



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

VOTE SHEET

DATE: May 12, 2010

TO: The Commission
 Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel *CAF*
 Maruta Budetti, Executive Director *MB*

FROM: Philip L. Chao, Assistant General Counsel *PLC*
 Jan Carlson, General Attorney *JC*

SUBJECT: Third Party Testing for Certain Children's Products; Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity with Part 1216 of Title 16, Code of Federal Regulations

May 26, 2010

Ballot Vote Due: _____

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 to test infant walkers pursuant to the final rule also currently before the Commission, *Safety Standard for Infant Walkers*, which, if approved, will appear at 16 CFR Part 1216. Publication of this notice will be coordinated with publication of the final rule so that they both appear in the same issue of the *Federal Register*.

Please indicate your vote on the following options.

- I. Approve the publication of the attached document in the *Federal Register* as drafted.

 (Signature)

 (Date)

RH 5/12/2010
 CLEARED FOR PUBLIC RELEASE
 UNDER CPSC 6(b)(1)

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

(Signature)

(Date)

III. Do not approve the publication of the attached document in the *Federal Register*.

(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 Part 1216 of Title 16, Code of Federal Regulations"

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

CPSC Docket No. CPSC-2010-[INSERT NUMBER]

Third Party Testing for Certain Children's Products; Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity with Part 1216 of Title 16, Code of Federal Regulations

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 specific CPSC regulations relating to infant walkers. The Commission is issuing this notice of requirements pursuant to section 14(a)(3)(B)(vi) of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2063(a)(3)(B)(vi)).

DATES: Effective Date: The requirements for accreditation of third party conformity assessment bodies to assess conformity with 16 CFR part 1216 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 PUBLICATION IN THE FEDERAL REGISTER]. Comments on this notice should be captioned “Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity with Part 1216 of Title 16, Code of Federal Regulations.”

ADDRESSES: You may submit comments, identified by Docket No. CPSC-2010-[INSERT NUMBER] 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 <http://www.regulations.gov>.

Written Submissions:

Submit written submissions in the following ways:

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 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions:

All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. Do not submit

confidential business information, trade secret information, or other sensitive or protected information (such as a social security number) electronically; if furnished at all, such information should be submitted in writing.

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

FOR FURTHER INFORMATION CONTACT: Robert “Jay” Howell, Assistant Executive Director for Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; e-mail rhowell@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 14(a)(3)(B)(vi) of the CPSA, 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 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 a notice of the requirements for accreditation, 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. 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).

This notice provides the criteria and process for Commission acceptance of accreditation of third party conformity assessment bodies for testing pursuant to the safety standard for infant walkers which appears elsewhere in this issue of the Federal Register. The standard for infant walkers will be codified at 16 CFR part 1216. The standard contains the testing methods that conformity assessment bodies will use to assess infant walkers. The Commission is recognizing limited circumstances in which it will accept certifications based on product testing conducted before the infant walkers standard becomes effective in six months. The details regarding those limited circumstances can be found in part IV of this document below.

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 standard identified immediately above.

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.”

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)/International Electrotechnical Commission (IEC) Standard 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 Regulations)," 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 at <http://www.cpsc.gov/about/cpsia/labaccred.html>.

The Commission stayed the enforcement of certain provisions of section 14(a) of the CPSA in a notice published in the Federal Register on February 9, 2009 (74 FR 6396); the stay applied to testing and certification of various products, including infant walkers. On December 28, 2009, the Commission published a notice in the Federal Register (74 FR 68588) revising the terms of the stay. One section of the December 28,

2009, notice addressed “Consumer Products or Children’s Products Where the Commission Is Continuing the Stay of Enforcement Until Further Notice,” due to factors such as pending rulemaking proceedings affecting the product or the absence of a notice of requirements. The infant walkers testing and certification requirements were included in that section of the December 28, 2009, notice. As the factors preventing the stay from being lifted in the December 28, 2009, notice with regard to testing and certifications of infant walkers were the absence of approved standards and a notice of requirements, publication of this notice, along with the final rule on Safety Standard for Infant Walkers which appears elsewhere in this issue of the Federal Register, have the effect of lifting the stay with regard to these CPSC regulations for infant walkers.

This notice of requirements is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The final rule announcing the Safety Standard for Infant Walkers is effective [INSERT DATE SIX MONTHS AFTER PUBLICATION IN THE FEDERAL REGISTER]. The effect of these twin publications is that each manufacturer (including the importer) or private labeler of a product subject to 16 CFR part 1216 must have any such product manufactured on or after [INSERT DATE ONE DAY AFTER SIX MONTHS AFTER PUBLICATION IN FEDERAL REGISTER] tested by a third party conformity assessment body accredited to do so and must issue a certificate of compliance with 16 CFR part 1216 based on that testing.

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 the test method for infant walkers included in 16 CFR part 1216, Safety Standard for Infant Walkers. 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. Once the Commission adds a third party conformity assessment body to that list, the third party conformity assessment body may commence testing of infant walkers 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/about/cpsia/labaccred.html>. The applicant provides, in English, basic identifying information concerning its location, the type of accreditation it is seeking, and electronic copies of its 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/about/cpsia/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.

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. Acceptance of Children's Product Certifications Based on Third Party Conformity Assessment Body Testing to the New Safety Standard for Infant Walkers Prior to Their Effective Date

Elsewhere in this issue of the Federal Register, the Commission is publishing a new safety standard for infant walkers, which will be codified at 16 CFR part 1216. The effect of this notice of requirements and the final rule is that each manufacturer (including the importer) or private labeler of a product subject to 16 CFR part 1216 must have any such product manufactured on or after [INSERT DATE ONE DAY AFTER SIX MONTHS AFTER PUBLICATION IN FEDERAL REGISTER] tested by a third party conformity assessment body accredited to do so and must issue a certificate of compliance with 16 CFR part 1216 based on that testing.

To ease the transition to the new standard and avoid a "bottleneck" of products at conformity assessment bodies at or near the effective date of 16 CFR 1216, the Commission will accept certifications based on testing that occurred prior to the effective

date of the new standard in certain prescribed circumstances. However, any such testing must comport with all CPSC requirements, including:

- At the time of product testing, the product was tested by a third party conformity assessment body that was ISO/IEC 17025 accredited by an ILAC-MRA member, and had been accepted by the Commission;
- The accreditation scope in effect for the third party conformity assessment body at the time of testing expressly included testing to the test method(s) included in 16 CFR part 1216; and
- The test results show compliance with the test methods in the new regulation (16 CFR part 1216).

Dated: _____.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission