UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

This document has been electronically approved and signed.

BALLOT VOTE SHEET

Date: March 23, 2011

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director

FROM : Philip L. Chao, Assistant General Counsel
Hyun S. Kim, Attorney

SUBJECT : Revision to Notice of Requirements – Lead Paint Under 16 C.F.R. part 1303

BALLOT VOTE Due: March 29, 2011

Attached is a draft *Federal Register* notice revising the notice of requirements (NOR) for accreditation of third party conformity assessment bodies (TPCABs) to assess conformity with 16 C.F.R. part 1303. The current version of the NOR (which the Commission published in the *Federal Register* in September 2008, as required by section 14(a)(3)(B)(i) of the Consumer Product Safety Act), does not specify the use of any specific test method. The revised NOR would require TPCABs to reference one or more of the following test method(s) on a going forward basis: the existing CPSC Standard Operating Procedure for Determining Lead (Pb) in Paint and Other Similar Surface Coatings, CPSC–CH–E1003–09 (April 26, 2009); revised CPSC Standard Operating Procedure for Determining Lead (Pb) in Paint and Other Similar Surface Coatings CPSC–CH–E1003–09.1 (February 25, 2011); and/or ASTM F2853-10, "Standard Test Method for Determination of Lead in Paint Layers and Similar Coatings or in Substrates and Homogenous Materials by Energy Dispersive X-Ray Fluorescence Spectrometry Using Multiple Monochromatic Excitation Beams."

Please indicate your vote on the following options.

I. Approve publication of the draft notice in the *Federal Register*.

_____ _____
(Signature) (Date)

II. Approve publication of the draft notice in the *Federal Register* with changes. (Please specify.)

_____

_____

_____

_____ _____
(Signature) (Date)

III. Do not approve publication of the draft notice in the *Federal Register*.

_____ _____
(Signature) (Date)

IV. Take other action. (Please specify.)

_____

_____

_____

_____ _____
(Signature) (Date)

Attachments:

Briefing Package: Accreditation Requirements for Third Party Conformity Assessment Bodies to Test to the Requirements for Lead in Paint to Assess Conformity with Part 1303 of Title 16 Code of Federal Regulations, from Joel R. Recht, Ph.D., Director, Division of Chemistry, Directorate for Laboratory Sciences, March 2011.

Federal Register Notice: Third Party Testing for Certain Children's Products: Revision to Notice of Requirement for Accreditation of Third Party Conformity Assessment Bodies to Test Children's Products for Conformity with Part 1303 of Title 16, Code of Federal Regulations.

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MARYLAND 20814

This document has been electronically approved and signed.

Memorandum

Date: March 23, 2011

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director

FROM : Joel R. Recht, Ph.D.
Director, Division of Chemistry
Directorate for Laboratory Sciences

Mary F. Toro
Director of Regulatory Enforcement
Office of Compliance and Field Operations

Robert J. Howell
Assistant Executive Director
Office of Hazard Identification and Reduction

SUBJECT : Accreditation Requirements for Third Party Conformity Assessment Bodies to Test to the Requirements for Lead in Paint to Assess Conformity with Part 1303 of Title 16 Code of Federal Regulations; *Staff's Proposed Revision of Testing Terms*

I. Introduction

Section 102 of the Consumer Product Safety Improvement Act (hereafter referred to as the "Act" or the "CPSIA") mandates that third party testing be conducted for certain children's products. Before importing for consumption or warehousing or distributing in commerce any children's product that is subject to a children's product safety rule, every manufacturer of such children's product (and the private labeler of such children's product if such product bears a private label) shall: (A) submit sufficient samples of the children's product, or samples that are identical in all material respects, to a third party conformity assessment body (hereafter referred to as a third party testing laboratory) accredited under requirements to be established by the Commission to be tested for compliance with such children's product safety rule; and (B) based on the assessment by the third party testing laboratory, issue a certificate that certifies that such

children's product complies with the children's product safety rule[1]. Section 235 of the Act defines "children's product" to mean a consumer product designed or intended primarily for children 12 years of age or younger.

The CPSIA defines a third party testing laboratory as one that is not owned by the manufacturer or private labeler of a product assessed by such testing laboratory. Nevertheless, a laboratory that is so owned, in certain specified circumstances, may be accredited as a third party testing laboratory. The Act specifies that a third party testing laboratory may also include a government owned or controlled laboratory under certain conditions.

Special provisions are established in the Act for laboratories that are owned by a manufacturer or private labeler. Such laboratories are commonly referred to as "proprietary laboratories" or "first party" laboratories. The Act stipulates that the Commission may accredit a proprietary laboratory as a third party testing laboratory if the Commission, by order, makes certain findings that the laboratory is protected from undue influence by the manufacturer, private labeler, or other interested party, and that procedures are in place for immediate and confidential reporting to the Commission of any attempts by the manufacturer, private labeler, or other interested party to hide or exert undue influence over test results. The Commission must also find that accrediting the proprietary laboratory would provide equal or greater consumer safety protection than the manufacturer's or private labeler's use of an independent laboratory. A laboratory that satisfies these requirements is defined in the statute as a "firewalled" testing laboratory.

The Act provides that accreditation of third party testing laboratories may be conducted by either the Commission or an independent accreditation organization designated by the Commission and requires that the Commission maintain on its website an up-to-date list of laboratories that have been accredited to assess conformity with children's product safety rules.

On September 22, 2008, the Commission published a notice of requirements in the *Federal Register* (73 FR 54564),[2] providing the criteria and process for Commission acceptance of accreditation of third party conformity assessment bodies (third party laboratories) for testing pursuant to 16 C.F.R. part 1303, "The Lead Paint Ban."

II. Background on Requirements of 16 C.F.R. Part 1303

The U.S. Consumer Product Safety Commission (CPSC) established the "Ban of Lead-Containing Paint and Certain Consumer Products Bearing Lead-Containing Paint" for products manufactured after February 27, 1978, as described in 16 C.F.R. part 1303. The regulation states that "Toys and other articles intended for use by children that bear "lead-containing paint" are banned hazardous substances" (16 C.F.R. part 1303) and defines "lead-containing paint" as "paint … containing lead … in excess of 0.06 percent by weight…." The ban does not describe the methodology for testing, but rather, sets the scope of the products to be banned and the concentration of lead in the paint or surface coating. Enactment of the CPSIA reduced the allowable concentration of lead in lead-containing paint to 0.009 percent (or 90 ppm). To assist

[1] CPSC regulations at 16 C.F.R part 1110 limits the parties who must certify to the U.S. importer, and in the case of domestically produced products, the U.S. manufacturer.
[2] http://www.cpsc.gov/BUSINFO/frnotices/fr08/testhldprod.pdf.

the testing community, industry, and other interested parties in meeting the requirements of the ban on lead-containing paint, CPSC staff published guidance documents that described the methods which CPSC staff uses to analyze paint for its lead content. Prior to the CPSIA, the Office of Compliance gave guidance on the methodology used for compliance determinations; however, there was no formal guidance document written and no methodology specified in the Code of Federal Regulations.

The CPSIA requires manufacturers/importers to certify that the children's products bearing a surface coating that they manufacture, import, sell, or offer for consumption meet the requirements of 16 C.F.R. part 1303 based on testing by laboratories with accreditation accepted by the CPSC. The CPSC's rules for acceptance of accreditation[3] for lead in paint testing included requiring laboratories to be ISO/IEC 17025-accredited by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (ILAC-MRA) and have a specific reference in their accreditation scope documents to 16 C.F.R. part 1303. These rules for accreditation did not require a specified test method; however, staff published the method used by the CPSC's Directorate for Laboratory Sciences on the CPSC's website as CPSC-CH-E1003-09.[4] CPSC staff received comments from the American Association for Laboratory Accreditation (A2LA) and the International Laboratory Accreditation Cooperation (ILAC), which indicated their preference for specifying test methods that the CPSC finds acceptable; however, they did support the approach of designating ILAC-MRA signatory accreditation bodies (see Tab A).

III. Discussion

The existing framework for enforcement of 16 C.F.R. part 1303 and the certification requirements for products subject to it, provide flexibility for firms to test, so long as paint does not contain lead in excess of 0.009 percent (calculated by weight of the dried paint film). However, the comments from A2LA and ILAC suggest that it would be beneficial for the rules of accreditation for lead in paint to include reference to test methods that are acceptable to the CPSC. Also, staff has reported that a new method, ASTM F2853-10[5], may also be used as a test method and could be as effective, precise, and reliable as the methodology used by the Commission for compliance determinations prior to the CPSIA (Tab B). CPSC staff is working with the National Institute of Standards and Technology (NIST) to develop and release a lead in paint standard reference material (SRM) 2569, consisting of a thin, uniform film with thickness and lead concentrations appropriate to testing of painted surfaces, and which would be suitable for validating ASTM F2853-10. This SRM may become available at some point in the year 2011. CPSC staff is also aware that commercial reference materials are now available that may be suitable for validating ASTM F2853-10. XRF methods and equipment other than those specified in ASTM F2853-10 are not considered effective for testing lead in paint and surface coatings for the purpose of determining conformity with 16 C.F.R. part 1303 at this time.

[3] 73 FR 54564, September 22, 2008.
[4] http://www.cpsc.gov/about/cpsia/CPSC-CH-E1003-09.pdf.
[5] ASTM F2853 - 10 Standard Test Method for Determination of Lead in Paint Layers and Similar Coatings or in Substrates and Homogenous Materials by Energy Dispersive X-Ray Fluorescence Spectrometry Using Multiple Monochromatic Excitation Beams, 2010.

Section 101(f)(4)(b) of the CPSIA states that the Commission may promulgate regulations governing the use of alternative methods for measuring lead in paint:

> RULEMAKING.—If the Commission determines, based on the study in subparagraph (A), that x-ray fluorescence technology or other alternative methods for measuring lead in paint are as effective, precise, and reliable as the methodology used by the Commission for compliance determinations prior to the date of enactment of this Act, the Commission may promulgate regulations governing the use of such methods in determining the compliance of products with part 1303 of title 16, Code of Federal Regulations, as modified pursuant to this subsection. Any regulations promulgated by the Commission shall ensure that such alternative methods are no less effective, precise, and reliable than the methodology used by the Commission prior to the date of enactment of this Act.

Staff recommends that the Commission change the Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity with Part 1303 of Title 16, Code of Federal Regulations to include specific reference to CPSC-CH-E1003-09 and/or CPSC-CH-E1003-09.1[6], and/orASTM F2853-10, while allowing two years for laboratories with existing CPSC-acceptance of accreditation for lead in paint testing to address this in their accreditation scope documents, as well as have a reapplication approved by the CPSC for continued CPSC acceptance of 16 C.F.R. part 1303 (with reference to one or both test methods). Currently, the accreditation must be to ISO Standard ISO/IEC 17025:2005–General Requirements for the Competence of Testing and Calibration Laboratories, and the scope of the accreditation must expressly include testing to the requirements of 16 C.F.R. part 1303. CPSC staff propose the following change: "The accreditation must be by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation—Mutual Recognition Arrangement (''ILAC–MRA'') and the scope of the accreditation must include testing to the requirements of 16 C.F.R. part 1303 in accordance with the *CPSC Standard Operating Procedure for Determining Lead (Pb) in Paint and Other Similar Surface Coatings,* CPSC-CH-E1003-09 and/or CPSC-CH-E1003-09.1 and/or ASTM F2853-10." XRF methods and equipment other than those specified in ASTM F2853-10 are not considered effective for testing lead in paint and surface coatings for the purpose of determining conformity with part 1303 of Title 16, Code of Federal Regulations at this time.

Staff recommends that laboratories previously accepted by CPSC be given a period of two years from the date of publication of the notice to amend the scope documents for their accreditation to reflect the methods described above, reapply with the CPSC, and be approved by the CPSC for acceptance of accreditation for 16 C.F.R. part 1303. This period of time would be given in recognition of the fact that many accreditation bodies work on a two year cycle for review and renewal of accreditation, or at a minimum, have surveillance activities within a two year cycle.

[6] Changes made to CPSC-CH-E1003-09 are incorporated in CPSC-CH-E1003-09.1 (attached as Tab C). The changes reflect ministerial edits and remove the statement that the rules for accreditation for lead in paint testing do not explicitly require the use of a particular standard operating procedure. Additionally, the following statement was added. "Adjustments may be necessary to achieve total digestion for certain paints and should be based on sound chemistry knowledge and appropriate acids for the sample material being analyzed."

IV. Environmental Considerations

Generally, mandatory CPSC requirements are considered to have little or no potential for affecting the human environment, and environmental assessments are not usually prepared for such actions (see 16 C.F.R § 1021.5(c)(1)). Nothing in these revisions to the recommended accreditation requirements alters that expectation. Therefore, staff does not expect the revision to have any negative environmental impact.

V. Effective Date

Staff recommends that the revised Accreditation Requirements for Third Party Conformity Assessment Bodies to Test to the Requirements for Lead in Paint to Assess Conformity with Part 1303 of Title 16 Code of Federal Regulations become effective upon publication of notice thereof in the *Federal Register*, with a phase-in period for CPSC acceptance of accreditation, as described in the draft *Federal Register* notice. Specifically, staff is recommending that new applicants for CPSC acceptance of accreditation to 16 C.F.R. part 1303 would have the option to apply to the CPSC without reference to a specific test method or to apply for CPSC acceptance to include a specific reference to 16 C.F.R. part 1303 (CPSC–CH–E1003–09 and/or CPSC–CH–E1003–09.1) and/or 16 C.F.R. part 1303 (ASTM F2853-10) for up to one year after publication of this notice in the Federal Register. After one year, the option to apply for accreditation to 16 C.F.R. part 1303 without reference to a CPSC required test method would not be permitted. CPSC-accepted third party conformity assessment bodies for 16 C.F.R. part 1303 without a reference to one of the specified test methods would have up to two years from the date of publication of this notice in the Federal Register to reapply and become accepted by the CPSC for 16 C.F.R. part 1303 (CPSC-CH-E1003-09 and/or CPSC-CH-E1003-09.1) and/or 16 C.F.R. part 1303 (ASTM F2853-10). To maintain CPSC-accepted status, third party conformity assessment bodies that are CPSC-accepted for 16 C.F.R. part 1303 without reference to one of the required test methods would be required to reapply with, and be accepted by, the CPSC within the two-year period, irrespective of whether the scope document from their accreditation body that was supplied with their earlier CPSC application included a reference to one of the required test methods. Previously CPSC-accepted third party conformity assessment bodies for 16 C.F.R. part 1303 (including those that had one of the specified test methods in their accreditation scope document that was supplied with their earlier CPSC application) would be required to reapply to maintain CPSC acceptance because the CPSC previously did not record references to test methods, and will now be recording the references through the reapplication process.

VI. Staff Recommendation for Revising Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies for Conformity to the Lead Paint Ban:

Staff recommends that the Commission approve staff's proposed revised Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies for Conformity to the Lead Paint Ban, including requirements for the use of methods CPSC-CH-E1003-09 and/or CPSC-CH-E1003-09.1 and/or ASTM F2853-10, as described in the draft *Federal Register* notice (Tab C).

Tab A

1. Email comment from The American Association for Laboratory Accreditation (A2LA)

From: Adam Gouker [mailto:agouker@a2la.org]
Sent: Tuesday, October 07, 2008 1:49 PM
To: CPSC-OS
Subject: ``Laboratory Accreditation Process for Lead Paint Ban Testing.

Dear Office of the Secretary (CPSC) and/or Mr. Jay Howell:

This email relates to the Commission's request for comments regarding the new accreditation requirements for third party testing labs in support of the CPSIA. Our organization, The American Association for Laboratory Accreditation (A2LA), is a full-member signatory to the ILAC MRA and thus will likely accredit many of these third party testing labs. We feel there could be a few additional pieces of information that would be helpful to add to the federal register notices in the future (for both the accrediting bodies and the testing laboratories). The majority of questions we have fielded from testing labs, since inception of the CPSIA requirements, relate to "what technology is recognized by the CPSC, and what test methods should be utilized". Many labs have a misunderstanding that XRF is an acceptable technology to use for this testing. While the CPSC open meetings have been very helpful to aid with the implementation process of the new law, it may be helpful to add more specific scope of accreditation requirements for the future (if possible).

By simply requiring 16 CFR 1303 to be on the lab's scope for the lead paint requirement, there leaves some room for interpretation as to which technology is to be used to test for these limits, as well as which test methods are to be used (since this specific CFR does not seem to clarify these issues). We understand that some CFRs do contain a specified test method; however, we feel it would add clarification if this information was in the federal register notices in the future.

I would add that we have contacted members of the Commission staff for questions regarding these issues, and they have been very helpful and responsive in clarifying our questions. Our concerns lie with the individuals who do not have a direct contact at the CPSC, and are looking for guidance in the legislation as to what they need to be accredited to (i.e. listings on their scope).

We hope these comments are considered for the future, and would greatly appreciate any feedback received from the Commission staff.

Respectfully,

Adam Gouker
Senior Accreditation Officer, A2LA
350 Buckeystown Pike, Suite 350
Frederick, MD 21704-8373
Main: 301 644 3248
Direct: 301 644 3217

2. Comment from International Laboratory Accreditation Corporation (ILAC)

17 October 2008

Office of the Secretary: cpsc-os@cpsc.gov

Subject: Laboratory Accreditation Process for Lead Paint Ban Testing

I am writing on behalf of the International Laboratory Accreditation Cooperation (ILAC) in response to your request for comments in FR Notice Vol. 73, No. 184, Monday, September 22, 2008.

ILAC welcomes the role that its Mutual Recognition Arrangement (MRA) will play in support of the CPSC regulation of lead paint on children's products. We understand there will be future regulatory initiatives on children's products in which internationally recognized accreditation bodies (i.e., the ILAC MRA signatories) may play a role. ILAC is happy to accept such a responsibility.

In reference to the September 22nd notice, while it is accepted that 16 CFR Part 1303 needs to be identified in each accredited laboratory's scope of accreditation, there is some question about what test technologies and methods the CPSC finds acceptable. Without specified test methods, the technical assessors of the accreditation bodies will determine the acceptable technologies and methods for lead analyses at the 600 parts-per-million level and these test methods will also be identified in the laboratory's scope of accreditation. We are pleased to note that several other parts of the CFR do cite specified test methods.

The tight deadlines imposed on the Commission by the CPSIA of 2008, places pressure on accreditation bodies to accredit laboratories to the specified tests. ILAC MRA signatories are committed to respond as expeditiously as possible without compromising the integrity of the accreditation process. Nonetheless, there may only be a limited number of laboratories accredited to the CPSC requirements by the specified deadlines. We would welcome further discussions to explore alternatives that may assist in overcoming any difficulties in implementation.

ILAC looks forward to working with the Commission staff to better understand the current and emerging regulatory needs where accreditation plays a role.

If you have any queries, please feel free to contact Annette Dever at the ILAC Secretariat at ilac@nata.asn.au

Sincerely

Daniel Pierre
ILAC Chair

cc: rhowell@cpsc.gov

Secretariat: PO Box 7507, Silverwater, NSW 2128, Australia
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TAB B

Update on Use of X-ray Fluorescence Spectrometry for Measuring Lead in Paint

December, 2010

David Cobb
U. S. Consumer Product Safety Commission
Directorate for Laboratory Sciences
Division of Chemistry
10901 Darnestown Road, Gaithersburg, MD 20878

This report was prepared by the CPSC staff, and has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

Background:

In August 2009, U.S. Consumer Product Safety Commission (CPSC) staff completed a study to evaluate the effectiveness, precision, and reliability of X-ray Fluorescence (XRF) methods and other alternative methods for measuring lead (Pb) in paint or other surface coatings when used on a children's product.[1] CPSC staff determined that XRF had the potential to accurately measure lead content in painted films on children's products at the limits required under the Consumer Product Safety Improvement Act (CPSIA) of 2008, but noted that appropriate standard reference materials (SRMs) and standard analytical methods needed to be developed before a complete evaluation or determination was possible. This report provides an update on the development of standard reference materials, the performance-based standard methods needed for certifying that paints on children's products contain less than 0.009% Pb (or 90 mg/kg), as required under CPSIA section 101(f).

Current Test Method:

The current CPSC staff test method[2] for determining total Pb in paint involves removing paint from a product by scraping or using a solvent, dissolving the paint scrapings in nitric acid, and analyzing the acid solution by spectroscopic means, such as inductively coupled plasma optical emission spectrometry (ICP-OES), inductively coupled plasma mass spectrometry (ICP-MS), flame atomic absorption spectrometry (FLAA), or graphite furnace atomic absorption spectrometry (GFAA). These analytical techniques are capable of yielding precise and accurate results and have low enough detection limits to measure Pb in paint at the new limits of 90 mg/kg. Paint powder SRMs, such as National Institute of Standards and Technology (NIST) SRM 2581 (contains 0.45% Pb) and 2582 (contains 0.02% Pb), are available to laboratories to verify performance. The current test method is based on standard test procedures, such as ASTM International (formerly the American Society for Testing and Materials) ASTM E1645,[3] ASTM E1613-04,[4] and Association of Official Analytical Chemists (AOAC) standard AOAC 974.02.[5] This test method is time-consuming, typically requiring several hours to prepare and analyze samples, and is sample destructive. An insufficient quantity of paint, such as from an item with a thin coating of paint in a small area, also can impact the use of this procedure. The current test method recommends that a minimum of 5 mg of paint be collected. Collecting at least 5 mg of paint from products with small painted areas can be difficult, sometimes requiring compositing of like paints from multiple items to obtain sufficient material for analysis.

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[1] US CPSC. *Study on the Effectiveness, Precision, and Reliability of X-ray Fluorescence Spectrometry and Other Alternative Methods for Measuring Lead in Paint, August 2009,* http://www.cpsc.gov/about/cpsia/leadinpaintmeasure.pdf.

[2] US CPSC. Test Method CPSC-CH-E1003-09 *Standard Operating Procedure for Determining Lead (Pb) in Paint and Other Similar Surface Coatings, March 2009,* http://www.cpsc.gov/about/cpsia/CPSC-CH-E1003-09.pdf.

[3] ASTM E1645-01(2007) Standard Practice for Preparation of Dried Paint Samples by Hotplate or Microwave Digestion for Subsequent Lead Analysis, 2007.

[4] ASTM E1613-04 Standard Test Method for Determination of Lead by Inductively Coupled Plasma Atomic Emission Spectrometry (ICP-AES), Flame Atomic Absorption Spectrometry (FAAS), or Graphite Furnace Atomic Absorption Spectrometry (GFAAS) Techniques, 2004.

[5] Association of Official Analytical Chemists (AOAC) standard AOAC 974.02 (Lead in Paint Test) 1976.

Potential Advantages of Using XRF for Paint Analysis:

The main advantages of utilizing XRF over the current digestion/ICP method would be:

1. XRF analysis is often nondestructive, and the paint can be tested *in situ* on the item.
2. Little to no sample preparation is required, which greatly reduces the analysis time and cost. Sample times for XRF *in situ* analysis are typically less than five minutes. It takes several hours to collect, digest, and analyze paint scrapings using the current test method.
3. XRF has the potential to directly test small painted areas, without the sometimes difficult task of removing enough paint from a small area to quantitatively analyze using the current digestion and ICP method. XRF analyzers equipped with video cameras can be used to analyze spot sizes of a few millimeters.
4. Some XRF analyzers are portable, allowing for field-screening of products.

Availability of Standard Reference Materials:

Standard reference materials should be used to validate any test method. Paint film standards that contain certified levels of Pb closer to the allowable limits of the CPSIA need to be developed to validate *in situ* XRF analysis of paint films on children's products. The paint film standards should have certified Pb values on a mass per area unit basis (mg/cm^2) as well as a mass per mass unit basis (weight %). The paint films should also be well characterized and certified with respect to dry film thickness and density.

Currently, NIST is developing paint film SRMs that have these characteristics and could be used for calibrating and validating *in situ* XRF analysis of paint films on children's products. CPSC staff is working with NIST in this effort. The paint films should be available to the public at some point in the year 2011.

Availability of Standard Test Methods:

A standard test method, ASTM F2853-10, for determining lead in paint layers by energy dispersive XRF using multiple monochromatic beams was developed by ASTM International Committee F40 on Declarable Substances. The standard has been published and is available on the ASTM website at: http://www.astm.org/Standards/F2853.htm. The associated interlaboratory research report[6] may be obtained by contacting ASTM and requesting Research Report RR:F40-1001. The repeatability (the difference in results obtained by the same operator for the same material) was reported to be 26 mg/kg for a paint layer on plastic or metal containing 90 mg/kg Pb. The reproducibility (the difference in results obtained by different laboratories for the same material) was reported to be 35 mg/kg for a paint layer on plastic or metal containing 90 mg/kg Pb. ASTM E-1613 reports similar, although slightly lower repeatability and reproducibility data for ICP-OES. Because of the additional impact of imprecision due to scraping, weighing, and digesting in acid, which are all required before performing ASTM E-1613 testing on painted coatings of consumer products, staff recognizes

[6] ASTM Research Report RR:F40-1001 Interlaboratory Study to Establish Precision Statements for ASTM F2853-10, July 1, 2010.

that ASTM F2853-10 is expected to be as effective, precise, and reliable as the methodology used by CPSC staff for compliance determinations prior to the date of enactment of the CPSIA.

Currently, ASTM Committee F40 is also developing a second proposed new standard, WK21957, Test Method for Identification and Quantification of Lead in Paint and Other Coatings Using Energy Dispersive X-ray Spectrometry (EDXRF). This proposed standard would apply to handheld XRFs, and an interlaboratory study of the proposed test method currently is being conducted. CPSC staff is collaborating with ASTM in these efforts, and will evaluate the effectiveness of the test method when the interlaboratory study is completed and available.

Conclusion:

The use of energy dispersive XRF according to ASTM F2853-10, using multiple monochromatic excitation beams for determining Pb content in paint or similar surface coatings on children's products, is expected to be as effective, precise, and reliable as the current CPSC staff method[2] and the methodology used by CPSC staff for compliance determinations prior to the date of enactment of the CPSIA. CPSC staff is working with NIST staff to develop appropriate (SRMs) that can be used to calibrate and verify performance, and these will be available soon. Additionally, commercial reference materials, consisting of thin films of paint with appropriate levels of lead, are available already. CPSC staff has worked with the ASTM to develop appropriate standard test methods. A standard test method, ASTM F2853-10,[7] using X-ray fluorescence (XRF) spectrometry for determining lead content in paint films, has been developed by ASTM.

XRF technology using multiple monochromatic beams is suitable in many cases for the accurate determination of lead in paint or similar surface coatings, provided the appropriate test method, ASTM F2853, is followed with the use of appropriate reference materials. CPSC staff considers both CPSC-CH-E1003-09 and ASTM F2853 to be acceptable for use in testing to the lead paint ban at 16 C.F.R. part 1303.

[7] ASTM F2853-10 Standard Test Method for Determination of Lead in Paint Layers and Similar Coatings or in Substrates and Homogenous Materials by Energy Dispersive X-Ray Fluorescence Spectrometry Using Multiple Monochromatic Excitation Beams, 2010.

TAB C

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
DIRECTORATE FOR LABORATORY SCIENCES
DIVISION OF CHEMISTRY

Test Method: CPSC-CH-E1003-09.1
Standard Operating Procedure for Determining Lead (Pb) in Paint and Other Similar Surface Coatings*
February 25, 2011

This document provides information on the test methodology that is used by the U.S. Consumer Product Safety Commission's (CPSC) Product Testing Laboratory, Chemistry Division (LSC), in the analysis of paint and certain painted products. The methodology is used to determine the total lead content of paint, or a painted surface, on a dry paint basis. This method supersedes all previously published standard operating procedures for lead in paint testing.

CPSC staff has concluded that this test methodology is sufficient to make appropriate determinations concerning lead (Pb) in paint, as defined in 16 C.F.R Part1303, with a regulatory limit of 0.009% by weight. Adjustments may be necessary to achieve total digestion for certain paints, and should be based on sound chemistry knowledge and appropriate acids for the sample material being analyzed. Screening tests by X-ray fluorescence may sometimes be employed by CPSC staff to determine samples in need of such testing.

Definitions

1. Sample – an individual consumer product or a group of identical consumer products from a batch to be tested
2. Component Part – individual sub-unit within the total sample. Each separate paint color on a sample is a component part.
3. Composite Testing-like parts – combining like paints from several like parts or products to obtain sufficient sample size for analysis when there is insufficient quantity of paint on one item to perform testing.
4. Composite Testing-different parts – combining different paints (*e.g.*, multiple colors) from one or more samples to reduce the number tested.
5. Instrument Detection Limit (IDL) – 3 times the standard deviation of 10 replicate measurements of reagent blank.
6. Method Detection Limit (MDL) – reagent blank fortified with 2-3 times the IDL. Seven replicate measurements are made. Calculate the MDL as follows: MDL = t X S, t = 3.14 (99% confidence level for 7 replicates), S = standard deviation.

* This document was prepared by CPSC staff, has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

7. Laboratory Reagent Blank (LRB) – an aliquot of the digestion reagents that is treated exactly as a sample including exposure to glassware, digestion media, apparatus, and conditions used for a particular Pb test, but with no added sample. LRB data are used to assess contamination from the laboratory environment.
8. Calibration Blank – deionized water acidified with nitric acid (3 ml concentrated nitric acid diluted to 100 ml with deionized water).
9. Stock Standard Solution – 1000 µg/ml solution of Pb purchased from reputable commercial source, used to prepare calibration standards. Replace before expiration date.
10. Calibration Standards – solutions containing 0 to 25 µg/ml of Pb in 3% nitric acid matrix are used. A minimum of 4 calibration standards are used. Calibration standards should be prepared weekly.
11. Quality Control Sample (QCS) – a solution containing Pb that is used to evaluate the performance of the instrument system. QCS is obtained from a source external to the laboratory and Stock Standard Solution.
12. Certified Reference Material (CRM) – CRMs are materials with similar matrices as test samples with known lead levels. The CRMs are used to verify digestion and analysis methods. For example, standard reference materials (SRMs) are CRMs that are available from the National Institute of Standards and Technology (NIST), such as those listed in the Equipment and Supplies section below.

Equipment and Supplies: The materials used for sampling and analysis are as follows:

1. Nitric acid, trace metal grade
2. Disposable plastic digestion vessels, 50 ml, or glass test tubes
3. Hot block digester or hot plate with test tube block
4. Disposable razor blade or scalpel
5. Methylene chloride (optional)
6. Distilled water
7. Microwave digestion apparatus
8. CRMs such as NIST SRMs[1] 2581 and 2582 lead in powdered paint. CRMs such as NIST SRM 2569 that are paint films should be used if X-ray fluorescence spectroscopy methods conducted
9. Internal Standard (such as yttrium, from a stock standard solution of that element appropriate to the instrument parameters of the ICP used for the analysis)

Note on composite testing: Composite testing-like parts (as defined above) is appropriate and may be necessary to obtain valid analytical results. Composite testing-different parts (as defined above) must be done with adequate care, planning, and understanding of the limitations and propagations of error in measurements or the test may fail to detect excessive lead in one individual paint because of dilution. If composite testing-different parts is used, great care must be taken to accurately weigh each component paint and account for the propagation of errors due to weighing and measuring, and the analyst must ensure that the compositing will not result in a Pb measurement being below the detection limit for a paint component that would exceed 0.009% Pb.

[1] NIST SRMs 2581 and 2582, and other reference materials, are available from the National Institute of Standards and Technology. See http://ts.nist.gov/measurementservices/referencematerials/index.cfm

Each individual paint must be weighed individually with sufficient precision and sufficient safety factors to assure that no false negatives are reported.

Sufficient paint must be used for each of the paints giving proper consideration for the weighing capabilities of the balance used and the detection limits and necessary dilution for the subsequent instrumental analysis. The combined paints could then be digested according to the procedure given below for a single paint, before analysis by Inductively Coupled Plasma (ICP) spectroscopy. Appropriate weights for each of the individual paints that are composited depend on final dilution volumes, weighing accuracy, and detection limits. All of the lead found in the digestate for the combined composite could be attributed to the weight of each of the individual paints as though all of the lead could possibly come from any one of the individual paints. The measured lead should be treated in calculations as if it originated solely from one part of the composite; the lead concentration calculation should be carried out for each part unless identical weights of each sample were used in the analysis. An example is given at the end of this document.

In considering results from such a composite sample, it is imperative that a sufficient "safety factor" be applied to account for weighing inaccuracy and propagation of errors from each step in the analytical procedure to ensure no violative paints are misrepresented as nonviolative. It has been suggested, for example for a composite of three samples, that any sample possibly having greater than 80 percent of the limit for lead in paint in any of the composited paints should be retested[2][3].

I. Acid Digestion

Method: The digestion method is based on the Association of Official Analytical Chemists (AOAC) standard AOAC 974.02[4] (Lead in Paint). Alternate microwave digestion based on ASTM E1645[5] may be used as well. Analysis by Inductively Coupled Plasma (ICP) spectroscopy is based on ASTM E1613[6].

1. For testing of wet paint, apply a thin coating to a glass slide, and dry completely prior to testing by heating in an oven at nominally 105 °C (105 °C + 2 °C) until the weight is stable for at least two successive readings; the readings should be separated by 30 minutes of heating in the oven.
2. For products coated with paint or a similar surface coating, remove and digest the coating, separately from the substrate material. Care should be taken to remove as little of the substrate

[2] *Intertek Proposed Operating Procedure: Multiple Color Testing for Lead in Paint and Similar Surface Coating Materials (16 CFR 1303)*, Comment submitted to CPSC, February 13, 2009.

[3] Toy Industry Association Inc. Laboratory Testing Technical Work Group, that includes (but is not limited to) representatives of the following laboratories: Specialized Technology Resources(STR), SGS consumer Testing Services; EMC Inc., Bureau Veritas,(BV), CMA Testing NSF International, Intertek (ITS) and Toy Safety and Quality, Inc. *Compositing Acceptance Method for Lead in Surface Coatings*, Comment submitted to CPSC, March 18, 2009.

[4] AOAC Official Method 974.02 *Lead in Paint*

[5] ASTM E1645 *Standard Practice for Preparation of Dried Paint Samples by Hotplate or Microwave Digestion for Subsequent Lead Analysis*

[6] ASTM E1613 *Standard Test Method for Determination of Lead by Inductively Coupled Plasma Atomic Emission Spectrometry (ICP-AES)*

as possible. It may be necessary to add a few drops of solvent, such as methylene chloride, to soften the paint and aid in its removal from the
substrate. If used, such solvent must be evaporated fully prior to analysis. The scraped paint should be finely divided to help in digesting.
3. Scrape approximately 5-100 mg of paint from the product. If it is not possible to collect this much paint, it may be necessary to combine more than one unit of such product to collect sufficient paint.
4. Prepare a reagent blank sample and digest and test a standard reference paint material, such as National Institute of Standards and Technology (NIST) SRM 2581 - Powdered
Paint Nominal 0.5% Lead or NIST SRM 2582 - Powdered Paint Nominal 0.02% Lead, with each batch of samples tested.
5. Digest appropriately according to AOAC 974.02 or ASTM E1645 in either a disposable glass test tube with a heating block, a disposable plastic digestion vessel in a hot block digester, or in a suitable digestion vessel and digestion microwave oven system.
6. Dilute samples so that Pb results are within the calibration range of the instrument. Be careful not to dilute a sample that could have 0.009% Pb to a level below the method detection limit.
7. Analyze diluted samples for Pb concentration using an ICP spectrometer (or Atomic Absorption spectrometer). Analysis procedures for ICP-OES, flame atomic absorption spectrometry (FLAA), and graphite furnace atomic absorption spectrometry (GFAA) are based on the methodology in ASTM E1613-04. Inductively coupled plasma mass spectrometry (ICP-MS) may also be employed with appropriate procedures, such as EPA 6020A[7].

ICP Operating Procedures and Quality Control Measures

Analysis

1. Ignite plasma. Perform wavelength calibration or torch alignments per instrument manufacturer recommendations.
2. Allow the instrument to become thermally stable before continuing.
3. Ensure the following element and wavelength are selected in analytical method:
    a. Pb 220.353

    One other Pb line such as Pb 217.00 should be used to ensure spectral interferences are not occurring during analysis.
4. An internal standard such as 2 µg/ml yttrium should be used.
5. Perform calibration using calibration blank and at least 3 standards. Calibration should be performed a minimum of once a day when used for analysis, or each time the instrument is set up. Results for each standard should be within 5% of the true value. If the values do not fall within this range, recalibration is necessary.
6. Analyze the QCS immediately after the calibration. The analyzed value of Pb should be within ±10% of the expected value. If the Pb value is outside the ±10% limit, recalibration is required.
    a. At least one LRB must be analyzed with each sample set. If the Pb value exceeds 3 times the MDL, laboratory or reagent contamination should be expected. The source of the contamination should be identified and resolved before continuing analyses. The LRBs should be at the same acid concentration as that of the

[7] EPA 6020A *Inductively Coupled Plasma-Mass Spectrometry*

sample and should be taken through the same digestion procedure as that of a sample.

7. At least one certified reference material (CRM) should be analyzed with each batch of samples. The CRM should have a known amount of Pb and be of a material similar to a test specimen. Analyte recoveries should be within ±15% of expected values. If recoveries are outside this limit, the source of the problem should be identified and resolved before continuing analyses.
8. Dilute any samples that have Pb values exceeding 1.5 times the high calibration standard, and reanalyze.

Calculations and Results Reported

Results for the Pb test methods are calculated and reported as follows:

1. Total Pb concentration:[8] %Pb (wt./wt.) = 0.10cd/w
   a. c = concentration of Pb detected (µg/ml)
   b. d = dilution volume (ml)
   c. w = weight of aliquot digested (mg)

Example 1: Single Paint Tested

An aliquot of 10 mg of yellow paint scrapings is digested in acid and diluted to a final volume of 50 ml. When analyzed on the ICP-OES, the analytical result is 0.080 µg/ml lead in the acid. The paint therefore contained 0.10 x 0.080 µg/ml x 50 ml /10 mg = 0.04% (400 ppm).

Table 1: Total Pb Analysis

	(c)	(d)		(w)	
Item	Analytical result Pb (µg/ml)	Dilution volume (ml)	Total Pb (µg)	Sample wt (mg)	Pb (%)
Yellow Paint	0.080	50	5	10	0.04

Example 2: Composite Testing – Different Parts

One example of composite testing of different paints would be as follows, and considers the case of weighing to the nearest 0.01 mg, digesting in acid, diluting to a final volume of 10 ml, and testing on an ICP-OES with an MDL of 0.01 µg/ml. A sample bears red, green, and orange paint. The paints are removed from the sample and 4.90 mg of red paint is combined with 5.00 mg of green paint, and 5.10 mg of orange paint. The resulting 15 mg of composite paint from this example is digested in acid and diluted to 10 ml, and then the diluted digest is found to contain 0.05 µg/ml lead. The combined 3 aliquots of paint would have contributed to a total of 0.50 µg of lead for the composite sample. Although the average concentration in this case would be 33 ppm, the individual contributions are not known, and one must calculate the lead

[8] The factor 0.10 in this formula is the mathematical conversion of the units used for concentration (µg/ml), and weight of paint (mg) into percent, and represents 100% x 1 mg / 1000 µg.

concentration of each paint as if all of the lead originated from it. Thus, the red paint could contain up to 0.50 µg / 0.0049 g = 102 ppm (µg/g), with similarly calculated results of 100 ppm and 98 ppm for the green and orange paints. See Table 2 below.

Table 2: Total Pb Analysis – Composite Testing

	(c)	(d)		(w)		
Item	Analytical result Pb (µg/ml)	Dilution volume (ml)	Total Pb (µg)	Sample wt (mg)	Potential Pb (%) per component	Pb (%) Composite
Red Paint	*0.05	10	0.5*	4.90	0.102	
Green Paint	*0.05	10	0.5*	5.00	0.100	
Orange Paint	*0.05	10	0.5*	5.10	0.098	
Total Composite	0.05	10	0.5	15.00		0.0033**

*In a composite of different component paints, the analytical result for the total composite would be applied to each component part as if all the Pb was in that component paint.
** In this example, the Pb concentration of the combined paints is <0.009%, but when estimating potential Pb per component, each component potentially could have >0.009% Pb and would require additional testing without compositing to ensure Pb <0.009%

Summary of changes in Revision CPSC-CH-E1003-09.1

Ministerial changes were made to the method as well as a change in the introduction to remove the disclaimer that the rules for accreditation for lead in paint testing did not require the use of the method. Additionally, the following statement was added. "Adjustments may be necessary to achieve total digestion for certain paints and should be based on sound chemistry knowledge and appropriate acids for the sample material being analyzed."

Billing Code CPSC-6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

CPSC Docket No. CPSC-

16 CFR Part 1303

Third Party Testing for Certain Children's Products; Revision to Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Test Children's Products for Conformity With Part 1303 of Title 16, Code of Federal Regulations.

AGENCY: U.S. Consumer Product Safety Commission.

ACTION: Notice of requirements; revision of testing terms.

SUMMARY: The U.S. Consumer Product Safety Commission ("CPSC," "Commission," or "we") is issuing a notice amending the criteria and process for Commission acceptance of accreditation of third party conformity assessment bodies for testing to the lead paint ban at 16 CFR part 1303. We are taking this action to require CPSC and/or ASTM published test methods to be referenced by a third party conformity assessment body in the scope of its accreditation.

DATES: The revised notice of requirements is effective upon publication in the *Federal Register*.

Comments in response to this notice of requirements should be submitted by [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Comments on this notice should be captioned, "Third Party Testing for Certain Children's Products; Requirements for Accreditation of Third Party Conformity Assessment Bodies – Lead Paint."

ADDRESSES: You may submit comments, identified by Docket No. CPSC-2011-___, by any of the following methods:

Electronic Submissions: Submit electronic comments in the following way:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (email) except through http://www.regulations.gov.

Written Submissions: Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions) preferably in five copies, to: Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. Do not submit confidential business information, trade secret information, or other sensitive or protected information (such as a Social Security Number) electronically; if furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Robert "Jay" Howell, Assistant Executive Director for he Office of Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; email: rhowell@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 14(a)(3)(B)(i) of the Consumer Product Safety Act (CPSA), as added by section 102(a)(2) of the Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110-314, directed the CPSC to publish a notice of requirements for accreditation of third party conformity assessment bodies to test children's products for conformity with the Commission's regulations at 16 CFR part 1303, *Ban of Lead-Containing Paint and Certain Consumer Products Bearing Lead-Containing Paint* (the lead paint ban). In the *Federal Register* of September 22, 2008, the Commission published a notice of requirements for accreditation of third party conformity assessment bodies to test children's products for conformity with the lead paint ban under 16 CFR part 1303 (73 FR 54564).

In response to the September 22, 2008 notice of requirements, the International Laboratory Accreditation Cooperation (ILAC) and the American Association for Laboratory Accreditation (A2LA) submitted letters asking us to specify test methods to ensure that accreditation bodies are able to determine the acceptable technologies and methods for lead analyses. The September 22, 2008 notice of requirements stated that the accreditation must be to the International Standards Organization (ISO)/International Electrotechnical Commission (IEC) Standard ISO/IEC 17025:2005, "General Requirements for the Competence of Testing and Calibration Laboratories," and that the scope of the accreditation must include testing to the requirements of 16 CFR part 1303. However, these requirements for accreditation did not reference a specific test method, although the CPSC staff's test method (CPSC-CH-E1003-09) was made available on the CPSC website at: http://www.cpsc.gov/about/cpsia/CPSC-CH-E1003-09.pdf. Therefore, to require certain test methods that are acceptable to the CPSC for testing for

lead in paint, we are amending the notice of requirements to state that the scope of the third party conformity assessment body's accreditation shall specify certain test methodologies.

The Commission is revising the September 22, 2008 notice of requirements to require reference of specific test methods for CPSC acceptance of accreditation of third party conformity assessment bodies to assess conformity with 16 CFR part 1303. One or more of the following test methods must be referenced: the existing CPSC Standard Operating Procedure for Determining Lead (Pb) in Paint and Other Similar Surface Coatings, CPSC–CH–E1003–09 and/or CPSC–CH–E1003–09.1 and/or, ASTM F2853-10, "Standard Test Method for Determination of Lead in Paint Layers and Similar Coatings or in Substrates and Homogenous Materials by Energy Dispersive X-Ray Fluorescence Spectrometry Using Multiple Monochromatic Excitation Beams."

Test Method CPSC–CH–E1003–09 was revised in Test Method CPSC–CH–E1003–09.1 to reflect ministerial edits and remove the statement that the rules for accreditation for lead in paint testing do not explicitly require the use of a particular standard operating procedure. Additionally, the following statement was added. "Adjustments may be necessary to achieve total digestion for certain paints and should be based on sound chemistry knowledge and appropriate acids for the sample material being analyzed." It is still based on standard test procedures, such as ASTM International (formerly the American Society for Testing and Materials) ASTM E1645, ASTM E1613-04, and Association of Official Analytical Chemists (AOAC) standard AOAC 974.02. This test method will be made available on the CPSC website at: http://www.cpsc.gov/about/cpsia/CPSC-CH-E1003-09.pdf.

In addition to the CPCS's test methods, CPSC staff finds that ASTM F2853-10, "Standard Test Method for Determination of Lead in Paint Layers and Similar Coatings or in

Substrates and Homogenous Materials by Energy Dispersive X-Ray Fluorescence Spectrometry Using Multiple Monochromatic Excitation Beams." which uses a specific type of X-Ray Fluorescence (XRF) technology, may be used as a test method and is as effective, precise, and reliable as method CPSC-CH-E1003-09 posted on the CPSC website. The standard is available on the ASTM website at: http://www.astm.org/Standards/F2853.htm. Supporting data about the associated interlaboratory research report has been filed with ASTM and can be obtained by contacting ASTM and requesting Research Report RR:F40-1001. Our findings are based on a study conducted in August 2009, as updated in December 2010, which evaluates the effectiveness, precision, and reliability of XRF methods and other alternative methods for measuring lead in paint or other surface coatings when used in children's products. The studies on XRF are published on the CPSC's website at: http://www.cpsc.gov/ABOUT/Cpsia/leadinpaintmeasure.pdf. XFR methods and equipment other than those specified in ASTM F2853-10 are not considered effective for testing in paint and surface coatings for the purpose of determining conformity with 16 CFR part 1303 at this time. We are working with the National Institute of Standards and Technology (NIST) to develop and release a lead in paint standard reference material (SRM) 2569, consisting of a thin, uniform film with thickness and lead concentrations appropriate to testing of painted surfaces, and which would be suitable for validating ASTM F2853-10. This SRM may become available in 2011. We also are aware that other commercial reference materials are now available that may be suitable for validating ASTM F2853-10.

Many third party conformity assessment bodies operate on a two year cycle for review and renewal of accreditation. Accordingly, in order to give third party conformity assessment bodies sufficient time to amend their scope documents to reflect the specific test methods

accepted by the Commission, CPSC–CH–E1003–09 and/or CPSC–CH–E1003–09.1 and/or ASTM F2853-10, CPSC-accepted third party conformity assessment bodies that are listed on the CPSC website as approved to 16 CFR part 1303 (without reference to a test method) will have two years from the date of publication of this notice in the *Federal Register* to reapply and be accepted by the CPSC for CPSC–CH–E1003–09 and/or CPSC–CH–E1003–09.1 and/or ASTM F2853-10 for testing to the lead in paint regulation at 16 CFR part 1303. After that date, previously accepted third party conformity assessment bodies that test for 16 CFR part 1303 must have been accepted by the CPSC for one or more of the required test methods to maintain CPSC-accepted status. All accreditations must be by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation—Mutual Recognition Arrangement (ILAC–MRA) and the scope of the accreditation must include:

- 16 CFR part 1303 (CPSC-CH-E1003-09 and/or CPSC-CH-E1003-09.1),

  and/or

- 16 CFR part 1303 (ASTM F2853-10).

New applicants seeking CPSC acceptance of accreditation to test to 16 CFR part 1303 will have the option to apply without reference to a specific test method under 16 CFR part 1303 or to apply to the CPSC for acceptance to test to 16 CFR part 1303 according to one or more test methods for up to one year after publication of this notice in the *Federal Register*. After one year from the publication of this notice in the *Federal Register*, the option for third party conformity assessment bodies to apply for CPSC-acceptance of accreditation to 16 CFR part 1303 without reference to a CPSC required test method will not be permitted.

To make it easier for interested parties to understand the nature of the revisions, we are republishing the notice of requirements in its entirety for readability. The republished notice

incorporates several nonsubstantive changes or grammatical changes, such as replacing the term "laboratory" with "third party conformity assessment body." These changes were made to make the notice of requirements consistent with other recent notices of requirements published in the *Federal Register*. See, e.g. *Third Party Testing for Certain Children's Products; Children's Sleepwear, Sizes 0 Through 6X and 7 Through 14: Requirements for Accreditation of Third Party Conformity Assessment Bodies*, (75 FR 70911 (November 19, 2010)); *Third Party Testing for Certain Children's Products; Youth All-Terrain Vehicles: Requirements for Accreditation of Third Party Conformity Assessment Bodies*, (75 FR 52616 (August 27, 2010)).

II. Accreditation Requirements

The notice of requirements that appeared in the *Federal Register* on September 22, 2008 (73 FR 5456) is amended to read as follows:

A. Baseline Third Party Conformity Assessment Body Accreditation Requirements

For a third party conformity assessment body to be CPSC-accepted as accredited to test children's products for conformity with the lead paint ban and 16 CFR part 1303, it must be accredited to ISO/IEC 17025-2005 by an accreditation body that is a signatory to the ILAC-MRA, and the accreditation must be registered with, and accepted by, the Commission. A listing of ILAC-MRA signatory accreditation bodies is available on the Internet at: http://ilac.org/membersbycategory.html. The scope of the accreditation must include 16 CFR part 1303 (CPSC–CH–E1003–09 and/or CPSC–CH–E1003–09.1) and/or 16 CFR part 1303 (ASTM F2853-10).

The Commission will maintain on its website an up-to-date listing of third party conformity assessment bodies whose accreditations it has accepted and the scope of each accreditation. Once the Commission adds a third party conformity assessment body to that list,

the third party conformity assessment body may commence testing of children's products to support the manufacturer's certification that the product complies with 16 CRF part 1303.

B. Additional Accreditation Requirements for Firewalled Conformity Assessment Bodies

In addition to the baseline accreditation requirements in Section II.A of this document above, firewalled conformity assessment bodies seeking accredited status by the CPSC must submit to the Commission copies, in English, of their training documents ,showing how employees are trained to notify the Commission immediately and confidentially of any attempt by the manufacturer, private labeler, or other interested party to hide or exert undue influence over the third party conformity assessment body's test results. This additional requirement applies to any third party conformity assessment body in which a manufacturer or private labeler of a children's product to be tested by the third party conformity assessment body owns an interest of 10 percent or more. While the Commission is not addressing common parentage of a third party conformity assessment body and a children's product manufacturer at this time, it will be vigilant to see whether this issue needs to be addressed in the future.

As required by section 14(f)(2)(D) of the CPSA, the Commission must accept formally, by order, the application from a third party conformity assessment body before the third party conformity assessment body can become accredited by the CPSC as a firewalled conformity assessment body.

C. Additional Accreditation Requirements for Governmental Conformity Assessment Bodies

In addition to the baseline accreditation requirements of part II.A of this document above, the CPSIA permits accreditation of a third party conformity assessment body owned or controlled, in whole or in part, by a government if:

- To the extent practicable, manufacturers or private labelers located in any nation are permitted to choose conformity assessment bodies that are not owned or controlled by the government of that nation;
- The third party conformity assessment body's testing results are not subject to undue influence by any other person, including another governmental entity;
- The third party conformity assessment body is not accorded more favorable treatment than other third party conformity assessment bodies in the same nation who have been accredited;
- The third party conformity assessment body's testing results are accorded no greater weight by other governmental authorities than those of other accredited third party conformity assessment bodies; and
- The third party conformity assessment body does not exercise undue influence over other governmental authorities on matters affecting its operations or on decisions by other governmental authorities controlling distribution of products based on outcomes of the third party conformity assessment body's conformity assessments.

The Commission will accept the accreditation of a governmental third party conformity assessment body if it meets the baseline accreditation requirements of part II.A of this document above and meets the additional conditions stated here. To obtain this assurance, CPSC staff will engage the governmental entities seeking accreditation.

III. How Does a Third Party Conformity Assessment Body Apply for Acceptance of Its Accreditation?

The Commission has established an electronic accreditation acceptance and registration system accessed via the Commission's Internet site at:

http://www.cpsc.gov/about/cpsia/labaccred.html. The applicant provides, in English, basic identifying information concerning its location, the type of accreditation it is seeking, and electronic copies of its accreditation certificate and scope statement by its ILAC-MRA signatory accreditation body, and firewalled third party conformity assessment body training document(s), if relevant.

Commission staff will review the submission for accuracy and completeness. In the case of baseline third party conformity assessment bodies and government-owned or government-operated conformity assessment bodies, when that review and any necessary discussions with the applicant are completed satisfactorily, the third party conformity assessment body in question is added to the CPSC's list of accredited third party conformity assessment bodies at: http://www.cpsc.gov/about/cpsia/labaccred.html. In the case of a firewalled conformity assessment body seeking accredited status, when the CPSC staff's review is complete, the CPSC staff transmits its recommendation on accreditation to the Commission for consideration. (A third party conformity assessment body that ultimately may seek acceptance as a firewalled third party conformity assessment body also initially can request acceptance as a third party conformity assessment body accredited for testing of children's products other than those of its owners.) If the Commission accepts a CPSC staff recommendation to accredit a firewalled conformity assessment body, the firewalled conformity assessment body will be added to the CPSC's list of accredited third party conformity assessment bodies. In each case, the Commission will notify the third party conformity assessment body electronically of acceptance of its accreditation. All information to support an accreditation acceptance request must be provided in the English language.

Once the Commission adds a third party conformity assessment body to the list, the third party conformity assessment body then may begin testing children's products to support certification of compliance with 16 CFR part 1303, for which it has been accredited.

New applicants for CPSC acceptance of accreditation to 16 CFR part 1303 will have the option to apply to the CPSC without reference to a specific test method or to apply for CPSC acceptance to include a specific reference to 16 CFR part 1303 (CPSC–CH–E1003–09 and/or CPSC–CH–E1003–09.1) and/or 16 CFR part 1303 (ASTM F2853-10) for up to one year after publication of this notice in the *Federal Register*. After one year, the option to apply for accreditation to 16 CFR part 1303 without reference to a CPSC required test method will not be permitted.

CPSC-accepted third party conformity assessment bodies for 16 CFR part 1303 without a reference to one of the specified test methods have up to two years from the date of publication of this notice in the *Federal Register* to reapply and become accepted by the CPSC for 16 CFR part 1303 (CPSC-CH-E1003-09 and/or CPSC-CH-E1003-09.1) and/or 16 CFR part 1303 (ASTM F2853-10). To maintain CPSC-accepted status, third party conformity assessment bodies that are CPSC-accepted for 16 CFR part 1303 without reference to one of the required test methods must reapply with, and be accepted by, the CPSC within the two-year period, irrespective of whether the scope document from their accreditation body that was supplied with their earlier CPSC application included a reference to one of the required test methods. Previously CPSC-accepted third party conformity assessment bodies for 16 CFR part 1303 (including those that had one of the specified test methods in their accreditation scope document that was supplied with their earlier CPSC application) must reapply to maintain CPSC acceptance because the CPSC did not record references to test methods. If accepted, the third

party conformity assessment body will remain on the list of accepted third party conformity bodies whose accreditations the CPSC has accepted for 16 CFR part 1303.

IV. Acceptance of Children's Product Certifications Based on Third Party Conformity Assessment Body Testing to 16 CFR Part 1303

The September 22, 2008 *Federal Register* Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity with Part 1303 of Title 16, Code of Federal Regulations established that each manufacturer (including the importer) or private labeler of children's products subject to the lead paint ban must have products that are manufactured after December, 21, 2008 tested by a laboratory accredited (by the CPSC) and must issue a certificate of compliance with the lead paint ban based upon that testing.

This amended notice of requirements published today addresses only the CPSC acceptance criteria for a third party conformity assessment body for testing to the lead paint ban at 16 CFR part 1303. This amended notice does not affect the already-established criteria for CPSC acceptance of certificates of compliance. A product manufacturer's certificate of compliance to 16 CFR part 1303 must be based on testing by a third party conformity assessment body that is posted on the CPSC website as accepted for 16 CFR part 1303 at the time the product is tested. The Commission will accept a certificate of compliance with 16 CFR part 1303, Ban of Lead-Containing Paint for a children's product based on testing performed by an accredited (CPSC-accepted) third party conformity assessment body (including a government-owned or government-controlled conformity assessment body, or a firewalled conformity assessment body) if the testing was conducted on a date for which the third party conformity assessment body was listed as accepted by the CPSC for testing to the lead paint ban at 16 CFR part 1303.

Dated: _____.

_____
Todd A. Stevenson,
Secretary, Consumer Product Safety Commission