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

BALLOT VOTE SHEET

Date NOV 4 2008

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Patricia Semple, Executive Director PS
Cheryl F. Falvey, General Counsel CAF

FROM : Lowell F. Martin, Attorney LFM.

SUBJECT : Third Party Conformity Assessment Body Accreditation Requirements for Testing Compliance with 16 C.F.R. Part 1501 (Small Parts Regulations)

Ballot Vote Due: November 10, 2008

The attached staff memorandum recommends an approach to establishing accreditation requirements for third party conformity assessment bodies to test to the small parts regulations of 16 C.F.R. part 1501. The Commission is required to issue such requirements pursuant to the Consumer Product Safety Improvement Act of 2008, P.L. 110-314. By separate (official use only) memorandum, the Office of the General Counsel is providing a draft Federal Register notice that would publish the recommended requirements.

Please indicate your vote on the following options.

1. Accept the staff's recommended approach and publish the Federal Register notice as drafted.

_____ _____
Signature Date

2. Accept the staff's recommended approach and publish the Federal Register notice with changes (please specify).

_____
_____
_____

_____ _____
Signature Date

CPSA 6(b)(1) CLEARED for PUBLIC
11/4/08
NO MFRS/PRVTLBLRS OR PRODUCTS IDENTIFIED

EXCEPTED BY: PETITION
RULEMAKING ADMIN. PRCDG

WITH PORTIONS REMOVED: _____

Note: This document has not been reviewed or accepted by the Commission.
Initials TLA Date 11/4/08

3. Do not accept the staff's recommended approach.

_____ _____

Signature Date

Attachment:

Staff briefing memorandum, *Third Party Conformity Assessment Body Accreditation Requirements for Testing Compliance with 16 C.F.R. Part 1501 (Small Parts Regulations) as Required by the Consumer Product Safety Improvement Act of 2008,* October 2008.

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Third Party Conformity Assessment Body Accreditation Requirements for Testing Compliance with 16 C.F.R. Part 1501 (Small Parts Regulation)

As Required by the Consumer Product Safety Improvement Act of 2008

For Further Information, Contact:

Scott Heh, 301-504-7646
Special Assistant
Office of the Executive Director

Or

Robert J. Howell, 301-504-7621
Acting Assistant Executive Director
Office of Hazard Identification and Reduction

Note: This document has not been reviewed or accepted by the Commission.
Initials rh Date 11/4/08

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Memorandum

Date:
NOV 4 2008

TO : The Commission
Todd Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel CAF
Patricia M. Semple, Executive Director PS

FROM : Scott Heh SH
Special Assistant
Office of the Executive Director

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

SUBJECT : Accreditation Requirements for Third Party Conformity Assessment Bodies to Test to the Requirements at 16 C.F.R. Part 1501 - Method For Identifying Toys And Other Articles Intended For Use By Children Under 3 Years Of Age Which Present Choking, Aspiration, Or Ingestion Hazards Because Of Small Parts

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 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.

The third party testing requirements apply to any children's product manufactured more than 90 days after the Commission has published requirements for accreditation of third party testing laboratories to assess conformity with a children's product safety rule. The Act sets a schedule for the Commission to publish notice of requirements for accreditation of third party testing laboratories. The full schedule for CPSC action on accreditation requirements is at Tab A. The first two items for Commission action on the accreditation schedule were for the lead paint regulation and the cribs and pacifier regulations. The staff submitted memoranda to the Commission with recommended accreditation requirements for laboratories to test for compliance with each of these regulations[1]. Federal Register notices establishing these requirements were published on September 22, 2008 for the lead paint regulation and on October 22, 2008 for the cribs and pacifier regulations.

The third item for Commission action on the accreditation schedule is for the CPSC regulation that bans toys and other articles intended for use by children under 3 years of age which present choking, aspiration, or ingestion hazards because of small parts as determined by the test method at 16 C.F.R. Part 1501, hereafter referred to as the small parts regulation.

The Act requires that not later than November 12, 2008 (i.e., 90 days after enactment of the CPSIA), the Commission publish notice of requirements for the accreditation of third party testing laboratories to assess conformity with the small parts regulation. In the sections that follow, the staff recommends the same approach as approved by the Commission for laboratory accreditation requirements for the lead paint, cribs, and pacifier regulations. Much of the discussion from the staff's earlier memoranda to the Commission is repeated below for the benefit of those with an interest in accreditation requirements associated with the small parts regulation, and who may not be familiar with the Commission approved process in the first two phases of Commission accreditation requirements.

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

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[1] CPSC staff briefing memorandum Accreditation Requirements for Third Party Conformity Assessment Bodies to Test to the Lead Paint Requirements of 16 C.F.R. Part 1303, September 2, 2008, available on the CPSC web site at http://www.cpsc.gov/library/foia/foia08/brief/thirdp.pdf

CPSC staff briefing memorandum Accreditation Requirements for Third Party Conformity Assessment Bodies to Test to the Requirements for Full-Sized Cribs at 16 C.F.R. Part 1508, Non-Full-Sized Cribs at 16 C.F.R. Part 1509, and Pacifiers at 16 C.F.R. Part 1511, October 3, 2008 available on the CPSC web site at http://www.cpsc.gov/library/foia/foia09/brief/tpacp.pdf

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.

II. 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 an approach that allows for certain testing laboratories to test toys and other articles intended for use by children under 3 years of age for compliance with the small parts safety regulation.

There is a rapidly growing demand for conformity assessment entities that can facilitate the acceptance of products across nations' borders. This demand 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) is an organization that 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 government 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.[2]

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.

[2] http://ilac.org/membersbycategory.html contains a complete list of ILAC-MRA accrediting bodies.

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]

III. Different Categories of Laboratories and Proposed CPSC Acceptance

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 government 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 ILAC-MRA member, any of these types of laboratories can be accredited to ISO 17025. For example, in addition to many commercial laboratories, CPSC staff is aware that at least one major U.S. based toy manufacturer owns a laboratory that is accredited by an ILAC-MRA organization in accordance with ISO/IEC 17025. Also, there are government affiliated laboratories that are similarly accredited. Under the ISO 17025 accreditation, not only commercial laboratories, but manufacturer (first party) laboratories and government 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 17025 accreditation by an ILAC-MRA accrediting body serve as the baseline criterion for CPSC acceptance of <u>any</u> laboratory, (e.g., commercial third party, government, or manufacturer owned). The staff also recommends certain additional criteria as directed by the CPSIA, depending on the type of laboratory.

<u>Laboratories Owned or Controlled by a Manufacturer or Private Labeler</u>

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

> 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. 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 IV on laboratory registration with the Commission.

Government Owned Laboratories

The CPSIA provides that government owned or controlled laboratories 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 government 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. To obtain this assurance, CPSC staff will engage the government entities relevant to the accreditation request.

IV. Third Party Laboratory Registration with the CPSC 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 baseline documentation must include the ISO 17025 accreditation certificate by an ILAC-MRA Signatory, including a statement of scope that clearly identifies the regulation for which accreditation is sought (the small parts regulation at 16 C.F.R. Part 1501).

The staff previously established a CPSC web site online process for laboratories to register for accreditation for the lead paint regulation, the crib regulations, and the pacifier regulation (http://www.cpsc.gov/businfo/labaccred.html). If approved by the Commission, the staff will expand the existing laboratory registration web page so that laboratories may also register with the CPSC for testing conformity with the small parts regulation. Tab B shows a draft format for the on-line registration form with the expansion to allow registration for the small parts regulation.

On the application form, the laboratory must identify if it is a third party, government, or firewalled laboratory. If the laboratory is owned or controlled in part or in whole by a government, it must identify the government entity on the registration. An important piece of the staff's recommended registration process is a section that requires a listing of manufacturers of any products subject to any of the regulations for which accreditation is sought and who hold a ten percent or greater interest in the facility.[3] The staff recommends this approach to identify which laboratories must comply with the statutory requirements for accreditation of "first party" or "firewalled" laboratories. Those laboratories 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, thus satisfying the statutory requirements for accreditation if the Commission finds the laboratory's application to be satisfactory.

After a laboratory has submitted the required documentation associated with ISO/IEC 17025 accreditation and has been accepted as a third party laboratory for the small parts regulation, the staff recommends that the laboratory contact information and testing scope be posted on the CPSC web site (see http://www.cpsc.gov/businfo/labaccred.html).

For laboratories seeking acceptance under the firewalled provision, the staff recommends an examination by staff of all relevant materials required by the registration. If additional information is necessary for the Commission to find by order that a firewalled laboratory can

[3] 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.

meet the statutory requirements, additional information will be requested from that laboratory for staff review. The results of the staff review would be submitted to the Commission for its official consideration of whether to accredit the laboratory as a firewalled laboratory.

V. 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. These systems may already dictate testing by third party laboratories that are accredited by an ILAC-MRA signatory body in accordance with ISO 17025. Therefore, there may be many products in the marketplace that have already undergone testing earlier than the mandatory effective date in a way that would support certification of compliance with 16 C.F.R. Part 1501.

For these children's 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 small parts regulation certifications if the product[4] was tested on or after May 16, 2008 (90 days prior to the date of CPSIA enactment) by a laboratory that is CPSC-accepted as accredited no later than January 20, 2009.[5] 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 regulation. Under this approach, firms who were already voluntarily getting products tested by competent laboratories will not have to have those same products retested during this start-up period. 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.[6] Manufacturers and private labelers that did not already utilize third party testing, or that based their certifications on test dates prior to May 16, 2008, 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 government laboratories be treated similarly as 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 government laboratories also will need to meet the conditions for governmental entities as required by the Act. If the CPSC accepts accreditation of a government laboratory by January

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[4] 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.

[5] The staff recommends January 20, 2009 as a practical intermediate date in the period between Commission notice of laboratory accreditation requirements and the date when small parts certification is required (accreditation notice date plus 90 days).

[6] 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.

20, 2009, testing by that laboratory conducted on or after May 16, 2008 can be used to support third party certification to the small parts regulation.

The staff recommends that prior testing by first party laboratories (e.g., manufacturer owned laboratories), even if ISO 17025 accredited, would not be accepted since the firewall provisions established by the CPSIA for the small parts regulation would not have been in place at the time of the test.

In summary, the staff recommends that the Commission will accept a certificate of compliance with the small parts regulation based on testing performed by an accredited laboratory on or after May 16, 2008, but prior to the Commission's acceptance of the laboratory's accreditation if:

- the third party laboratory was ISO/IEC 17025 accredited by an ILAC-MRA Signatory at the time of the test;
- the accreditation scope in effect for the laboratory at that time expressly included testing to 16 C.F.R. Part 1501;
- the laboratory's accreditation application is accepted by the Commission under the procedures proposed in this memorandum by January 20, 2009; and
- the laboratory's accreditation and inclusion of the small parts regulation in its scope remains in effect through the effective date for mandatory third party testing and certification for children's products subject to the small parts regulation.

VI. 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 C.F.R 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.

VII. Recommended Effective Date

The staff recommends that the requirements for accreditation for third party laboratories to test to the small parts regulation at 16 C.F.R. Parts 1501 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 the coming into force of new mandatory requirements.

An FR publication of third party laboratory accreditation requirements would also establish an effective date of 90 days after FR publication for third party testing to support certifications of compliance of children's products that are subject to the small parts regulation at 16 C.F.R. Part 1501[7].

[7] The CPSIA confirms existing law that compliance of any children's product with third party testing and certification does not exempt such children's product from complying with the underlying safety rule or standard to which the product is certified [15 U.S.C. 2063(h)]. Therefore, the Commission may take action against firms that distribute children's products that are not in compliance with 16 C.F.R. Part 1501, even if those products are certified based on third party testing.

VIII. Staff Recommendation for Accreditation Requirements for Third Party Laboratories to Test to the Small Parts Regulation

The staff recommends that the Commission approve posting its recommended accreditation requirements on the CPSC web site and publishing them in a Federal Register (FR) notice as drafted by the Office of the General Counsel (provided separately under restricted cover). The FR notice would establish the requirements for laboratories to become accredited to test to the small parts regulation at 16 C.F.R. Part 1501. In addition, the FR notice would solicit comments from interested parties on the established approach for laboratory accreditation associated with the small parts regulation and on the overall approach for accreditation.

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.aclasscorp.com

[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

TAB A

Time Line for Establishing Laboratory Accreditation Requirements

- Lead paint ban at 16 C.F.R. part 1303 -- not later than 30 days after enactment [September 13, 2008]

- Full-size cribs at 16 C.F.R. part 1508, non-full-size cribs at 16 C.F.R. part 1509, and pacifiers at 16 C.F.R. part 1511 -- not later than 60 days after enactment [October 13, 2008]

- Small parts at 16 C.F.R. part 1501 -- not later than 90 days after enactment [November 12, 2008]

- Children's metal jewelry under the standards for lead at section 101(a)(2) of CPSIA -- not later than 120 days after enactment [December 12, 2008]

- Baby bouncers, walkers and jumpers at 16 C.F.R. §§ 1500.18(a)(6) and 1500.86(a) -- not later than 210 days after enactment [March 12, 2009]

- Children's products subject to the 300 ppm lead content limit of Section 101 of the CPSIA other than metal jewelry -- not later than May 16, 2009

- All other current CPSC children's product safety rules -- not later than 10 months after enactment of CPSIA [June 14, 2009]

TAB B

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 Acceptance

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. Please see the box between sections 9 and 10 below for details.

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.

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. Registering as a (select one):

- Firewalled Conformity Assessment Body
- Third Party Conformity Assessment Body
- Government Conformity Assessment Body

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:

Family name(s): First (Given) name:

Title: E-mail:

Telephone #: Fax #:

7. Laboratory Accreditation Information:

Date of accreditation to ISO/IEC 17025:2005

Name of ILAC-MRA member providing accreditation

Certificate number

Expiration date

8. Laboratory web site (optional):

9. Ownership:

Name(s) of all manufacturers and/or private labelers, of children's products subject to the safety standards for which you are applying, holding ten percent or greater interest in this conformity assessment body.

Identification of such owners is required in the boxes below. You may request by checking the box below that the CPSC consider this submitted ownership information as confidential and exempt from public disclosure.

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

	Name of Owner	Percent Owned
*a.		
b.		
c.		
d.		
e.		
f.		
g.		
h.		

i.

j.

If this conformity assessment body is owned or controlled in part or in whole by a government, name the government entity(s) in the boxes below. Ownership or control by a government entity may not be considered as confidential and exempt from public disclosure.

Name of Government Entity	Percent Owned
*a.	
b.	
c.	
d.	
e.	

All registrants must provide a copy of the laboratory accreditation certificate and relevant scope documents in addition to this registration form.

Firewalled conformity assessment bodies must also submit copies of the training materials noted in section 11.

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

10. Seeking CPSC acceptance for the following (check all that apply; if you have applied for one of them previously, please do not check it again):

- Lead Paint, 16 CFR Part 1303
- Small Parts Regulation, 16 CFR Part 1501
- Pacifiers, 16 CFR Part 1511
- Non Full-Size Cribs, 16 CFR Part 1509
- Full-Size Cribs, 16 CFR Part 1508

* **You must check at least one of the boxes above**

11. Firewalled conformity assessment body training materials

If any manufacturer or private labeler of children's products, subject to the safety standards 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

12. Applicant Information:

Family name(s): First (Given) name:

Title: E-mail:

Current Date:

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.

Submit | Reset Form

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 4b