIONS BETWEEN ≥10 AND <50 PPB)

Level II toxicity test guidelines include the Level I genetic toxicity tests, a subchronic 90-day study (preferably oral route) in one species (preferably rat), and optional Supplemental Studies, if indicated. The results of genetic toxicity testing are evaluated as described above in Level I. Results from the subchronic testing and Supplemental Studies will be used to calculate a Maximum Allowable Level (MAL in mg/L) for the contaminant based on the No-Observed-Adverse-Effect-Level (NOAEL) of the most appropriate species and toxic effect (see Appendix A, Section 3.0.2 and Table A5). If the estimated contaminant concentration exceeds the MAL, then a supplemental subchronic 90-day study may be conducted with additional dose levels to define the highest NOAEL. The MAL may then be recalculated based on the full complement of data. If the estimated contaminant concentration still exceeds the MAL, then the manufacturer may reformulate to reduce exposure or a chronic toxicity study (preferably in the rat and by the oral route) may be undertaken to define the highest NOAEL and to calculate an MAL. Concentrations of the contaminant in water will be allowed at or below the MAL. Genetic toxicity and one subchronic study will satisfy minimum testing requirements, provided exposure to the contaminant is less than or equal to the MAL. Should the anticipated contaminant concentration exceed the chronic MAL, the manufacturer may adjust the product formulation or dose to reduce potential exposure. Supplemental Studies may be useful to further define the relevance to humans of results observed in genetic toxicity, subchronic, or chronic studies.

C. LEVEL III (POTENTIAL HUMAN EXPOSURE FROM

DRINKING WATER AT NORMALIZED CONTAMINANT CONCENTRATIONS BETWEEN ≥50 AND <1000 PPB)

Level III toxicity test guidelines include all requirements of Level II, a teratology study in two species, and a reproductive toxicity study in one species (preferably rat). Teratology tests which provide data on toxic effects occurring in fetuses exposed during gestation are required in two species, unless supporting evidence is adequate to justify the use of one species only. Such evidence could include, but is not limited to, pharmacokinetics/metabolism data indicating the degree of similarity of absorption, distribution, metabolism, excretion (ADME) between laboratory species and humans, and existing data including teratology endpoints as a subset of a reproductive toxicity study. Supplemental Studies may be required.

Reproductive toxicity studies provide information on male and female reproductive function and prenatal and postnatal developmental effects in the offspring. The required two-generation reproductive toxicity study shall examine only first litters in each generation unless adverse or suspect reproductive or developmental affects are observed, in which case second litters may be required from at least one generation.

Results from the subchronic study, the reproductive toxicity and teratology studies, and Supplemental Studies will be used to calculate a MAL for the contaminant based on the NOAEL of the most appropriate species and toxic effect (see Appendix A, Section 3.0.2 and Table A5). The need for further supplemental testing will be evaluated by comparing the estimated contaminant concentration and the calculated MAL. If the estimated contaminant concentration exceeds the MAL, additional studies may be undertaken to more precisely define the highest NOAEL for the pertinent endpoint(s). The MAL may then be recalculated from the full complement of data. Should the estimated contaminant concentration exceed the MAL, which was derived from one or more subchronic studies, then the manufacturer may adjust the formulation to reduce exposure or data from a chronic study (preferably in the rat and via the oral route) may be submitted. Exposure to the contaminant will be allowed at or below the MAL in water. Genetic toxicity, subchronic, and reproductive and teratology studies comprise the minimum testing requirements, provided exposure to the contaminant is less than or equal to the MAL. When chronic toxicity data are provided, a new MAL shall be calculated from these results and shall supersede any MAL

derived from studies of shorter duration. Should that estimated contaminant concentration continue to exceed the chronic MAL, the manufacturer may adjust product formulation or dose to reduce or eliminate the presence of the contaminant. Supplemental Studies may be useful to further define the relevance to humans of results observed in genetic toxicity, subchronic, reproductive, teratology, and chronic studies.

D. LEVEL IV (POTENTIAL HUMAN EXPOSURE FROM DRINKING WATER AT NORMALIZED CONTAMINANT CONCENTRATIONS $\geq$1000 PPB)

Level IV toxicity testing guidelines include all requirements of Level III, as well as a chronic toxicity study (which includes a long-term cancer bioassay), and, if indicated, Supplemental Studies. (NOTE: Unlike Level I in which a long-term cancer bioassay is dependent on positive or equivocal results from the genetic toxicology studies, Level IV guidelines require a long-term feeding study for chronic toxicity, including cancer endpoints, with no consideration to the outcome of genetic toxicity tests.)

Results from the testing at this level shall be used to calculate a MAL for the contaminant based on the NOAEL of the most appropriate species and toxic effect (see Section 3.2 and Table A5). Presence of the contaminant in water shall be deemed acceptable at or below the MAL. If estimated contaminant concentrations exceed the MAL, the manufacturer may adjust the product formulation or application rate to reduce or eliminate the presence of the contaminant. Supplemental Studies may be useful to further define results observed in testing at this level.

2.0.8 POTENTIAL EXPOSURE RESULTING FROM SHORT-TERM, HIGH-LEVEL CONTAMINANTS: Contaminant concentrations from many products used in contact with drinking water are initially high, but rapidly decline with continued product contact with water. (Examples may include, but are not limited to, solvent-containing coatings and cements.) Short-term exposure paradigms, appropriate for potentially high initial contaminant concentrations, may be implemented at the request of the applicant or at the discretion of the certifying agency. In these cases, leachate tests will be used to determine the slope of the contaminant concentration curve. If the initial (day 1) laboratory concentration of the contaminant is less than or equal to the 90-day No-Observed-Adverse-Effect-Level (NOAEL), divided by 100, and the contaminant concentration is calculated to be at or below the MAL within 90 days, then no additional toxicity data may be required. If no

subchronic (90-day) data exist and a 90-day MAL cannot be calculated, then a single-dose acute toxicity study in rodents with a 14-day observation period, clinical observations, hematology and clinical chemistry, and gross pathology may be required. Then, the normalized initial contaminant concentration is acceptable when it is less than or equal to the NOAEL calculated from the study results, divided by a safety factor of 1000 (or 100 if appropriate additional toxicology endpoints are evaluated). If there is evidence that a contaminant is classifiable as either an A, B_1 or B_2 carcinogen, then the allowable contaminant concentration must be considered on a case-by-case basis, taking into account available information including carcinogenic potency, mechanism of action, and slope of the decay curve. The contaminant concentration for carcinogens and non-carcinogens must be at or below the MAL within 90 days.

The contaminant concentration at 90 days determines which toxicity evaluation category requirements must be fulfilled.

2.0.9 APPLICATION VERIFICATION: The applicant shall certify that, to the best of the applicant's knowledge, the information is accurate and complete.

3.0 RISK ESTIMATION: Calculation of the Maximum Allowable Level (MAL)

3.0.1 REGULATED CONTAMINANTS: If a contaminant is regulated by EPA's National Primary Drinking Water Regulations, the MAL for contribution by a single product shall not exceed ten (10) percent of the USEPA final Maximum Contaminant Level (MCL) as cited in Appendix B. Exposure to the contaminant in water shall be deemed acceptable at or below the MAL. The estimated contaminant concentrations for test substances shall be determined as described in Appendix B. Alternate estimates of levels of the contaminant contributed to the water shall be substantiated by the applicant. (NOTE: If the manufacturer requests review relevant to Canadian requirements, the certifying agency may consider alternative regulatory levels; e.g., Canadian Maximum Acceptable Concentrations [MACs] as cited in Appendix B).

3.0.2 UNREGULATED CONTAMINANTS: The Maximum Drinking Water Level (MDWL) shall be calculated, as follows, depending on whether the contaminant is considered to be a noncarcinogen or at least a probable human carcinogen. For purposes of this standard, a contaminant is considered a carcinogen if it meets the USEPA criteria for classification as group A, B_1, or B_2, as defined in the current EPA guidelines (1982) for risk assessment. The Maximum Allowable Level (MAL) for a contaminant contributed by a single product and <u>not</u> regulated by EPA's National Primary Drinking Water Regulations shall not exceed ten (10) percent of the Maximum Drinking Water Level (MDWL). Occurrence of the contaminant in water shall be acceptable at or below the MAL. The estimated contaminant concentrations for test substances shall be determined as described in Appendix B for each product category.

Alternate estimates of concentrations of contaminants contributed to the water shall be substantiated by the applicant. The substantiation for alternate estimates of concentration shall include sources of the contaminant other than water.

NONCARCINOGENS: For noncarcinogenic effects, the general formula for determining the maximum drinking water level (MDWL) is as follows:

$$\frac{\text{NOAEL}^1}{\text{UF}} = \text{RfD}$$

then,

$$\frac{(\text{RfD})\,(\text{BW})}{\text{I}} = \text{MDWL}$$

Where:

NOAEL = Highest No-Observable-Adverse-Effect-Level for most appropriate species and toxic effect (mg/kg/day)

BW = Assumed body weight of individual to be protected (kg) (generally 10 kg for a child, 50 kg for evaluation of a reproductive toxicant, and 70 kg for an adult)

RfD = Reference dose based on highest NOAEL and indicating levels of exposure unlikely to cause injury (mg/kg/day). This approach is equivalent to the acceptable daily intake (ADI) used by the World Health Organization (WHO).

UF = Uncertainty factors based upon the applicability of the test data in extrapolating to actual conditions of human exposure (see Table A5). These are often referred to as safety factors.

I = Intake; Assumed average daily drinking water consumption (liters/day) (generally 1 liter for a child and 2 liters for an adult)

MDWL = Maximum Drinking Water Level (mg/L) (Based on lowest RfD)

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[1]If no NOAEL is available, the Lowest-Observed-Adverse-Effect-Level (LOAEL) may be used with a corresponding increase (1X to 10X) in the uncertainty factor.

CARCINOGENS: For chemical carcinogens, the following assumptions shall be applied to the estimation of risk in the absence of toxicologic, metabolic, pharmacokinetic, physiologic, or mechanistic data to the contrary:

A. Lifetime incidence in humans is taken to be the same as in animals receiving an equivalent dose rate.

B. The linearized multi-stage model is appropriate for low-dose extrapolation, and the upper 95% confidence limit on risk of the linear term is appropriate for expressing the upper-bound of potency.

C. Animal doses are converted to human-equivalent doses using a surface area correction.

D. Humans are taken to be as sensitive to the carcinogenic influence of the substance as the most sensitive animal species.

E. If the cancer study is terminated prematurely, lifetime incidence is calculated to increase by the third power of age.

F. Human data are preferable to animal data as a basis for estimating risk. For human data, the method of analysis is tailored to the completeness and quality of data available. A model that is linear at low dose is used for extrapolation. Negative (i.e., no association) epidemiologic human data can be used to suggest a theoretical upper-limit of risk.

G. The general formula for determining the MDWL is as follows:

$$\frac{(R)\,(BW)}{q1^*\,(I)} = MDWL$$

Where:

R = Acceptable risk level (i.e., 10^{-5})

BW = Assumed body weight of protected individual (kg) (usually 70 kg for an adult)

$q1^*$ = Slope factor for humans for the linearized multistage risk assessment model $(mg/kg/day)^{-1}$

I = Intake; Assumed average daily drinking water consumption (liters/day) (generally 2 liters/day)

MDWL = Maximum Drinking Water Level (mg/L)

TABLE A5

UNCERTAINTY FACTORS

Test	Uncertainty Factor[2]
Mutagenicity	Not Applicable
90-Day Study	1000
Chronic Study	100
Reproductive/Developmental Toxicity[3] (2 generations)	100-1000
Teratogenicity[3]	100-1000

[2]If based on NOAEL values; UF(s) based on LOAEL values may be 1X to 10X higher, depending upon the toxicology data available.

[3]Dependent on most sensitive species and severity of the effect.

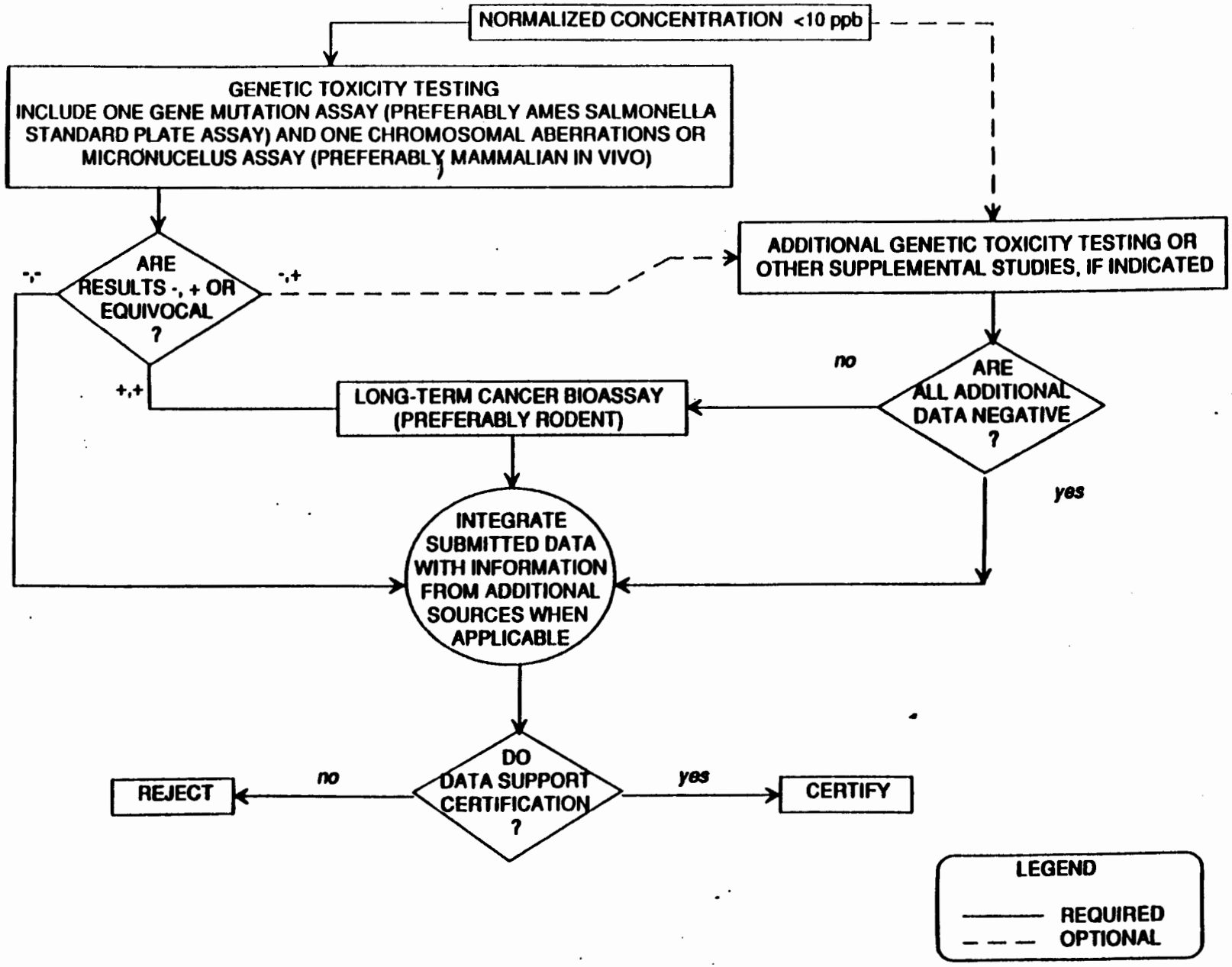

Figure A1 PROPOSED LEVEL I MINIMUM TOXICITY TESTING GUIDELINES

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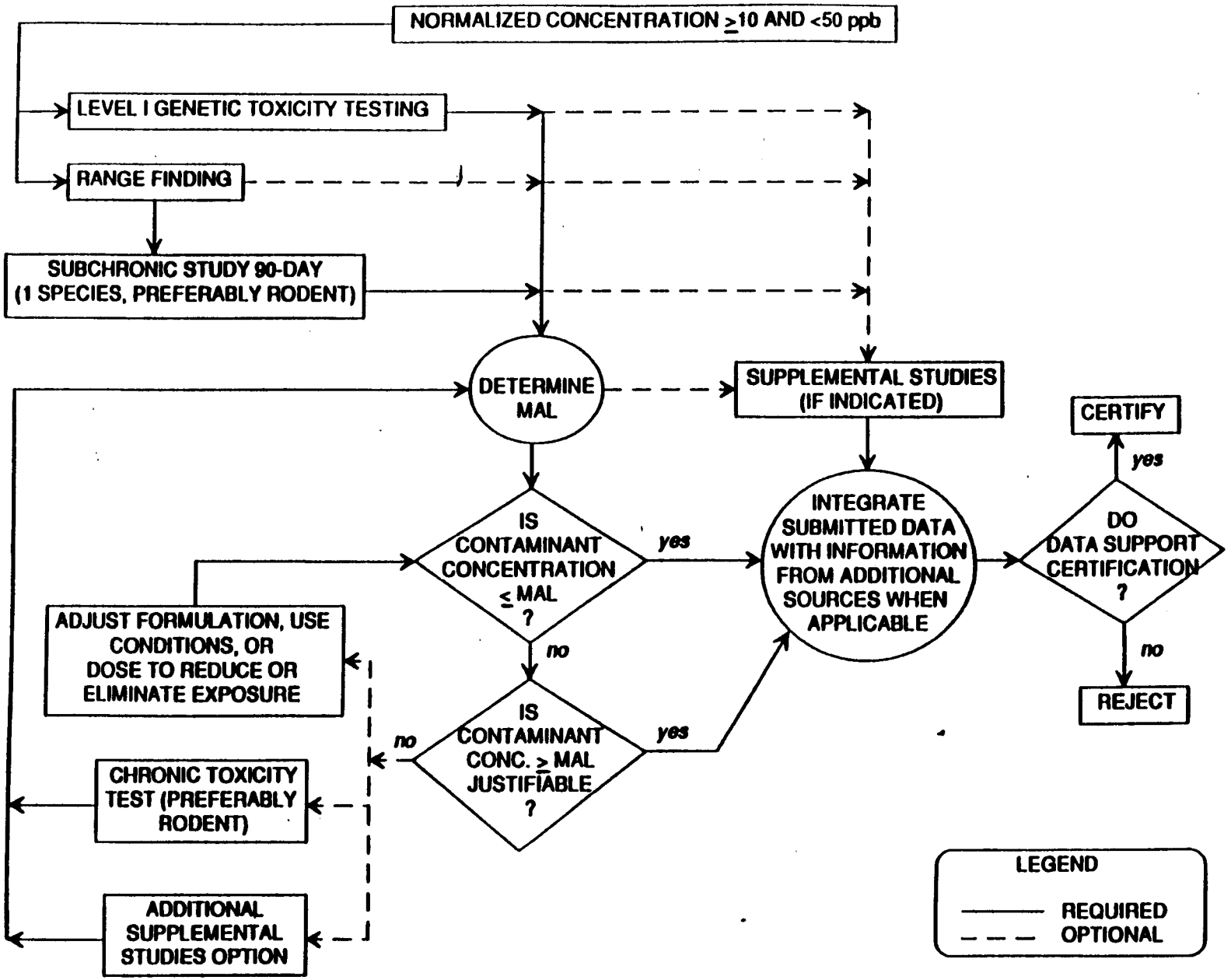

Figure A2 PROPOSED LEVEL II MINIMUM TOXICITY TESTING GUIDELINES

cav31/STD01CHT.ORF

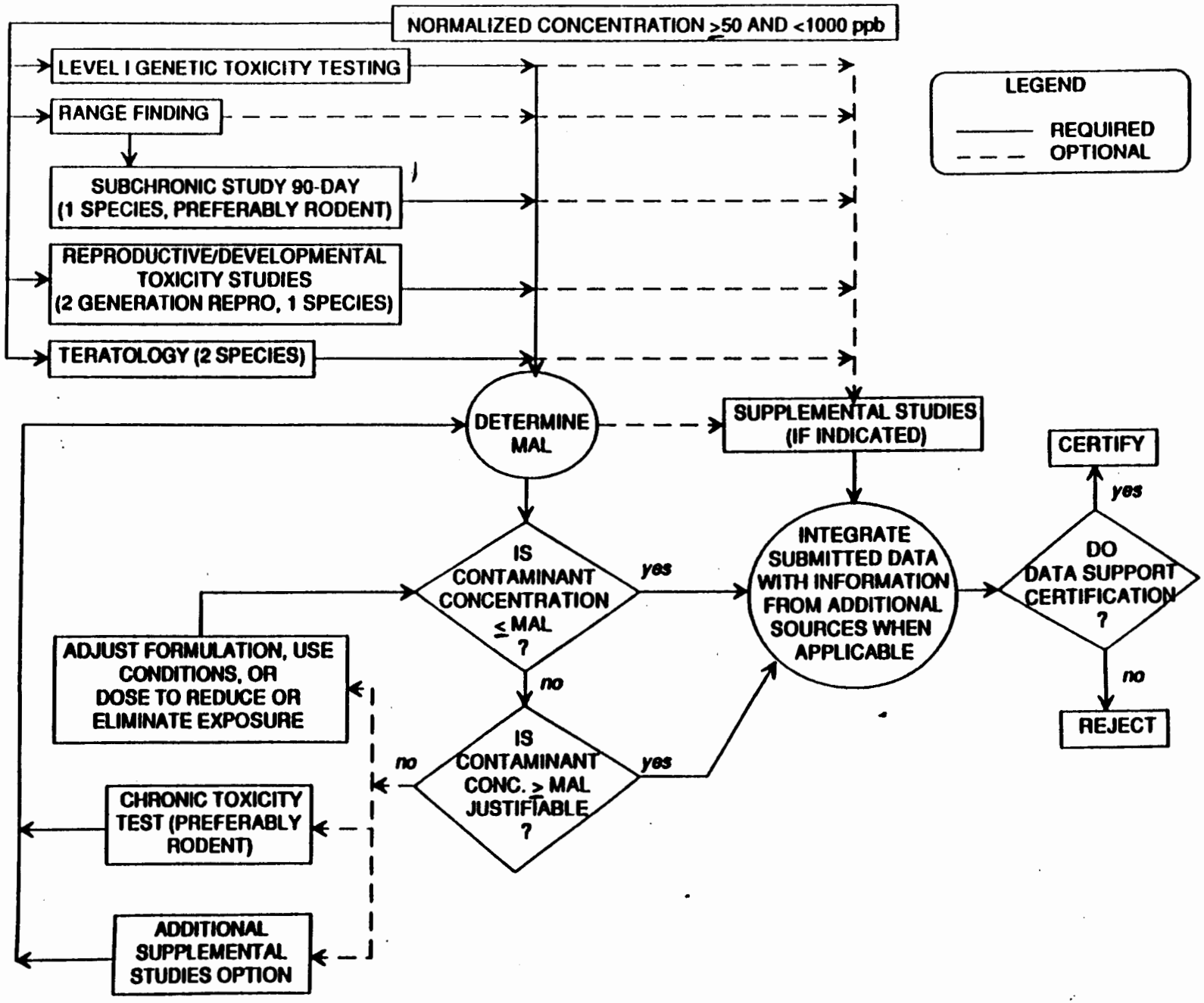

Figure A3 PROPOSED LEVEL III MINIMUM TOXICITY TESTING GUIDELINES

cdv31/STD61CHT.ORF

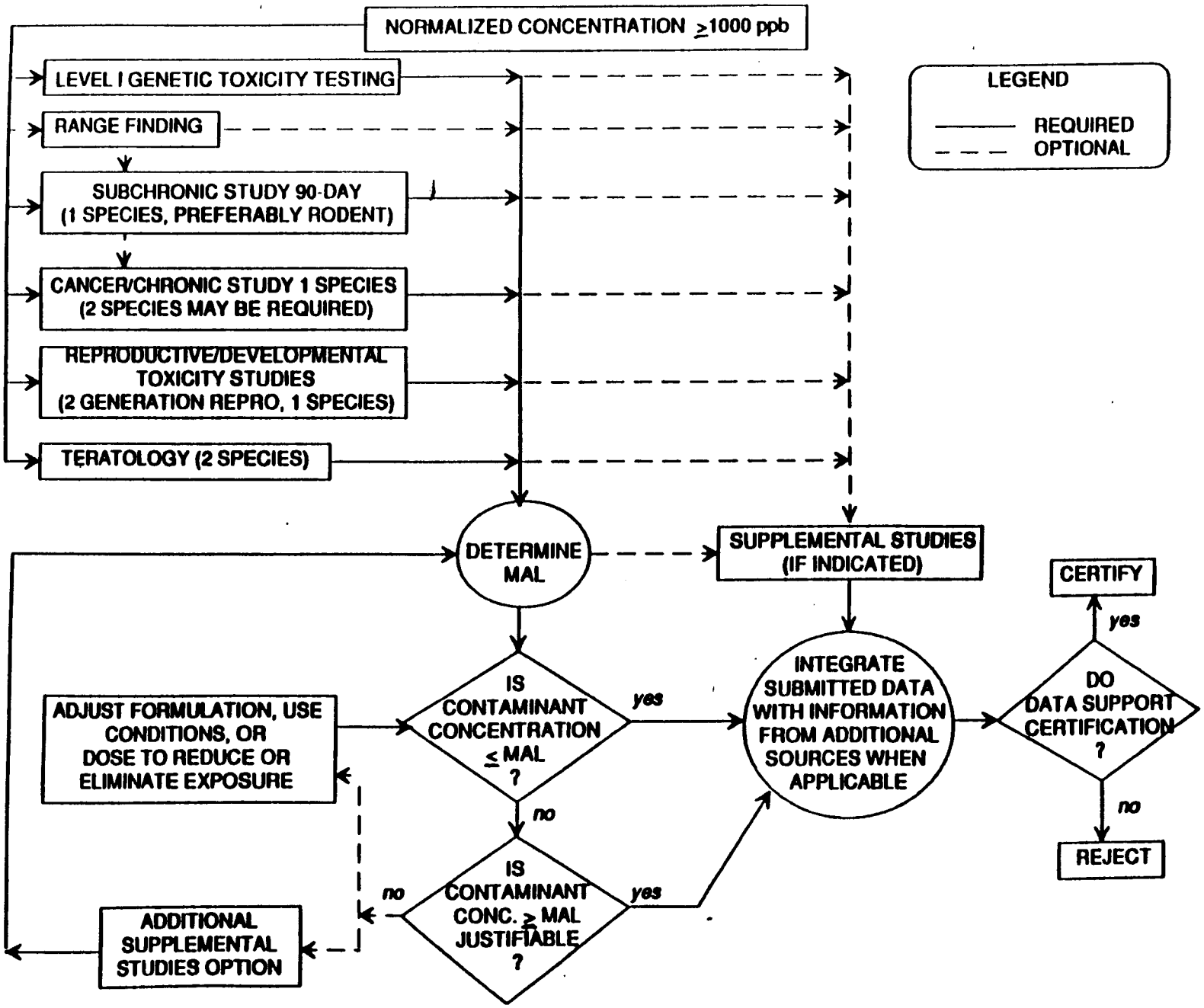

Figure A4 PROPOSED LEVEL IV MINIMUM TOXICITY TESTING GUIDELINE

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REFERENCES

1. EPA (1982) Pesticides Assessment Guidelines Subdivision F Hazard Evaluation--Human and Domestic Animals.

2. FDA (1982) Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives in Food.

3. OECD (1985) Organization for Economic Cooperation and Development Guidelines for Testing of Chemicals.

APPENDIX B

PRODUCT/MATERIAL EVALUATION

(This Appendix is part of the Standard)

1.0 Background

2.0 General Evaluation Requirements

- 2.1 General
- 2.2 QA/QC and Safety
- 2.3 Samples
- 2.4 Washing
- 2.5 Extraction Waters
- 2.6 Product Exposure
- 2.7 Material Exposure
- 2.8 Exposure Conditions

3.0 Pipes and Related Products

- 3.1 Sample Requirements
- 3.2 Conditioning
- 3.3 Exposure Conditions

4.0 Protective (Barrier) Materials

- 4.1 Sample Requirements
- 4.2 Preparation
- 4.3 Conditioning
- 4.4 Exposure for Solvent-Based Containing Protective (Barrier) Materials
- 4.5 Exposure for Other Protective (Barrier) Materials

5.0 Joining and Sealing Materials

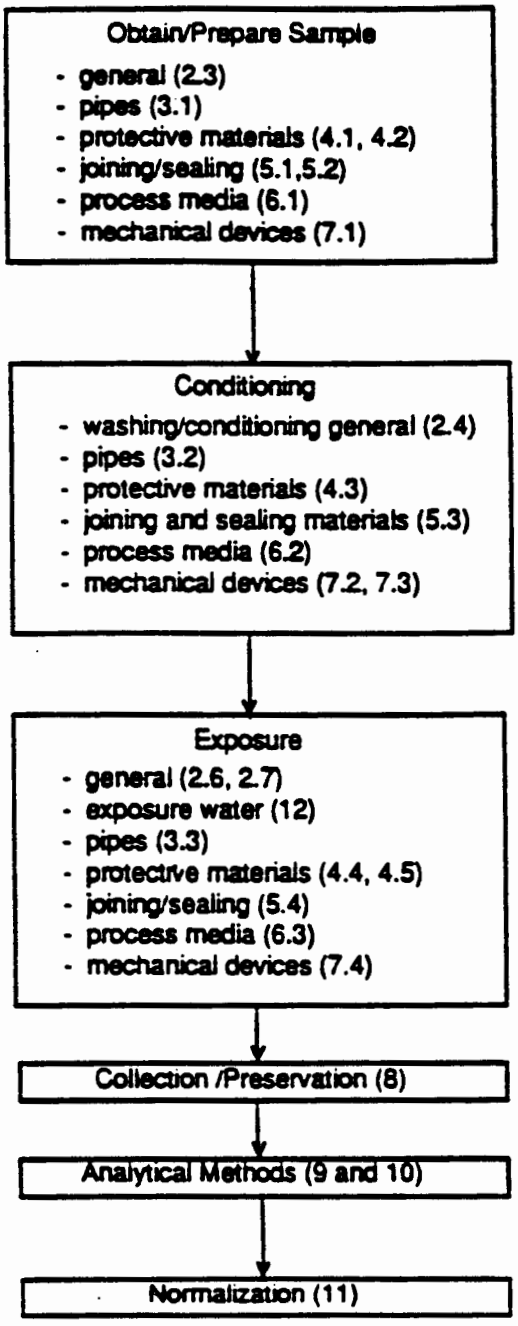
- 5.1 Sample Requirements
- 5.2 Preparation
- 5.3 Conditioning
- 5.4 Exposure

6.0 Process Media

- 6.1 Sample Requirements
- 6.2 Conditioning
- 6.3 Exposure

APPENDIX B OVERVIEW

Below is a flow diagram summarizing the major steps for product/material testing. The numbers in parentheses refer to sections in Appendix B.



APPENDIX B

PRODUCT/MATERIAL EVALUATION

1.0 BACKGROUND: Products/materials to be evaluated shall be prepared, exposed, and the extraction medium (e.g., water, chemical) analyzed as described in this Appendix. Examples of products/materials covered by this Appendix are shown in Table B.1.

Table B.2 outlines the various preparation and exposure methods for the products/materials covered by the Appendix.

The analytical methods included are based on contaminants that may be present when established methods of production are used and the materials are derived from known sources. If products/materials are produced using alternate methods or originate from alternate sources, the analytical procedures may need to be modified accordingly.

2.0 GENERAL EVALUATION REQUIREMENTS:

2.1 GENERAL: The requirements described in this section are general requirements and apply to all products/materials covered by Standard 61. Appendix B Sections 3 to 8 describe specific preparation, conditioning, and exposure sequences unique to individual product/material categories.

2.2 QA/QC AND SAFETY: The methods included in Appendix B, Sections 3 to 8 have been written for trained chemical laboratory personnel. Appropriate quality assurance procedures and safety precautions must be followed.

2.3 SAMPLES: Whenever practical, samples of the actual product (e.g., pipe, fitting, device) shall be used for exposure testing. When it is not practical to test a finished product or if a material is proposed for acceptance under the Standard, a representative sample of the material or product surface exposed to drinking water or water treatment chemical under intended end-use conditions may be used. In every case, the ratio of the exposed surface area of the sample to volume of the extraction medium shall not be less than the surface area-to-volume ratio representative of intended end-use, and preferably, shall be greater.

2.4 WASHING: To remove any extraneous debris or contamination that may have occurred due to shipping and handling, samples shall be rinsed with cold tap water prior to testing, followed by a deionized water (ASTM D1193 Type II) rinse, unless the manufacturer's instructions direct otherwise. If the exterior of a product is exposed, any printed markings (e.g., ink markings) shall be removed.

TABLE B.1
STANDARD 61 PRODUCTS

PIPES AND RELATED PRODUCTS	PROTECTIVE (BARRIER) MATERIALS	JOINING AND SEALING MATERIALS	PROCESS MEDIA	MECHANICAL DEVICES
Fittings	Coatings/Linings	Adhesives	Adsorption Media	Chemical Feeders
Couplings	Vehicles	Brazing Materials	Activated Alumina	Dry Feeders (e.g. pellet droppers)
Pipes	Pigments	Solders	Aeration Packing Material	Pressure Gas Injection Systems
Tubing	Vehicle Extenders	Fluxes	Carbonaceous Resins	Pumps
Flexible	Solvents	Caulks	Cheleting Polymers	Vacuum Injection Systems
Rigid	Additives	Gaskets	Granular Activated Carbon	Disinfection/Generators
Well Screens	Concrete Admixtures	Grouts	Powdered Activated Carbon	Chlorine Dioxide
Casings	Concrete Release Agents	Lubricants	Filtration Media	Hypochlorite
Drop Pipe	Concrete Sealers	O-rings	Aluminum Silicates	Ozone
	Diaphragms/Bladders	Packing	Anthracite	Ultraviolet
	Sheet Liners	Primers	Diatomeceous Earth	Electrical Wire
	Thermoset Polymers	Sealants	Garnet	Submersible Well Pump
	Thermoplastic Polymers		Gravel	Pumps
	Rubbers		Ilmenite	Switches and Sensors (e.g. water level, flow, pressure, temperature)
			Ion Exchange Resins	Valves and Related Fittings (transmission/distribution system)
			Oxidative Media	Water Process Treatment Devices
			Sand	Aeration Equipment
			Synthetic Media	Clarifiers
				Electrodialysis
				Microfiltration
				Mixers
				Reverse Osmosis
				Screens
				Strainers
				Ultrafiltration

TABLE B.2
EXPOSURE
SUMMARY

CATEGORY	APPENDIX B REFERENCE SECTION	TYPE OF SAMPLES (SURFACE AREA)	REQUIRED PREPARATION	PRODUCT EXPOSURE
PIPES AND RELATED PRODUCTS	3	Actual product when feasible. Smallest diameter pipe is used for product line of varying sizes. Fittings are dimensioned.	Washing to remove debris accumulated by shipping and handling.	Products conditioned prior to exposure (2 weeks) for hot or cold exposure. Cold exposure = 16 hr. at 30 °C Hot exposure = 1/2 hr. at 82 °C followed by 16 hr. at 30 °C.
NOTE: There is a separate residual vinyl chloride analysis required for polyvinyl chloride and chlorinated polyvinyl chloride materials. This is an in-the-product-wall determination, not an extraction.				
PROTECTIVE (BARRIER) MATERIALS	4	50 cm2/L	When applicable, test samples shall be prepared in accordance with the manufacturers published instructions under the supervision of the certification agency. Coatings/paints are applied to glass slides, or other appropriate substrate, in accordance with the manufacturer's published instructions. Linings are sized to the appropriate surface area. Concrete admixtures/ sealers/release agents are applied to concrete blocks. Prepared samples are washed to remove debris accumulated during handling.	Products are disinfected and then rinsed to remove excess chlorine. Solvent containing coatings are exposed for extended period. (37 days) Exposure for other products: Cold exposure = 24, 24, 72 hrs at 23 °C Domestic hot exposure = 24, 24, 72 hrs at 60 °C Commercial hot exposure = 24, 24, 72 hrs at 82 °C

TABLE B.2
PRODUCT EXPOSURE
SUMMARY (cont.)

CATEGORY	APPENDIX B REFERENCE SECTION	TYPE OF SAMPLES (SURFACE AREA)	REQUIRED PREPARATION	PRODUCT EXPOSURE
JOINING & SEALING MATERIALS	5	15 cm^2/L	Some products applied to an appropriate substrate. Some products cut to appropriate size. Washed to remove debris accumulated during shipping and handling.	Cold exposure - 24, 24, 24 hrs at 30 °C Hot Exposure = 1, 1, 1 hr at 82 °C
PROCESS MEDIA	6	Dependant on media	See special sampling instructions. Wet product to wash away fines.	Exposure = 1, 1, 1 hr. at 23 °C.
MECHANICAL DEVICES	7	Entire device, component, or material specimen [1]	Wash to remove debris accumulated during shipping and handling	Conditioning period prior to exposure (2 weeks maximum). Cold exposure = 24, 24, 24 hrs at 23 °C

[1] A material specimen shall be exposed using a minimum surface area to volume ratio of 50 cm^2/L.

2.5 EXTRACTION WATERS: Samples shall be exposed, based on a formulation review and determination of the most severe condition, to one or more extraction waters as detailed in Table B.3, except for process media (see Appendix B, Section 6.3), and Mechanical Plumbing Devices (see Appendix B, Section 8.5). The characteristics and preparation of the waters are described in Appendix B, Section 12.

Table B.3
Extraction Water Selection

ANALYTES OF INTEREST	pH 5		pH 8		pH 0
Metals	X				X
Solvents[1]	X	or	X	or	X
Volatile Organic Chemicals			X		
Other Organics	X	or	X	or	X

2.5.1 EXCEPTIONS: The manufacturer may specifically request a change in the extraction water used, based on the intended application and/or the materials used in the device/product, provided the manufacturer's use instructions indicate the use limitations.

2.5.2 PROCESS MEDIA: Process media products are exposed using organic-free deionized water (ASTM D1193 Type II).

2.5.3 MECHANICAL PLUMBING DEVICES: Mechanical plumbing devices (Section 9.0), are exposed to the pH 8 extraction water described in Appendix B, Section 8.5.

2.6 PRODUCT EXPOSURE: Samples may be evaluated either "in-the-product/ device" or in an exposure vessel.

2.6.1 EXPOSURE IN-THE-PRODUCT/DEVICE: When practical, products/devices shall be evaluated such that only the (exposed) wetted surface is exposed to extraction medium.

[1]Solvents = The organic liquid component of a formulation used to dissolve solid or other liquid components of protective (barrier) materials or joining and sealing materials to facilitate their application.

2.6.2 EXPOSURE IN VESSELS: Samples that are not evaluated as described in Section 2.6.1 shall be exposed to the extraction medium in clear glass containers (e.g., 1L) with PTFE (polytetrafluoroethylene) lined lids, with no headspace.

Products exposed in vessels shall be exposed such that the surface area-to-volume ratio described in the appropriate section (Appendix B, Sections 3 to 8) shall be maintained.

2.6.3 RESIDUAL VINYL CHLORIDE: Polyvinyl chloride (PVC) and chlorinated polyvinyl chloride (CPVC) pipe products/materials shall be evaluated for residual vinyl chloride (RVC). RVC is measured in PVC and CPVC pipe walls because good correlation exists with extraction data and the diffusion science is well understood. Residual vinyl chloride shall be determined in the product wall, rather than by extraction, in accordance with Appendix B, Section 10.

2.7 MATERIAL EXPOSURE: Materials shall be exposed according to the protocol outlined for the materials' specified end use(s). If a material is intended for use in the manufacture of products covered under more than one section of this standard, the most stringent exposure condition shall be followed (e.g. temperature, surface area to volume ratio). A material intended to be processed by more than one method (e.g. Injection molding, extrusion, stamping) shall be tested in each of the processed forms.

2.7.1 EXPOSURE OF A MATERIAL SAMPLE: A materials manufacturer may request to have its material tested as a material sample (e.g., plaque, sheet) if, and only if, there is no chemical or physical difference in the material characteristics between the material sample and the material as it is used in covered applications. If the material is intended to be used only for the manufacture of products falling under the scope of a single section of this standard, the material shall be exposed under the conditions set forth in the corresponding section of Appendix B. The normalized contaminant concentrations shall meet the requirements of Appendix A.

2.7.2 EXPOSURE IN PRODUCT FORM: A materials manufacturer may request to have its materials tested in the form of a finished product according to the protocol set forth in the appropriate section(s) of Appendix B.

2.7.3 SURFACE AREA TO VOLUME RATIO (S/V): When testing the material in the form of a material sample or in product form, the dimensions of the material or the product sample tested and the extraction medium volume shall be recorded and the laboratory tested

surface area to volume ratio calculated. If a material exceeds an MAL the S/V may be scaled down to provide an acceptable MAL.

2.8 EXPOSURE CONDITIONS: Exposure begins immediately following washing or the appropriate conditioning.

2.8.1 METHOD BLANKS: Method blanks are prepared using the same reagent and in the same manner as product samples, but no product is added. An uncoated substrate, as applicable, shall be included. Method blanks shall be processed with all samples.

2.8.2 METHOD STANDARDS: Method standards shall be prepared along with all samples. Method standards are prepared in the same manner as method blanks, except a known amount of the expected contaminant is added.

2.8.3 SEQUENTIAL EXPOSURE: Tests for evaluation shall be conducted using a sequential exposure procedure. There shall be no significant time interval between exposures (decant, discard, fill, continue exposure). The products shall be exposed depending on the intended end-use application, as described in the appropriate section (Appendix B, Sections 3 to 8). Analyses shall be performed only on the final extraction medium, unless otherwise noted.

3.0 PIPES AND RELATED PRODUCTS:

3.1 SAMPLE REQUIREMENTS: Whenever practical, samples of actual product shall be used for exposure testing. The size with the highest surface area to volume ratio (typically the smallest diameter) should be evaluated. Successful evaluation of the highest surface area to volume ratio shall qualify all lower surface area to volume ratios.

3.1.1 RESIDUAL VINYL CHLORIDE: Polyvinyl chloride (PVC) and chlorinated polyvinyl chloride (CPVC) products/materials shall be evaluated for residual vinyl chloride in accordance with Appendix B, Section 9.

3.2 CONDITIONING: Following washing (Appendix B, Section 2.4), and prior to exposure, product/material samples (except those for RVC analysis) shall be conditioned to simulate pre-use flushing and/or disinfection procedures. The samples shall be exposed for evaluation immediately after conditioning. Pipes and related products are conditioned at different temperatures, depending on the intended end use: 23°C (cold application) or 82°C (hot application). The product samples are conditioned as described below.

3.2.1 COLD APPLICATION: Following washing (Appendix B, Section 2.4), the samples shall be conditioned at room temperature (23° ± 5°C) with

the applicable pH 8 extraction water for 14 days, or less if specified by the manufacturer. The water shall be changed at least 10 times, with a minimum period of 24 hours per conditioning period. There shall be no time interval between exposures. To simulate disinfection, the first (initial) exposure shall contain 50 mg/L available chlorine. After the initial 24 hour period, the extraction water shall contain 2 mg/L chlorine.

3.2.2 HOT APPLICATION: Following washing (Appendix B, Section 2.4), and the cold application conditioning, the samples shall be further conditioned at the elevated temperature by exposure with the applicable pH 8 extraction water using the sequence in Table B.4. There shall be no time interval between exposures.

TABLE B.4

Time	Temperature	Comment
1 Hour ± 5 min	82°C ± 0.5°C	decant, discard, refill
1 Hour ± 5 min	82°C ± 0.5°C	decant, discard, expose as shown in Section 3.3

3.3 EXPOSURE CONDITIONS: Exposure begins immediately following conditioning. The samples shall be exposed in the appropriate extraction water (see Appendix B, Section 2.5) based on end use or application. The extraction water shall be collected for analysis as described in Section 8 of this appendix.

3.3.1 COLD APPLICATION: Products which, in actual field use, are not used with hot water shall be exposed as follows: 16 hours ± 1 hour at 30°C ± 1°C.

3.3.2 HOT APPLICATION: Products which, in actual field use, are used with hot water shall be exposed as follows:

Expose for 0.5 hour ± 5 minutes at 82°C ± 0.5°C, immediately followed by exposure for 16 hours ± 1 hour at 30°C ± 1°C.

The test sample shall be allowed to cool in the 30°C chamber. Successful evaluation using this procedure precludes the cold exposure.

4.0 PROTECTIVE (BARRIER) MATERIALS:

4.1 SAMPLE REQUIREMENTS: Test samples of coatings/linings shall be prepared such that, upon exposure, a surface area-to-volume ratio of 50 cm^2/L is obtained.

4.2 PREPARATION: Samples shall be prepared such that the entire surface to be exposed is covered by extraction water. Products (when appropriate/required) shall be applied to a glass slide in a manner consistent with the manufacturer's written (published) instructions. Products requiring a reactive substance (i.e., when glass is inappropriate) shall be applied to an appropriate alternate substrate.

4.2.1 FIELD APPLIED COATING SYSTEMS: These products shall be applied at the appropriate film thicknesses and cured (time, temperature, etc.) per the manufacturer's published instructions and under the supervision of the certifying agency. Multiple layer coating systems shall be applied in a stepped manner so as to expose all layers. See Table B.5 for dimensions of exposed areas.

TABLE B.5
MULTIPLE LAYER COATING SYSTEM SAMPLE PREPARATION

# of Layers in System	Layer	Panel Surface Area Exposed
One coat	----	Entire panel
Two coat	Primer	1/3
—	Finish coat	2/3
Three coat	Primer	1/6
	First coat	1/3
	Finish coat	1/2
Four coat	Primer	1/12
	First coat	1/6
	Second coat	1/4
	Finish	1/2

4.2.2 FACTORY PRODUCED, APPLIED, AND/OR CURED MATERIALS: Systems requiring factory application and curing shall be prepared in accordance with Appendix B, Sections 4.1 and 4.2.

4.2.3 CEMENT MORTAR BLOCKS: Cement mortar test blocks shall be prepared for systems requiring cement as a substrate. Two-inch test sample cubes are prepared according to ASTM C-109. The blocks are removed from the mold after 24 hours and allowed to air cure at room temperature for 14 days.

- Concrete Admixtures: These products shall be added to the cement mixture using the manufacturer's highest recommended admixture dosage level. The test samples shall be prepared as described in Appendix B, Section 4.2.3 and shall be exposed immediately after they have cured.

- Concrete Sealers: These products shall be applied to the test samples prepared in Appendix B, Section 4.2.3 in accordance with the manufacturer's recommendation. The coated cubes shall be allowed to cure for the manufacturer's recommended period and then shall be immediately exposed.

- Concrete Mold/Form Release Agents: These products shall be applied to the mold used to prepare the cubes described in Appendix B, Section 4.2.3. The test samples shall be prepared as described in Appendix B, Section 4.2.3 and exposed immediately after the 14-day cure period.

4.3 CONDITIONING: Following washing (Appendix B, Section 2.4), and prior to exposure, the test sample shall be disinfected. This procedure simulates the disinfection of water storage tanks prior to operation. The method described is based on Method 2 of AWWA Standard C652-86.

4.3.1 DISINFECTION METHOD 2:

- Prepare 200 mg/L available chlorine solution using sodium hypochlorite (NaOCl) (reagent grade or equivalent).

- Using a spray bottle, spray the previously rinsed test sample panels, coating all surfaces to be exposed.

- Let the test samples stand for at least 30 minutes and rinse well.

- The test samples are placed in racks, rinsed with cold tap water,

and then rinsed with ASTM D1193 Type II deionized water. The samples shall be exposed immediately. If immediate exposure is not feasible, dry the test samples in a laminar flow hood and expose within four hours.

4.4 EXPOSURE FOR SOLVENT-BASED CONTAINING PROTECTIVE (BARRIER) MATERIALS: Tests for qualification of solvent-containing materials shall include the determination of solvent leaching rates over time. The relationship between contaminant concentration(s) and time shall be determined, plotted with a minimum of five points, and then used for evaluation. Table B.6 describes the exposure sequence for determining the solvent leaching rates. Extraction water (see Appendix B, Section 2.5) for contaminants of interest (other than solvents) shall be collected following the first seven-day exposure period. The extraction water shall be collected as described in Appendix B, Section 8.

4.4.1 COLD APPLICATION: Products/materials which are not intended to be used with hot water shall be exposed at 23°C ± 2°C (73.4°F ± 3.6°F). Extraction water samples for solvents are collected and analyzed as described in Table B.6. Extraction water samples for other analyses are collected as described in Appendix B, Section 8.

4.4.2 DOMESTIC HOT APPLICATION: Products/materials which are intended for hot residential applications (i.e., single family dwellings) shall be exposed at 60°C ± 0.5°C (140°F ± 0.9°F). Successful evaluation using this procedure precludes the cold exposure.

4.4.3 COMMERCIAL HOT APPLICATION: Products/materials which are intended for hot commercial application use (e.g., multiple-family dwellings, restaurants, hospitals) shall be exposed at 82°C ± 0.5°C (180°F ± 0.9°F). Extraction water samples for solvents are collected and analyzed as described in Table B.6. Extraction water samples for other analyses are collected as described in Appendix B, Section 9. Successful evaluations using this procedure, precludes the cold and domestic hot exposures.

TABLE B.6
SOLVENT CONTAINING MATERIALS
EXPOSURE SEQUENCE

NOTE: Sample exposures are sequential: decant volume for analysis, discard remaining extraction water, refill container, and continue exposure.

	EXPOSURE TIME	ELAPSED TIME	TEMPERATURE[2]	SAMPLE COLLECTION
I.	24 ± 1 hour	1 day	A, B, C	Extraction water for solvent analysis is collected in a 250-500 mL clear glass bottle with PTFE lined lid that contains sodium thiosulfate in a quantity sufficient to neutralize the chlorine. Store at 4°C until analysis.
II.	24 ± 1 hour	2 days	A, B, C	Same as I
III.	7 ± 1 day	9 days	A, B, C	Same as I (Extraction water for analyses other than solvents is collected as described in Appendix B, Section 9).
IV.	7 ± 1 day	16 days	A, B, C	Collection and analysis optional
V.	7 ± 1 day	23 days	A, B, C	Same as I
VI.	7 ± 1 day	30 days	A, B, C	Collection and analysis optional
VII.	7 ± 1 day	37 days	A, B, C	Same as I

[2]The exposure temperature is application dependent.
(A) Cold application = 23 ± 2°C (73.4 ± 3.6°F)
(B) Domestic hot application = 60 ± 0.5° (140 ± 0.9°F)
(C) Commercial hot application = 82 ± 0.5°C (180 ± 0.9°F)

4.5 EXPOSURE FOR OTHER PROTECTIVE (BARRIER) MATERIALS: For materials other than solvent containing coatings, exposure is based on the intended end-use application and is described in Table B.7. Extraction water samples are collected after the final exposure period as described in Appendix B, Section 9. Successful evaluation at an elevated temperature precludes testing at a lower temperature.

TABLE B.7
EXPOSURE SEQUENCE FOR
OTHER THAN SOLVENT CONTAINING MATERIALS

NOTE: Sample exposures are sequential: Decant and discard extraction water, refill container, and continue exposure. Extraction water samples are collected for analysis after the final exposure period, as described in Appendix B, Section 9.

Application	Exposure Time	Elapsed Time	Temperature
Cold	24 ± 1 hour	1 day	23 ± 2°C (73.4 ± 3.6°F)
	24 ± 1 hour	2 days	23 ± 2°C (73.4 ± 3.6°F)
	72 ± 4 hours	5 days	23 ± 2°C (73.4 ± 3.6°F)
Hot (Domestic)	24 ± 1 hour	1 day	60 ± 0.5°C (140 ± 0.9°F)
	24 ± 1 hour	2 days	60 ± 0.5°C (140 ± 0.9°F)
	72 ± 4 hours	5 days	60 ± 0.5°C (140 ± 0.9°F)
Hot (Commercial)	24 ± 1 hour	1 day	82 ± 0.5°C (180 ± 0.9°F)
	24 ± 1 hour	2 days	82 ± 0.5°C (180 ± 0.9°F)
	72 ± 4 hours	5 days	82 ± 0.5°C (180 ± 0.9°F)

5.0 JOINING AND SEALING MATERIALS:

5.1 SAMPLE REQUIREMENTS: Test samples of joining and sealing materials shall be prepared such that, upon exposure, a surface area to volume ratio of 15 cm^2/L (8.8 in^2/gal) is obtained. Test samples for the various types of joining and sealing materials are described in Table B.8.

TABLE B.8
TEST SAMPLES
JOINING AND SEALING MATERIALS

Material	Form
Gasket Materials	ASTM D3182 tensile sheets or finished product
Caulks, Greases Lubricants, Sealants	Applied to glass panels
Adhesives and Cements	Applied to overlapping panels
Solders and Solder/Flux Combinations	Product heated in ceramic combustion boats
Flux	Applied to copper sheet and heated

5.2 PREPARATION: Samples shall be prepared so that the entire surface to be exposed is covered by extraction water. Products (as appropriate) shall be applied to a glass panel in a manner consistent with the manufacturer's published instructions. Products requiring a reactive substrate (i.e., when glass is inappropriate), shall be applied to an appropriate alternate substrate.

5.2.1 GASKET MATERIALS: These products shall be cut to the appropriate size as described in Appendix B, Section 5.1.

5.2.2 CAULKS, GREASES, LUBRICANTS, AND SEALANTS: These products shall be applied to a glass panel in such a manner that an even film, consistent with end-use, is exposed and the surface area to volume ratio described in Appendix B, Section 5.1 is maintained. The slides shall be allowed to air-dry and/or cure according to the manufacturer's published instructions.

5.2.3 ADHESIVES AND CEMENTS: These products shall be prepared by joining overlapping plastics panels of the appropriate material (i.e., PVC or CPVC depending on the adhesive or cement), using the product being evaluated. The panels shall be overlapped in a manner simulating a typical installation. The adhesive or cement shall be applied in accordance with the manufacturer's published instructions and cured for 48 hours. The 1/8" thick panels are prepared as follows:

Panels: 16.5 cm x 4.3 cm (6.5" x 1.7")
Overlap: 14 cm x 4.3 cm (5.5" x 1.7")
Exposed Adhesive or
Cement: 2.5 cm x 4.3 cm (1.0" x 1.7") (one side/only)

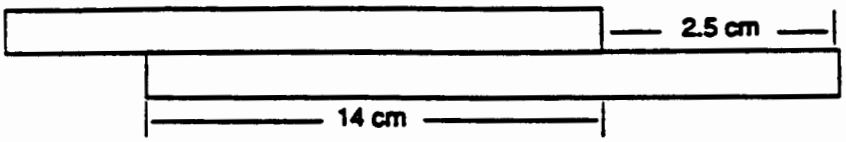


Figure B.1

5.2.4 SOLDERS: These products shall be prepared by placing the solder in a ceramic combustion boat (96 mm x 12 mm x 10 mm). The amount of solder used shall be sufficient to cover the bottom of the boat. The boat (with solder) is then placed in a muffle furnace that has been set to a temperature which is 20°C (36°F) above the liquidus temperature of the product being evaluated. For example:

95/5 tin/antimony solder has a melting range of 232-240°C (450-464°F). The oven is set at 260°C (500°F) for this solder.

The boat (with solder) is placed in the oven and allowed to heat until the solder has melted (approximately 1-2 minutes). The boat is allowed to cool and the solder piece is removed.

5.2.5 FLUXES: These products shall be prepared by applying a thin film to a copper sheet of the appropriate size as described in Section 5.1. The copper sheet is then placed in a muffle furnace that has been set to 300°C (572°F). The copper sheet (with flux) is allowed to heat until the flux flows (approximately 30 seconds to 1 minute). The copper sheet is allowed to cool prior to exposure.

5.3 CONDITIONING: Following preparation, the test samples are washed as described in Appendix B, Section 2.4.

5.4 EXPOSURE: Following conditioning, these materials are exposed in the appropriate extraction water (see Appendix B, Section 2.5) in accordance with the intended end-use application as described below. The extraction water samples are collected as described in Appendix B, Section 8.

5.4.1 COLD APPLICATION: Products to be evaluated for cold applications shall be exposed using the following sequence:

(1) 24 $\pm$ 1 hours @ 30 $\pm$ 0.5°C (86 $\pm$ 0.9°F)
(2) 24 $\pm$ 1 hours @ 30 $\pm$ 0.5°C (86 $\pm$ 0.9°F)
(3) 24 $\pm$ 1 hours @ 30 $\pm$ 0.5°C (86 $\pm$ 0.9°F)

5.4.2 HOT APPLICATION SAMPLES: Products to be evaluated for hot applications shall be exposed using the sequence that follows. However, the manufacturer

may specify an alternate maximum temperature.

(1) 1 hour @ 82 ± 0.5°C (180 ± 0.9°F)
(2) 1 hour @ 82 ± 0.5°C (180 ± 0.9°F)
(3) 1 hour @ 82 ± 0.5°C (180 ± 0.9°F)

5.4.3 EXTENDED EXPOSURE: If the normalized concentration of a contaminant exceeds the Appendix A criteria (chronic exposure), further exposure testing may be undertaken (at the manufacturer's discretion). The additional testing will be used to determine a contiminant leaching rate(s) over time. The relationship between contaminant concentration and time shall be determined, plotted with a minimum of five points, and then used for evaluation. Testing should continue until contaminant concentrations are reduced to ten percent of the initial contaminant concentration. The normalized contaminant concentrations are then compared to the MAL as specified in Appendix A, Section 2.0.8 (potential exposure resulting from short-term high level leachates).

6.0 PROCESS MEDIA:

6.1 SAMPLE REQUIREMENTS: A representative sample of the product/material shall be obtained for evaluation purposes as described below. The sampling procedures outlined below are designed to obtain a representative grab sample and are provided as guidance. Samples shall be taken at the point of manufacture. Appropriate chain-of-custody procedures shall be followed.

6.1.1 SAMPLING FROM BULK: A composite sample shall be obtained by selecting five individual 2500 g (approximately five pound) or 0.006 cubic meter (approximately 0.21 cubic feet) samples from either various depths or sectors of the bulk storage vessel. The individual samples shall be combined and mixed thoroughly to form a single composite of not less than 11 kg (approximately 24 pounds) or 0.028 cubic meter (approximately 1 cubic foot), whichever is less, to be further divided as described in Appendix B, Section 6.1.4.

6.1.2 SAMPLING FROM PACKAGES: A composite sample from packaged lots where bulk storage is not available, shall be obtained by selecting individual samples from approximately 5% of the lot, with a minimum of five and a maximum of fifteen containers sampled. If less than five containers are available, the sampling procedures shall be identical to those used for bulk vessels (see Appendix B, Section 6.1.1). The individual samples shall be combined and mixed thoroughly to form a single composite of not less than 11 kg (approximately 24 pounds) or 0.028 cubic meter (approximately one cubic foot), whichever is less, to be further divided as described in Appendix B, Section 6.1.4.

6.1.3 SAMPLING FROM PRODUCTION: In lieu of sampling in accordance with Appendix B, Section 6.1.1 or 6.1.2, composite samples obtained and composited by the manufacturer's sampling procedures during production shall be acceptable, if the procedures used result in a representative sample (as determined by the certification entity). The sample shall be further prepared in accordance with Appendix B, Section 6.1.4.

6.1.4 ANALYSIS SAMPLE: The composite sample obtained in Appendix B, Section

6.1.1 or 6.1.2 or 6.1.3 shall be reduced, using a riffle sampler (if appropriate), to three (3) samples of sufficient quantity for exposure as described in Appendix B, Section 6.2. The samples shall be stored in airtight, moisture proof, sealed glass containers. If a glass container is inappropriate, the manufacturer shall recommend a type of sample container. Each container shall be clearly labeled with product name, type of container sampled, manufacturer name, sampling data, production location, lot number, and be signed by the person responsible for sampling. One sample is used for exposure and analysis as described in Appendix B, Sections 6.2 and 11. The remaining two samples are retained, for reevaluation purposes (if necessary), for up to one year.

6.2 CONDITIONING: Special preparation procedures (e.g., backwashing) may be required for some samples. Initial preparation shall be in accordance with the manufacturer's written instructions.

General guidelines are described in Table B.9. Prior to exposure, the liquid portion is decanted and discarded.

TABLE B.9
PROCESS MEDIA CONDITIONING

Media	Amount
Filtration Media Other than Gravel or Anthracite	1250 ± 50 g
Gravel[3] and Anthracite[4]	
≤ 3/8 inch diameter (.95 cm)	1250 ± 50 g
> 3/8 inch diameter (.95 cm)	2500 ± 50 g
Adsorption Media	Half the sample collected in Section 6.1
Ion Exchange Resins	1250 ± 50 g
Chelating Polymers	1250 ± 50 g
Synthetic Media	Half the sample collected in Section 6.1

6.3 EXPOSURE: These products shall be exposed using reagent water and 4-liter Erlenmeyer flasks. These products are exposed as described below and the extraction water collected as described in Appendix B, Section 9.

[3]For the size range of gravel specified, not more than 8% by weight shall be neither finer nor coarser than the designated size limit (AWWA B100-80).

[4]For the size range of anthracite specified, not more than 8% by weight shall be neither finer nor coarser than the designated size limit.

6.3.1 FILTRATION MEDIA, ION EXCHANGE RESINS, AND CHELATING POLYMERS: Immediately following conditioning, place the media in a 4-liter Erlenmeyer flask. Add two liters of organic-free reagent water, mix to ensure that all media are wetted, and seal the flask with PTFE. Expose the media using the sequence shown in Table B.10.

TABLE B.IO
EXPOSURE SEQUENCE

Time	Temperature	
1 hour ± 5 minutes	23 ± 2°C (73.4 ± 3.6°F)	decant, discard, and replace extraction water
1 hour ± 5 minutes	23 ± 2°C (73.4 ± 3.6°F)	decant, discard, and replace extraction water
1 hour ± 5 minutes	23 ± 2°C (73.4 ± 3.6°F)	filter and collect samples for analysis as described in Appendix B, Section 9

6.3.2 ADSORPTION MEDIA: Following conditioning, the media samples shall be allowed to dry for 3 hours at 110°C (or 2 hours at 140°C). The dried media are exposed as described below.

(1) Prepare extraction solution:

(A) Add 47 mL of 0.1 N Sodium Hydroxide (NaOH) to 100 mL of 0.1 M Sodium Hydrogen Phthalate (or equivalent).
(B) Dilute to 200 mL with reagent water.

(2) Weigh five (5) grams of sample into 400 mL beaker.[5]
(3) Add 200 mL extraction solution (Step #1) SLOWLY (this will effervesce).[6]
(4) Cover and extract at room temperature on a magnetic stirrer for one (1) hour ± five (5) minutes.[7]
(5) Filter through a Whatman #41 filter paper (or equivalent), using filtrate for analysis.
(6) Collect analysis sample as described in Appendix B, Section 9.

6.3.3 SYNTHETIC MEDIA: Following conditioning, the media are placed in 2-liter (approximately 2-quart) glass jar with PTFE lined lid. The vessel shall be completely filled. Add reagent water to overflowing. Seal the jar and expose using the sequence shown in Table B.10.

7.0 MECHANICAL DEVICES:

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[5]Activated alumina needs to be ground to pass through a 40-mesh screen.

[6]Powdered activated carbon and activated alumina require the addition of a nonionic detergent (wetting agent).

[7]For powdered activated carbon, in the extraction step (Step #4), start stirring slowly until all of the sample is wetted and in suspension.

7.1 SAMPLES: Samples shall consist of the entire device, or portion(s)/ component(s) of the device, or a specimen of the material(s). The samples may represent a product line of varying sizes, as described below. When it is necessary to calculate normalization factor(s), the wetted exposed surface area of the sample shall be calculated and recorded prior to testing.

7.1.1 ENTIRE DEVICE: A single device shall represent a product line of varying sizes when:

- materials are of the same alloy, composition, or formulation, and
- designs are analogous, and
- it has the greatest exposed wetted surface area to volume ratio.

7.1.2 COMPONENT: A component shall represent a product line of varying sizes when:

- materials are of the same alloy, composition, or formulation, and
- designs are analogous, and
- it has the greatest exposed wetted surface area to volume ratio.

7.1.3 MATERIAL: The material shall be representative of that used in the component and/or device. It may also be a sample of the material not related to a specific component or device.

- materials shall be evaluated using a minimum surface area to volume ratio of 50 cm^2/L.

7.2 WASHING: Prior to conditioning and exposure, the samples shall be washed as described in Appendix B, Section 2.4, unless the manufacturer's instructions direct otherwise. When required, the device shall be properly prepared per the manufacturer's recommendations.

7.3 CONDITIONING: Conditioning may be either in the device or in a vessel. Table B.11 provides examples of typical exposures for the various products covered by this section. The test samples shall be preconditioned by exposure at room temperature (23 ± 2°C) to the extraction water used for testing (see Appendix B, Section 2.5) for fourteen (14) days, or less if specified by the manufacturer. The water shall be changed at least ten (10) times (during the 14-day conditioning period), or less if specified by the manufacturer. There is a minimum period of 24 hours per exposure.

7.4 EXPOSURE: Following conditioning, the samples shall be exposed as described in Table B.11 in the appropriate extraction media (see Appendix B, Section 2.5). Devices/components which in actual field use are not used with hot water (e.g., distribution system valves), shall be exposed using the sequence shown in Table B.12. Devices/components which are used in contact with water at a temperature in excess of 23°C (73°F) shall be exposed using the same exposure sequence, at the maximum temperature encountered under use conditions. The extraction media is collected as described in Appendix B, Section 8.

7.5 CHEMICAL EXPOSURE: The samples shall be exposed to the appropriate drinking water treatment chemical or chemical mixture for four (4) hours (or as recommended by the manufacturer) at 23 ± 2°C (73.4°F). For devices that normally operate at lower or high temperatures, the exposure shall be at the normal operating temperature. The extractant shall be collected in a vessel appropriate for shipping and storage. For chemical feeders, a sample of the

chemical prior to feeding shall be collected if possible. For chemical generators, samples of the raw chemicals shall be collected. For all devices where the extractant is a mixture of water and the chemical(s), a sample of the influent water shall be collected and preserved as described in Appendix B, Section 9. Analysis of the extractant shall be in accordance with the requirements of NSF Standard 60, Drinking Water Treatment Chemicals - Health Effects. Samples of the chemicals prior to feeding samples of raw materials, and influent water samples shall be analyzed for background levels of contaminants only if, after normalization, the concentration of a contaminant(s) exceeds the MAL (see Appendix B, Section 12.6).

TABLE B.11
PRODUCT EXPOSURE[8]

Product	In-the-Product	In-a-Vessel	Other
Aeration Equipment	x		Material exposed in a vessel
Chemical Feeders	x		Material exposed in a vessel
Clarifiers			Material exposed in a vessel
Disinfection Equipment			Material exposed in a vessel
Electrical Wire		x	
Mixers			Materials exposed in a vessel
Pumps	x		
Reverse Osmosis			
Membranes/Cartridges	x		
Screens		x	
Strainers		x	
Switches/Sensors		x	
Valves	x		

TABLE B.12
EXPOSURE SEQUENCE

Application	Exposure Time	Elapsed Time[9]	Temperature
Cold	24 hours	24 hours	23 ± 2°C (73.4°F)
	24 hours	48 hours	23 ± 2°C (73.4°F)
	24 hours	72 hours	23 ± 2°C (73.4°F)

[8]For the purposes of this table, product may represent either the entire device or a component. These are the typical exposure conditions. However, products may be exposed in any fashion provided the exposure is consistent with requirements in Appendix B, Section 2.

[9]Elapsed time does not include the initial 14-day conditioning period.

8.0 MECHANICAL PLUMBING DEVICES

8.1 SAMPLES: Samples shall consist of the entire device, portion(s)/component(s) of the device, or a specimen of the material(s) of the device. The samples may represent a product line of varying sizes, as described below. When it is necessary to calculate normalization factor(s), the wetted surface area of the sample shall be determined. When testing materials and components, the actual wetted surface area and the volume of water in the extraction vessel shall be determined.

8.1.1 DEVICE: A single device shall represent a product line of varying sizes when:

1. Materials are of the same alloy, composition, or formulation; and
2. Design and manufacturing processes are analogous; and
3. It has the greatest wetted surface area to volume ratio.

8.1.2 COMPONENT: A component shall represent a product line of varying sizes when:

1. Materials are of the same alloy, composition, or formulation; and
2. Design and manufacturing processes are analogous; and
3. It has the greatest wetted surface area to volume ratio.

8.1.3 MATERIAL: The material shall be representative of that used in the component and/or device. It may also be a sample of the material not related to a specific component or device. Materials shall be exposed at a surface area to volume ratio sufficient to ensure that the required laboratory detection limits are achieved for all analytes after normalization.

8.2 WASHING: Flush device for 15 minutes with tap water under pressure, then rinse with 3 volumes of DI water (ASTM D-1193, Type II). Alternate preparation of the device shall be performed when required by published manufacturer's instructions. Components and materials shall be washed according to Appendix B, Section 2.4.

8.3 CONDITIONING: Conditioning of the sample shall be performed in the sample or in a vessel. Endpoint devices, components, and materials shall be conditioned by rinsing with three (3) volumes of extraction water (specified in Section 8.5) at room temperature (23 $\pm$ 2°C). The units or exposure vessels shall be filled with extractant water and held until the start of the exposure sequence for a period not to exceed 72 hours.

8.4 EXPOSURE: Following conditioning, the sample shall be exposed to extraction water according to the applicable scheme detailed in Section 8.4.1 through Section 8.4.3. Reflecting the sample's intended use, samples shall be exposed to extraction waters at the specified temperatures for the entire duration of the exposure. Exposure shall be limited to cold temperature (23 $\pm$ 2°C) except for instant hot water dispensers, in which case the manufacturer's specified thermostat setting shall be used.

Evaluation of endpoint devices, components, and materials for contaminants other than lead shall require exposure of at least three samples according to the timetable of Figure B.2. The number

of products to be tested shall be specified by the manufacturer. The geometric mean of normalized contaminant concentrations from exposure on Day 19 shall be compared to the MAL.

Evaluation of endpoint devices, components and materials for the contaminant lead shall require exposure of at least three (3) devices (more if specified by the manufacturer), according to the timetable of Figure B.2. It is recommended that product lines thought to be marginally acceptable, and those that leach levels of lead approaching the maximum allowable level, should be tested for more than the minimum number of products. The rationale for selecting a number greater than three (3) products is provided in Appendix B, Section 12.11. On Days 3, 4, 5, 10, 11, 12, 17, 18, and 19, the 16 hour dwell extractant water shall be collected. The lead dosage shall be determined as described in Appendix B, Section 12.10 and compared to 11 µg. Lead dosage is equivalent to lead concentration times the volume of the device.

Additional samples may need to be exposed to extraction water in order to have a sufficient volume of extraction water for all analyses.

8.4.1 EXPOSURE SEQUENCE FOR ENDPOINT DEVICES:

The device shall be inverted and filled with extraction water and held according to Figure B.2 during the exposure sequence. Hot water dispensers shall be heated to operating temperature, then exposed following the sequence in Figure B.2 at the elevated temperature.

The final exposure water shall be collected and preserved in accordance with applicable analytical methods. Only the contaminant levels present in the sixteen hour dwell samples shall be used to evaluate the product's leaching characteristics.

For endpoint devices, the exposure sequence in Figure B.2 shall be conducted and the Days 3, 4, 5, 10, 11, 12, 17, 18 and 19 lead dosages shall be determined.

8.4.2 EXPOSURE SEQUENCE FOR COMPONENTS AND MATERIALS: The exposure procedures provided in Appendix B, Section 8.4.1 shall be followed except that in-vessel exposures shall be used. Samples shall be tested at a surface area to volume ratio at least as high as the ratio that exists in the device.

8.4.3 METHOD BLANKS: Method blanks are prepared using the same reagents and in the same manner as samples, but no sample is added. An uncoated substrate, as applicable, shall be included. Method blanks shall be processed with all samples.

8.4.4 METHOD STANDARDS: Method standards shall be prepared along with all samples. Method standards are prepared in the same manner as method blanks, except a known amount of the expected contaminants are added.

8.5 EXTRACTION WATER: The extraction water shall be prepared by combining:

8.5.1 25 ml of 0.4M sodium bicarbonate;

8.5.2 Chlorine stock solution as per Appendix B, Section 13.2.4; and

8.5.3 Deionized water meeting specification ASTM D1193 Type II (make up to one liter), and adjust pH as needed using 0.1M HCl (approximately 1.3 ml) to meet the following requirements:

This water shall have a pH of 8.0 (± 0.5), alkalinity of 500 ppm (± 25), dissolved inorganic carbon of 122 ppm (± 5), and 2 ppm (± .5) of free chlorine.

9.0 COLLECTION AND PRESERVATION OF EXTRACTION MEDIA FOLLOWING EXPOSURE:

9.1 GENERAL: Immediately following the exposure period, the extraction media shall be poured into previously prepared sample bottles for storage until analysis as detailed in Table B.13. The procedures described in Table B.14 are based on collection methods included in "Manual For The Certification of Laboratories Analyzing Drinking Water," (EPA-570/9-82-002) and Standard Methods For the Examination of Water and Wastewater (18th Edition).

TABLE B.13
EXTRACTANT WATER
COLLECTION AND PRESERVATION

Contaminant	Preservative	Container	Storage
Herbicide	None	500 mL (16 ounce) amber glass bottles with PTFE lid	4•C
Mercury	Conc. HNO_3 to pH <2 (1 mL)	125 mL (4 ounce) amber glass bottles with PTFE lid	room temp.
Metals other than Mercury	Conc. HNO_3 to pH <2 (1 mL)	125 mL (4 ounce) polyethylene bottles	room temp.
Misc. Organics	None	500 mL amber bottle with PTFE lid	4•C
Pesticides	None	500 mL (16 ounce) amber glass bottle with PTFE lid	4•C
Phenols	H_2SO_4 to pH <2	250 mL (8 ounce) (1 mL) amber glass bottle with PTFE lid	4•C
Phthalate	None	1 L glass bottle with PTFE lid (in duplicate)	4•C
Polyaromatic Hydrocarbon	None	1 L glass bottle (in duplicate)	4•C
Radionuclides	None	500 mL (16 ounce) polyethylene bottle	room temp.
Solvents	None	500 mL (16 ounce) glass bottle with PTFE lid	4•C
Total Kjeldahl Nitrogen	H_2SO_4 to pH <2	250 mL amber bottle with PTFE lid	4•C
Total Organic Carbon	None	250 mL amber bottle with PTFE lid	4•C
Volatile Organic Chemical (purgeable halocarbons	Sodium Thiosulfate (a few grains to neutralize the chlorine)	40 mL amber glass vial with PTFE lid	4•C

10.0 RESIDUAL VINYL CHLORIDE (RVC) EXTRACTION:[10]

10.1 GENERAL: Polyvinyl chloride (PVC) and chlorinated polyvinyl chloride (CPVC) products shall be evaluated for residual vinyl chloride (RVC) in the product wall. The RVC concentration is determind in the wall, rather .than in the extraction water, because very low levels of vinyl chloride cannot be as reliably detected in the extraction water as in the wall.

10.2 SAMPLE PREPARATION: PVC and CPVC samples shall be prepared as described below, and then analyzed according to Appendix B, Section 11.6. All samples are prepared in duplicate.

10.2.1 Chop a section of PVC or CPVC product sample into coarse pieces.

10.2.2 Weigh 0.500 g $\pm$ 0.005 g, of chopped sample pieces into a 20 mL glass vial.

[NOTE: The sample and duplicate should not differ by more than 0.005 g.]

10.2.3 Add 10 mL of N,N-Dimethylacetamide (distilled in glass) to the sample bottle, seal and cap.

10.2.4 Shake sample bottle at least 30 minutes on a reciprocating shaker.

10.3 STANDARDS: Both a standard stock solution and a secondary dilution standard shall be prepared for the RVC analysis, using vinyl chloride gas (99.9%) and N,N-Dimethylacetamide (DMAC).

10.3.1 STANDARD STOCK SOLUTION: Prepare the standard stock solution as described below:

(1) Pipet approximately 9.8 mL of DMAC into a 10 mL volumetric flask.
(2) Allow the flask to stand unstoppered until the wetted surface has dried.
(3) Weigh the flask and stopper to the nearest 0.1 mg. Record weight.
(4) Fill a 50 mL valved gas-tight syringe with vinyl chloride gas to the 50 mL mark.
(5) Lower the needle to 5 mm above the meniscus of the DMAC and slowly introduce the standard above the surface.
(6) Immediately reweigh the flask and contents. Record weight.
(7) Dilute to volume with DMAC, stopper, and mix.
(8) Transfer the solution into a PTFE sealed screw-cap vial.
(9) Store at -10°C to -20°C.
(10) Calculate stock standard solution with respect to a 0.500 g sample as follows:

$$\frac{(\text{Gram of vinyl chloride})(1 \times 10^6)}{0.500\ \text{g}} = \text{ppm (mg/kg)}$$

10.3.2 SECONDARY DILUTION STANDARD: Using the stock standard solution, prepare a secondary dilution in DMAC that contains a concentration that can be used to make calibration standards and spikes.

[10]Synonyms for residual vinyl chloride are residual viny chloride monomer and vinyl chloride.

10.4 EVALUATION

10.4.1 GENERAL: The samples prepared in 10.2 shall be analyzed as described in Appendix B, Section 11.6. Appendix B, Section 10.4.2 describes the calculations used to determine if the RVC concentration is acceptable under this standard.

10.4.2 PASS/FAIL CRITERIA: PVC and CPVC products, with an RVC concentration of less than or equal to 3.2 mg/kg, shall be considered acceptable. This acceptance criteria was determined using the equation described below:

$$M_w = 4/r\,[D/\pi]^{1/2}\,[(t + t_o)^{1/2}]M_p$$

where Mw = RVC diffused into water (mg/L)
Mp = RVC concentration in the PVC wall (mg/kg)
(NOTE: A factor of 1.4 corrects for the ratio of density of water to PVC)
r = Pipe radius (cm)
D = Diffusivity constant, where:

$D = D_o \times e^{(-17{,}000/RT)}$
R = Gas Constant $1.987\,^{\circ}K^{-1}$
T = Temperature (°K)
D_o = 3.7 cm^2/sec
= 319680 cm^2/day
t_o = Diffusion time period (days)
t = Product age at beginning of the diffusion time (days)
30°C = 303°K

The calculations are as follows:

Assumptions: 30 day old product is tested equivalent to 1 inch inner pipe diameter
t_o = 16 hours (0.67 days)
M_w = 0.2 ppb (0.0002 mg/L)[11]

$$M_w = 4/r\,[D/\pi]^{1/2}\,[(t + t_o)^{1/2} - t^{1/2}](M_p \times 1.4\ kg/L)$$

$$M_p = \frac{Mw}{4/r\,[D/\pi]^{1/2}\,[(t + t_o)^{1/2} - t^{1/2}]\,(1.4\ kg/L)}$$

$$M_p = \frac{0.0002\ mg/L}{(3.15)(0.000235)(0.061)(1.4\ kg/L)}$$

M_p = 3.2 mg/kg

[11]This concentration is based on the USEPA MCL for vinyl chloride (2 ppb or 0.002 mg/L), and since the MAL = 1/10 MCL, the MAL = 0.2 ppb, or 0.0002 mg/L.

11.0 ANALYSIS METHODS

11.1 GENERAL: This section is divided into five parts: metals, organics, (other than RVC and solvent), radionuclides, residual vinyl chloride, and solvents analyses. The specific analyses performed shall be formulation dependent.

11.2 DEFINITIONS:

11.2.1 METHOD VALIDATION: Following the procedures of Hubaux and Vos[12], validation spikes are prepared and evaluated on each of four days. The parameter concentration in the validation spike shall cover the range from 0.5T, 1.0T, 2.0T, 5.0T, and 10.0T (where T represents the target limit). The reporting limit (RL) for the method is derived from the regression analysis of the compiled validation spike data.

11.2.2 REPORTING LIMIT (RL): The lowest concentration of analyte that can be reliably reported following the statistical methods of Hubaux and Vos.

11.2.3 TARGET LIMIT (T): The lowest derived concentration level at which a method can reliably measure a parameter. This is the "T" used in the Hubaux and Vos evaluation of the method (e.g., 0.5T, 1.0T).

11.2.4 VALIDATION SPIKE: The addition of precisely measured quantities of analyte to the solution which represents the actual sample matrix to be analyzed by a method.

11.3 METALS: Analyses for metals shall be performed, except as otherwise provided for herein, in accordance with currently accepted U.S. Environmental Protection Agency (EPA) Methods (see 40 CFR Part 141 and Methods for Chemical Analysis of Water and Wastes, EPA 600/4-79-020). When no EPA method is provided, analyses may be performed in accordance with Standard Methods for the Analysis of Water and Wastewater (17th edition).

If neither of these two references address the required parameters and matrix, or if an alternate method is desired, method validation must be completed prior to the application of the method. The reporting limit obtained from the method can be no greater than one half the contaminant control level or Maximum Acceptable Level (MAL) specified for the parameter. Validation spikes shall be run at concentrations of 0.5, 1.0, 2.0, 5.0, and 10.0 times T, where T represents the target limit (the initial number used to develop the report limit). Each batch of samples, or with every 10 samples (whichever is smaller), shall include a validation spike of 2.0T.

The methods detailed below are considered the referee methods and shall be used when there is a dispute.

11.3.1 ANTIMONY: EPA Method 204.2.

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[12]Hubaux, A. and G. Vos, "Decision and Detection Limits for Linear Calibration Curves." Analytical Chemistry, 42:849-55 (1970).

11.3.2 ARSENIC: EPA Method 206.2.

11.3.3 BARIUM: EPA Method 208.2.

11.3.4 CADMIUM: EPA Method 213.2.

11.3.5 CHROMIUM: EPA Method 218.2.

11.3.6 COPPER: EPA Method 220.2.

11.3.7 LEAD: EPA Method 239.2.

11.3.8 MERCURY: EPA Method 245.2.

11.3.9 SELENIUM: EPA Method 270.2.

11.3.10 SILVER: EPA Method 272.2.

11.3.11 TIN: EPA Method 282.2.

11.3.12 ZINC: EPA Method 289.1.

11.4 ORGANICS: Analyses for organics shall be performed, except as otherwise provided for herein, in accordance with currently accepted EPA methods (see 40 CFR Part 141 and Methods for Chemical Analysis of Water and Wastes, EPA 600/4-79-020). When no EPA method is provided, analyses may be performed in accordance with Standard Methods for the Analysis of Water and Wastewater (17th edition).

If neither of these two references address the required parameters and matrix, or if an alternate method is desired, method validation must be completed prior to the application of the method. The reporting limit obtained from the method can be no greater than one half the contaminant control level or Maximum Acceptable Level (MAL) specified for the parameter. Validation spikes shall be run at concentrations of 0.5, 1.0, 2.0, 5.0, and 10.0 times T, where T represents the target limit (the initial number used to develop the report limit). Each batch of samples, or with every 10 samples (whichever is smaller), shall include a validation spike of 2.0T.

The methods detailed below are considered the referee methods and shall be used when there is a dispute.

11.4.1 PHENOLS: EPA Method 420.2.

11.4.2 PURGEABLE HALOCARBONS: EPA Method 501.1, 502.1, 503.1, or 524.1, 502.2, 524.2 depending on which is applicable.

11.4.3 PHTHALATES: EPA Method 606.

11.4.4 POLYNUCLEAR AROMATIC HYDROCARBONS: EPA Method 610.

11.4.5 PESTICIDES: ASTM D3806-79.

11.4.6 HERBICIDES: ASTM D3478-79.

11.4.7 TOTAL ORGANIC CARBON (TOC): EPA Method 415.2.

11.5 RADIONUCLIDES: Analyses for radionuclides shall be performed in accordance with Prescribed Procedures for Measurement of Radioactivity in Drinking Water, EPA-600/4-80-032. When no EPA method is provided, analyses may be performed in accordance with Standard Methods for the Analysis of Water and Wastewater (17th edition).

If neither of these two references address the required parameters and matrix, or if an alternate method is desired, method validation must be completed prior to the application of the method. The reporting limit obtained from the method can be no greater than one half the contaminant control level or Maximum Acceptable Level (MAL) specified for the parameter. Validation spikes shall be run at concentrations of 0.5, 1.0, 2.0, 5.0, and 10.0 times T, where T represents the target limit (the initial number used to develop the report limit). Each batch of samples, or with every 10 samples (whichever is smaller), shall include a validation spike of 2.0T.

The methods detailed below are considered the referee methods and shall be used when there is a dispute.

11.5.1 GROSS ALPHA: EPA Method 900.0.

11.5.2 GROSS BETA: EPA Method 900.0.

11.6 RESIDUAL VINYL CHLORIDE (RVC) ANALYSIS

11.6.1 GENERAL: This method covers the analysis of residual vinyl chloride monomer in PVC and CPVC potable water products using gas chromatography. Method sensitivity is 0.5 ppm (mg/Kg) when analyzing 0.5 g plastic, using Flame Ionization Detector (FID).

11.6.2 APPARATUS: Gas Chromatograph (GC) - Equipped with a ml headspace sampling system, 80°C oil bath, FID, data recording system, autosampler.

Column: 6 foot x 2 mm ID glass column packed with 1 percent SP-1000 on Carbopack B 60/80 mesh. Equivalent columns may be used as long as the column provides maximum separation from interferences and the ability to meet established accuracy and precision. A minimum of 8 sample spikes of 1 ppm (mg/Kg) should be analyzed to determine a column's acceptability. A column is acceptable if the percent relative standard deviation is five percent or less.

GC Conditions: The analysis will be performed using an oven temperature program whereby the initial temperature of 80°C is held for 2 minutes, increased at 70°C/minute to 220°C and held until N,N-Dimethylacetamide (DMAC) elutes (total run time about 16 minutes). The injector, detector, and sample loop temperature should be held at 200°C, 250°C, and 85°C, respectively.

The nitrogen carrier gas will have a flow rate of 20 ml/minute. The headspace will have a flow rate of 5 ml/minute. The hydrogen and air flows for the flame will be approximately 30 and 400 ml/minute. All of these flow rates will vary somewhat between GCs to optimize separation and response. The above are given only as guidelines.

11.6.3 ANALYSIS: The sample and standards prepared in Sections 10.2 and 10.3 should be loaded into an auto sampler with oil at 80°C. The samples/standards should be in the oil bath at least 30 minutes prior to analysis.

11.6.4 QUALITY CONTROL: Duplicate analysis shall be performed on each sample. Duplicate spiked samples shall be run at the rate of one (1) set per ten samples. An instrument standard is run with every 10 analyses (5th sample), and a reagent blank is required for each sample set. Quality control charts shall be developed and maintained and used as a check on the analytical system.

11.7 SOLVENT ANALYSIS: This section outlines the general procedure for determining solvent levels in the extraction water. The method described below is based on direct injection gas chromatography with flame ionization detection (FID). In some instances, an enhancement step (e.g., purge and trap [cold or heated], headspace analysis) may be required to complete the analysis. The choice of enhancement will be dependent on the desired detection levels of the solvent of interest. The method sensitivity for direct injection is approximately 0.1 mg/L (100 ppb) for selected solvents.

11.7.1 SOLVENT-CONTAINING MATERIALS: For initial qualification, these products are evaluated to determine the solvent leaching rates over time. The relationship between contaminant concentration and time shall be determined by plotting a minimum of five points. In many instances, direct injection will be sufficient only for the early testing period. When direct injection is no longer adequate for determining a concentration, a more sensitive method is required (i.e., purge and trap).

11.7.2 APPARATUS: The equipment and method described below are presented as a guideline. The analysis conditions may require adjustment relative to the specific solvent or solvent system being evaluated.

Gas Chromatograph (GC) equipped with an FID, temperature programming, data recording system, autosampler. A purge and trap (with and without heat) system and headspace sampling system should also be available.

11.7.3 QUALITY CONTROL: Duplicate standard addition samples are run at the rate of one (1) set per ten samples or less. An instrument standard is run with every 10 analysis (fifth sample) and a reagent blank is required for each sample set. Quality control charts should be developed, maintained, and used as a check on the analytical system.

12.0 NORMALIZATION:

12.1 GENERAL: This section provides the calculations used to determine the level of contaminants projected "at-the-tap" based on the level of contaminants identified during laboratory analysis. The normalized contaminant concentration is then compared to the requirements established in Appendix A.

12.1.1 PROCESS MEDIA EXCEPTION: Process media that are dosed at a specified concentration shall be normalized to reflect the manufacturer's maximum dose concentration.

Process media not dosed, but used in the form of a filtration bed are tested in a manner that simulates field use. Therefore, the resulting concentrations of contaminants detected are compared directly to the MAL without normalization.

12.2 DEFINITIONS:

12.2.1 RESIDENTIAL: Products used in buildings.

12.2.2 SERVICE LINE: Products used from the water main to building plumbing systems.

12.2.3 MULTIPLE USER SERVICE LINE: Products used between the water main and multiple family residences or commercial buildings.

12.2.4 WATER MAIN (DISTRIBUTION): Products used in locations other than buildings or service lines.

12.3 NORMALIZATION FACTOR: To account for any differences in surface area-to-volume ratios between laboratory and actual field-use conditions, an adjustment or conversion may be needed using the equation below.

$$NF = (N1) \times (N2)$$

$$N1 = \frac{SA_F \times V_L}{SA_L \times V_F \text{ (static)}}$$

$$N2 = \frac{V_F \text{ (static)}}{V_F \text{ (flow)}}$$

Where:

SA_F = Surface area exposed in the field
SA_L = Surface area exposed in the laboratory
V_L = Volume of extraction water used in the laboratory
V_F (static) = Volume of water the product is exposed to in the field for the static condition
V_F (flow) = Volume of water the product is exposed to in the field under flow conditions during a period of time equivalent to the laboratory test

12.4 NORMALIZATION OF RESIDENTIAL PRODUCTS AND MECHANICAL PLUMBING DEVICES EXCLUDING ENDPOINT DEVICES, COMPONENTS, AND MATERIALS: For service line and residential pipes, fittings, joining materials and mechanical plumbing devices, two normalized values (static conditions and flowing conditions) shall be determined as specified below. Under static conditions, the normalized concentration of any contaminant shall be less than or equal to the EPA Maximum Contaminant Level (MCL) or the Maximum Drinking Water Level (MDWL) calculated per Appendix A. Under flow conditions, the normalized concentration of any contaminant shall be less than or equal to the MAL, as established in Appendix A (10 percent of the MCL or 10 percent of the MDWL). The requirements of <u>both</u> normalization procedures shall be met.

12.4.1 STATIC CONDITION: Initially, the laboratory concentration is adjusted to reflect differences in surface area-to-volume relationships between laboratory and field exposures under static conditions. This calculation uses the N1 term defined in Appendix B, Section 12.3. For products with V_f (static) equal to one liter or more, the N2 term equals one. For products that under static field conditions are in contact with less than one liter of water, V_f (static) = 1 liter. Table B.14 provides some example calculations for typical product categories.

12.4.2 FLOWING CONDITION: In addition to the static condition, the laboratory concentration is also adjusted to reflect differences between laboratory and field exposures under flowing conditions. For this calculation, N2 will vary depending on use. Table B.16 details the assumptions and resulting N2 values for typical product categories.

12.5 NORMALIZATION FOR PRODUCTS USED IN TANKS/STORAGE VESSELS GREATER THAN 3,600 SQUARE FEET: Products used as protective barriers for tanks/storage vessels greater than 3,600 square feet (approximately $\geq$ 50,000 gallons) or greater in capacity shall use the normalization factors shown in Table B.15. Normalization factors for products used as protective barriers in tanks/storage vessels with an area less than 3,600 square feet shall be determined on a case-by-case basis, as described in Section 12.7.

TABLE B.14
PRODUCT EXAMPLES
STATIC CONDITION NORMALIZATION

$$NF = \frac{SA_F}{SA_L} \times \frac{V_L}{V_F\ (static)} \times N2$$

Where:

NF	=	Normalization factor
SA_F	=	Surface area under field conditions
SA_L	=	Surface area exposed in the laboratory
V_L	=	Volume of extraction water used in the laboratory
V_F (flow)	=	Volume of water the product is exposed to during a period of time equivalent to the laboratory test
N2	=	1 (static conditions)
V_F (static)	=	Volume of water the product holds to capacity

Conversion Factors: 1 liter = 1000 cm^3 = 61.02 in^3 = 0.26417 U.S. gallons
1 inch = 2.54 cm
1 U.S. gallon = 231 in^3

PIPES

1. Service Line:

   Products < 4" i.d., but ≥ 1" i.d.
   Based on 1" i.d., 20' length for static volume

   SA_F = 754 in^2 V_F = 0.816 gal.
   SA_L = 247 in^2 V_L = 0.205 gal. (based on PVC in-the-vessel exposure)

   $$NF = \frac{SA_F}{SA_L} \times \frac{V_L}{V_F} = \frac{754}{247} \times \frac{0.205}{0.816} = 0.77$$

2. Residential:

   Products < 1" i.d., but ≥ 1/2" i.d.
   Based on 1/2" i.d., 140' length for static volume (cold water)[13]

   SA_F = 2638 in^2 V_F = 1.43 gal.
   SA_L = 865 in^2 V_L = 0.355 gal. (based on copper water tube in-the-vessel exposure)

   $$NF = \frac{SA_F}{SA_L} \times \frac{V_L}{V_F} = \frac{2638}{865} \times \frac{0.355}{1.43} = 0.76$$

[13]This example is based on copper tube. Actual inside diameters, not nominal diameters, should be measured and recorded for use in the calculation.

TABLE B.14 (Cont.)

JOINING MATERIALS

1. Service Line:

   Products < 4" i.d., but ≥ 1" i.d.
   Based on 1" i.d., 20' length for static volume
   Mechanical Joint: 1/2" gasket width exposed; 2 joints per 20' length

   $SA_F = 3.14\ in^2$ $V_F = 0.816$ gal.
   $SA_L = 2.4\ in^2$ $V_L = 0.264$ gal.

   $$NF = \frac{SA_F}{SA_L} \times \frac{V_L}{V_F} = \frac{3.14}{2.4} \times \frac{0.264}{0.816} = 0.42$$

2. Residential:

   Products < 1" i.d., but ≥ 1/2" i.d.
   Based on 1/2" i.d., 140' length for static volume (cold water)
   1/4" weld width exposed (e.g., solders, solvent cements)
   100 joints (50 fittings)

   $SA_F = 39.2\ in^2$ $V_F = 1.43$ gal.
   $SA_L = 28.4\ in^2$ $V_L = 0.476$ gal.

   $$NF = \frac{SA_F}{SA_L} \times \frac{V_L}{V_F} = \frac{39.2}{28.4} \times \frac{0.476}{1.43} = .46$$

TABLE B.15
NORMALIZATION FACTOR
TANKS/STORAGE VESSELS GREATER THAN 3,600 SQUARE FEET

Surface Area[15] Normalization[16] (sq. ft.)	Approximate Capacity (1,000 gal.)	Factor
3600	50	0.351[17]
8100	250	0.159[18]
17000	1000	0.082[19]

12.6 NORMALIZATION FOR CHEMICAL FEEDERS AND GENERATORS: Chemical feeders and generators, feeder components, and materials used therein, present a special case because the materials are in contact with a concentrated chemical, rather than in direct contact with water, which is then diluted at the prescribed feed rate.

In lieu of the equation described in Appendix B, Section 12.3, the following equation shall be used to estimate the concentration of a contaminant in the finished drinking water.

$$NF = N1 \times N2 \times N3$$

Where $N3 = \frac{V_{SF} ED}{CD}$

ED = Evaluation dose (concentration) per NSF Standard 60 or a maximum dose specified and reported by the manufacturer.

CD = Concentration of treatment chemical dosed.

N1 and N2 are defined in Appendix B, Section 12.3.

[15]This area includes the sides and floor of a tank, but not the roof.

[16]Based on laboratory exposure ratio of 50 cm^2/L.

[17]For tanks with an area of 3,600 to 8,099 square feet, use this factor.

[18]For tanks with an area of 8,100 to 16,999 square feet, use this factor.

[19]For tanks with an area of 17,000 square feet or greater, use this factor, or the exact surface area and volume of the tank to derive the normalization factor by Appendix B, Section 12.3.

12.7 NORMALIZATION FOR OTHER PRODUCTS: The normalization factors described below shall be applied to products and materials, other than those covered in Appendix B, Sections 12.4, 12.5 and 12.6. Products/components/ materials are divided into three use categories: (1) service line; (2) multiple user service line; (3) water mains. Normalization factors which are not included in the sub-sections or tables below shall be determined on a case-by-case basis using the equation in Appendix B, Section 12.3. Where a product is available in various sizes, the product with the highest surface area-to-volume ratio (typically the smallest diameter) shall be evaluated. For products, components, or materials that may be used in any of the four categories, qualifying by use of the largest normalization factor shall qualify other use categories. Table B.17 details the assumptions and resulting N_2 values for various product categories.

12.8 NORMALIZED CONCENTRATION: The concentration of a contaminant in the finished drinking water shall be estimated using the following calculation.

Normalized Concentration = (Laboratory Concentration) x (Normalization Factor)

12.8.1 STATIC CONDITION: The normalized contaminant concentration under static conditions is compared to the EPA MCL or the calculated MDWL (as specified in Appendix A), and shall be less than or equal to the MCL or MDWL.

12.8.2 FLOWING CONDITION: The normalized contaminant concentration under flowing conditions is compared to the Maximum Acceptable Level (MAL) (as specified in Appendix A), and shall be less than or equal to the MAL.

12.8.3 PROTECTIVE (BARRIER) MATERIALS CONTAINING SOLVENTS: Products/materials containing solvents are exposed such that the solvent leaching rates over time are determined. The relationship between normalized contaminant concentrations and time are determined and plotted with a minimum of five points. The normalized contaminant concentrations are then compared to the MAL as specified in Appendix A, Section 2.0.8 (Potential exposure resulting from short-term, high-level leachates).

12.8.4 JOINING AND SEALING MATERIALS CONTAINING SOLVENTS: Additional exposure testing may be undertaken, at the manufacturer's discretion, to determine contaminant concentrations over time for solvent-containing materials. The relationship between contaminant concentrations and time are determined, and plotted with a minimum of five points. The normalized contaminant concentrations are calculated and are then compared to the MAL as specified in Appendix A, Section 2.0.8 (potential exposure resulting from short-term, high-level leachates).

12.9 NORMALIZATION FOR MATERIALS AND COMPONENTS: Materials and components shall be tested under Appendix B of this standard. Materials and components cannot have associated normalization factors.

The following process shall be used when qualifying devices produced from previously tested materials or components:

C_{IMEV} = Concentration of contaminant, I, for material or component, M, in the extraction vessel (EV).

V_{LM} = Volume of extractant water used in the laboratory for material or component M.

SA_{LM} = Surface area exposed in the laboratory, for material or component, M.

W_{IM} = Weight of contaminant, I, leached from material or component, M.

W_I = Weight of contaminant, I, which would leach from the device.

SA_{FM} = Surface area of component or material, M, that would be exposed to water in the actual device.

C_I = Concentration of contaminant, I, which would be in the water if the device had been tested.

V_F = Volume of water the product is exposed to in the field for the static condition.

For each material or component tested, calculate the weight of contaminant, I, leached by the material or component, M, per unit surface area.

$$\frac{W_{IM}}{SA_{LM}} = \frac{C_{IMEV} \times V_{LM}}{SA_{LM}}$$

Determine the weight of contaminant, I, contributed by material or component, M, based on the surface area in the device.

$$W_{IM} = \frac{W_{IM} \times SA_{FM}}{SA_{LM}}$$

Sum the weight of contaminant, I, contributed by all the materials or components:

$$W_I = EW_{IM}$$

Divide the weight of contaminant, I, by the V_F to arrive at the concentration of contaminant, I, which would have been found in the extractant water if the device had been tested.

$$C_I = \frac{W_I}{V_F}$$

Normalize, C_I, by following the procedure detailed in Appendix B, Section 12 applicable to the device being qualified.

TABLE B.16
NORMALIZATION FACTOR

Product	Exposure Type	Category	Assumptions[1]	N1[2]	N2	NF[2]
PIPE						
Inner Diameter >4"	in-the-product; inside surface only	water main	N2 value equal to one. Assumes the laboratory volume is exposed to the same material from the treatment plant to the point of use.	1	1	1
Inner diameter >4"	in-the-product; alternate diameter or surface area		surface area adjustment adjustment N2 value equal to one based on the above assumptions for in-the-product.	tbd	1	1 TBD
Inner diameter = 4"	in-the-product or in a vessel	multiple user service line	72 feet from water main to the residential connection 2 connections per length	tbd	0.21	tbd
Inner diameter <4" but ≥ 1"	in-the-product or in a vessel	service line	100 feet from street to the meter 1 connection per length 120 gallons per 16 hours (based on residential usage).	tbd	0.034	tbd
Inner diameter <1" but ≥ 1/2"	in-the-product or in a vessel	residential	260 feet of piping/tubing per residence (140' hot and 140' cold) 120 gallons per 16 hours water usage (60 gallons hot and 60 gallons cold) 2.86 gallon static volume (1.43 gallons hot and 1.43 gallons cold)		0.024	tbd
FITTINGS						
For pipe with inner diameter >4"	in-the-product or in a vessel	water main	fittings represent 2% of the total system	tbd	0.02	tbd
For pipe with inner diameter = 4"	in-the-product or in a vessel	multiple user service line	fittings represent 2% of the total system	tbd	0.0042	tbd

TABLE B.16
NORMALIZATION FACTORS
(cont.)

Product	Exposure Type	Category	Assumptions[1]	N1[2]	N2	NF[2]
FITTINGS (cont.)						
For pipe with inner diameter <4" but ≥ 1"	in-the-product or in a vessel	service line	fittings represent 2% of the total system	tbd	0.00068	tbd
For pipe with inner diameter <1" but ≥ 1/2"	in-the-product or in a vessel	residential	fittings represent 6% of the total system	tbd	0.0014	tbd
JOINING MATERIALS						
Used with products with inner diameter >4"	in a vessel	water main	surface area adjustment the N2 value of one (1) assumes that there is no flow dilution because a given volume of water is assumed to remain in the distribution system for 24 hours.	tbd	1	tbd

Product example - Mechanical Joint for 6" I.d. pipe

Assumptions: 6" diameter
1/2" gasket width exposed to water
20' pipe length

SAI = 9.72 in^2 SAI = 2.4 in^2 (15 cm^2) VI = 0.264 gal (1L) VI (static) = 20.4 gal VI (flow) = 29.4

$$N1 = \frac{SAI}{SAI} \times \frac{VI}{VI\ (static)} = \frac{9.72}{2.4} \times \frac{0.264}{29.4} = 0.036 \qquad N2 = \frac{VI\ (static)}{VI\ (flow)} = \frac{20.4}{20.4} = 1$$

NF = N1 x N2 = 0.036 x 1 = 0.036

Used with products with inner diameter = 4"	in a vessel	multiple user service line	72 feet from water main to the residential connection 20 foot pipe lengths (therefore, 5 joints) 2 user connections per line 180 gallons/day/user (based on residential usage)	tbd	0.26	tbd

[1] N2 for service line fittings and valves is 0.00068

TABLE B.16
NORMALIZATION FACTORS
(cont.)

Product	Exposure Type	Category	Assumptions[1]	N1[2]	N2	NF[2]
JOINING MATERIALS (cont.)						
Used with products with inner diameter = 4" (cont.)						
Product Example - Mechanical Joint for 4" I.d. pipe						
Assumptions:			4" diameter 1/2" gasket width exposed to water 20' pipe length			
SAI = 6.26 in^2 SAI = 2.4 in^2 (15 cm^2) VI = 0.264 gal (1L) VI (static) = 47 gal VI (flow) = 180						
$N1 = \frac{SAI}{SAI} \times \frac{VI}{VI\ (static)} = \frac{31.4}{2.4} \times \frac{0.264}{47} = 0.073$ $N2 = \frac{VI\ (static)}{VI\ (flow)} = \frac{47}{180} = 0.26$						
NF = N1 x N2 = 0.073 x 0.26 = 0.019						
Used with products with inner diameter <4" but >1"	In a vessel	service line	100 feet from street to the meter 1 user connection per line 180 gallons per day	tbd	0.23	tbd
For a product example, see multiple user service line above. Only change is the pipe diameter.						
Used with products with inner diameter <1" but ≥1/2"	In a vessel	residual	280 feet of piping/tubing per residence (140' hot and 140' cold) 120 gallons per 16 hours water usage (60 gallons hot and 60 gallons cold) 2.86 gallons static volume (1.43 gallons hot and 1.43 gallons cold)	tbd	0.016	tbd

TABLE B.16
NORMALIZATION FACTORS
(cont.)

Product	Exposure Type	Category	Assumptions[1]	N1[2]	N2	NF[2]
JOINING MATERIALS (cont.)						
Used with products with inner diameter <1" but 1/2"						
Product Example - Solder/Solvent Cement joint for 1/2" pipe						
Assumptions:	1/2" diameter 1/4" weld width 280' total pipe length for residence 200 welds (based on 100 fittings)					
SAI = 78 in^2	SAI = 2.4 in^2 (15 cm^2)	Vl = 0.264 gal (1L)	Vl (static) = 1.43 gal	Vl (flow) = 90		
$N1 = \frac{SAI}{SAI} \times \frac{Vl}{Vl\ (static)} = \frac{78}{2.4} \times \frac{0.264}{1.43} = 3$			$N2 = \frac{Vl\ (static)}{Vl\ (flow)} = \frac{1.43}{90} = 0.016$			
NF = N1 x N2 = 3 x 0.016 = 0.048						
VALVES						
Used with products with inner diameter ≥4"	in-the-product	water main and multiple user service line	20 valves per mile 4" I.d. 6" valve length	1	0.002	0.002
	in-the-vessel	water main and multiple user service line	20 valves per mile 4" I.d. 6" valve length	tbd	0.002	tbd
Used with products with inner diameter <4" but ≥1/2"	in-the-vessel	service line	fittings represent 2% of the total system	tbd	0.00068	tbd
	in-the-vessel	service line		tbd	0.00068	tbd

General Assumptions: 180 gallons per day used per residence
20' pipe lengths (mains and service lines)
280' pipe/tubing within a residence (plumbing system)
100 fittings per residence (2% of total system surface area)
200 joints/welds per residence
Static volumes for the residence are based on 1/2" I.d. copper tube. For other products, the actual diameter should be used, and the volume adjusted to reflect difference.

tbd = to be determined. These values will be determined based on the laboratory surface area to volume exposure ratio, and based on whether they are factors for flowing or static conditions.

12.10 NORMALIZATION FOR ENDPOINT DEVICES, COMPONENTS, AND MATERIALS:

12.10.1 NORMALIZATION FOR LEAD: Each laboratory concentration shall be normalized to one liter using the equation in Section 12.3 where $V_{F(static)} = 1$ liter and $N_2 = 1$ and shall be multiplied by the cold mix volume adjustment factor (CMV) where:

CMV = cold water volume/total volume of device.

For commercial kitchen and bar faucets, $V_{F(static)} = 5$ gallons (18.9 liters) and $N_2 = 1$.

A parametric data evaluation (Section 12.11) shall be used to evaluate the test results for lead.

12.10.2 NORMALIZATION FOR ALL ANALYTES EXCEPT LEAD: The laboratory concentration is normalized to one liter using the equation in Section 12.3 where $V_{F(static)} = 1$ liter and $N_2 = 1$. For commercial kitchen and bar faucets, $V_{F(static)} = 5$ gallons (18.9 liters) and $N_2 = 1$. The geometric mean of normalized contaminant concentrations from exposure at Day 19 shall be compared to the MAL.

12.11 PARAMETRIC DATA EVALUATION: The term "product" in Section 12.11 connotes "endpoint devices, components, and materials." This procedure is based on testing a sampling of products to determine the lead leaching concentrations of the product line. A derived test statistic determines whether the product line is acceptable under this standard. The calculations assume that the lead dosage leached from the product is lognormally distributed.

The number of products to be tested shall be specified by the manufacturer, though a minimum of three is required. It is recommended that product lines thought to be marginally acceptable (those that leach higher, but acceptable, dosages of lead) should be tested for more than the minimum number of products. For each of the products tested, the "product dosage" D_i is derived from the test data as detailed in Section 12.11.2. These dosages are used to calculate the test statistic Q, which determines whether the product line is acceptable. Q is an exact 90% upper confidence bound on the 75th percentile product dosage.

In the event of a product failure, there is provision for a single retest. Retest results shall be combined with those from the initial test. The accumulated product dosages shall be used to calculate the retest statistic, R, which determines whether the product line is acceptable. R is an exact 99% upper confidence bound on the 75th percentile product dosage.

12.11.1 TEST DATA: The analytical protocol described in Appendix B, Section 8.4 generates nine measured lead dosages (on days 3, 4, 5, 10, 11, 12, 17, 18, and 19) leached from each of the products sampled from a particular product line. The number of products tested is defined as "n". The test data is described as

9·n data values of x_{ij} (ith product measured on the jth day) and is shown in Table B.17. This data is used to calculate the product dosage D_i, for each of the tested products.

Table B.17. Data Available for Determination of Lead Test Statistic

Product #	Measured Lead Dosage on Day								
	3	4	5	10	11	12	17	18	19
1	$X_{1\,3}$	$X_{1\,4}$	$X_{1\,5}$	$X_{1\,10}$	$X_{1\,11}$	$X_{1\,12}$	$X_{1\,17}$	$X_{1\,18}$	$X_{1\,19}$
2	$X_{2\,3}$	$X_{2\,4}$	$X_{2\,5}$	$X_{2\,10}$	$X_{2\,11}$	$X_{2\,12}$	$X_{2\,17}$	$X_{2\,18}$	$X_{2\,19}$
3	$X_{3\,3}$	$X_{3\,4}$	$X_{3\,5}$	$X_{3\,10}$	$X_{3\,11}$	$X_{3\,12}$	$X_{3\,17}$	$X_{3\,18}$	$X_{3\,19}$
•	•	•	•	•	•	•	•	•	•
•	•	•	•	•	•	•	•	•	•
•	•	•	•	•	•	•	•	•	•
n	$X_{n\,3}$	$X_{n\,4}$	$X_{n\,5}$	$X_{n\,10}$	$X_{n\,11}$	$X_{n\,12}$	$X_{n\,17}$	$X_{n\,18}$	$X_{n\,19}$

This data is used to calculate the statistics Q and R for the initial test and retest, respectively.

12.11.2 CALCULATIONS: The test statistic depends upon the log-dosage mean and standard deviation. These values are derived as follows. Calculate the natural log-transformed value $Y_{ij} = \ln(X_{ij})$ of the original data values. For each of the products tested, calculate the product dosage D_i across the nine measured days, where:

$$D_i = e^{Yi}$$

and

$$Y_i = \frac{Y_{i3}+Y_{i4}+Y_{i5}+Y_{i10}+Y_{i11}+Y_{i12}+Y_{i17}+Y_{i18}+Y_{i19}}{9}$$

Calculate the log-dosage mean of Y_i and the log-dosage standard deviation of Y_i for each product, where:

$$\text{Log-Dosage Mean} = \bar{Y} = \frac{\sum_{i=1}^{n} Y_i}{n}$$

and

$$\text{Log-Dosage Standard Deviation} = S = \sqrt{\frac{\sum_{i=1}^{n} (Y_i - \bar{Y})^2}{(n-1)}}$$

12.11.3 INITIAL TEST STATISTIC: The test statistic, Q shall be determined as

$$Q = e^{\bar{Y}} e^{k_1 S}$$

where the log-dosage mean, $\bar{Y}$ and the log-dosage standard deviation, S are determined using the procedures described in Section 12.11.2. The value of k_1 depends upon the sample size. Table B.18 presents the value of k_1 for a range of sample sizes. The acceptability of the product line depends upon the value of the test statistic, where:

Case I. If $Q \leq 11$ µg, the product line has tested as acceptable.
Case II. If $Q > 11$ µg, the product line has tested as unacceptable.

12.11.4 RETEST STATISTIC: The retest statistic, R shall be determined as

$$R = e^{\bar{Y}} e^{k_2 S}$$

where the log-dosage mean, $\bar{Y}$ and the log-dosage standard deviation, S are determined using the procedures described in Section 12.11.2. The value of k_2 depends upon the sample size. Table B.19 presents the value of k_2 for a range of sample sizes. The acceptability of the product line depends upon the values of the retest statistic, where:

Case I. If $R \leq 11$ µg, the product line has tested as acceptable.
Case II. If $R > 11$ µg, the product line has tested as unacceptable.

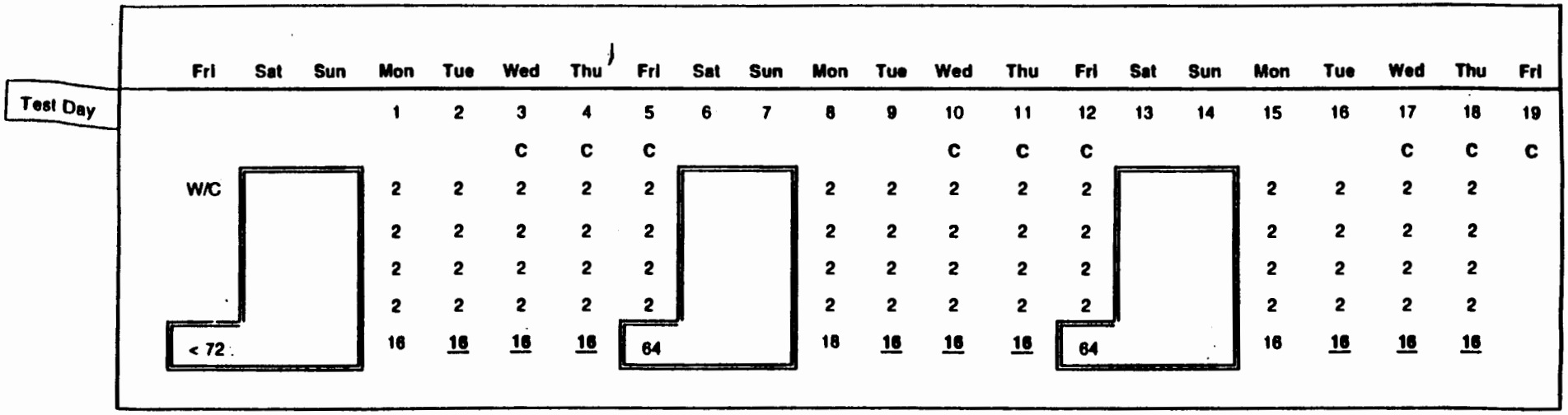
Table B.18 Values of k_1 for Determining Test Statistic Q

Sample Size	k_1	Sample Size	k_1	Sample Size	k_1
3	2.60281	19	1.05769	35	0.94208
4	1.97224	20	1.04590	36	0.93783
5	1.69779	21	1.03510	37	0.93377
6	1.53987	22	1.02517	38	0.92990
7	1.43526	23	1.01598	39	0.92618
8	1.35984	24	1.00747	40	0.92262
9	1.30234	25	0.99954	41	0.91921
10	1.25672	26	0.99213	42	0.91592
11	1.21943	27	0.98520	433	0.91277
12	1.18824	28	0.97869	44	0.90973
13	1.16167	29	0.97256	45	0.90680
14	1.13870	30	0.96677	46	0.90397
15	1.11859	31	0.96130	47	0.90125
16	1.10080	32	0.95612	48	0.89861
17	1.08491	33	0.95120	49	0.89607
18	1.07063	34	0.94653	50	0.89361

Table B.19 Values of k_2 for Determining Retest Statistic R

Sample Size	k_2	Sample Size	k_2	Sample Size	k_2
6	2.84809	21	1.39862	36	1.18574
7	2.49072	22	1.37611	37	1.17721
8	2.25337	23	1.35548	38	1.16907
9	2.08314	24	1.33647	39	1.16130
10	1.95433	25	1.31889	40	1.15387
11	1.85297	26	1.30257	41	1.14676
12	1.77079	27	1.28738	42	1.13994
13	1.70259	28	1.27319	43	1.13340
14	1.64491	29	1.25989	44	1.12711
15	1.59536	30	1.24740	45	1.12107
16	1.55224	31	1.23565	46	1.11526
17	1.51431	32	1.22455	47	1.10966
18	1.48063	33	1.21407	48	1.10425
19	1.45048	34	1.20413	49	1.09904
20	1.42329	35	1.19470	50	1.09401

FIGURE B.2



KEY	
	W/C = Washing and conditioning
	< 72 = Dwell between conditioning and exposure sequence (Maximum: 72 hours)
	2 = Dump and fill 2 hour intervals
	16 = 16 hour dwell (overnight)
	<u>16</u> = 16 hour dwell for data
	C = Collect prior day's 16 hour dwell
	64 = 64 hour dwell (weekend)

13.0 EXTRACTION WATER PREPARATION:

13.1 CHEMICAL CHARACTERISTICS: Three extraction waters are available for exposure: (a) pH=5, with 2 mg/L available chlorine and 100 mg/L hardness; (b) pH=8, with 2 mg/L available chlorine and 100 mg/L hardness and (c) pH=lO, with 2 mg/L available chlorine.

13.2 REAGENTS

13.2.1 REAGENT WATER: Deionized water prepared to meet specifications for ASTM D1193 type II reagent water.

13.2.2 PHOSPHATE BUFFER STOCK SOLUTIONS (0.1M): Dissolve 13.89g sodium dihydrogen phosphate monohydrate in reagent water, dilute to 1.0 L and mix thoroughly. Prepare fresh weekly. This buffer should be used with only the magnesium hardness reagent.

13.2.3 MAGNESIUM HARDNESS STOCK SOLUTION (0.04M): Dissolve 8.13g magnesium chloride hexahydrate in reagent water, dilute to 1.0 L, mix thoroughly. Prepare fresh weekly.

13.2.4 CHLORINE STOCK SOLUTION (0.025M): Dilute 7.3 mL reagent grade sodium hypochlorite (5 percent NaOCl) to 200 mL with reagent water., Store in tightly stoppered amber reagent bottle protected from light and stored at 20°C. Prepare fresh weekly.

1. Determining Chlorine Stock Solution Strength - Determine the strength of the chlorine stock solution by diluting 1.0 mL to 1.0 L with reagent water. Immediately analyze for total available residual chlorine. Refer to this determination as "A".

2. Determining Amount of Chlorine Stock Solution Required to Obtain 2% Residual Chlorine - To determine the volume of chlorine stock solution necessary to add to the extraction water to obtain 2.0 mg/L chlorine residual, use the following formula:

$$\text{mL Stock Solution} = \frac{2.0 \times B}{A}$$

where A = Chlorine equivalent per mL of Chlorine stock solution (determined above)

where B = liters of extraction water

13.2.5 CALCIUM HARDNESS STOCK SOLUTION (0.04M): Dissolve 4.44g anhydrous calcium chloride in reagent water, dilute to 1.0L, mix thoroughly. Prepare fresh weekly.

13.2.6 SODIUM BICARBONATE BUFFER (0.04M): Dissolve 3.36g sodium bicarbonate in reagent water and dilute to 1.OL mixing thoroughly. Prepare fresh weekly.

13.2.7 SODIUM HYDROXIDE SOLUTION (0.1M): Dissolve 4.0g of sodium hydroxide in reagent water, dilute to 1.0 L and mix well.

13.2.8 SODIUM BORATE SOLUTION (0.05M): Dissolve 19.07g of sodium borate decahydrate ($Na_2B_4O_7 \cdot 10H_2O$) in reagent water, dilute to 1.0 L and mix well.

13.3 pH=5 WATER: Prepare pH 5 extraction water to contain 100 mg/L hardness and 2 mg/L available chlorine. Stock reagent solutions in the amounts shown in Table B.20, should be diluted to the desired water volume with reagent water.

13.4 pH=8 WATER: Prepare pH 8 extraction water to contain 100 mg/L hardness and 2 mg/L available chlorine. Stock reagent solutions in the amounts shown in Table B.20, should be diluted to the desired water volume with reagent water.

13.4.1 pH = 8 WATER (ORGANIC ANALYSIS): Prepare pH 8 organic extraction water to contain 100 mg/L hardness and 0 mg/L available chlorine. Stock reagent solutions in the amounts shown in Table B.20 should be diluted to the desired water volume with reagent water.

13.5 pH=10 WATER: Prepare pH 10 extraction water to contain 2 mg/L available chlorine. Stock reagent solutions in the amounts shown in Table B.20, should be diluted to the desired water volume with reagent water.

TABLE B.20
One Liter Volume of Extraction Waters

pH	Solution #1	Solution #2	Chlorine Stock Solution
5	25 mL of 0.1M NaH_2PO_4	25 mL of 0.04M $MgCl_2y$	See 12.2.4
8	25 mL of 0.04M $NaHCO_3$	25 mL of 0.04M $CaCl_2$	See 12.2.4
8 (organic)	25 mL of 0.04M $NaHCO_3$	25 mL of 0.04M $CaCl_2$	
10	50 mL of 0.1M NaOH	50 mL of 0.05M $Na_2B_4O_7$	See 12.2.4

APPENDIX C

MECHANICAL DEVICES
ACCEPTABLE MATERIALS

(This Appendix is part of the Standard)

1.0 BACKGROUND

This Appendix is intended to provide materials that have been shown to comply with Item 8.2.2 of the Standard.

APPENDIX C
MECHANICAL DEVICES
ACCEPTABLE MATERIALS

MATERIALS	STANDARD REFERENCE	ALLOY/COMPOUND IDENTIFICATION	SURFACE AREA/VOLUME	PRIMARY/POTENTIAL CONSTITUENTS [WEIGHT PERCENT]	REMARKS
Cast Iron ASTM A-126 Class B	ASTM A-126	Class B	473 cm^2/L	Carbon 3.20-3.55% Silicon 1.60-2.20% Phosphorus 0.40% Max. Sulphur 0.15% Max. Manganese 0.40-0.80% Chrome 0.05-0.40% Aluminum 0.005% Max. Lead 0.005% Max. Tin 0.10% Max Iron balance	1

[1] Chemical content will vary from those shown, depending upon wall thickness and other characteristics of castings to be poured from melt, to ensure desired physical properties of the iron in the casting.

APPENDIX D

EVALUATION OF MICROBIOLOGICAL GROWTH SUPPORT POTENTIAL (MDOD TEST METHOD)

(This Appendix is part of the Standard)

APPENDIX D
EVALUATION OF MICROBIOLOGICAL GROWTH SUPPORT POTENTIAL (MDOD TEST METHOD)

1.0 BACKGROUND

1.1 GENERAL: This appendix contains the protocol for determining a product's potential to support microbiological growth in the distribution system. The protocol presented in this section was derived from the method described by J. S. Colbourne and D. A. Brown (1979)[1]. The protocol involves exposing a product sample to dechlorinated tap water inoculated with a fresh aliquot of water from a surface water source river of suitable quality for treatment as drinking water. The uptake of dissolved oxygen (DO) is measured and compared with water to an inert control (e.g., glass). The DO is measured using a calibrated electrode during the fourth, fifth, and sixth weeks. The mean of the DO values for the fourth, fifth, and sixth weeks is calculated for each sample and subtracted from the mean DO for the fourth, fifth, and sixth week of the control. This value is described as the mean dissolved oxygen difference (MDOD). In addition, during the final week of the protocol, the samples are analyzed for the enumeration of Pseudomonas species and total coliforms.

2.0 SAMPLES

2.1 REQUIREMENTS: Test samples of materials for evaluation shall be prepared such that upon exposure, a surface area-to-volume ratio of 150 cm^2/L is obtained. Sufficient sample shall be supplied to perform the test in triplicate.

2.1.1 TEST SAMPLE SPECIFICATION: Test samples specifications for the products covered by the standard are given in Table D.1.

[1]Colbourne, J. S., and Brown, D. A.: "Dissolved Oxygen Utilization as an Indicator of Total Microbiological Activity on Non-metallic Materials in Contact with Potable Water," Journal of Applied Bacteriology, 1979, 47:223-231.

TABLE D.1
TEST SAMPLES
MICROBIOLOGICAL GROWTH SUPPORT

MATERIAL	FORM
Gasket Materials (e.g., NBR, EPR, SBR, etc.)	ASTM D3182 Tensile Sheets
Plasticized Pipes	12 inch lengths of smallest diameter available
Solvent Based Coatings	Six 2" x 4" glass slides coated on one side with the product, per test
Plasticized Liners	2" x 4" coupons
Caulks, Sealants, Greases Lubricants	Six 2" x 4" glass slides coated on one side with the product, per test
Solvent Cements	Six 2" x 4" glass slides coated on one side with the product, per test

2.2 PREPARATION: Samples shall be prepared so that the entire surface to be exposed is covered by extractant water.

2.2.1 SIZING SAMPLES: The product (when appropriate) shall be cut to an appropriate size to fit the exposure vessel and to maintain the surface area-to-volume ratio in Section 2.1.

2.2.2 APPLICATION: The product (when required) shall be applied per manufacturer's written instructions. If glass is inappropriate, an alternate substrate may be used.

(1) COATINGS: These products shall be applied to a clean glass slide at the appropriate film thicknesses per manufacturer's written instructions. Multiple layer coating systems shall be applied so that each layer (as appropriate) covers the entire slide. The prepared slides shall be cured 28 days prior to exposure.

(2) CAULKS, GREASES, LUBRICANTS, AND SEALANTS: These products shall be applied to a clean glass slide in a manner that an even thin film is achieved. The slides are allowed to air-dry and/or cure according to the manufacturer's written instructions.

(3) SOLVENT CEMENTS: These products shall be applied to a clean glass slide in a manner that an even film is achieved. The solvent cement shall be applied and cured according to the manufacturer's written instructions.

2.2.3 WASHING: Prior to exposure, the samples (where appropriate) shall be washed with laboratory detergent and tap water. Prior to exposure, the samples shall be rinsed three times with organic free deionized water.[2]

3.0 EXPOSURE

3.1 EXPOSURE WATER: The samples shall be exposed in oxygenated, dechlorinated tap water that has been initially inoculated with a fresh sample of river water.

3.1.1 INOCULUM: Water from a surface water source suitable for treatment as drinking water (e.g., river, lake) shall be collected on the day of the test at a site near the inlet to a water treatment plant. The river water samples shall be characterized by coliform analysis and heterotrophic plate count prior to use.

3.1.2 DECHLORINATED TAP WATER: Tap water shall be prepared as described below for use as exposure water. The water shall have no greater than 0.1 mg/L total residual chlorine and shall be saturated with oxygen.

(1) Fresh tap water shall be collected in a 30-liter glass jar and warmed to 30•C on a hot plate.

(2) The water shall be dechlorinated by adding sufficient sodium thiosulfate according to volume.

(3) The total residual chlorine content of the water shall be checked by the iodometric technique prior to use. This value shall be less than 0.1 mg/L.

(4) The water shall be continuously aerated to saturation by passing compressed air through a silicone rubber tube and diffused through a coarse glass air stone.

3.2 VESSEL EXPOSURE: Test samples shall be placed in vessels to maintain the surface area to volume ratio described in Section 2.1. Test samples shall be exposed in clear, 1 quart glass jars that have been cleaned prior to use and which have PTFE (polytetrafluoroethylene) lined lids.

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[2]The deionized water shall meet ASTM D1193 Type II specifications.

3.3 EXPOSURE: Tests for qualification of a product shall be conducted using a multiple exposure procedure. Analyses are performed only during the final three weeks of the exposure. The test shall be performed in triplicate. Exposure times and temperatures are listed in Table D.2.

3.3.1 BLANKS: Reagent blanks, including an uncoated substrate as applicable, shall be prepared for each product sample.

3.3.2 INITIAL INOCULATION: The test shall be set up as described below:

1. Place 100 cm^2 of test sample in the vessel.
2. Add 65 mL of the inoculum (Section 3.1.1).
3. Bring the volume of exposure water to 650 mL using dechlorinated tap water (Section 3.1.2).
4. Seal the jar and incubate in a 30•C BOD incubator.

3.3.3 MULTIPLE EXPOSURE: The samples prepared in Section 3.3.2 shall have 99% (643.5 mL) of the water changed twice weekly, as described in Table D.2, during a total period of six weeks. The volume shall be replaced using dechlorinated tap water (Section 3.1.2).

3.3.4 EXTENSION OF TESTING: To accommodate products which test marginally by this criteria, the test may be extended. If, after the 6th week, the apparent MDOD value is between 2.0 and 3.0 mg/L the test procedure shall be continued for an additional two weeks (Table D.2), and the MDOD recalculated based on all five measurements (4th, 5th, 6th, 7th, and 8th weeks).

TABLE D.2
EXPOSURE SEQUENCE

EXPOSURE TIME	ELAPSED TIME	TEMPERATURE	COMMENT
3 days	3 days	30•C	Discard and replace 99% of the exposure water
4 days	7 days	30•C	Discard and replace 99% of the exposure water
3 days	10 days	30•C	Discard and replace 99% of the exposure water
4 days	14 days	30•C	Discard and replace 99% of the exposure water
3 days	17 days	30•C	Discard and replace 99% of the exposure water
4 days	21 days	30•C	Discard and replace 99% of the exposure water
3 days	24 days	30•C	Discard and replace 99% of the exposure water
4 days	28 days	30•C	Take first dissolved oxygen reading. Discard and replace 99% of the exposure water
3 days	31 days	30•C	Discard and replace 99% of the exposure water
4 days	35 days	30•C	Take second dissolved oxygen reading. Discard and replace 99% of the exposure water
3 days	38 days	30•C	Discard and replace 99% of the exposure water
4 days	42 days	30•C	Take third dissolved oxygen reading.

Is the mean dissolved oxygen difference between 2.0 and 3.0 mg/L?

No	Yes
Discontinue test	Discard and replace 99% of the extractant water
and	and
Test for enumeration of Pseudomonas species and total coliform bacteria	Continue test for two additional weeks

EXPOSURE TIME	ELAPSED TIME	TEMPERATURE	COMMENT
3 days	45 days	30•C	Discard and replace 99% of the exposure water
4 days	49 days	30•C	Take fourth dissolved oxygen reading. Discard and replace 99% of the exposure water
3 days	52 days	30•C	Discard and replace 99% of the exposure water
4 days	56 days	30•C	Take fifth dissolved oxygen reading Discontinue test Test for enumeration of Pseudomonas species and total coliform bacteria

4.0 ANALYSIS

4.1 GENERAL: Beginning with the 4th week of the exposure, the exposure vessels shall be measured weekly for dissolved oxygen content. Following completion of the test, the exposure water shall be analyzed for Pseudomonas species and total coliforms.

4.2 DISSOLVED OXYGEN MEASUREMENTS: Using a YSI Model 58 Dissolved Oxygen Meter (or equivalent) determine the dissolved oxygen content of both the controls and samples.

4.2.1 STANDARDIZATION: The instrument shall be calibrated prior to each set of readings. The instrument shall be standardized using split samples of water having the same oxygen content and temperature (Solution A and Solution B).

(1) SOLUTION A: The oxygen content of the first sample (Solution A) shall be determined using the Winkler Titration Method.

(2) SOLUTION B: Solution B shall be used to calibrate the meter to give a reading equal to the dissolved oxygen content of Solution A.

4.3 PSEUDOMONAS DETERMINATION: The Psuedomonas species shall be counted via serial dilution and spread plate technique on dry plates of Pseudomonas isolation agar.

4.4 TOTAL COLIFORM DETERMINATION: Total coliforms shall be counted by the membrane filtration method (Standard Methods, 16th Edition).

5.0 EVALUATION CRITERIA

5.1 MDOD CRITERIA: A maximum MDOD value has not been established for the products/materials covered by this standard. Data developed through MDOD testing shall be reported over the 24 months following adoption of the standard. These data shall be used in setting future limits.

5.2 ADDITIONAL CRITERIA: In addition to the MDOD value, total coliform and Pseudomonas analyses shall be performed. These analyses shall be performed only during the final week of the test. Although pass/fail criteria have not been established, if a product has a low MDOD value, but a one hundred fold increase in either or both of these organisms over the control, this value shall be reported. These data shall be used in setting future limits.

6.0 RATIONALE FOR MDOD EVALUATION OF PRODUCTS FOR MICROBIOLOGICAL GROWTH SUPPORT POTENTIAL: The Mean Dissolved Oxygen Difference (MDOD) protocol for determining a product's potential to support microbiological growth in the drinking water distribution system is based on a method developed by J. Colbourn and D. Brown.[3]

This protocol is based on the measurement of dissolved oxygen as an indirect indicator of the magnitude of microorganisms' ability to utilize the test material as a source of carbon and energy. Growing aerobic bacteria require oxygen for the biochemical degradation of organic materials and oxidization of inorganic compounds (i.e., sulfides and ferrous iron). The rate at which dissolved oxygen is utilized is directly proportional to the level of microbiological activity.

In summary, the procedure used in this appendix involves the exposure of a sample to dechlorinated tap water inoculated with a fresh aliquot of water from a surface water source of suitable quality for treatment as drinking water. The uptake of dissolved oxygen (DO) is measured and compared with water exposed to an inert control (usually glass). Twice per week, 99% of the exposure water is changed with fresh dechlorinated tap water. This is continued for six weeks. The DO is measured with a calibrated electrode during the fourth, fifth, and sixth weeks. The mean of the DO values for these three weeks is calculated for each sample and subtracted from the mean DO of the control container. This value is described as the mean dissolved oxygen difference (MDOD).

An MDOD value of 2.1 mg/L has been recommended and accepted by some European regulatory authorities as the upper tolerance limit of certain materials in contact with drinking water. Interlaboratory studies have shown that the method has excellent reproducibility when testing is performed by different laboratories, using different natural inocula. To accommodate the inherent variability of the protocol and individual laboratory performance, a value of 2.1 ± 0.5 mg/L, or acceptance of products with an MDOD of 2.6 mg/L or less is recommended by Colbourne and Brown.

To accommodate products which test marginally by this criteria, the test may be extended. If the apparent MDOD after the 6th week is between 2.0 and 3.0 mg/L the testing procedure is continued for an additional two weeks. The MDOD is recalculated based on all five measurements (4th, 5th, 6th, 7th, and 8th weeks).

Colbourne and Brown, using 50 different materials, demonstrated a clear correlation between the microbial growth response as measured by the MDOD method and microbiological problems experienced in the field as defined by Schoenen and Scholer. Table D.3 correlates the MDOD values determined in the laboratory with field observations.

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[3]Colbourne, J. S., and Brown, D. A. "Dissolved Oxygen Utilization as an Indicator of Total Microbial Activity of Non-metallic Materials in Contact With Potable Water," Journal of Applied Bacteriology, 1979, 47:223-231.

TABLE D.3
RELATIONSHIP BETWEEN MICROBIAL GROWTH
AND MEAN DISSOLVED OXYGEN VALUES

Laboratory System (Colbourne & Brown 1979)	In Service Problems (Schoenen & Scholer 1985)	
Range of mean dissolved oxygen difference (mg/L) exhibited in defined laboratory tests	Degree of microbial growth observed under "in-service" conditions	
	Surface Growth	Increased Bacterial Counts In Water
0.0 - 2.1	Negative	Negative
2.2 - 3.4	Positive	Negative
3.5 - 8.0	Positive	Positive

Schoenen and Scholer[4] have identified the primary problem with using an inoculum based on laboratory cultures as a lack of correlation between test results and in-service performance. A natural inoculum of mixed organisms has consistently demonstrated microbiological effects in laboratory tests closely matching field observations of test compounds. Questions have also been raised regarding the variability associated with mixed natural inocula. An extensive trial using eight different sources of natural inocula and test tap waters found no obvious differences in results when using different inocula or waters in various laboratories (Warren, 1985).[5]

In addition to the MDOD value, analyses of total coliforms and Pseudomonas species are also recommended. These analyses are performed because selective enhancement of these indicator organisms may occur in test water with low MDOD values. The work of Elgas and Lee[6] in the area of system regrowth of indicator organisms due to component materials suggests a limit of a one hundred fold increase in either one or both of these organisms over the control as a basis for rejection. These analyses are performed only on the final week of the test.

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[4]Schoenen, D., and Scholer, H. F., Drinking Water Materials, Field Observations and Methods of Investigation, Ellis Horwood, Ltd., Chichester, England, 1985.

[5]Warren, I., "The Effect of Water Quality of Certain Test Methods Used to Assess Microbiological Growth on Materials in Contact With Potable Water," Report 1059, WRC Environment, 1985.

[6]Elgas, and Lee, "Reservoir Coatings CAL Support Bacterial Growth," Journal of American Water Works Association, December 1980, pp. 693-695.

APPENDIX E

RATIONALE DOCUMENT FOR ADDITIVES TOXICOLOGY REVIEW AND EVALUATION PROCEDURES (APPENDIX A)

(This Appendix is not part of the Standard)

I. Background

II. Information Sources

III. Evaluation Criteria and Requirements

IV. Description of Toxicity Tests

V. Risk Estimation

APPENDIX E
RATIONALE DOCUMENT FOR ADDITIVES TOXICOLOGY REVIEW AND EVALUATION PROCEDURES

I. BACKGROUND:

This document was prepared by the National Sanitation Foundation (NSF) Health Effects Task Group of the Drinking Water Additives Program. The information presented provides a rationale for the scientific criteria described in Appendix A of NSF Standard 61 (Drinking Water System Components - Health Effects) for use in evaluating the health safety of indirect drinking water additives.

Characterization of the health safety of products used in drinking water applications consists of the following elements:

1. Identification of substances contributed to potable water by the product or material (referred to as product) being evaluated.

2. Estimation of the human exposure to the substance through drinking water.

3. Evaluation of potential health safety concerns presented by this exposure.

4. Estimation of the acceptable risk associated with the use of the product in drinking water.

The risk assessment areas involved in making this characterization are:

1. Compound identification
2. Dose
3. Dose-response relationship, toxicity, risk estimation
4. Risk management.

Appendix B (Sampling, Preparation, and Analysis) has been designed to provide information on exposure. Appendix B includes the laboratory analytical and exposure methods for identifying contaminant(s) extracted into water and the mechanism for estimating normalized contaminant concentration "at-the-tap." Appendix A is designed to address the potential health effects resulting from normalized contaminant concentrations. Appendix A is divided into two main sections. Section 2.0 (Application and Evaluation Stage) describes information and toxicology testing requirements. Section 3.0 (Risk Estimation) presents calculations which bring together the quantifiable aspects of exposure and health effects.

The Appendix A toxicology evaluation is <u>not</u> required for additives covered by U.S. Environmental Protection Agency (EPA) National Primary Drinking Water Regulations; i.e., substances for which Maximum Contaminant Levels exist. In addition, substances which are Generally Recognized as Safe (GRAS) by the Food and Drug Administration (FDA), which have received prior sanctions as food additives, or which are appropriately referenced by other

documentable sources may not require further toxicology evaluation. The purpose of the tiered toxicology evaluation system is to provide a means to evaluate additives which have not been evaluated to a degree equivalent to current EPA, FDA, or other similar requirements as explained below.

It is important to note that each additive product may contribute one or more contaminants to water. The testing protocols described in Appendix B, along with a review of the product formulation, are intended to identify contaminants contributed to drinking water as a result of additive use. Contaminants appearing in the water may originate as ingredients, impurities of ingredients, or as unique chemical species formed during the manufacture and/or use of the product. The normalized contaminant concentration will determine the information and test requirements for that contaminant as detailed in Figures 1, 2, 3, 4, and Appendix A.

The toxicology testing schemes presented in Figures 1, 2, 3, and 4 are guidelines to the minimum test requirements for health safety evaluations. These guidelines are intended to provide flexibility for both the applicant and the certifying agency. Throughout the review process, technical communication is encouraged between the applicant and the certifying agency to facilitate efficient and expeditious product review. Final decisions concerning the acceptability of a product for additive use are made by the certifying agency through a process of risk estimation and risk management based on the information supplied by the applicant.

II. INFORMATION SOURCES:

The health safety information required in Appendix A may be available to the applicant from the following sources:

1. Published literature
2. Contracted laboratory studies
3. In-house laboratory studies
4. Published regulations, limitations, and sanctions, such as the Water Chemicals Codex, Direct/Indirect Food Additives (21 CFR) GRAS compounds, and other prior sanction substances, when appropriate.

The applicant is required to provide a rationale justifying how the submitted health safety information fulfills the requirements of Appendix A. Prior acceptances will not automatically qualify a substance under Standard 61, due to differences in exposure levels, new available toxicity data, and possible differences in use and application.

The suitability of any data submitted for evaluation is subject to review by the certifying agency to determine the following:

1. Adherence to recognized toxicology protocol guidelines (see Section 2.0.7 Appendix A)
2. Appropriateness of the information
3. Use of acceptable scientific judgment.

III. EVALUATION CRITERIA AND REQUIREMENTS

The toxicological evaluation procedures and requirements have been developed based on the principle of "commensurate effort." This principle states that the amount of data needed to determine the safety of an additive should relate in some manner to its potential for causing an adverse health effect. The basic precepts of toxicology suggest that the potential for any chemical to cause an adverse health effect is related to the level of exposure or dose. Therefore, the system described below increases toxicological testing requirements as potential human exposure increases.

The principle of commensurate effort was incorporated because it is a balanced approach for developing toxicological testing guidelines and requirements which effectively uses limited resources. This approach concentrates more resources on a smaller number of high exposure, potentially higher-risk additives, and a reduced level of effort is expended on low exposure, potentially lower-risk additives.

The Standard 61 procedures are similar to those used by the Food and Drug Administration (FDA) in its evaluation of food additives. Both systems use exposure concentrations in grouping additives for evaluation. In addition, testing requirements are more extensive for the high exposure chemicals than they are for low exposure chemicals (FDA, 1982). Unlike Standard 61, the FDA system uses estimates of potential toxicity based on structure/activity relationships. The potency groupings are integrated with exposure data in determining the rigor demanded in the initial testing of direct additives only. The Standard 61 approach does not formally incorporate estimates of toxic potency based on structure/ activity relationships into its toxicity testing requirements because of the inadequacy of the available information in this arena. However, structure/activity inferences relative to toxicity are always available to both the applicant and the certifying agency as a point of scientific reference. These estimates can be used to justify either increased or decreased testing requirements for a specific substance.

A. Toxicity Testing Exposure Categories

As described above, minimum testing requirements are related to estimated contaminant concentrations. The contaminant concentration range associated with each toxicity testing category is as follows:

Level I < 10 ppb
Level II ≥ 10 ppb to < 50 ppb
Level III ≥ 50 ppb to < 1000 ppb
Level IV ≥ 1000 ppb (1 ppm)

Practical considerations were used in the selection of contaminant concentration limits for the four testing levels. For example, most non-carcinogenic chemicals found in drinking water are regulated at concentrations between 10 to 1000 ppb. Consequently, it is important that the potential for target organ toxicities of any contaminant that would be present in tap water within this range be characterized before the contaminant is used

in a drinking water system. In contrast, carcinogenic chemicals are regulated at concentrations even lower than 10 ppb.

B. Toxicity Testing Guidelines For Each Contaminant Concentration Range

Following are brief descriptions of the toxicology testing guidelines for the four contaminant concentration ranges:

LEVEL I - Testing focuses on genetic toxicity studies when exposure to a contaminant is determined to be <10 ppb. Although, classically the carcinogenic potential associated with a contaminant is determined by lifetime studies in experimental animals, such expensive studies are not warranted for every contaminant that might be contributed to water by an additive product. As a result, the Health Effects Task Group has required genetic toxicity testing as the primary screen for the concentration range <10 ppb. This type of testing is intended to address the carcinogenic potential of contaminants occurring at very low levels. If a contaminant produces positive results in genetic toxicity testing, then it would be subjected to additional testing, possibly including lifetime studies in experimental animals before it could be employed in a drinking water system. If genetic toxicity testing results were negative, lifetime testing would not be conducted. This policy may be modified if a contaminant has a chemical structure which would be highly suspect, or if its properties precluded valid genetic toxicity testing. When contaminant concentrations for individual Standard 61 toxicity categories are compared to FDA Concern Levels, there is good agreement in values and test requirements, especially at lower concentrations (Table 1). If the total normalized contaminant concentrations are <10 ppb and the analysis of individual contaminants is technically impractical and/or can not be synthesized in quantities sufficient for testing, then genetic toxicity testing of the total contaminants should be considered.

Level I is initially the least extensive and includes a gene mutation study, preferably the Ames Salmonella assay with and without activation, and a chromosomal aberration (preferably mammalian in vivo) or micronucleus test. The applicant may attempt mitigation of positive results from both the Ames test and an in vivo mammalian chromosome aberration or micronucleus test by submitting information from additional genetic toxicity testing or other special studies. If this approach is selected, a rationale must be supplied as to the significance of such additional data. It is anticipated that the long-term cancer bioassay, generally conducted in rats, will be the most reliable indicator of mammalian carcinogenic/mutagenic potential at low levels of exposure. The long-term cancer bioassay is required when results from the gene mutation and chromosome aberration studies are positive and all additional special studies data do not provide mitigating support. If one of the first two required tests is positive and one is negative, resolution may be provided by additional genetic toxicology testing or other Supplemental Studies before initiating the long-term cancer bioassay.

LEVEL II - Minimum testing requirements for Level II include genetic toxicity studies as described for Level I, with the addition of subchronic toxicity testing. Further testing may require additional subchronic studies to further define the highest NOAEL and more closely identify the MAL, or if desired, chronic toxicity studies, depending on the observations made during the subchronic study. If the results of the subchronic study are acceptable, and the normalized contaminant concentration is less than the Maximum Allowable Level (MAL), then chronic studies may not be required, as long as genetic toxicity studies do not indicate mammalian mutagenic potential. Special studies such as investigations of pharmacokinetics and metabolism may be used to mitigate or further define the relevance to humans of the effects observed in 90-day subchronic animal studies.

LEVEL III - Minimum testing requirements for Level III are more extensive than Level II, with the addition of a test for reproductive and developmental toxicity in two generations (preferably oral exposure in rats) and teratology tests in two species. Two-generation reproductive toxicity studies provide information on male and female fertility, and prenatal and postnatal developmental effects in the offspring. Teratology tests provide data on fetal effects occurring due to exposure during pregnancy. Severity of observed effects as well as the most sensitive species will be considered in the final decision-making process and risk calculations. Again, chronic toxicity studies may not be required if subchronic studies show that estimated human exposure is less than the MAL. Special studies or additional testing may be used to further define the highest NOAEL and calculated MAL, or mitigate or clarify the relevance to humans of the effects observed in the reproductive, developmental, or subchronic studies.

LEVEL IV - Minimum testing requirements for Level IV are the most rigorous. In addition to the genetic toxicity requirements and reproductive and teratology studies of Level III, required tests include chronic/toxicity studies with a long-term cancer bioassay component. The results of subchronic range-finding studies and genetic toxicity data can be used to most efficiently determine the design and desired endpoints for the chronic studies. The genetic toxicity data may also be useful in determining an additive's potential to product heritable mutations. Again, special studies or additional testing may be used to mitigate or further define the relevance to humans of the effects observed in the animal testing.

The basic tests for each exposure category are summarized below:

Level I

(a) Short-term tests for genetic toxicity and carcinogenic potential.
(b) Supplemental Studies, if indicated.

Level II

(a) Short-term tests for genetic toxicity and carcinogenic potential.
(b) Subchronic study (at least 90 days, preferably in a rat).
(c) Supplemental Studies, if indicated.

Level III

(a) Short-term tests for genetic toxicity and carcinogenic potential.
(b) Subchronic study (at least 90 days, preferably in a rat).
(c) Reproductive and developmental toxicity study (2 generations).
(d) Teratology study (two species).
(e) Supplemental Studies, if indicated.

Level IV

(a) Short-term tests for genetic toxicity and carcinogenic potential.
(b) Chronic toxicity studies which include a long-term cancer bioassay (preferably oral exposure in a rat).
(c) Reproductive and developmental toxicity study (2 generations).
(d) Teratology study (two species).
(e) Supplemental Studies, if indicated.

The following two items appear in the flow diagrams for each level of testing (Figures 1, 2, 3, and 4).

- Integrate submitted data with information from additional sources when applicable.
- Do data support certification?

The first item offers the certifying agency an opportunity to consider all information and sources supplied by the applicant and/or available to the certifying agency. This allows review that may determine that a particular test result, species sensitivity, health effect, or current regulation outweighs other available information. This information would then form the basis for the risk estimation calculations and the final decision as to whether a product is certified or rejected. In contrast, the information reviewed may demonstrate that the overall data are equivocal or nonsupportive. In this case, the applicant may be offered the option of further toxicity testing before a final decision is made about the product/material.

The second statement indicates a point at which testing or other information is sufficient to make a decision for or against product/ material certification.

IV. DESCRIPTION OF TOXICITY TESTS

As a means of ensuring valid data, testing protocols should be established in practice, consistent, and validated. Protocols that are generally accepted as meeting these requirements are described in the most current guidelines endorsed by the U.S. Environmental Protection Agency (EPA,

1982), Food and Drug Administration (FDA, 1982), the Organization for Economic Cooperation and Development (OECD, 1985), and the European Economic Communities (EEC). Any of these procedures are acceptable under the standards. All studies submitted for evaluation under these standards should be conducted in accordance with good laboratory practices.

In general, toxicity tests which are designed to determine chronic toxicity, and/or have endpoints such as carcinogenic, mutagenic, reproductive, or developmental effects are emphasized in the Standard 61-based evaluation of additives. These endpoints are those likely to occur at low levels of exposure. Acute toxicity studies, which determine the immediate adverse effects following a single (and generally high) dose of a substance are of limited value and, therefore, not required.

A brief description of the required studies follows:

A. Subchronic Toxicity Studies

Subchronic studies are designed to determine the adverse effects of an additive administered in regularly repeated doses over periods of 90 days to one year.

This standard specifies a 90-day test period in one rodent species, preferably the rat (Preferably Fischer 344 as recommended by the National Toxicology Program [NTP]). It is recommended that the test compound be administered by the oral route, in drinking water, when practical. The chemical can also be administered in food or by gavage if drinking water does not provide an appropriate medium. Requests to use other routes of administration (respiratory, dermal, intravenous, etc.) may be submitted for consideration to the certifying agency. Any request of this type should be accompanied by a justification for the alternate route of administration and a rationale for its relationship to drinking water exposure.

The test animals are observed throughout the test period and then sacrificed for analysis of organs, tissues, enzymes, or other physiological parameters. Any deleterious effects which may have been caused by the test substance are noted. The results from chronic testing are used to determine a No-Observable-Adverse-Effect-Level (NOAEL) and/or Lowest-Observable-Adverse-Effect-Level (LOAEL), and to further explore the toxic manifestations of chronic exposure.

B. Chronic Toxicity/Carcinogenicity Studies

Chronic toxicity studies are designed to determine the adverse effects of an additive administered in regularly repeated doses for a period of one to two years. This standard requests a two-year study in one rodent species, preferably the rat (Fischer 344). Fischer 344 rats are recommended because of the extensive database developed for this strain by the NTP in prechronic, subchronic, and chronic toxicity/carcinogenicity studies. The route of administration requirements are those described for subchronic studies. In some instances, tests on a second species (rodent or nonrodent) may be requested. These chronic studies will identify noncarcinogenic effects of exposure and determine if a dose-

response relationship exists. Properly designed and conducted chronic studies should focus on functional impairment of the target organ systems identified in subchronic tests. The results of the chronic studies may also warrant the design of special studies to better define the dose-response relationship and the physiological and/or biochemical changes leading to the observed effect in the appropriate target organ (e.g., nervous system, reproductive organs, liver, kidney).

The objective of chronic studies, which include a long-term cancer bioassay component, is to determine the potential carcinogenic and non-carcinogenic effects of an additive administered on a regular basis for a major portion of a test animal's lifespan. The route of administration, species, and duration requirements parallel those of the chronic studies.

C. Reproductive and Developmental Studies

Reproductive studies are conducted in a test species over two generations. They must be designed to provide information on an additive's potential to affect gonadal function, estrous cycles, mating behavior, conception, parturition, lactation, weaning, and the growth and development of offspring. The test substance is generally administered to the parental (F_0 or P) generation from a period prior to mating, through pregnancy, birth and lactation, to weaning of the F_1 offspring. First generation (F_1) offspring are allowed to mate producing a second generation. The first generation animals are exposed to the test substance throughout their lifetime, from conception through weaning of the second generation. The study is generally terminated when the second generation is of weaning age (3-4 weeks old). Functional abnormalities and developmental landmarks should be examined. Often, biochemical abnormalities are also examined.

First litters (F_{1a}) from the parental generation (F_0) are examined. If adverse or suspect development and reproductive effects are observed, then the F_0 animals may be re-bred to produce a second litter (F_{1b}) for observation. Similarly, if suspect or adverse effects are observed from the first litters produced by mating the F_1 animals (F_{2a}), a second (F_{2b}) litter may be required.

Teratology testing is required in two species. A teratology test is designed to examine an additive's potential for inducing structural birth defects following acute exposure of the fetuses during gestation. Testing in two species is required due to differential sensitivities of various species to chemical insult during pregnancy. No single species is the best predictor of human fetal response to all chemicals.

Although a two-generation reproductive toxicity study provides information on prenatal survival and growth as well as postnatal development and behavior it cannot provide accurate information on the type and frequency of structural birth defects which are detected in a teratology study. Rodent dams frequently cannibalize structurally or behaviorally abnormal pups immediately after birth. In addition, many structural anomalies occur in the fetal skeleton or internal organs and cannot be detected without appropriate preparation and dissection of the fetuses. Dose levels administered subchronically during a reproduction study are usually lower than the doses which can

be administered acutely in a teratology study, and frequently do not provide sufficient fetal exposure levels to detect induced malformations with statistical certainty.

D. Short-Term Genetic Toxicity and Carcinogenic Potential Tests

The tests in this category refer to a number of in vitro and in vivo tests which have been developed to determine the potential genetic toxicity and carcinogenicity of a substance in a relatively short amount of time (generally, several days to several months). These tests employ any number of prokaryotic or eukaryotic cells or organisms and measure point mutation, chromosomal abnormalities, nonspecific DNA damage, and cell transformation.

The conceptual basis for extrapolating from these endpoints to humans is supported by experimental evidence which indicates the following:

1. Chemicals that are mutagenic in one species are generally mutagenic in other species (de Serres, 1981; Hollstein, 1979). Semiquantitative consistencies also exist because a strong mutagen in one species tends to be strongly mutagenic in others. However, this quantitative relationship often does not hold if in vitro systems are compared to in vivo systems (Ashby, 1986).

2. Mutations are involved in the mechanism of carcinogenesis (Straus, 1981). A significant percentage of chemicals that are carcinogenic in mammals are mutagenic in short-term test systems (Ames, 1987; Bartsch, 1980; Campbell, 1980; McCann, 1978, 1975; Purchase, 1978).

3. Carcinogenicity in rodents is generally presumed to be predictive of carcinogenicity in humans (Crouch, 1979; Rall, 1979; Tomatis, 1977).

However, the correlation between in vivo carcinogenicity and short-term test results is not entirely accurate for any one test. Therefore, to reduce false negatives without substantially increasing false positives, a carefully constructed batter of tests is generally recommended.

For Category I testing, the Ames Salmonella typhimurium gene mutation test, with and without a mammalian metabolic activation system (S9 fraction), is suggested. The test is simple, rapid, and economical. It has been validated by EPA and has been shown to yield a higher degree of concordance when the mutagenicity and carcinogenicity of chemicals are compared. Particularly for complex mixtures, the Ames preincubation assay may be appropriate. This assay modification allows direct preincubation of the bacterial test strains with the test substance prior to plating, and may provide enhanced assay sensitivity.

To complement this well-characterized gene mutation assay using bacteria, the second recommended endpoint to be assayed is a mammalian in vivo chromosome aberration or micronucleus test. In two studies conducted by the International Collaborative

Programme for the Evaluation of Short-Term Tests for Carcinogens (IPESTTO) (Ashby et al., 1985) and the International Programme on Chemical Safety (IPCS) (Sobels, 1985), the chromosome aberration assay was found to be the most sensitive, giving 51% positive response for those chemicals that are either inactive or difficult to detect as positive in the Salmonella test. Chromosome aberrations can include a number of indicators of chromosome breakage such as changes in chromosome number, chromosome rearrangements, sister chromatid exchanges, and micronuclei. The advantage of the micronucleus test is its simplicity of scoring since only one specific chromosome aberration is used as an index of chromosome breakage (Doull et al., 1980).

There are some cases where in vitro testing for chromosome aberrations may have an advantage over in vivo testing. This is particularly true to the target cells in vivo testing. Accordingly, pharmacokinetic data on absorption, distribution, and excretion can be very useful in interpretation of in vivo test results and their comparison with the in vitro data.

In order to permit some flexibility, other assay systems for genotoxicity may be used to augment the above recommended assays. However, extensive and clearly appropriate scientific justifications must be made in such cases. Several alternative assays which may be considered as additional genetic toxicity tests are discussed in the following paragraphs.

DNA damage/repair assays, particularly the in vitro Unscheduled DNA Synthesis (UDS) assay, have not performed well in distinguishing carcinogens and non-carcinogens in recent studies. It should be recognized, however, that the assay is simple and sensitive. Although many known carcinogens are missed with this test, any positive result as shown by UDS assay would most likely identify a true mammalian carcinogen.

Cytogenetic assays using mammalian cells in culture are more convenient than in vivo test systems and may be considered as additional genetic toxicity tests. As mentioned above, testing of cultured mammalian cells may be a more accurate method of determining mutagenicity in circumstances where pharmacokinetic factors limit access of the test chemical to target cells in in vivo testing. In addition, cultured human cells can be used to evaluate the impact of a test chemical on human chromosomes in an in vitro system (Doull et al., 1980).

One must use caution, however, in interpreting the results of in vitro tests. The published literature was recently reviewed for chemicals that had been tested in both in vitro and in vivo cytogenetic assays (Thompson, 1986). Two-hundred sixteen chemicals were identified, and definitive test results were obtained for 181 of them. Results from the two assays were in agreement on 126 of the compounds. Of the 55 compounds for which the results did not agree, 53 were positive in vitro and negative in vivo. The large portion of false positive in vitro assays is presumably due to various inactivation mechanisms or barriers present in the intact animal that are lacking in cultured cells. Since the most tedious part of the chromosome aberration assay is microscopic analysis by trained cytogeneticists, it seems advisable, at the present time, to use in vivo instead

of in vitro cell systems for this purpose. The amount of work is comparable, and the bulk of false positive results may be avoided.

The short-term tests of mutagenic/carcinogenic potential are, unfortunately, unable to detect chemicals which act as promoters in carcinogenesis. However, there are no well-established tests to identify this function in a chemical. Structure activity relationships which suggest that a chemical may have promoter activity can be used to justify special tests to investigate the possibility that a chemical may have promoter characteristics.

E. Supplemental Studies

A Supplemental Studies option is indicated at each level of testing. These studies would be used to provide more in-depth information concerning any results observed in the basic set of studies. Supplemental Studies might also be requested if structure/activity relationships suggest that a compound may have a unique toxicological property. Studies of pharmacokinetics (absorption, distribution, elimination), metabolism, immunotoxicity, neurotoxicity, and other specific endpoints of toxicity would be categorized as supplemental. Specific tests for dermal sensitivity would also be considered as supplemental. In some cases, testing with a second rodent or nonrodent species might be requested under this testing option.

F. Potential Exposure Resulting From Short-Term, High-Level Contaminant Concentrations

Contaminant concentrations from many products used in contact with drinking water are initially high, but rapidly decline with continued product contact with water. (Examples may include, but are not limited to, solvent-containing coatings and cements.) Short-term exposure paradigms, appropriate for potentially high initial contaminant concentrations, may be implemented at the request of the applicant or the discretion of the certifying agency. In these cases, laboratory tests will be used to determine the slope of the contaminant concentration curve. If the initial (day 1) laboratory concentration of the contaminant is less than or equal to the 90-day No-Observed-Adverse-Effect-Level (NOAEL), divided by 100, and the contaminant concentration is calculated to be at or below the MAL within 90 days, then no additional toxicity data may be required. If no subchronic (90-day) data exist and a 90-day MAL cannot be calculated, then a single-dose acute toxicity study in rodents with a 14-day observation period, clinical observations, hematology and clinical chemistry, and gross pathology may be required. Then, the normalized initial leachate concentration is acceptable when it is less than or equal to the NOAEL calculated from the study results, divided by a safety factor of 1000 (or 100 if appropriate additional toxicology endpoints are evaluated). Additional endpoints may include, but are not limited to, histopathology, blood or tissue enzyme levels, or pharmacokinetic parameters. If there is evidence that a contaminant is classifiable as either A, B_1 or B_2 carcinogen, then the allowable contaminant concentration must be considered on a case-by-case basis, taking into account available information including carcinogenic potency, mechanism of action, and slope of the decay curve. The concentration of the contaminant for both carcinogens and non-carcinogens

must be at or below the MAL within 90 days. The contaminant concentration at 90 days determines which toxicity evaluation category requirements must be fulfilled.

V. RISK ESTIMATION

In the course of the development of the environmental and toxicological sciences, a mechanism has evolved for determining health risk through a series of calculations. Although the mechanism may not be perfect, it is currently widely used by government and private agencies to estimate safe levels of exposure to specific chemicals. These risk estimation calculations integrate exposure information and health effects information to provide an estimation of safe levels of exposure to chemicals. The USEPA has published a series of guidelines available describing Risk Assessment procedures (51 FR 33992, September 24, 1986). These guidelines have been followed for both carcinogens and non-carcinogens in the proposed NSF standard for drinking water additive chemicals, because it is essential that risk estimation methodology be consistent. This use of similar methodology for regulated and unregulated compounds will reduce points of confusion or contradiction.

It has been noted that the Office of Science and Technology policy advocates considerable flexibility in making decisions on the carcinogenicity of chemicals in humans. The Standard 61 approach will consider all relevant factors and take into account information from long-term animal studies, short-term tests, and studies of mechanism. No single mathematical procedure is recognized as the most appropriate for low-dose extrapolation in carcinogenesis. If relevant data on mechanism are available, the models employed will be consistent with the evidence. Identification of the sources of uncertainty are important when selecting parameters used in the risk estimate itself. Sources which should be addressed include the statistical uncertainty associated with the risk estimate, the variability introduced by the selection of a particular low-dose extrapolation procedure, and the biological variability associated with the use of a particular test organism.

A. Maximum Allowable Levels (MALs)

For the purpose of risk estimation for drinking water additives, the Standard 61 scheme often requires the calculation of a Maximum Allowable Level (MAL) for a specific contaminant. The MAL, based on health effects information, is compared to the normalized contaminant concentration. Certification of a product will be granted when normalized contaminant concentrations contributed by that product occur at the tap in levels at or below the MAL for the contaminant.

Determination of the MAL of a drinking water contaminant to which a human may be exposed takes into consideration the nature of both the exposure and the potential toxic effect. From the standpoint of exposure, one must assume that ingestion of a contaminant in drinking water could occur on a daily basis over a person's lifetime.

The Standard 61 scheme uses the EPA established exposure scenario used for long-term health advisories and Maximum Contaminant Level Goals (MCLGs). MAL values are designed to be low enough to protect against probable toxic effects. Therefore, the MAL

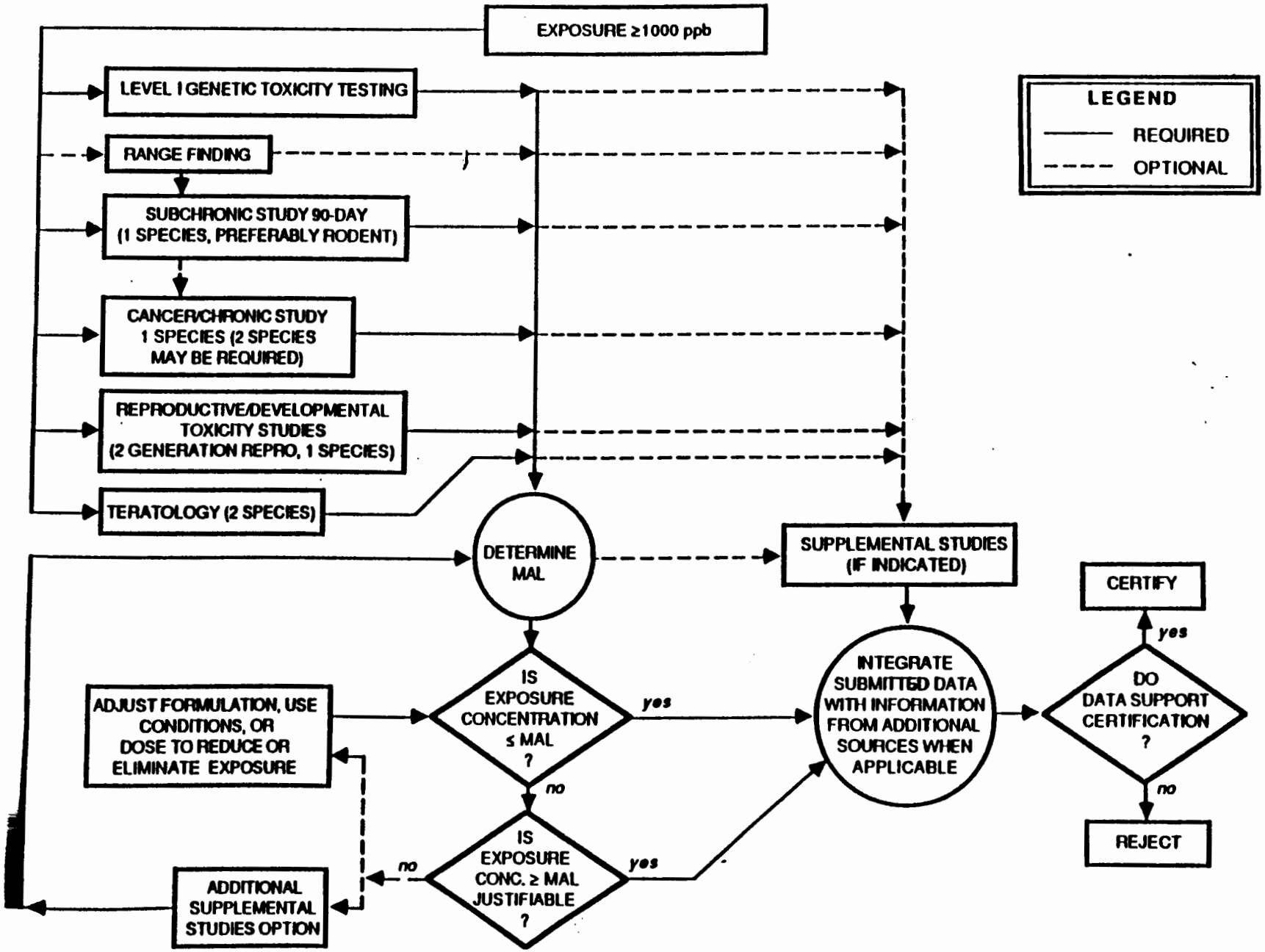

Figure 4 PROPOSED LEVEL IV MINIMUM TOXICITY TESTING GUIDELINE

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APPENDIX F

U.S. ENVIRONMENTAL PROTECTION AGENCY NATIONAL PRIMARY DRINKING WATER STANDARDS (NOVEMBER 1994)

(This Appendix is not part of the Standard)

APPENDIX F
U.S. ENVIRONMENTAL PROTECTION AGENCY
NATIONAL PRIMARY DRINKING WATER STANDARDS
(November 1994)

Primary Contaminant	Regulated MCL (mg/l)
Organics:	
Acrylamide	TT* (0.05% dosed at 1 ppm, or equivalent)
Adipate (diethylhexyl)	0.4
Alachlor	0.002
Atrazine	0.003
Benzene	0.005
Benzo(a)pyrene (PAH)	0.0002
Carbofuran	0.04
Carbon tetrachloride	0.005
Chlordane	0.002
2,4-D	0.07
Dalapon	0.2
Di(2-ethylhexyl)adipate	0.4
Dibromochloropropane (DBCP)	0.0002
Dichlorobenzene o-	0.6
Dichlorobenzene m-	0.6
Dichlorobenzene p-	0.075
Dichloroethane (1,2-)	0.005
Dichloroethylene (1,1-)	0.007
Dichloroethylene (cis-1,2-)	0.07
Dichloroethylene (trans-1,2)	0.1
Dichloromethane	0.005
Dichloropropane (1,2-)	0.005
Diethylhexyl phthalate (PAE)	0.006
Dinoseb	0.007
Diquat	0.02
Endothall	0.1

Primary Contaminant	Regulated MCL (mg/l)
Endrin	0.002
Epichlorohydrin	TT* (0.01% dosed at 20 ppm, or equivalent)
Ethylbenzene	0.7
Ethylene dibromide (EDB)	0.00005
Glyphosate	0.7
Heptachlor	0.0004
Heptachlor epoxide	0.0002
Hexachlorobenzene	0.001
Hexachlorocyclopentadiene	0.05
Lindane	0.0002
Methoxychlor	0.04
Monochlorobenzene	0.1
Oxamyl (Vydate)	0.2
Pentachlorophenol	0.001
Picloram	0.5
Polychlorinated biphenyls (PCB)	0.0005
Simazine	0.004
Styrene	0.1
2,3,7,8-TCDD (Dioxin)	3E-08
Tetrachloroethylene	0.005
Toluene	1
Toxaphene	0.003
2,4,5-TP	0.05
Trichlorobenzene (1,2,4-)	0.07
Trichloroethane (1,1,1-)	0.2
Trichloroethane (1,1,2-)	0.005
Trichloroethylene	0.005
Vinyl chloride	0.002
Xylenes	10

Primary Contaminant	Regulated MCL (mg/l)
Regulated Metals	
Antimony	0.006
Arsenic	0.05
Barium	2
Beryllium	0.004
Cadmium	0.005
Chromium (total)	0.1
Copper	TT* (action level 1.3 mg/L)
Lead (at tap)	TT* (action level 0.015 mg/L)
Mercury (inorganic)	0.002
Nickel	0.1
Selenium	0.05
Thallium	0.002
Other Inorganics	
Asbestos	7 MFL**
Fluoride	4
Nitrate (as N)	10
Nitrite (as N)	1
Nitrate + Nitrite (both as N)	10

* TT = Treatment Technique
** MFL = million fibers per liter, with fiber length >10 microns

APPENDIX G

CANADIAN MAXIMUM ACCEPTABLE CONCENTRATIONS PRIMARY DRINKING WATER STANDARDS (1993)

(This Appendix is not part of the Standard)

APPENDIX G
CANADIAN MAXIMUM ACCEPTABLE CONCENTRATIONS[1]
PRIMARY DRINKING WATER STANDARDS
(1993)

Primary Contaminant	MAC (mg/ℓ)
aldicarb	0.009
aldrin + dieldrin	0.0007
arsenic	0.05[2]
azinphos-methyl	0.02
barium	1.0
bendiocarb	0.04
benzene	0.005
benzo(a)pyrene	0.00001
cadmium	0.005
carbaryl	0.09
carbofuran	0.09
carbon tetrachloride	0.005
chlordane	0.007
chlorpyrifos	0.09
chromium	0.05
cyanide	0.2
diazinon	0.02
dicamba	0.12

[1]These guidelines are subject to ongoing revision. The reader is encouraged to contact the Environmental Health Directorate, Health and Welfare Canada, Ottawa, Ontario K1A 0L2 for current information.

[2]At the point of consumption

Primary Contaminant	MAC (mg/ℓ)
dichlorobenzene, 1,2-	0.2
dichlorobenzene, 1,4-	0.005
dichlorodiphenyltrichloroethane (DDT) + metabolites	0.03
dichloromethane	0.05
dichlorophenol, 2,4-	0.9
diclofop-methyl	0.009
dinoseb	0.01
diquat	0.07
diuron	0.15
fluoride	1.5
heptachlor + heptachlor epoxide	0.003
lead[2] (at the tap)	0.01
lindane	0.004
malathion	0.19
mercury	0.001
methoxychlor	0.9
metribuzin	0.08
monochlorobenzene	0.08
nitrate[3]	45.0
nitrilotriacetic acid (NTA)	0.4
parathion	0.05

[3]Equivalent to 10.0 mg/ℓ nitrate as nitrogen. Where nitrate and nitrite are determined separately, levels of nitrite should not exceed 3.2 mg/ℓ.

Primary Contaminant	MAC (mg/ℓ)
pentachlorophenol	0.06
selenium	0.01
tetrachlorophenol, 2,3,4,6-	0.1
triallate	0.23
trichloroethylene	0.05
trichlorophenol, 2,4,6-	0.005
trichlorophenoxyacetic acid, 2,4,5- (2,4,5-T)	0.28
trihalomethanes	0.35
turbidity	1 NTU[4]
uranium	0.1

[4]NTU = nephelometric turbidity unit

APPENDIX H

PARTICIPATING COMMITTEES

(This Appendix is not part of the Standard)

NSF JOINT COMMITTEE ON DRINKING WATER ADDITIVES

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Manning, Bruce, St. Louis County Water Company, 535 N. New Ballas Road, St. Louis, MO 63141. 314/542-6430. Fax: 314/542-6427 (Utility)

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Scarano, Anthony L., Plastics Piping Consultant, 1319 Moon Drive, Yardley, PA 19067. 215/295-4788. Fax: (call before faxing) 215/295-4788 (American Society of Sanitary Engineering)

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STANDARDS AND CRITERIA

The following standards and criteria established and adopted by NSF as minimum voluntary consensus standards are used internationally:

1 Soda Fountain and Luncheonette Equipment
2 Food Equipment
3 Commercial Spray-Type Dishwashing Machines
4 Commercial Cooking, Rethermalization and Powered Hot Food Holding and Transport Equipment
5 Water Heaters, Hot Water Supply Boilers, and Heat Recovery Equipment
6 Dispensing Freezers
7 Food Service Refrigerators and Storage Freezers
8 Commercial Powered Food Preparation Equipment
12 Automatic Ice Making Equipment
13 Refuse Compactors and Compactor Systems
14 Plastics Piping Components and Related Materials
18 Manual Food and Beverage Dispensing Equipment
20 Commercial Bulk Milk Dispensing Equipment
21 Thermoplastic Refuse Containers
24 Plumbing System Components for Manufactured Homes and Recreational Vehicles
25 Vending Machines for Food and Beverages
26 Pot, Pan, and Utensil Washers
29 Detergent and Chemical Feeders for Commercial Spray-Type Dishwashing Machines
30 Cabinetry and Laboratory Furniture for Hospitals
35 Laminated Plastics for Surfacing Food Service Equipment
36 Dinnerware
37 Air Curtains for Entranceways in Food and Food Service Establishments
40 Individual Aerobic Wastewater Treatment Plants
41 Wastewater Recycle/Reuse and Water Conservation Devices
42 Drinking Water Treatment Units - Aesthetic Effects
44 Cation Exchange Water Softeners
49 Class II (Laminar Flow) Biohazard Cabinetry
50 Circulation System Components and Related Materials for Swimming Pools, Spas/Hot Tubs
51 Plastic Materials and Components Used in Food Equipment
52 Supplemental Flooring
53 Drinking Water Treatment Units - Health Effects
54 Flexible Membrane Liners
55 Ultraviolet Microbiological Water Treatment Systems
56 Pitless Well Adapters
58 Reverse Osmosis Drinking Water Treatment Systems
59 Food Carts
60 Drinking Water Treatment Chemicals - Health Effects
61 Drinking Water System Components - Health Effects
62 Drinking Water Distillation Systems
C-2 Special Equipment and/or Devices
C-9 Evaluation of Special Processes, Components, or Devices Used in Treating Wastewater

***THE HOPE OF MANKIND** rests in the ability of man to define and seek out the environment which will permit him to live with fellow creatures of the earth, in health, in peace, and in mutual respect.*

Printed 12/9/94

EXHIBIT B

Exhibit B

Definition of Covered Products

Exhibit B

Covered Products

As used in this Consent Judgment the term "Covered Products" means mechanical plumbing devices, components, and materials which are typically installed within the last liter of the distribution system (endpoint devices) intended by the manufacturer to dispense water for human ingestion, which are manufactured for sale or use in California. In-line devices are excluded from definition of Covered Products. Point-of-use and point-of-entry water treatment devices are also excluded.

Endpoint devices specifically included in this definition are:

a) Lavatory single and two handle faucets (for example: centersets, widespread, mini-spread, and basin cocks) without a hose-end spout and which are not metering, self-closing, or electronic.

b) Bar faucets.

c) Kitchen single and two handle faucets (for example: top mounts, concealed fittings, pull-out spouts and wall mounts) without a hose-end spout.

d) Supply stops and endpoint control valves.

e) Elkay Manufacturing Company sink with faucet and bubbler combinations (current bubbler model numbers LK1141 and LK2507, and the same or any similar bubblers which may be manufactured by Elkay in the future under different model numbers).

Endpoint devices specifically excluded from this definition are:

1. Bath and shower valves, shower heads of all types, and Roman tub valves.

2. All drains.

3. Laundry fittings, shampoo fittings, and faucets with a hose-end spout.

4. All commercial, industrial, and institutional devices that are not specifically included in this definition, such as:

a. Self-closing, metering, or electronically activated faucets

b. Utility, laundry, laboratory, bidet, and shampoo fittings

c. Faucets with a hose-end spout.

5. Backflow prevention devices

6. Any other endpoint device not specifically included in this definition.

EXHIBIT C

Exhibit C

Modified Preliminary Injunction

CALIFORNIA PROPOSITION 65 WARNING

This faucet contains lead, a chemical known to the State of California to cause birth defects or other reproductive harm.

(Plumber: California law requires that this warning be given to the consumer.)

CONSUMER INFORMATION

ABOUT CALIFORNIA PROPOSITION 65 WARNING

All faucets made of leaded brass alloys, even those that comply with U.S. Environmental Protection Agency regulations, contribute small amounts of lead to water that is allowed to stand in contact with the brass. This faucet complies with all E.P.A. regulations regarding the amount of lead used in plumbing brass and solder. The amount of lead contributed by any faucet is highest when the faucet is new.

The following steps will reduce potential exposure to lead from faucets and other parts of the plumbing system:

- Always run the water for a few seconds prior to use for drinking or cooking.
- Use only cold water for drinking or cooking.
- If you wish to flush the entire plumbing system of water that has been standing in the pipes or other fittings, run the cold water until the temperature of the water drops, indicating water coming from the outside main.
- If you are concerned about lead in your water, have your water tested by an EPA-certified laboratory in your area.

EXHIBIT D

Exhibit D

Additional Forms of Warning

CALIFORNIA PROPOSITION 65 WARNING

This faucet contains lead, a chemical known to the State of California to cause birth defects or other reproductive harm.

(Plumber: California law requires that this warning be given to the consumer)

CONSUMER INFORMATION

ABOUT CALIFORNIA PROPOSITION 65 WARNING

All faucets made of leaded brass alloys, even those that comply with U.S. Environmental Protection Agency regulations, contribute small amounts of lead to water that is allowed to stand in contact with the brass. This faucet complies with all E.P.A. regulations regarding the amount of lead used in plumbing brass and solder. The amount of lead contributed by any faucet is highest when the faucet is new.

The following steps will reduce potential exposure to lead from faucets and other parts of the plumbing system:

- Always run the water for a few seconds prior to use for drinking or cooking.
- Use only cold water for drinking or cooking.
- If you wish to flush the entire plumbing system of water that has been standing in the pipes or other fittings, run the cold water until the temperature of the water drops, indicating water coming from the outside main.
- If you are concerned about lead in your water, have your water tested by an EPA-certified laboratory in your area.

HELPLINE: Call our toll free Helpline number,

(800) 321-6636

for answers to any product, installation, replacement parts, or warranty questions.

MOEN®

To Eliminate Cross-Piping On Back-To-Back Installations, or to Correct Reversed Rough-In Where Hot and Cold Positions are Reversed:

Remove handle knob, easy grip handle, lever handle, handle parts and stop tube (see "Disassembly"). Turn valve stem around so that the notched flat is turned one half turn or 180°. Re-install handle parts and handle knob or lever. Tighten handle screw securely; replace handle cover (on knob handles and lever handles).

Cleaning & Care Instructions for Special Finish Models:

All that is necessary to clean these faucets is to wipe them with a soft, damp cloth such as terrycloth. Warm water will remove dry water spots.

CAUTION: DO NOT use cleansers which contain abrasives or harsh chemicals. NEVER use alcohol or other organic solvents. A high quality, non-abrasive wax polish applied occasionally, will help to preserve the deep tones of the finish.

CALIFORNIA PROPOSITION 65 WARNING

This faucet contains lead, a chemical known to the State of California to cause birth defects or other reproductive harm.

(Plumber: California law requires that this warning be given to the consumer).

CONSUMER INFORMATION

ABOUT CALIFORNIA PROPOSITION 65 WARNING

All faucets made of leaded brass alloys, even those that comply with U.S. Environmental Protection Agency regulations, contribute small amounts of lead to water that is allowed to stand in contact with the brass. This faucet complies with all E.P.A. regulations regarding the amount of lead used in plumbing brass and solder. The amount of lead contributed by any faucet is highest when the faucet is new.

The following steps will reduce potential exposure to lead from faucets and other parts of the plumbing system:

- Always run the water for a few seconds prior to use for drinking or cooking.
- Use only cold water for drinking or cooking.
- If you wish to flush the entire plumbing system of water that has been standing in the pipes or other fittings, run the cold water until the temperature of the water drops, indicating water coming from the outside main.
- If you are concerned about lead in your water, have your water tested by an EPA-certified laboratory in your area.

HELPLINE: Call our toll free Helpline number,

(800) 321-6636

for answers to any product, installation, replacement parts, or warranty questions.

MOEN®

25300 Al Moen Drive, North Olmsted, OH 44070-8022

ENGLISH

MOEN
LIFETIME LIMITED WARRANTY

Moen products have been manufactured under the highest standards of quality and workmanship. Moen warrants to the original consumer purchaser that this faucet will be leak and drip free during normal domestic use for as long as you own it. If this faucet should ever develop a leak or drip during this time, Moen will FREE OF CHARGE provide the parts necessary to put the faucet back in good working condition.

Moen warrants to the original consumer purchaser all other aspects of this faucet to be free from defects in material and workmanship for two (2) years from date of purchase except for decorator finishes which are warranted for one (1) year from date of purchase. A replacement for any defective part will be supplied free of charge for installation by the consumer. Defects or damage caused by the use of other than genuine Moen parts are not covered by this warranty. This warranty shall be effective from date of purchase as shown on purchaser's receipt. Some states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you.

This warranty is valid for the original consumer purchaser only and excludes industrial, commercial, or business use of the product, product damage due to installation error, product abuse, or product misuse, whether performed by a contractor, service company, or yourself. Moen will not be responsible for labor charges and/or damage incurred in installation, repair or replacement, nor for incidental or consequential damages.

Some states, provinces and nations do not allow the exclusion or limitation of incidental or consequential damages, so the above limitations or exclusions may not apply to you. This warranty gives you specific legal rights and you may also have other rights which may vary from state to state, province to province, and nation to nation. Moen will advise you of the procedure to follow in making warranty claims. Simply write to Moen Incorporated using the address below. Explain the defect and include proof of purchase and your name, address and telephone number.

FRANÇAIS

MOEN
GARANTIE À VIE LIMITÉE

Les produits de Moen ont été fabriqués selon les normes de qualité et de fabrication les plus élevées. Moen garantit à l'acheteur-consommateur d'origine que ce robinet sera à l'épreuve des fuites et des égouttements lors d'un usage domestique normal pour aussi longtemps que vous en serez le propriétaire. Si ce robinet devait fuir ou s'égoutter lors de cette période, Moen procurera SANS FRAIS les pièces nécessaires pour rétablir le bon fonctionnement du robinet.

Moen garantit à l'acheteur-consommateur d'origine tous les autres aspects de ce robinet contre tous défauts de matériaux et de fabrication pour une période de deux (2) ans à partir de la date d'achat sauf les finissages décorateurs qu'on garantit pour une période d'un (1) an à partir de la date d'achat. Une pièce de rechange en remplacement de toute pièce défectueuses vous sera fournie et devra être installée par vous-même. Les défectuosités et les dommages causés par l'emploi de pièces autres que celles d'origine de Moen ne sont pas couverts par cette garantie. Cette garantie entre en vigueur à partir de la date d'achat indiquée sur la facture. Certaines provinces interdisent de limiter la durée d'une garantie, aussi les limitations ci-dessus peuvent ne pas s'appliquer à votre cas.

Cette garantie s'applique à l'acheteur-consommateur d'origine seulement, et exclut l'usage industriel, commercial ou d'affaires du produit, les dommages causés au produit par une erreur d'installation, un abus ou un mauvais usage du produit, que ce soit le fait d'un entrepreneur, d'une compagnie de service ou de vous-même. Moen n'est pas responsable des frais de main d'oeuvre et/ou des dégâts causés lors de l'installation, de la réparation, ou du remplacement, ni des dommages résultants et fortuits.

Certains états, provinces et nations interdisent l'exclusion ou la limitation des dommages résultants ou fortuits; aussi les limitations ou les exclusions décrites ci-dessus peuvent ne pas s'appliquer à votre cas. Cette garantie vous confère certains droits légaux spécifiques et vous pouvez aussi posséder d'autres droits qui peuvent varier entre états, provinces ou nations. Moen vous informera des procédures à suivre pour loger des réclamations de garantie. Écrivez simplement à Moen Incorporée à l'adresse ci-dessous, en expliquant le problème et en joignant une preuve d'achat, votre nom, votre adresse et votre numéro de téléphone.

ESPAÑOL

MOEN
GARANTIA DE POR VIDA LIMITADA

Los productos Moen han sido manufacturados bajo los estándares más altos de calidad y mano de obra. Moen garantiza al consumidor comprador original que esta mezcladora estará libre de fugas y goteo durante el uso normal doméstico por el tiempo que usted sea el propietario. Si esta mezcladora llegase a presentar fugas o goteo durante este periodo, Moen proveerá sin costo alguno las partes necesarias para volver la mezcladora a buenas condiciones de trabajo.

Moen garantiza al comprador original en todos los demás aspectos de esta mezcladora que están libre de defectos en material y mano de obra por dos (2) años desde la fecha de compra, excepto para los acabados de decoración los cuales están garantizados por un (1) año desde la fecha de compra. El reemplazo de cualquier pieza defectuosa será suministrado libre de costo de instalación para el cliente. Defectos o daños causados por el uso de piezas diferentes a las genuinas Moen no son cubiertos por esta garantía. Esta garantía será efectiva desde la fecha de compra mostrada en el recibo de compra. Algunos estados no permiten limitaciones en cuanto a la duración de una garantía mencionada, de tal forma que la limitación arriba mostrada puede no ser aplicable para usted.

Esta garantía es válida para el consumidor comprador original solamente y excluye el uso del producto industrial, comercial o en negocios, daños causados por errores de instalación, abusos del producto, o mal uso de él, ya sea hecho por un contratista, una compañía de servicios, o usted mismo. Moen no será responsable por costos de mano de obra y/o daños incurridos en instalación, reparación o reemplazo, o daños accidentales o consecuentes.

Algunos estados, provincias y naciones no permiten la exclusión o limitación de daños accidentales o consecuentes, de tal forma que las limitaciones o exclusiones arriba mostradas pueden no ser aplicables para usted. Esta garantía le dá derechos legales específicos y usted tambien puede tener otros derechos los cuales pueden variar de estado a estado, provincia a provincia, y nación a nación. Moen le aconsejará el procedimiento a seguir en efectuar reclamos de garantías. Simplemente escriba a Moen Incorporated usando la dirección abajo mostrada. Explique el defecto e incluya la prueba de compra y su nombre, dirección y número telefónico.

CALIFORNIA PROPOSITION 65 WARNING

This faucet contains lead, a chemical known to the State of California to cause birth defects or other reproductive harm.

(Plumber: California law requires that this warning be given to the consumer).

CONSUMER INFORMATION

ABOUT CALIFORNIA PROPOSITION 65 WARNING

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The following steps will reduce potential exposure to lead from faucets and other parts of the plumbing system:

- Always run the water for a few seconds prior to use for drinking or cooking.
- Use only cold water for drinking or cooking.
- If you wish to flush the entire plumbing system of water that has been standing in the pipes or other fittings, run the cold water until the temperature of the water drops, indicating water coming from the outside main.
- If you are concerned about lead in your water, have your water tested by an EPA-certified laboratory in area.

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MOEN®

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SHERLE WAGNER

INTERNATIONAL INC.

60 East 57th St New York 10022 Fax 8-2300

CALIFORNIA PROPOSITION 65 WARNING

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CONSUMER INFORMATION ABOUT CALIFORNIA PROPOSITION 65 WARNING

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If you are concerned about lead in your water, have your water tested by an E.P.A. certified laboratory in your area.

CONSUMER WARNING

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

Most materials used in plumbing products contain small quantities of various chemicals known or suspected to cause birth defects, other reproductive harm or cancer. Specifically, lead is present in this and other brass faucets, brass plumbing fittings and in much of the solder used to hold copper pipes together. Other listed chemicals are found in rubber and plastic compounds used in faucets, fittings and tubings. You may be exposed to minute quantities of such chemicals through the normal use of your plumbing system. Hot water accelerates the dissolving of such chemicals from brass, as well as from rubber and plastic components. Moreover, the water which is held for several hours by a closed faucet may dissolve chemicals out of the faucet and the rest of the plumbing system, particularly where the water is corrosive.

You can greatly reduce unnecessary exposure to chemicals from faucets and nearby plumbing by taking the following steps:

1) Never drink the first glass of water out of the tap when the water has been standing unused for several hours, during the day or overnight. Run the faucet for a few seconds to "flush" it and nearby plumbing components, or for no more than 30 seconds to "flush" the average home of standing water to building service water line.

2) Avoid drinking or cooking with water drawn from the hot water side of the tap.

3) Should you wish to have your water tested, there are many private laboratories certified by the U.S. EPA, or your state's EPA, that can do such testing.

BrassCraft®

P.O. BOX 2020
SOUTHFIELD, MI 48037

EXHIBIT E

Exhibit E

Hang Tag

12017624

OUTSIDE

California
PROPOSITION 65

(Plumber: This warning may be removed only by consumer)

INSIDE

CALIFORNIA PROPOSITION 65 WARNING

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CONSUMER INFORMATION

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