



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

BALLOT VOTE SHEET

DATE: March 23, 2011

TO: The Commission
 Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel *UTS for CCF*
 Kenneth R. Hinson, Executive Director *KRH*

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

SUBJECT: Third Party Testing for Certain Children's Products; Toddler Beds: Requirements for Accreditation of Third Party Conformity Assessment Bodies

Ballot Vote Due: April 13, 2011

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 toddler beds pursuant to the final rule also currently before the Commission, *Safety Standard for Toddler Beds*. The final rule, if approved, will appear at 16 CFR part 1217. 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 publication of the attached document in the *Federal Register* as drafted.

 (Signature)

 (Date)

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

(Signature)

(Date)

III. Do not approve 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; Toddler Beds: Requirements for Accreditation of Third Party Conformity Assessment Bodies."

BILLING CODE 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

[CPSC Docket No. CPSC-2009-0064]

16 CFR Part 1217

Third Party Testing for Certain Children's Products; Toddler Beds: Requirements for Accreditation of Third Party Conformity Assessment Bodies

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 CPSC regulation relating to toddler beds. 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 parts 1217 are effective [insert date of publication in the FEDERAL REGISTER].

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 toddler beds, which appears elsewhere in this issue of the *Federal Register*. The standard for toddler beds will be codified at 16 CFR part 1217. The standard contains the test methods that conformity assessment bodies will use to assess toddler beds. The Commission is recognizing limited circumstances in which it will accept certifications based on product testing conducted before the toddler bed 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 regulation identified immediately above.

The CPSC also recognizes that section 14(a)(3)(B)(vi) of the CPSA is captioned: “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 to require a notice of requirements for “all” other children’s product safety rules, rather than as 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 Commission staff is continuing to evaluate which rules, regulations, standards, or bans constitute “children’s product safety rules.” The CPSC intends to issue additional notices of requirements for other rules that 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 website 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 website at <http://www.cpsc.gov/about/cpsia/labaccred.html>.

As stated in part I of this document, the Commission, elsewhere in this issue of the *Federal Register*, is issuing a new standard for toddler beds that will be codified at 16 CFR part 1217. This notice of requirements is effective on [insert date of publication in the FEDERAL REGISTER]. The final rule announcing the Safety Standard for Toddler Beds is effective on [insert date 6 months after date of 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 1217 must have any such product manufactured on or after [insert date 6 months after date of publication in the 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 1217 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 toddler beds included in 16 CFR part 1217, Safety Standard for Toddler Beds. 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 website an up-to-date listing of third party conformity assessment bodies whose accreditations it has accepted and the scope of each accreditation. Once the Commission adds a third party conformity assessment body to

that list, the third party conformity assessment body may commence testing of toddler beds 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, 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 10 percent or more. While the Commission is not addressing common parentage of a third party conformity assessment body and a children's product manufacturer at this time, it will be vigilant to determine whether 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. The Commission's order must also find that accrediting the firewalled conformity assessment body would provide equal or greater

consumer safety protection than the manufacturer's or private labeler's use of an independent 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 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 website 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 completed satisfactorily, the third party conformity assessment body in question is added to the CPSC's list of accredited third party conformity assessment bodies at <http://www.cpsc.gov/about/cpsia/labaccred.html>. In the

case of a firewalled conformity assessment body seeking accredited status, when the staff's review is complete, the staff transmits its recommendation on accreditation to the Commission for consideration. (A third party conformity assessment body that ultimately may seek acceptance as a firewalled third party conformity assessment body may 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 then will be added to the CPSC's list of accepted third party conformity assessment bodies. In each case, the Commission will notify the third party conformity assessment body electronically of acceptance of its accreditation. All information to support an accreditation acceptance request must be provided in the English language.

Once the Commission adds a third party conformity assessment body to the list, the third party conformity assessment body then may begin testing of children's products to support certification of compliance with the regulation 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 Toddler Beds Prior to Their Effective Date

Elsewhere in this issue of the *Federal Register*, the Commission is publishing a new safety standard for toddler beds, which will be codified at 16 CFR part 1217. 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 1217 must have any such product manufactured on or after [insert date 6 months after date of publication in the 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 1217 based on that testing.

To ease the transition to the new standards and avoid a “bottlenecking” of products at conformity assessment bodies at or near the effective date of 16 CFR part 1217, 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:

1. The product¹ was tested by a third party conformity assessment body that was ISO/IEC 17025 accredited by a signatory to the ILAC-MRA at the time of the test. For firewalled conformity assessment bodies, the firewalled conformity assessment body must be one that the Commission has accredited by order at or before the time the product was tested, even if the order did not include the test methods specified in this notice. If the third party conformity assessment body has not been accredited as a firewalled conformity assessment body by a Commission order, the Commission will not accept a certificate of compliance based on testing performed by the third party conformity assessment body before it is accredited, by Commission order, as a firewalled conformity assessment body;

¹ 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 third party conformity assessment body's application is accepted by the CPSC by [insert date 6 months after date of publication in the FEDERAL REGISTER], as established by the Commission;

3. The test results show compliance with 16 CFR part 1217;

4. The product was tested on or after [insert date of publication in the FEDERAL REGISTER] and before [insert date 6 months after date of publication in the FEDERAL REGISTER]; and

5. The third party conformity assessment body's accreditation remains in effect through the effective date for mandatory third party testing and manufacturer/private labeler certification for the subject product's respective regulation.

Dated: _____.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.



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

Memorandum

This document has been electronically
approved and signed.

Date: March 23, 2011

TO: The Commission
Todd A. Stevenson, Secretary

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

FROM: Robert J. Howell, Assistant Executive Director
Office of Hazard Identification and Reduction
Celestine T. Kiss, Project Manager
Division of Human Factors, Directorate for Engineering Sciences

SUBJECT: Accreditation Requirements for Third Party Conformity Assessment Bodies to
Test Toddler Beds for Compliance to 16 C.F.R. Part 1217, *Safety Standard for
Toddler Beds*

I. Introduction

On August 14, 2008, the Consumer Product Safety Improvement Act (hereafter referred to as the "Act" or "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 U.S. Consumer Product Safety Commission (CPSC) children's product safety rule, every manufacturer of such children's product (and the private labeler of such children's product if such product bears a private label) shall: (A) submit sufficient samples of the children's product, or samples that are identical in all material respects, to a third party conformity assessment body (hereafter referred to as a third party testing laboratory) accredited under requirements to be established by the Commission to be tested for compliance with such children's product safety rule; and (B) based on the assessment by the third party testing laboratory, issue a certificate which certifies that such children's product complies with the children's product safety rule.¹

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 nevertheless, in certain specified circumstances, may be accredited as a third party testing laboratory. The Act specifies that a third party testing

¹ Commission regulations at 16 CFR part 1110 limit the parties who must certify to the U.S. importer and, in the case of domestically produced products, the U.S. manufacturer.

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, private labeler, or other interested party and that procedures are in place for immediate and confidential reporting to the Commission of any attempts by the manufacturer, private labeler, or other interested party to hide or exert undue influence over test results. The Commission must also find that accrediting the proprietary laboratory would provide equal or greater consumer safety protection than the manufacturer’s or private labeler’s use of an independent third party conformity assessment body. 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 website 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 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, pacifier, and small parts regulations, children’s metal jewelry, and other children’s products) for laboratories wanting to test products for compliance to the regulation for toddler beds. The test methods for toddler beds are described in 16 CFR part 1217, *Safety Standard for Toddler Beds*.

II. Categories of Laboratories and Proposed Requirements

There are some accepted terms used to describe conformity assessment, depending upon 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 or privately labels the product. Independent commercial laboratories and governmental laboratories often are 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) accreditation body 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, *International Standard—General Requirements for the Competence of Testing and Calibration*

Laboratories. 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 affect adversely the quality of their work.

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 accreditation body serve as the baseline criterion for CPSC acceptance of any laboratory (e.g., commercial third party, governmental, or manufacturer-owned, -controlled, or -managed).

Staff also recommends additional criteria as directed by the CPSIA, depending upon the type of laboratory.

Laboratories Owned, Controlled, or Managed by a Manufacturer or Private Labeler

The Act specifies that a laboratory owned, controlled, or managed 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:

- 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/IEC 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 that safeguards against undue influence are in place. Staff recommends that the Commission consider ISO/IEC 17025 accreditation by an ILAC-MRA signatory accreditation body as part of the criteria for firewalled laboratories to meet the

CPSIA requirements for equal or greater consumer safety and the mandates related to undue influence.

For a proprietary laboratory to be considered under the firewalled provision, 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.

Staff recommends that governmental laboratories be accepted as third party testing laboratories if they are accredited in accordance with ISO/IEC 17025 by an ILAC-MRA signatory accreditation body 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

Staff recommends that the Commission implement a process by which a third party laboratory must submit documentation to the CPSC, which 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 must provide additional information, and firewalled laboratories must go through the additional step of approval by an order of the Commission. The steps are:

1. *All* types of laboratories (third party, firewalled, governmental, combinations) submit an application and supporting (baseline) documents to CPSC staff.
2. Commission staff reviews the ISO/IEC 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).
 - b. Firewalled laboratory applicants must provide 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.
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 website (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/IEC 17025 *accreditation certificate* issued by an ILAC-MRA signatory accreditation body.
2. An ILAC-MRA accreditation body *statement of scope* that clearly identifies the regulations, requirements, and/or test methods for which accreditation is sought: Safety Standard for Toddler Beds, 16 C.F.R. part 1217.
3. A *disclosure* of ownership, management, or controlling interests, including:
 - a. 10 percent or more control² by manufacturers or private labelers of children's products subject to the safety requirements for which the laboratory is applying to test, and
 - b. whole or partial government interest, including indirect ownership or control through government ownership of interests in any partners of the laboratory.

² This 10 percent or greater criterion is also used by the U.S. Federal Communications Commission [47 C.F.R. §1.2112] for potential control by an affiliated business entity.

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

Staff's recommended accreditation approach uses and builds upon existing systems of conformity assessment based upon ISO/IEC standards and internationally recognized accrediting bodies. In the field of children's products, some manufacturers, importers, and/or retailers have instituted their own processes for third party testing to demonstrate conformity with certain mandatory and voluntary safety standards. Some of these systems already may dictate testing by third party laboratories that are accredited by an ILAC-MRA signatory accreditation body in accordance with ISO/IEC 17025. It is possible that some products in the marketplace will undergo testing earlier than the mandatory effective date, as established by the Commission, in a way that would support certification with the safety standard for toddler beds.

For certifications of toddler beds to the new regulation, staff recommends that the Commission allow certifications to be based on prior testing under certain conditions. Specifically, staff proposes that the Commission accept a certificate of compliance to the subject regulation based on testing performed by an accredited third party conformity assessment body (including a government-owned or -controlled conformity assessment body, and a firewalled conformity assessment body) if:

1. the product³ was tested by a third party conformity assessment body that was ISO/IEC 17025 accredited by an ILAC-MRA accreditation body at the time of the test. For firewalled conformity assessment bodies, the firewalled conformity assessment body must be one that the Commission has accredited by order at or before the time the product was tested, even if the order did not include the test methods specified in this notice. If the third party conformity assessment body has not been accredited by a Commission order as a firewalled conformity assessment body, the Commission will not accept a certificate of compliance based on testing performed by the third party conformity assessment body before it is accredited, by Commission order, as a firewalled conformity assessment body;
2. the laboratory's application is accepted by the CPSC before [insert six months after date of publication in the FEDERAL REGISTER], as established by the Commission;
3. the test results show compliance with 16 CFR part 1217;
4. the product was tested on or after [insert date of publication of Final Rule in the FEDERAL REGISTER], and before [insert six months after date of publication in the FEDERAL REGISTER]; and
5. the third party conformity assessment body's accreditation remains in effect through the effective date for mandatory third party testing and manufacturer/private labeler certification for the safety standard for toddler beds.

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. Specifically, staff proposes that the Commission accept toddler bed certifications if the product was tested on or after [insert date of publication of

³ 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.

Final Rule in the FEDERAL REGISTER], by a laboratory whose application is accepted by the CPSC by the mandatory effective date, as established by the Commission. Under this approach, firms that elect voluntarily to have their toddler beds tested by competent laboratories before the safety standard's effective date will not be required to have those same products retested to verify initial product compliance once the standard becomes effective to certify compliance to the standard. 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.⁴ Manufacturers and private labelers that do not elect voluntarily to have their toddler beds tested by competent laboratories prior to the effective date of the safety standard must have third party testing conducted by a CPSC-accepted laboratory to certify products manufactured on or after the effective date.

Staff recommends that governmental laboratories be treated like other third party laboratories with respect to certifications based on testing prior to the effective date. Nonetheless, manufacturers and private labelers must consider carefully 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 the effective date of the safety standard, testing by that laboratory conducted on or after [insert date of publication of Final Rule in the FEDERAL REGISTER], and before [insert 6 months after date of publication in the FEDERAL REGISTER] can be used to support third party certification to the requirements for the safety standard for toddler beds.

Staff recommends that laboratories owned, managed, or controlled by a manufacturer or private labeler be treated like 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) must consider carefully that such laboratories also must meet the conditions for firewalled conformity assessment bodies, as required by the Act. If the CPSC accepts accreditation of a firewalled laboratory by the effective date of the safety standard, testing by that laboratory conducted on or after after [insert date of publication of Final Rule in the FEDERAL REGISTER], and before [insert 6 months after date of publication in the FEDERAL REGISTER] can be used to support third party certification to the requirements for the safety standard for toddler beds.

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, staff does not expect such requirements to have any negative environmental impact.

VI. Recommended Effective Date

⁴ 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.

Staff recommends that the requirements for accreditation for third party laboratories to test products for compliance with the regulation for toddler beds at 16 CFR part 1217 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 Toddler Beds

Staff recommends that the Commission approve staff's proposed approach for accepting accreditation of laboratories to test for compliance with the regulation for toddler beds at 16 CFR part 1217. 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. The FR notice would establish the requirements for laboratories to become accredited to test for compliance with the regulation for toddler beds.

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 related 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 on accreditation to the Commission, “third party conformity assessment body” is synonymous with “third party testing laboratory.” For proposed CPSC requirements for accreditation of testing laboratories, CPSC staff recommends allowing certain testing laboratories to test products for compliance with the requirements established by the Code of Federal Regulations if they are accredited by 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/IEC 17025 for a specified technical scope. This statement of scope comprises part of the laboratory's accreditation, and can include items such 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 affect adversely 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 reexamined regularly, at least every two years, with either onsite 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 the nations' accrediting bodies. The peer evaluation process provides assurance that accrediting bodies are operating in accordance with the ISO/IEC 17011 standard. The standard provides specifications for accrediting body procedures for conducting laboratory assessments and also sets forth 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 accrediting body'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 more than 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 and the United States have three or more MRA signatory accreditation bodies.⁵

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 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 founded 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 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

⁵ 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

TAB A

DRAFT FORM FOR LABORATORY REGISTRATION WITH CPSC

U.S. Consumer Product Safety Commission
CPSC Form 223 – Lab Accreditation

Consumer Product Conformity Assessment Body (Testing Laboratory)

Registration Form: Initial request for first time user

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 capitalize only the first letter of words and names (except for abbreviations) when filling out this form. Note an asterisk (*) denotes a required field. Thank you!

*1. Legal name of the laboratory:

2. Full address of the laboratory:

*Street (Line 1)

Street (Line 2)

*City/Town/County State/Province:

*Country or Administrative Area Postal Code:

3. Laboratory website (optional):

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

5. Laboratory's authorized representative (to be displayed on the CPSC website):

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

Title: *Email:

Telephone #: Fax #:

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

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

Title Email:

7. 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 government entity (as defined below for Government Laboratory)

Firewalled Laboratory: Ownership of the applicant laboratory of 10% or more by a manufacturer or private labeler 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 a manufacturer or private labeler 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 Conformity Assessment Body
- Firewalled Conformity Assessment Body
- Governmental Conformity Assessment Body

C. Registration (complete the appropriate section) Third Party Laboratory Registration

If Third Party Conformity Assessment Body 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).

Yes Check this box and submit your name below to confirm third party laboratory attestation. If attestation is completed, skip to Section 8.

Name of Laboratory Representative making attestation that applicant is a third party laboratory.

Firewalled Laboratory Registration

Registration as a firewalled conformity assessment body (firewalled laboratory) is required if there is an ownership interest in this laboratory of 10% or more by a manufacturer or private labeler 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 Manufacturer or Private Labeler, Owner or Controlling Party	Percent Owned	(Do Not use "%".)
a.			
b.			
c.			
d.			
e.			

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.

Yes, I claim that this information should be considered as confidential and exempt from public disclosure.

Registration for 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.

	Name of Governmental Entity	Percent Owned	(Do Not use "%".)
a.			
b.			
c.			
d.			
e.			

8. Laboratory Accreditation Information and Scope for which you are applying:

The Laboratory must be accredited by an ILAC-MRA signatory accreditation 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 the CPSC rules and/or test methods for which you are applying.

If all CPSC rules and/or test methods for which you are applying fall under one certificate, enter the information under **Certificate 1** and check all of the applicable CPSC rules and/or test methods. Leave **Certificate 2** information blank.

If the list of CPSC rules and/or test methods on your application are split between different certificates (from the same or different ILAC-MRA signatory accreditation body), enter the information for both **Certificate 1** and **Certificate 2** and check only the CPSC rules and/or test methods that are applicable to each certificate.

Certificate 1

You must select an ILAC-MRA signatory accreditation body from the drop-down list.

*Name of ILAC-MRA signatory accreditation body providing accreditation

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

*Certificate number

Expiration date (mm/dd/yyyy)

You must upload at least one certificate and scope document for each certificate you reference above. The form will not submit until you upload them using the "Upload Document" button below.

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 10% 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 include these materials when clicking "Upload Document" to upload your certificate and scope documents.

[Upload Document](#)

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).

[Submit](#) | [Reset](#) | [Logout](#)

CPSC
OMB Control Number 3014-0143

Select CPSC Rules and/or Test Methods for

Accreditation Body:

Certificate Number:

The accreditation and certificate information below applies to the following CPSC rules and/or test methods (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 item below for which it is applying.**

- | | |
|--|---|
| <input type="radio"/> Bicycle Helmets Regulation, 16 CFR Part 1203 | <input type="radio"/> Infant Bath Seats, 16 CFR Part 1215 |
| <input type="radio"/> Infant Walkers, 16 CFR Part 1216 | <input type="radio"/> Safety Standard for Toddler Beds, 16 CFR Part 1217 |
| <input type="radio"/> Safety Standard for Full-Size Cribs, 16 CFR Part 1219 | <input type="radio"/> Safety Standard for Non-Full-Size Cribs, 16 CFR Part 1220 |
| <input type="radio"/> Lead Paint Regulation, 16 CFR Part 1303 | <input type="radio"/> Requirements for All-Terrain Vehicles, 16 CFR Part 1420 |
| <input type="radio"/> Dive Sticks Regulation, 16 CFR Part 1500.86(a)(7) and (8) | <input type="radio"/> Clacker Balls, 16 CFR Part 1500.86(a)(5) |
| <input type="radio"/> Small Parts Regulation, 16 CFR Part 1501 | <input type="radio"/> Electrically operated toys/articles intended for use by children, 16 CFR Part 1505 |
| <input type="radio"/> Full-Size Cribs Regulation, 16 CFR Part 1508, Reference link 4 | <input type="radio"/> Non Full-Size Cribs Regulation, 16 CFR Part 1509, Reference link 4 |
| <input type="radio"/> Rattles Regulation, 16 CFR Part 1510 | <input type="radio"/> Pacifiers Regulation, 16 CFR Part 1511 |
| <input type="radio"/> Bicycles Regulation, 16 CFR Part 1512 | <input type="radio"/> Children's Bunk Beds Regulation, 16 CFR Part 1513 |
| <input type="radio"/> Lead Content in Children's Metal Jewelry, in accordance with the CPSC Laboratory SOP for Determining Total Lead Content in Children's Metal Jewelry or CPSC-CH-E1001-08, Reference link 1 or 2 | <input type="radio"/> Lead in Children's Metal Products, CPSC-CH-E1001-08, Reference link 1 |
| <input type="radio"/> Lead in Non-Metal Children's Products, CPSC-CH-E1002-08, Reference link 3 | <input type="radio"/> Standard for the Flammability of Clothing Textiles, 16 CFR Part 1610 |
| <input type="radio"/> Flammability of Vinyl Plastic Film, 16 CFR Part 1611 | <input type="radio"/> Standard for the Flammability of Children's Sleepwear: Sizes 0 through 6X (FF 3-71), 16 CFR Part 1615 |
| <input type="radio"/> Standard for the Flammability of Children's Sleepwear: Sizes 7 through 14 (FF 5-74), 16 CFR Part 1616 | <input type="radio"/> Surface Flammability of Carpets and Rugs, 16 CFR Part 1630 |
| <input type="radio"/> Surface Flammability of Small Carpets and Rugs, 16 CFR Part 1631 | <input type="radio"/> Standard for the Flammability of Mattresses and Mattress Pads (FF 4-72, Amended), 16 CFR Part 1632 |
| <input type="radio"/> Standard for the Flammability (Open Flame) of Mattress Sets, 16 CFR Part 1633 | |

References (See <http://www.cpsc.gov/about/cpsa/labaccred.html> for list of CPSC Laboratory Test Methods)

1. CPSC Test Method CPSC-CH-E1001-08 for Determining Total Lead in Children's Metal Products

2. The 'Screening Test for Total PB Analysis' Section of the 2005 CPSC Laboratory SOP for Determining Lead in Children's Metal Jewelry
3. CPSC Test Method CPSC-CH-E1002-08 Standard Operating Procedure for Determining Total Lead (Pb) in Non-Metal Children's Products
4. Revocation of 16 CFR Parts 1508 and 1509 becomes effective 6/28/2011. As of 6/28/2011, new crib regulations at 16 CFR Part 1219 and 1220 take effect.

OMB Control Number 3014-0143