



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

**VOTE SHEET**

**DATE:** October 7, 2009

**TO:** The Commission  
 Todd A. Stevenson, Secretary

**THROUGH:** Cheryl A. Falvey, General Counsel *File for CAE*  
 Maruta Budetti, Executive Director

**FROM:** Philip L. Chao, Assistant General Counsel *PLC*

**SUBJECT:** Third Party Testing for Certain Children's Products; Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity with the Limits on Total Lead in Children's Products

The Office of the General Counsel is providing a draft *Federal Register* document that would establish the accreditation requirements for third party conformity assessment bodies for testing pursuant to the limits on total lead in children's products:

- CPSC-CH-E1001-08, *Standard Operating Procedure for Determining Total Lead (Pb) in Children's Metal Products (Including Children's Metal Jewelry)*, issued December 4, 2008, and
- CPSC-CH-E1002-08, *Standard Operating Procedure for Determining Total Lead (Pb) in Non-Metal Children's Products*, issued February 1, 2009.

Please indicate your vote on the following options.

- I. Issue the *Federal Register* document as drafted.

\_\_\_\_\_  
 (Signature)

\_\_\_\_\_  
 (Date)

**CPSA 6(b)(1) CLEARED for PUBLIC**  
 2 NO MFRS/PRVTLBLRS OR PRODUCTS IDENTIFIED *10/2/09 RH*

~~EXCEPTED BY: PETITION~~  
~~RULEMAKING ADMIN. PRCDG~~

~~WITH PORTIONS REMOVED:~~ \_\_\_\_\_

CPSC Hotline: 1-800-638-CPSC(2772) H CPSC's Web Site: <http://www.cpsc.gov>

II. Do not issue the *Federal Register* document.

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

III. Issue the *Federal Register* document with changes. (Please specify.)

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

IV. Take other action. (Please specify.)

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

Attachment: Draft *Federal Register* document titled, "Third Party Testing for Certain Children's Products; Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity with the Limits on Total Lead in Children's Products"



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

**Memorandum**

Date: **OCT 07 2009**

TO : The Commission  
Todd Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel *cc to CA*  
Maruta Z. Budetti, Executive Director *mzb*

FROM : Scott Heh *SH*  
Special Assistant  
Office of Hazard Identification and Reduction

Richard McCallion *RM*  
Mechanical-Recreational Hazards Program Area Team Coordinator  
Office of Hazard Identification and Reduction

Jonathan D. Midgett, Ph.D. *JDM*  
Children's Hazards Program Area Team Coordinator  
Office of Hazard Identification and Reduction

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

SUBJECT : Accreditation Requirements for Third Party Conformity Assessment Bodies to Test for the Total Lead Content of Children's Consumer Products as Established by the Consumer Product Safety Improvement Act of 2008

**I. Introduction**

On August 14, 2008, the Consumer Product Safety Improvement Act (hereafter referred to as the "Act" or the "CPSIA") was signed into law [Public Law 110-314]. Section 102 of the Act 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

**CPSA 603(1) CLEARED for PUBLIC**  
*10/17/09 KH*  
**NO MFRS/PRVT LABELERS OR PRODUCTS IDENTIFIED**

CPSA Hotline: 1-800-638-CPSC (2772) ★ CPSC's Web Site: <http://www.cpsc.gov>

**EXCEPTED BY: PETITION RULEMAKING ADMIN. PRCDG**

Note: This document has not been reviewed or accepted by the Commission.  
Initials RH Date 10/17/09

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.<sup>1</sup>

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. A laboratory that is so owned may nevertheless, in certain specified circumstances, 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, managed, or controlled 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 or private labeler and that provisions are in place for immediate and confidential reporting to the Commission of any attempts by the manufacturer or other interested party to hide or exert undue influence over test results. 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 either by the Commission or by an independent accreditation organization designated by the Commission, and requires that the Commission maintain on its web site an up-to-date list of laboratories that have been accredited to assess conformity with children's product safety rules. Readers who may not be familiar with the Commission approved process in previous phases of the agency's implementation of the CPSIA may refer to Appendix A for background information on independent accreditation organizations that have been previously designated by the Commission.

This memorandum presents the CPSC staff's recommendation for establishing accreditation requirements (using an approach that is similar to that approved by the Commission for laboratory accreditation requirements for the lead paint, crib, pacifier, and small parts regulations, children's metal jewelry, and other children's products) for laboratories wanting to ascertain the total lead content of children's consumer products as limited by Section 101(a) of the CPSIA.

Two test methods are relevant to determining the total lead content of children's consumer products because metal products and non-metal products require different methods. The CPSC's Directorate for Laboratory Sciences has issued CPSC-CH-E1001-08, *Standard Operating Procedure for Determining Total Lead (Pb) in Children's Metal Products (Including Children's*

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<sup>1</sup> On November 18, 2008, the Commission published a final rule in the Federal Register that limits the parties who must certify to the U.S. importer and, in the case of domestically produced products, the U.S. manufacturer. The rule also specifies the requirements that an electronic certificate must meet. The FR notice is available on the CPSC web site at <http://www.cpsc.gov/businfo/frnotices/fr09/certification.pdf>

*Metal Jewelry*<sup>2</sup>), issued December 4, 2008, and CPSC-CH-E1002-08, *Standard Operating Procedure for Determining Total Lead (Pb) in Non-Metal Children's Products*<sup>3</sup>, issued February 1, 2009. For measuring total lead content of homogeneous polymeric materials (including natural and synthetic polymers or plastic materials in children's consumer products, the methods for using x-ray fluorescence spectrometry (XRF) described in CPSC-CH-E1002-08 may be used as a basis for certification. Both methods may be freely downloaded from the CPSC web site at <http://www.cpsc.gov/about/cpsia/labaccred.html>.

## **II. Categories of Laboratories and Proposed Requirements**

There are some accepted terms used to describe conformity assessment depending on who conducts the assessment. Third party conformity assessment testing is defined as testing that is conducted by a laboratory that is independent of the person or organization that manufactures the product. Independent commercial laboratories and governmental laboratories are often considered to be third party laboratories. First party conformity assessment testing is defined as testing performed by the person or organization that provides the product (e.g., a manufacturer owned laboratory that conducts testing of its own product).

Under the system of accreditation by an International Laboratory Accreditation Cooperation (ILAC) member with a mutual recognition arrangement (MRA) (see Appendix A for more details), any of these types of laboratories can be accredited to ISO/IEC 17025. Under the ISO/IEC 17025 accreditation, conformity assessment testing laboratories (commercial, manufacturer (first party), and governmental laboratories) must have arrangements to ensure that their management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work.

The CPSC staff recommends that ISO/IEC 17025 accreditation (that includes the relevant children's product rule or requirement in the accreditation scope) by an ILAC-MRA accrediting body serve as the baseline criterion for CPSC acceptance of any laboratory (e.g., commercial third party, governmental, or manufacturer owned). The staff also recommends certain additional criteria as directed by the CPSIA, depending on the type of laboratory.

### Laboratories Owned or Controlled by a Manufacturer or Private Labeler

The Act specifies that a laboratory owned or controlled by a manufacturer or private labeler may request Commission accreditation. The Commission may accredit such a laboratory under the firewalled provision if the Commission finds *by order* that:

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<sup>2</sup> Due to the Commission's stay of enforcement for certain products, at the time of publication only accessible, metallic parts of children's metal jewelry are to be tested. When the stay of enforcement is lifted, all accessible parts of children's metal jewelry, metals and non-metals, will need to be certified as compliant with the applicable regulations.

<sup>3</sup> <http://www.cpsc.gov/about/cpsia/CPSC-CH-E1001-08.pdf> and <http://www.cpsc.gov/about/cpsia/CPSC-CH-E1002-08.pdf>

A) accreditation of the laboratory would provide equal or greater consumer safety protection than the manufacturer's or private labeler's use of an independent third party conformity assessment body; and

B) the laboratory has established procedures to ensure that:

i.) its test results are protected from undue influence by the manufacturer, private labeler or other interested party;

ii.) the Commission is notified immediately of any attempt by the manufacturer, private labeler or other interested party to hide or exert undue influence over test results; and

iii.) allegations of undue influence may be reported confidentially to the Commission.

The Act specifies that in establishing standards for accreditation of a testing laboratory, the Commission may consider standards and protocols for accreditation of such laboratories by independent accreditation organizations that are already in effect.

ISO 17025 accreditation of a laboratory includes an assessment to confirm the technical competence of the laboratory for a given scope and also includes an assessment of a laboratory's management and organization to ensure safeguards against undue influence are in place. The staff recommends that the Commission consider ISO 17025 accreditation by an ILAC-MRA signatory as part of the criteria for firewalled laboratories to meet the CPSIA requirements for equal or greater consumer safety and those related to undue influence.

For a proprietary laboratory to be considered under the firewalled provision, the staff further recommends that the laboratory be required to submit additional documentation that is satisfactory to the Commission to demonstrate compliance with criteria on protections from undue influence. This is discussed further in Section III on laboratory registration with the Commission.

#### Government Owned Laboratories

Section 102 (b) of the CPSIA provides that laboratories owned or controlled in whole or in part by a government may be considered third party laboratories if:

- to the extent practicable, manufacturers or private labelers located in any nation are permitted to choose testing laboratories that are not owned or controlled by the government of that nation;
- the entity's testing results are not subject to undue influence by any other person, including another governmental entity;

- the entity is not accorded more favorable treatment than other testing laboratories in the same nation who have been accredited;
- the entity's testing results are accorded no greater weight by other governmental authorities than those of other accredited laboratories; and
- the entity 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 entity's conformity assessments.

The staff recommends that governmental laboratories be accepted as third party testing laboratories if they are accredited in accordance with ISO 17025 by an ILAC-MRA signatory and they meet the conditions outlined above. CPSC staff will engage the governmental entities relevant to any accreditation requests to obtain the necessary assurances.

### **III. Laboratory Registration with the CPSC: Process and Required Documents**

The staff recommends that the Commission implement a process by which a third party laboratory must submit documentation to the CPSC that demonstrates adherence to the proposed accreditation requirements. The process for independent third party laboratories requires five steps. Firewalled laboratories and laboratories owned or controlled in whole or in part by a government require an additional step:

1. *All* types of laboratories (third party, firewalled, governmental, combinations) submit an application and supporting documents to CPSC staff.
2. Commission staff reviews the ISO 17025 accreditation certificate, the scope of the accreditation documentation, and the applicant laboratory's ownership.
  - a. For governmental laboratories (with whole *or partial* ownership or control), staff will engage those governmental agencies to ensure that the laboratory meets the five conditions in Section 102(b) of the CPSIA (as defined in Section II above).
3. Staff makes a decision to approve or disapprove the application, or staff may request more information.
  - a. For firewalled laboratories, staff makes a recommendation to the Commission to approve or disapprove the application.
4. Staff notifies the laboratory of the final decision and, if rejected, the reason(s) for rejecting the application. (Rejected applicants may reapply after remediating the deficiencies in their documentation or certifications.)
5. If approved, staff posts the laboratory's contact information and testing scope on the CPSC web site (see <http://www.cpsc.gov/businfo/labaccred.html>).

The baseline documentation (submitted in Step 1 above) for *all* applicants (third party, firewalled, and governmental laboratories) must include:

1. An ISO 17025 *accreditation certificate* by an ILAC-MRA signatory accrediting body.

2. An ILAC-MRA accrediting body *statement of scope* that clearly identifies the regulations, requirements, and/or test methods for which accreditation is sought:
  - a. For total lead in metal components, the scope document must cite CPSC-CH-E1001-08.
  - b. For total lead in non-metal components, the scope document must cite CPSC-CH-E1002-08.
3. A *disclosure* of ownership or controlling interests, including:
  - a. 10% or more control<sup>4</sup> by manufacturers or private labelers of children's products subject to the safety requirements for which the laboratory is applying to certify, and,
  - b. whole or partial government interest, including indirect ownership or control through government ownership of interests in any partners of the laboratory.

If the applicant is a firewalled laboratory, it must provide the following additional information:

4. *Training materials* that address undue influence: a copy of the firm's established materials used for training its employees on the process and means by which allegations of any attempt by the manufacturer, private labeler, or other interested party to hide or exert undue influence over test results can be immediately and confidentially reported to the Commission.

#### **IV. Proposed Limited Acceptance of Children's Product Certifications Based on Testing Prior to the Effective Date**

The staff's recommended accreditation approach utilizes and builds upon existing systems of conformity assessment based on ISO/IEC standards and internationally recognized accrediting bodies. In the field of children's products, some manufacturers, importers, and/or retailers have put in place their own processes for third party testing to demonstrate conformity with certain mandatory and voluntary safety standards. Some of these systems may already dictate testing by third party laboratories that are accredited by an ILAC-MRA signatory in accordance with ISO 17025. It is possible that some products in the marketplace have already undergone testing earlier than the mandatory effective date (to be established by the Commission) in a way that would support certification with the subject products' respective safety standards or regulations.

For certifications of total lead content of components of children's consumer products, the staff recommends that the Commission allow certifications to be based on prior testing under certain conditions. Specifically, the staff proposes that the Commission accept certifications if:

1. The product<sup>5</sup> was tested by a laboratory that was ISO/IEC 17025 accredited by an ILAC-MRA signatory accrediting body at the time of the test;

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<sup>4</sup> This ten percent or greater criterion is also used by the Federal Energy Regulatory Commission [Standards of Conduct for Transmission Providers, Order No. 2004, 105 FERC P61,248 at 62,299 (2003) ] and the Federal Communications Commission [47 C.F.R. section 1.2112] as the criterion for potential control by an affiliated business entity.

<sup>5</sup> The CPSIA requires that certification be based on testing of sufficient samples of the product, or samples that are identical in all material respects to the product.

2. The laboratory's application is accepted by CPSC by December 31, 2009 or 30 days prior to the date that the Commission terminates the current stay of enforcement for the testing and certification requirements that was originally announced in the Federal Register on February 9, 2009 (74 FR 6396) for total lead content for certain products (whichever is the later date);
3. The product was tested on or after these respective test publication dates:

<u>Type of Children's Product Test</u>	<u>CPSC Test Method</u>	<u>Test Issue Date</u>
Total lead (Pb) in Metal Components	CPSC-CH-E1001-08	December 4, 2008
Total lead (Pb) in Non-metal Components	CPSC-CH-E1002-08	February 1, 2009

4. The accreditation scope in effect for the laboratory at the time of the test expressly included the applicable test methods in the list above;
5. The test results show compliance with the applicable *current* standards and regulations (i.e., the total lead limits in effect on the day the certification is presented, rather than those in effect on the day that the testing was performed).
6. The third party conformity assessment body's accreditation and inclusion of the CPSC test methods for determining total lead content in its scope remains in effect through the effective date for mandatory third party testing and manufacturer/private labeler certification for the total lead limit requirements for children's products.

This policy would allow for certification of products on the basis of testing performed relatively recently by an accredited third party laboratory, thereby providing a substantial degree of assurance of compliance with the standard. Under this approach, firms who were already voluntarily getting products tested by competent laboratories will not have to have those same products retested. This approach also may help prevent testing backlogs at accredited laboratories, making it less likely that the Commission will have to postpone the effective date for certification.<sup>6</sup> Manufacturers and private labelers that did not already utilize third party testing, or that based their certifications on test dates prior to the test issue dates listed above, would need to conduct third party testing by a CPSC-accepted laboratory to be able to certify products manufactured on or after the effective date.

The staff recommends that governmental laboratories be treated similarly to other third party laboratories with respect to certifications based on testing prior to the effective date. Nonetheless, manufacturers and private labelers will need to consider carefully the fact that governmental laboratories also will need to meet the conditions for governmental entities as required by the Act. If the CPSC accepts accreditation of a governmental laboratory by December 31, 2009 or 30 days prior to the date that the Commission terminates the current stay of enforcement<sup>7</sup> for the testing and certification requirements for total lead content for certain products (whichever is the later date), testing by that laboratory conducted on or after the dates

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<sup>6</sup> In accordance with the CPSIA, if the Commission determines that an insufficient number of third party laboratories have been accredited to permit certification for a children's product safety rule under the Act's accreditation schedule, the Commission may extend the deadline for certification to such rule by not more than 60 days.

<sup>7</sup> Refers to the stay of enforcement that was originally announced in the Federal Register on February 9, 2009 (74 FR 6396).

listed above can be used to support third party certification to the requirements for the subject products' respective regulations.

The staff recommends that laboratories owned by a manufacturer or private labeler be treated similarly to other third party laboratories with respect to certifications based on testing prior to the effective date. Nonetheless, manufacturers and private labelers (or other parties who seek product certification) will need to consider carefully the fact that manufacturer owned laboratories also will need to meet the conditions for firewalled conformity assessment bodies as required by the Act. If the CPSC accepts accreditation of a firewalled laboratory by December 31, 2009 or 30 days prior to the date that the Commission terminates the current stay of enforcement<sup>8</sup> for the testing and certification requirements for total lead content for certain products (whichever is the later date), testing by that laboratory conducted on or after the dates listed above can be used to support third party certification to the requirements for the subject products' respective regulations.

## **V. Environmental Considerations**

Generally, CPSC mandatory 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 CFR§1021.5(c)(1)). Nothing in these recommended accreditation requirements alters that expectation. Therefore, the staff does not expect such requirements to have any negative environmental impact.

## **VI. Recommended Effective Date**

The staff recommends that the requirements for accreditation for third party laboratories to test for compliance with the total lead content limits for children's consumer products become effective upon publication of notice thereof in the Federal Register. Publication in the Federal Register is typically the means by which the public is formally advised of new mandatory requirements.

## **VII. Staff Recommendation for Accreditation Requirements for Third Party Laboratories to Test for Total Lead Content**

The staff recommends that the Commission approve the staff's proposed approach for accepting accreditation of laboratories to test for compliance with the total lead content limits for children's consumer products according to the following test methods, published on the CPSC web site:

- CPSC-CH-E1001-08, *Standard Operating Procedure for Determining Total Lead (Pb) in Children's Metal Products (Including Children's Metal Jewelry)*
- CPSC-CH-E1002-08, *Standard Operating Procedure for Determining Total Lead (Pb) in Non-Metal Children's Products*

The staff recommends that the Commission approve publishing the accreditation acceptance requirements in a Federal Register (FR) notice as drafted by the Office of the General Counsel.

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<sup>8</sup> Ibid.

The FR notice would establish the requirements for laboratories to become accredited to test for compliance with the total lead content limits for children's consumer products. In addition, the FR notice would solicit comments from interested parties on the established approach for laboratory accreditation associated with the subject products and on the overall approach for accreditation.

## Appendix A

### **Background on International Accreditation of Conformity Assessment Bodies (Testing Laboratories)**

The term “conformity assessment” describes a variety of activities that can be used to demonstrate that specified requirements relating to a product are fulfilled. This broad term is often used to describe distinct activities such as testing, inspection, certification, as well as the accreditation of conformity assessment bodies. [1] Conformity assessment can include one or more of these activities.

In the context of this memorandum to the Commission on accreditation, “third party conformity assessment body” is synonymous with “third party testing laboratory.” For proposed CPSC requirements for accreditation of testing laboratories, the CPSC staff recommends allowing certain testing laboratories to test products for compliance with the requirements established by the Code of Federal Regulations if they belong to recognized accreditation organizations.

The rapidly growing global demand for conformity assessment entities that can facilitate the acceptance of products across nations’ borders has resulted in the establishment of international organizations and the development of international standards related to all aspects of conformity assessment. The International Laboratory Accreditation Cooperation (ILAC) was formed in 1977 to promote international acceptance of test results performed by accredited laboratories. A series of standards developed by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) provides specifications for organizations that conduct conformity assessment activities. The ISO/IEC is a specialized system for worldwide standardization. Technical committees comprised of members from across the globe (including the United States) collaborate to develop these conformity assessment standards to facilitate acceptance of testing results between countries. These standards were developed expressly to be used by accreditation bodies that have entered into mutual recognition arrangements (MRAs) with equivalent bodies in other countries. The most relevant ISO standards for testing laboratories and the accreditation of such laboratories are: (1) ISO/IEC 17025:2005 International Standard - General Requirements for the Competence of Testing and Calibration Laboratories, and (2) ISO/IEC 17011:2004 Conformity Assessment - General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies.

#### ISO/IEC 17025

The ISO/IEC 17025 standard sets out requirements for testing laboratories to demonstrate that they operate a quality system, are technically competent, and are able to generate technically valid results.

Throughout the world, many rely on laboratory accreditation as a means to independently evaluate laboratory competence. Laboratory accreditation is based upon criteria and procedures from ISO/IEC 17025 to determine the technical competence of laboratories. Technical assessors conduct a thorough evaluation of all factors of facility operations that affect the production of technical data. [2] ISO/IEC 17025 addresses factors relevant to a laboratory’s ability to produce

precise, accurate test and calibration data. Specifically, provisions in the standard include requirements and guidance for technical competency of staff; validity and appropriateness of the methods; traceability of measurements and calibrations to national standards; suitability, calibration, and maintenance of test equipment; and quality assurance of test, inspection, or calibration data. Laboratories are accredited to ISO 17025 for a specified technical scope. This statement of scope comprises part of the laboratory's accreditation, and can include such items as testing in accordance with mandatory standards, voluntary standards, or other types of testing regimes. A laboratory's certificate of accreditation includes the statement of scope for which it is accredited.

In addition to technical requirements, the ISO/IEC 17025 standard has management requirements on topics such as organization, management systems, document control, audits, and management reviews. Several of these management requirements address impartiality and safeguards against conflicts of interest. If the laboratory is part of an organization that performs activities other than testing, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest. The laboratory must have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work. Further, the laboratory must have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity. [3]

To ensure continued compliance, accredited laboratories are regularly re-examined, at least every two years, with either an on-site surveillance or a full reassessment, to ensure that they maintain their standards of independence and technical expertise. [2, 4]

### ISO/IEC 17011

The ISO/IEC 17011 standard establishes requirements for accrediting organizations that evaluate testing laboratories for conformance with ISO/IEC 17025.

ISO/IEC 17011 was created to be used within a framework of international MRAs that implement a peer evaluation mechanism among nations' accrediting bodies. The peer evaluation process provides assurance that accrediting bodies are operating in accordance with the 17011 standard. The standard provides specifications for accrediting body procedures for conducting laboratory assessments, and also provides the procedures for the peer evaluation of operations among accrediting bodies.

Major elements of the ISO/IEC 17011 standard include requirements for the structure, management, and supervision of the accreditation body organization, including documentation of responsibilities, and demonstration of expertise. A related section of requirements addresses impartiality of the accreditor's operations. For example, the standard requires that the accreditation body shall ensure a balanced representation of interested parties with no single party dominating. All accreditation body personnel must act objectively and shall be free from any undue commercial, financial, and other pressures that could compromise impartiality.

The standard requires that an accreditation body be a registered legal entity. A governmental accreditation body is deemed to be a legal entity on the basis of its governmental status. A government is responsible for identifying the accreditation body in such a way that there is no conflict of interest with governmental conformity assessment bodies (such as governmental laboratories).

Other provisions in the standard include specifications for document control, internal audits and management reviews, preventative actions, analysis of findings and reports, and appeals processing. [4]

### International Laboratory Accreditation Cooperation (ILAC)

ILAC officially established its charter in 1996 to create a network of MRAs among accreditation bodies to facilitate trade by promoting the acceptance of test and calibration results performed by accredited laboratories. The ILAC-MRA helped establish a global network of accredited testing and calibration laboratories that are assessed and determined to be competent by an ILAC arrangement signatory accreditation body.

There are over 60 ILAC-MRA signatory accrediting bodies located throughout the world. This includes MRA signatory organizations in Australia, Canada, China, many countries in the European Union, Japan, Mexico, the United States and several other countries. Many countries have one ILAC-MRA signatory accrediting body. Some countries have more than one accrediting organization. For example, Japan, Germany, and the United States have three or more MRA signatory accrediting bodies.<sup>9</sup>

The evaluation of an accreditation body to establish its qualifications to be a signatory involves a team of peers (generally senior staff of experienced accreditation bodies) who conduct evaluations in accordance with ISO/IEC 17011. The evaluations include audits at the headquarters office of the applicant body. Additionally, the evaluators witness the performance of the applicant's assessors during actual assessments/reassessments of laboratories to determine compliance with ISO/IEC 17025.

ILAC's uniform approach, based on ISO/IEC standards, allows countries to establish agreements based on mutual evaluation and acceptance of each other's laboratory accreditation systems. Each partner in such an arrangement recognizes the other partner's accredited laboratories as if they themselves had undertaken the accreditation of the other partner's laboratories. [5]

### **References**

[1] ISO/IEC 17000:2004 Conformity Assessment – Vocabulary and General Principles.

[2] White paper: Should Laboratories be Accredited to ISO/IEC 17025 or Certified to ISO 9001?  
[www.aiclasscorp.com](http://www.aiclasscorp.com)

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<sup>9</sup> The following link, <http://ilac.org/membersbycategory.html> contains a complete list of ILAC-MRA accrediting bodies.

[3] International Standard ISO/IEC 17025:2005 – General Requirements for the Competence of Testing and Calibration Laboratories

[4] ISO/IEC 17011:2004 Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies

[5] [www.ilac.org](http://www.ilac.org)

**TAB A**

DRAFT FORM FOR LABORATORY REGISTRATION WITH CPSC



# US Consumer Product Safety Commission

▶ Consumer Safety

▶ About CPSC

▶ Library - FOIA

▶ Business

U.S. Consumer Product Safety  
Commission  
4330 East West Highway, Bethesda, MD  
20814

CPSC Form  
#223

## Consumer Product Conformity Assessment Body (Testing Laboratory)

### Registration Form

**This registration form and all related materials (certificate, scope documents, and training materials, if required) must be submitted electronically and in the English language.**

The information you provide is encrypted for privacy during transit. Clicking on the Verisign logo to the left displays CPSC's specific server ID information and verifies that this is a legitimate Verisign Secure Site.

Please capitalize only the first letter of words and names (except for abbreviations) when filling out this form. Thank you!

1. Legal name of the laboratory:

2. Full address of the laboratory:

Address (Line 1)

Address (Line 2)

City

State/Province:

Country or Administrative Area

Please Select



Postal Code:

3. Laboratory web site

(optional):

4. Registration status (select one):

- New Registration
- Increase in scope from prior registration
- Renewal
- Reinstatement

5. Laboratory name as you wish it listed on the CPSC web site, if different than legal name (leave blank if same):

6. Laboratory's authorized representative (to be displayed on the CPSC web site):

Family name(s):  First (Given) name:   
  
 Title:  E-mail:   
  
 Telephone #:  Fax #:

7. Applicant Information (Point of contact for registration questions. Not for CPSC web site display. Leave blank if same as above):

Family name(s):  First (Given) name:   
  
 Title:  E-mail:   
  
 Current Date:  (mm/dd/yyyy)

8. Ownership / Type of Laboratory:

**A. Definitions:**

**Third Party Laboratory:** A testing laboratory that does not have a 10 percent or greater ownership interest by a manufacturer or private labeler of a product subject to the safety requirements for which you are applying and also is not owned or controlled, in whole or in part, by a governmental entity (as defined below for Governmental Laboratory).

**Firewalled Laboratory:** Ownership of the applicant laboratory of 10% or more by manufacturers or private labelers of children's products:

Registration as a firewalled conformity assessment body (firewalled laboratory) is required if there are ownership interests in this laboratory of 10% or more by manufacturers or private labelers of children's products subject to the safety requirements for which you are applying. These owners must be identified in the boxes below.

**Governmental Laboratory:** Ownership or control, in whole or in part, by a governmental entity:

Ownership or control, in whole or in part, of this conformity assessment body by a governmental entity requires registration as a governmental conformity assessment body. If this conformity assessment body is owned or controlled in part or in whole by a government, the governmental entity(s) must be named in the boxes below. This includes indirect ownership or control through governmental ownership of interests in any partners of this conformity assessment body.

The phrase "governmental entity" in this document refers to any governmental entity in your country or administrative area, whether national, provincial, territorial, local, etc., and includes state-owned entities even if those entities do not carry out governmental functions.

**B. Type of Laboratory (select one):**

- Third Party Laboratory (see attestation)
- Firewalled Laboratory
- Governmental Laboratory

**C. Registration (select one):**

**Third Party Laboratory:**

If Third Party Laboratory is selected, the laboratory representative attests that the laboratory does not have an ownership interest of 10 percent or more by a manufacturer or private labeler of a product subject to the safety requirements for which you are applying and the laboratory also is not owned or controlled, in whole or in part, by a governmental entity (as defined above for governmental laboratory).

Check this box and submit your name below to confirm third party laboratory attestation.

Name of Lab Representative making attestation that applicant is a third party laboratory. If attestation is completed, skip to Section 9.

**Firewalled Laboratory:**

Registration as a firewalled conformity assessment body (firewalled laboratory) is required if there are ownership interests in this laboratory of 10% or more by manufacturers or private labelers of children's products subject to the safety requirements for which you are applying. **These owners must be identified in the boxes below.**

Name of Owner	Percent Owned (Do not use "%")
a. <input type="text"/>	<input type="text"/>
b. <input type="text"/>	<input type="text"/>
c. <input type="text"/>	<input type="text"/>
d. <input type="text"/>	<input type="text"/>
e. <input type="text"/>	<input type="text"/>
f. <input type="text"/>	<input type="text"/>
g. <input type="text"/>	<input type="text"/>
h. <input type="text"/>	<input type="text"/>
i. <input type="text"/>	<input type="text"/>
j. <input type="text"/>	<input type="text"/>

You may request by checking the box below that the CPSC consider manufacturer or private labeler ownership information as confidential and exempt from public disclosure. This request of confidentiality does not relieve the applicant from the obligation to provide CPSC with the required ownership information.

Check this box if you claim that this information should be considered as confidential and exempt from public disclosure.

**Ownership or control, in whole or in part, by a governmental entity:**

Ownership or control, in whole or in part, of this conformity assessment body by a governmental entity requires registration as a governmental conformity assessment body. If this conformity assessment body is owned or controlled in part or in whole by a government, the governmental entity(s) must be named in the boxes below. This includes indirect ownership or control through governmental ownership of interests in any partners of this conformity assessment body.

Ownership or control by a governmental entity may not be considered as confidential and exempt from public disclosure.

Percent Owned

Name of Governmental Entity	or Controlled (Do not use "%")
a. <input type="text"/>	<input type="text"/>
b. <input type="text"/>	<input type="text"/>
c. <input type="text"/>	<input type="text"/>
d. <input type="text"/>	<input type="text"/>
e. <input type="text"/>	<input type="text"/>

9. Laboratory Accreditation Information and Scopes for which you are applying:

The laboratory must be accredited by an ILAC-MRA signatory accrediting body. 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 CPSC safety requirements for which you are applying.

**PLEASE NOTE: If you have scopes that are covered under different or multiple certificate numbers** (from the same or different ILAC-MRA member), please fill out the accreditation/certificate information for only those scopes covered under one ILAC-MRA member/certificate number. Follow the instructions in Section 10, and Click "Submit" at the bottom of the form. There will be an opportunity to fill in additional certificate information.

After submitting, you will receive an application summary page that provides an opportunity to verify the application information. Scroll down and put in the second certificate number (and different ILAC-MRA member if appropriate), deselect the scopes from the first submission (if appropriate), select new scopes that are covered by the second certificate, and resubmit. You can repeat this process as needed for multiple accreditation certificates.

You must select an ILAC-MRA member from the drop-down list.

Name of ILAC-MRA member providing accreditation

Date of accreditation to ISO/IEC 17025:2005   (mm/dd/yyyy)

Certificate number

Expiration date   (mm/dd/yyyy)

The accreditation and certificate information above applies to the following scopes (check all that apply; if you have been accepted for one of them previously, please do not check it again):

**The scope document for the laboratory seeking acceptance of its accreditation must include an explicit reference to each scope below for which it is applying.**

- Bicycle Helmets, 16 CFR Part 1203
- Lead Paint, 16 CFR Part 1303
- Dive Sticks and other similar articles, 16 CFR Part 1500.18 with exemptions in 16 CFR 1500.86(a)(7) and (8)
- Small Parts Regulation, 16 CFR Part 1501
- Full-Size Cribs, 16 CFR Part 1508
- Non Full-Size Cribs, 16 CFR Part 1509
- Rattles, 16 CFR Part 1510
- Pacifiers, 16 CFR Part 1511

- Bicycles, 16 CFR Part 1512
- Children's Bunk Beds, 16 CFR Part 1513
- Children's Metal Jewelry, CPSC Test Method CPSC-CH-E1001-08 for Determining Total Lead in Children's Metal Products and/or the "Screening Test for Total PB Analysis" Section of the 2005 CPSC Laboratory SOP for Determining Lead in Children's Metal Jewelry
- Children's Metal Products, CPSC Test Method CPSC-CH-E1001-08 for Determining Total Lead in Children's Metal Products
- Non-Metal Children's Products, CPSC Test Method CPSC-CH-E 1002-08 Standard Operating Procedure for Determining Total Lead (Pb) in Non-Metal Children's Products

10.

**All registrants must provide an English language copy of the laboratory accreditation certificate and relevant scope documents.**

**Please email these materials separately to [labaccred@cpsc.gov](mailto:labaccred@cpsc.gov) and be sure to include your Laboratory Name, Accreditation Certificate Number, and Scope (Regulation) in the subject line of your message and in the text of your email.**

**Please attach the full relevant scope document(s) to your application. Do not attach only sections of your scope document.**

**Your email should also include information on where to find the CPSC required scope references in your scope documents (e.g., page numbers).**

**Firewalled conformity assessment bodies must also submit copies of their training materials.**

**If any manufacturer or private labeler of children's products, subject to the safety requirements for which you are applying, holding ten percent or greater interest in this conformity assessment body is using this entity for the required testing of their products, the conformity assessment body must submit a copy of the firm's established materials used for training its employees on the process and means by which allegations of any attempt by the manufacturer, private labeler or other interested party to hide or exert undue influence over test results can be immediately and confidentially reported to the Commission.**

**Please email these materials with your certificate and scope documents to [labaccred@cpsc.gov](mailto:labaccred@cpsc.gov)**

**KNOWING AND WILLFUL FALSE STATEMENTS MADE ON THIS FORM OR IN ANY OTHER SUBMITTED MATERIALS ARE PUNISHABLE BY FINE AND/OR IMPRISONMENT FOR UP TO FIVE YEARS (U.S. Code, Title 18, Section 1001) AND/OR WITHDRAWAL OF CPSC ACCEPTANCE OF ACCREDITATION.**

**If you submit and nothing happens, look for a red asterisk(s) ( \* ) indicating a required entry; please complete the entry by the asterisk and re-submit. If submission is successful, you will get an immediate acknowledgment.**

CPSC  
Revision 4c

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**Draft *Federal Register* Notice**

Third Party Testing for Certain Children's Products; Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity with the Limits on Total Lead in Children's Products

[Billing Code 6355-01-P]  
CONSUMER PRODUCT SAFETY COMMISSION

[CPSC Docket No. CPSC-2009-00xx]

THIRD PARTY TESTING FOR CERTAIN CHILDREN'S PRODUCTS; NOTICE OF REQUIREMENTS FOR ACCREDITATION OF THIRD PARTY CONFORMITY ASSESSMENT BODIES TO ASSESS CONFORMITY WITH THE LIMITS ON TOTAL LEAD IN CHILDREN'S PRODUCTS

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of Requirements.

SUMMARY: The Consumer Product Safety Commission ("CPSC" or "Commission") is issuing a notice of requirements that provides the criteria and process for Commission acceptance of accreditation of third party conformity assessment bodies for testing pursuant to the limits on total lead in children's products. The Commission is issuing this notice of requirements pursuant to section 14(a)(3)(B)(vi) of the Consumer Product Safety Act (15 U.S.C. 2063(a)(3)(B)(vi)).

DATES: Effective Date: The requirements for accreditation of third party conformity assessment bodies for testing to the limits on total lead in children's products are effective upon publication of this notice in the FEDERAL REGISTER.

Comments in response to this notice of requirements should be submitted by [insert date 30 days after date of publication in the FEDERAL REGISTER]. Comments on this notice should be captioned "Third Party Conformity Assessment Body Accreditation Process for the Limits on Total Lead in Children's Products."

ADDRESSES: You may submit comments, identified by Docket No. CPSC-2009-00XX, 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 (e-mail) except through [www.regulations.gov](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, Consumer Product Safety Commission, Room 502, 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 of requirements. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to <http://www.regulations.gov>. Do not submit confidential business information, trade secret information, or other sensitive or protected information electronically. 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 Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; e-mail [rhowell@cpsc.gov](mailto:rhowell@cpsc.gov).

SUPPLEMENTARY INFORMATION:

I. Introduction

The Consumer Product Safety Act (“CPSA”), at section 14(a)(3)(B)(vi), as added by section 102(a)(2) of the Consumer Product Safety Improvement Act of 2008 (“CPSIA”), Public Law 110-314, directs the CPSC to publish a notice of requirements for accreditation of third party conformity assessment bodies (also referred to as “third party laboratories”) to assess children’s products for conformity with “other children's product safety rules.” Section 14(f)(1) of the CPSA defines “children’s product safety rule” as “a consumer product safety rule under [the CPSA] or similar rule, regulation, standard, or ban under any other Act enforced by the Commission, including a rule declaring a consumer product to be a banned hazardous product or substance.” Under section 14(a)(3)(A) of the CPSA, each manufacturer (including the importer) or private labeler of products subject to those regulations must have products that are manufactured more than 90 days after the *Federal Register* publication date of this notice tested by a third party conformity assessment body accredited to do so and must issue a certificate of compliance with the applicable regulations based on that testing. (The Commission notes, however, that in the FEDERAL REGISTER of February 9, 2009 (74 FR 6396), the Commission announced a stay of enforcement of certain provisions of section 14(a) of

the CPSA; the stay applies to the testing that would result from this notice of requirements.) Section 14(a)(2) of the CPSA, as added by section 102(a)(2) of the CPSIA, requires that certification be based on testing of sufficient samples of the product, or samples that are identical in all material respects to the product. The Commission also emphasizes that, irrespective of certification, the product in question must comply with applicable CPSC requirements (see, e.g., section 14(h) of the CPSA, as added by section 102(b) of the CPSIA).

The Commission also is recognizing limited circumstances in which it will accept certifications if the product was tested by a third party conformity assessment body that the CPSC accepts as being accredited by December 31, 2009 or 30 days before the Commission terminates the stay of enforcement that was originally announced in the FEDERAL REGISTER on February 9, 2009 (74 FR 6396), whichever date is later. The details regarding those limited circumstances can be found in part IV of this document below.

This notice provides the criteria and process for Commission acceptance of accreditation of third party conformity assessment bodies for testing pursuant to the following test methods:

- CPSC-CH-E1001-08, *Standard Operating Procedure for Determining Total Lead (Pb) in Children's Metal Products (Including Children's Metal Jewelry*<sup>1</sup>), issued December 4, 2008, and

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<sup>1</sup> Due to the Commission's stay of enforcement that appeared in the Federal Register on February 9, 2009 (74 FR 6396), at the time when the stay of enforcement was published, only accessible, metallic parts of children's metal jewelry were required to be tested. When the stay of enforcement is lifted, all accessible parts of children's metal jewelry, metals and non-metals, will need to comply with the applicable regulations.

- CPSC-CH-E1002-08, *Standard Operating Procedure for Determining Total Lead (Pb) in Non-Metal Children's Products*, issued February 1, 2009.

For measuring total lead content of homogeneous polymeric materials (including natural and synthetic polymers or plastic materials in children's consumer products), the methods for using x-ray fluorescence spectrometry (XRF) described in CPSC-CH-E1002-08 may be used. Both methods may be freely downloaded from the CPSC website at <http://www.cpsc.gov/about/cpsia/labaccred.html>.

Although section 14(a)(3)(B)(vi) of the CPSA directs the CPSC to publish a notice of requirements for accreditation of third party conformity assessment bodies to assess conformity with "all other children's product safety rules," this notice of requirements is limited to the test methods identified immediately above. The CPSC acknowledges that the test methods for determining total lead content are not, in themselves, rules, but we believe it is appropriate for the notice of requirements to apply to the CPSC test methods because section 101(g) of the CPSIA considers the lead content restrictions to be "a regulation of the Commission" under the Federal Hazardous Substances Act. Thus, the test methods would be used to assess conformity with the lead requirements.

The CPSC also recognizes that section 14(a)(3)(B)(vi) of the CPSA is captioned as "All Other Children's Product Safety Rules," but the body of the statutory requirement refers only to "other children's product safety rules." Nevertheless, section 14(a)(3)(B)(vi) of the CPSA could be construed as requiring a notice of requirements for "all" other children's product safety rules, rather than a notice of requirements for "some" or "certain" children's product safety rules. However, whether a particular rule

represents a “children’s product safety rule” may be subject to interpretation, and the Commission staff is continuing to evaluate which rules, regulations, standards, or bans are “children’s product safety rules.” The CPSC intends to issue additional notices of requirements for other rules which the Commission determines to be “children’s product safety rules.”

The CPSC also advises interested parties that, with respect to the materials which the CPSC has determined not to exceed the lead content limits specified in section 101(a) of the CPSIA, testing by third party conformity assessment bodies is not required to support a finding that a particular material is within the determinations. In the FEDERAL REGISTER of August 26, 2009 (74 FR 43031), the CPSC issued a final rule identifying those materials which do not exceed the lead content limits specified in section 101(a) of the CPSIA (the “determinations rule”). For example, the determinations rule includes natural fibers, such as cotton, in the determinations; this means that a cotton shirt would not need to be tested by a third party conformity assessment body for lead, and it also means that a third party conformity assessment body would not need to test the cotton shirt to show that it is, indeed, made out of cotton. The CPSC reminds interested parties that the obligation to have third party conformity assessment bodies test children’s products exists in relation to “children’s product safety rules” and that section 14(f)(1) of the Consumer Product Safety Act (CPSA) defines “children’s product safety rule” as a consumer product safety rule under the CPSA or “similar rule, regulation, standard, or ban under any other Act enforced by the Commission.” Section 3(a)(6) of the CPSA, in turn, defines “consumer product safety rule,” in part, as a consumer product safety standard...or a rule...declaring a consumer

product a banned hazardous product.” The rule determining that certain materials do not exceed the lead limits in section 101(a) of the CPSIA is not a “consumer product safety rule” as defined by section 3(a)(6) of the CPSA and, therefore, also is not a “children’s product safety rule” as defined by section 14(a)(1) of the CPSA. Consequently, to continue using the example of a cotton shirt, the cotton shirt manufacturer could decide, based on its own knowledge and expertise regarding the materials used in its product, that its cotton shirt is, indeed, made of cotton and within the determinations rule. The cotton shirt manufacturer would not need to submit samples of its cotton shirts to a third party conformity assessment body to determine whether the shirts were made of cotton.

This notice of requirements applies to all third party conformity assessment bodies as described in section 14(f)(2) of the CPSA. Generally speaking, such third party conformity assessment bodies are: (1) third party conformity assessment bodies that are not owned, managed, or controlled by a manufacturer or private labeler of a children’s product to be tested by the third party conformity assessment body for certification purposes; (2) “firewalled” conformity assessment bodies (those that are owned, managed, or controlled by a manufacturer or private labeler of a children’s product to be tested by the third party conformity assessment body for certification purposes and that seek accreditation under the additional statutory criteria for “firewalled” conformity assessment bodies); and (3) third party conformity assessment bodies owned or controlled, in whole or in part, by a government.

The Commission requires baseline accreditation of each category of third party conformity assessment body to the International Organization for Standardization (“ISO”) Standard ISO/IEC 17025:2005, “General Requirements for the Competence of

Testing and Calibration Laboratories.” 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 for any of the test methods identified earlier in part I of this document for which the third party conformity assessment body seeks to be accredited.

(A description of the history and content of the ILAC-MRA approach and of the requirements of the ISO/IEC 17025:2005 laboratory accreditation standard is provided in the CPSC staff briefing memorandum “Third Party Conformity Assessment Body Accreditation Requirements for Testing Compliance with 16 CFR Part 1501 (Small Parts Regulation),” dated November 2008 and available on the CPSC’s Web site at <http://www.cpsc.gov/library/foia/foia09/brief/smallparts.pdf>.)

The Commission has established an electronic accreditation registration and listing system that can be accessed via its web site.

This notice of requirements is effective on [insert date of publication in the FEDERAL REGISTER]. However, the CPSC will stay its enforcement of this notice of requirements at least until February 10, 2010; the date reflects the stay of enforcement that the CPSC published in the FEDERAL REGISTER on February 9, 2009 (74 FR 6396). Nevertheless, the Commission invites comments on the accreditation procedures as they apply to that testing and on the accreditation approach in general.

This notice of requirements is exempt from the notice and comment rulemaking requirements of the Administrative Procedure Act, 5 U.S.C. 553 (see section 14(a)(3)(G) of the CPSA, as added by section 102(a)(2) of the CPSIA (15 U.S.C. 2063(a)(3)(G))).

## II. Accreditation Requirements

### A. Baseline Third Party Conformity Assessment Body Accreditation Requirements

For a third party conformity assessment body to be accredited to test children's products for conformity with the test methods identified earlier in part I of this document, it must be accredited by an ILAC-MRA signatory accrediting body, and the accreditation must be registered with, and accepted by, the Commission. A listing of ILAC-MRA signatory accrediting bodies is available on the Internet at <http://ilac.org/membersbycategory.html>. 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 CPSC-CH-E1001-08, *Standard Operating Procedure for Determining Total Lead (Pb) in Children's Metal Products (Including Children's Metal Jewelry)*, issued December 4, 2008, and/or CPSC-CH-E1002-08, *Standard Operating Procedure for Determining Total Lead (Pb) in Non-Metal Children's Products*, issued February 1, 2009. A true copy, in English, of the accreditation and scope documents demonstrating compliance with these requirements must be registered with the Commission electronically. The additional requirements for accreditation of firewalled and governmental conformity assessment bodies are described in parts II.B and II.C of this document below.

The Commission will maintain on its web site an up-to-date listing of third party conformity assessment bodies whose accreditations it has accepted and the scope of each accreditation. Subject to the limited provisions for acceptance of "retrospective" testing performed by other than firewalled conformity assessment bodies noted in part IV below,

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 certification by the manufacturer or private labeler of compliance with the test methods identified earlier in part I of this document.

#### B. Additional Accreditation Requirements for Firewalled Conformity Assessment Bodies

In addition to the baseline accreditation requirements in part II.A of this document above, firewalled conformity assessment bodies seeking accredited status 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 ten 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 if this issue needs to be addressed in the future.

As required by section 14(f)(2)(D) of the CPSA, the Commission must formally accept, by order, the accreditation application of a third party conformity assessment body before the third party conformity assessment body can become an accredited 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 relevant to the accreditation request.

### 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/businfo/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 ILAC-MRA accreditation certificate and scope statement, 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 satisfactorily completed, 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/businfo/labaccred.html>. In the case of a firewalled conformity assessment body seeking accredited status, when the staff's review is complete, the staff transmits its recommendation on accreditation to the Commission for consideration. (A third party conformity assessment body that may ultimately seek acceptance as a firewalled third party conformity assessment body also can initially 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 staff recommendation to accredit a firewalled conformity assessment body, the firewalled conformity assessment body will then 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.

Subject to the limited provisions for acceptance of "retrospective" testing performed by other than accredited firewalled conformity assessment bodies noted in part IV of this document below, once the Commission adds a third party conformity assessment body to the list, the third party conformity assessment body may then begin testing of children's products to support certification of compliance with the regulations identified earlier in part I of this document for which it has been accredited.

#### IV. Limited Acceptance of Children's Product Certifications Based on Third Party Conformity Assessment Body Testing Prior to the Commission's Acceptance of Accreditation

The Commission will accept a certificate of compliance to the total lead content limits established by the CPSIA for children's products and tested in accordance with CPSC-CH-E1001-08, *Standard Operating Procedure for Determining Total Lead (Pb) in Children's Metal Products (Including Children's Metal Jewelry)*, issued December 4, 2008, and/or CPSC-CH-E1002-08, *Standard Operating Procedure for Determining Total Lead (Pb) in Non-Metal Children's Products*, issued February 1, 2009, based on testing

performed by an accredited third party conformity assessment body (including a government-owned conformity assessment body, a government controlled conformity assessment body, and a firewalled conformity assessment body) if:

- The product was tested by a third party conformity assessment body that was ISO/IEC 17025 accredited by an ILAC-MRA member at the time of the test;
- The third party conformity assessment body's application is accepted by the CPSC by December 31, 2009 or 30 days prior to the date the Commission terminates the stay of enforcement that was originally announced in the FEDERAL REGISTER on February 9, 2009 (74 FR 6396) (whichever is the later date);
- The product was tested on or after December 4, 2008 with respect to CPSC test method CPSC-CH-E1001-08, *Standard Operating Procedure for Determining Total Lead (Pb) in Children's Metal Products (Including Children's Metal Jewelry)* and/or was tested on or after February 1, 2009 with respect to CPSC test method CPSC-CH-E1002-08, *Standard Operating Procedure for Determining Total Lead (Pb) in Non-Metal Children's Products*.
- The accreditation scope in effect for the third party conformity assessment body at that time expressly included testing to the test methods identified earlier in part I of this document;
- The test results show compliance with the applicable *current* standards and regulations (i.e., the total lead limits in effect on the day the certification is presented, rather than those in effect on the day that the testing was performed);  
and

- The third party conformity assessment body's accreditation and inclusion of the test methods for determining total lead content (identified earlier in part I of this document) in its scope remains in effect through the effective date for mandatory third party testing and manufacturer/private labeler certification for the total lead limit requirements for children's products.

Dated: \_\_\_\_\_.

\_\_\_\_\_

Todd A. Stevenson,

Secretary, Consumer Product Safety

Commission