



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

BALLOT VOTE SHEET

DATE: October 27, 2010

TO: The Commission
 Todd A. Stevenson, Secretary

THROUGH: ^{for} Kenneth R. Hinson, Executive Director
 Cheryl A. Falvey, General Counsel ^{CAF}
 Philip L. Chao, Assistant General Counsel ^{PLC}

FROM: Harleigh P. Ewell, Attorney, GCRA ^{HE}

SUBJECT: Third Party Testing for Certain Children's Products; Children's Sleepwear, Sizes 0 Through 6 and 7 Through 14; Requirements for Accreditation of Third Party Conformity Assessment Bodies

Ballot Vote Due: **NOV - 3 2010**

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 children's sleepwear in sizes 0 through 6X and 7 through 14 to the flammability requirements of 16 C.F.R. parts 1615 and 1616, respectively.

Please indicate your vote on the following options.

- I. Approve the publication of the draft document in the *Federal Register*.

 (Signature)

 (Date)

RA 10/27/2010
 CLEARED FOR PUBLIC RELEASE
 UNDER CPSA 6(b)(1)
 THIS DOCUMENT HAS NOT BEEN
 REVIEWED OR ACCEPTED BY THE
 COMMISSION.

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

(Signature)

(Date)

III. Do not approve the publication of the draft 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; Children's Sleepwear, Sizes 0 Through 6 and 7 Through 14: Requirements for Accreditation of Third Party Conformity Assessment Bodies"

Draft *Federal Register* Notice

Third Party Testing for Certain Children's Products; Children's Sleepwear, Sizes 0 Through 6 and 7 Through 14: Requirements for Accreditation of Third Party Conformity Assessment Bodies

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

CPSC Docket No. CPSC-2010-00__

16 CFR Parts 1615 and 1616

Third Party Testing for Certain Children's Products; Children's Sleepwear, Sizes 0 Through 6 and 7 Through 14: 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 of children's sleepwear pursuant to 16 CFR parts 1615 and 1616, the CPSC regulations under the Flammable Fabrics Act (FFA) relating to the flammability of children's sleepwear. The Commission is issuing this notice of requirements pursuant to section 14(a)(3)(B)(vi) of the 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 1615 and 1616 are effective upon publication of this notice in the *Federal Register*.

FOR FURTHER INFORMATION CONTACT: Patricia K. Adair, Director, Division of Combustion and Fire Sciences, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone 301-504-7536; email padair@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Statutory Authority

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 establish and 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 an importer) or private labeler of products subject to those regulations must have products that are manufactured more than 90 days after the establishment and *Federal Register* publication 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. The Commission may extend the 90-day period by not more than 60 days if the Commission determines that an insufficient number of third party conformity assessment bodies have been

accredited to permit certification for a children's product safety rule. Any requests for an extension should contain detailed facts showing why an extension is necessary.

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, added by section 102(b) of the CPSIA).

Section 14(a)(3)(G) of the CPSA, 15 U.S.C. 2063(a)(3)(G), exempts notices of requirements from the notice and comment rulemaking requirements of the Administrative Procedure Act, 5 U.S.C. 553. Therefore, the Commission finds good cause that notice and public procedure thereon are unnecessary.

B. *The Children's Sleepwear Standards*

The Standards applicable to children's sleepwear (the "Standards") are 16 CFR part 1615, *Standard for the Flammability of Children's Sleepwear: Sizes 0 Through 6X (FF3-71)*, and 16 CFR part 1616, *Standard for the Flammability of Children's Sleepwear: Sizes 7 Through 14 (FF5-74)*. The Standards were issued in the early 1970s to reduce the unreasonable risk of burn injuries and deaths from fires associated with children's sleepwear. Most burn incidents involving children's sleepwear do not occur while children are sleeping; rather, the incidents occur while the children are awake, unsupervised, and wearing the sleepwear. The primary hazard is ignition of sleepwear by contact with hot surfaces and/or small open-flame ignition sources, such as stove

elements, matches, and lighters. The Standards require that children's sleepwear, and fabric intended for such sleepwear, stop burning when the flame source is removed.

The original children's sleepwear Standard for sizes 0 through 6X was revised in 1972, to include a statistical sampling plan for fabrics and garments. The sampling plan was devised to give assurance to manufacturers that sleepwear garments reaching the marketplace meet the flammability test, and that children wearing the sleepwear garments receive increased protection. The sampling plan also was intended to provide a framework for premarket testing, and thus, greatly assist in detecting noncomplying fabrics and garments before they are placed on the market. When the Standard for sizes 7 through 14 was issued in 1975, it incorporated the same sampling plan as the one in the Standard for sizes 0 through 6X.

The Standards require testing of the fabric to be used in children's sleepwear, of prototype garments involving seams and trim attached to the fabric, and of the seams of finished garments, by having fabric, seams, and trim exposed to a flame source under controlled conditions, as discussed below. To meet the criteria in § 1615.3(b) and § 1616.3(b), five specimens are tested, and the average char length of the sample must not exceed 17.8 centimeters (cm) (7.0 inches (in)) and no individual specimen may have a char length of 25.4 cm (10.0 in).

In 1996, the Commission published amendments to the Standards that except products of wearing apparel from the definition of children's sleepwear for the purpose of testing to the flammability requirements if they are:

- (1) Size 9 months and smaller;

- (2) A one-piece garment that does not exceed 64.8 cm (25.75 inches) in length or a two-piece garment that has no piece exceeding 40 cm (15.75 inches) in length;
- (3) Compliant with all applicable requirements of the Standard for the Flammability of Clothing Textiles (16 CFR part 1610) and the Standard for the Flammability of Vinyl Plastic Film (16 CFR part 1611); and
- (4) Tight-fitting as defined in §1615.1(o) and §1616.2(m), provided the garment is labeled with its size and provided with a specified warning statement on a hangtag attached to the garment and on a label on any package in which the garment is sold.

Children's sleepwear garments subject to the Standards must follow specific sampling plans and be tested for flammability performance at several stages of production. The Standards have performance requirements for fabric, prototypes (seams and trims), and garment production units. There are recordkeeping requirements at each stage of testing. The following summarizes the three stages of testing:

- (1) Fabric testing. Fabrics that are promoted for use in children's sleepwear are tested in the finished state (either original state or after one laundering) and may be tested after 50 launderings (wash and dry). Testing is of a Fabric Production Unit (FPU), which is an unseamed length of fabric up to 5,000 linear yards, or 10,000 linear yards for reduced sampling, which has a specified identity that remains unchanged throughout the unit, except for color or print pattern, as specified in the Standards. Samples are taken from the beginning and end of the FPU.

- (2) Prototype testing. Once a garment design is proposed, the seams and trims are tested to assure that satisfactory garment specifications have been chosen prior to production. All seam types and all seams over 10 inches are tested. Trims are tested in the orientation they will be used in the final garment; however, neckline, shoulder, and sleeve trim are only tested in the vertical configuration (the most severe scenario).
- (3) Production testing. Garment Production Unit (GPU) testing is carried out to assess the flammability of the garment as produced. The longest seam type is tested at this stage. Tests are conducted on each GPU, and each GPU is either accepted or rejected. The maximum number of garments in a GPU is 500 dozen (6,000 garments).

C. *This Notice of Requirements*

This notice provides the criteria and process for the Commission's acceptance of accreditation of third party conformity assessment bodies for testing pursuant to 16 CFR part 1615, *Standard for the Flammability of Children's Sleepwear: Sizes 0 Through 6X (FF3-71)*, and 16 CFR part 1616, *Standard for the Flammability of Children's Sleepwear: Sizes 7 Through 14 (FF5-74)*. Section 3(a)(2) of the CPSA defines a "children's product" as "a consumer product designed or intended primarily for children 12 years of age and younger." The sizes of sleepwear covered by the cited regulations are primarily intended for children age 12 years and younger; these sizes of sleepwear are therefore "children's products" as that term is defined in the CPSA.

This notice of requirements applies to all third party conformity assessment bodies as described in section 14(f)(2) of the CPSA that desire to test children's

sleepwear to the requirements of 16 CFR parts 1615 and/or 1616, where the test results will be used as the basis for a certification that the sleepwear complies with those requirements. Such third party conformity assessment bodies can be grouped into three general categories: (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.

This notice of requirements is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Further, the publication of this notice of requirements lifts the Commission's previous stay of enforcement with regard to testing and certifications related to 16 CFR parts 1615 and 1616. Therefore, each manufacturer of children's sleepwear subject to these regulations that is manufactured after [INSERT DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER] must have samples of any such product, or samples that are identical in all material respects to such product, tested by a third party conformity assessment body accredited to do so and, based on such testing, issue a certificate that the sleepwear complies with the applicable Standard, before the sleepwear is imported for consumption or warehousing or distributed in commerce.

Further, for such children's sleepwear manufactured after [INSERT DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER], the manufacturer must issue a certificate of compliance with 16 CFR part 1615 or 16 CFR part 1616, as applicable, based on that testing. (Under section 3(a)(11) of the CPSA, the term "manufacturer" includes anyone who manufactures or imports a product.) The Commission also is recognizing limited circumstances in which it will accept certifications based on product testing conducted before the third party conformity assessment body is accepted as accredited by the CPSC. The details regarding those limited circumstances are in part IV of this document below.

As noted above, these Standards require testing at three stages in the process of developing and producing the sleepwear (fabric, prototype seams and trim, and production seams). The tests at each of these stages are designed to detect risks that can be reflected in the production garments. In addition, the results of the tests cannot have meaning unless the sampling criteria in the Standards are followed. Therefore, in order for third party testing to serve as the basis for the required certificate that the garment complies with the applicable Standard, it is necessary for the tests by a third party conformity assessment body whose accreditation has been accepted by the Commission be performed as specified in the Standards, that is, tests at the three stages specified in the Standards according to the sampling criteria in the Standards. Of course, responsible parties must, in addition, comply with all recordkeeping requirements of the Standards. We do note, however, that 16 C.F.R. §§ 1615.35(b)(1) and 1616.35(c)(1) allow a firm to use another testing regime if the firm has proof that the other test is at least as stringent as the Standards.

In addition, the Commission will not require third party testing to demonstrate that a product meets the exception for “tight-fitting garments” as defined by §§ 1615.1(c) and 1616.2(m), as these garments are not subject to the Standards. However, all fabrics intended for sleepwear meeting the tight-fitting exception from 16 CFR parts 1615 and 1616 must meet the flammability requirements of 16 CFR part 1610, *Standard for the Flammability of Clothing Textiles*, and 16 CFR part 1611, *Standard for the Flammability of Vinyl Plastic Film*. The Commission also will not require that the presence of the required labels and hangtags for tight-fitting garments be subject to third party testing. This is consistent with the exemption from testing accorded to labeling requirements under the Federal Hazardous Substances Act (see NEWS from CPSC, December 18, 2009 (Release No. 10-083)).

D. *Lifting the Stay of Enforcement of Section 14(a) of the CPSA as to Children’s Sleepwear*

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 children’s sleepwear. On December 28, 2009, the Commission published a notice in the *Federal Register* (74 FR 68588) revising the terms of the stay. The December 28, 2009 notice did not lift the stay with regard to testing and certification of children’s sleepwear because no notice of requirements had been published applicable to the Standards for these products. Since this notice provides such a notice of requirements, it has the effect of lifting the stay with regard to 16 CFR parts 1615 and 1616.

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 in the regulations 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 regulations in 16 CFR parts 1615 and/or 1616. (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> . A true copy, in English, of the accreditation and scope documents demonstrating compliance with the requirements of this notice 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 the third party conformity assessment bodies whose accreditations it has accepted and the scope of each accreditation. Subject to the limited provisions for acceptance of “retrospective” testing noted in part IV below, once the Commission adds a third party conformity assessment body to that list, the third party conformity assessment body may commence testing of children’s products to support the manufacturer’s certification that the product complies with the regulations 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 10 percent or more. While the Commission is not addressing common parentage of a third party conformity assessment body and a children’s product manufacturer at this time, it will be vigilant to see 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 which have been accredited in the same nation;
- 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 registration and acceptance 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 and the type of accreditation it is seeking, as well as electronic copies of its ILAC-MRA accreditation certificate and scope statement and its firewalled third party conformity assessment body training document(s), if applicable.

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-controlled 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 ultimately may seek acceptance as a firewalled third party conformity assessment body also initially can request acceptance as a third party conformity assessment body accredited for testing of children's products other than those of its owners.) If the Commission accepts a staff recommendation to accredit a firewalled conformity assessment body, the Commission will issue an order making the required statutory findings, and the firewalled conformity assessment body then will be added to the CPSC's list of accredited third party conformity assessment bodies. In each case, the Commission will notify the third party conformity assessment body electronically of acceptance of its accreditation. All information to support an accreditation acceptance request must be provided in the English language.

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

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

The Commission will accept a certificate of compliance with 16 CFR part 1615 and/or 16 CFR part 1616 based on testing performed by an accredited third party conformity assessment body (including a government-owned or government-controlled

conformity assessment body, or a firewalled conformity assessment body) prior to the Commission's acceptance of its accreditation if all the following conditions are met:

- When the product was tested, the testing was done by a third party conformity assessment body that at that time was ISO/IEC 17025 accredited by an ILAC-MRA signatory and the scope of the accreditation included the regulations specified in this notice. For firewalled conformity assessment bodies, the Commission will not accept a certificate of compliance based on testing performed by the third party conformity assessment body unless the firewalled conformity assessment body was accredited by order as a firewalled conformity assessment body before the product was tested, even though the order will not have included the test methods in the regulations specified in this notice.
- The third party conformity assessment body's application for testing using the test methods in the regulations identified in this notice is accepted by the CPSC on or before [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].
- The product was tested on or after [INSERT DATE 1 YEAR PRIOR TO PUBLICATION] with respect to the regulations identified in this notice.
- The test results show compliance with the applicable current standards and/or regulations.
- The third party conformity assessment body's accreditation remains in effect from the date of testing through the effective date for mandatory third party testing and manufacturer certification for conformity with 16 CFR parts 1615 and/or 1616.

Dated: _____, 2010

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.



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

This document has been electronically
approved and signed.

Memorandum

Date: October 27, 2010

TO : The Commission
Todd Stevenson, Secretary

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

FROM : Patricia K. Adair
Director, Division of Combustion and Fire Sciences
Directorate for Engineering Sciences

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

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

SUBJECT : Accreditation Requirements for Third Party Conformity Assessment Bodies to
Test the Flammability of Children's Sleepwear as Required by the Consumer
Product Safety Improvement Act of 2008

I. Introduction

On August 14, 2008, the Consumer Product Safety Improvement Act of 2008 (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,¹ 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

¹ Section 14(f)(1) of the Consumer Product Safety Act ("CPSA"), 15 U.S.C.2063(f)(1), 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."

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.² Section 235 of the Act defines "children's product" to mean a consumer product designed or intended primarily for children 12 years of age or younger.

The CPSIA defines a third party testing laboratory as one that, except as otherwise provided (discussed below), is not owned, managed, or controlled by the manufacturer or private labeler of a product assessed by such testing laboratory.³ A laboratory that is so owned, managed, or controlled may nevertheless, in certain specified circumstances, be accredited as a third party testing laboratory. The Act specifies that a third party testing laboratory may also include a government owned or controlled laboratory under certain conditions.

Special provisions are established in the Act for laboratories that are owned 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, finds that the laboratory has established procedures to ensure that its test results are 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's order 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 referred to 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.

² On November 18, 2008, the Commission published a final rule, 16 CFR part 1110, that limits the parties who must certify to the importer and, in the case of domestically produced products, the manufacturer. The rule also specifies the requirements that an electronic certificate must meet.

³ The notices of requirements published previously for other children's product safety rules have not required laboratories be firewalled where a manufacturer or private labeler has an ownership interest in the laboratory of less than 10 percent. The staff recommends that this also apply to the notice of requirements applicable to the standards for the flammability of children's sleepwear. This 10 percent or greater criterion is also used by the Federal Communications Commission (47 CFR § 1.2112) as the criterion for potential control by an affiliated business entity.

This memorandum presents the Consumer Product Safety Commission (CPSC) staff's recommendation for establishing accreditation requirements for laboratories wanting to test products for compliance to the regulations for the flammability of children's sleepwear (using an approach that is similar to that approved by the Commission for laboratory accreditation requirements for the lead paint, crib, pacifier, and small parts regulations; children's metal jewelry; and other children's products). The method for testing the flammability of children's sleepwear is in 16 CFR part 1615, *Standard for the Flammability of Children's Sleepwear: Sizes 0 Through 6X (FF 3-71)*, and 16 CFR part 1616 *Standard for the Flammability of Children's Sleepwear: Sizes 7 Through 14 (FF 5-74)*. The Standards provide a test method to determine the flammability of children's sleepwear and include requirements for fabric or related material intended or promoted for use in children's sleepwear. Children's sleepwear and fabric or related material intended or promoted for use in children's sleepwear subject to third party testing under the CPSIA constitute any children's sleepwear and fabric or related material intended or promoted for use in children's sleepwear designed or intended primarily for children 12 years of age or younger. CPSC staff believes that children age 12 and younger wear apparel in sizes through 14.

Children's sleepwear means any product of wearing apparel size 0 through 14, such as nightgowns, pajamas, or similar or related items, such as robes, intended to be worn primarily for sleeping or activities related to sleeping; infant garments (defined in 16 CFR §1615.1(c); and "tight-fitting garments," as defined by §§ 1615.1(c) and 1616.2(m).

Scope and Summary of 16 CFR parts 1615 and 1616

The Standards were issued in the early 1970's to reduce the unreasonable risk of burn injuries and deaths from fires associated with children's sleepwear. Most children's burn incidents do not occur while children are sleeping but while they are awake, unsupervised, and wearing sleepwear. The primary hazard is ignition of sleepwear by contact with hot surfaces and/or small open flame ignition sources, such as stove elements, matches, and lighters. The Standards require that children's sleepwear and fabric intended for such sleepwear stop burning when the flame source is removed. The Standards are not intended to protect children from burns during larger-scale fires, such as structure fires or outdoor fires, or from fires involving flammable liquids.

The original children's sleepwear Standard (16 CFR part 1615) was revised in 1972 to include a statistical sampling plan for fabrics and garments. The sampling plan was devised to give assurance to manufacturers that sleepwear garments reaching the marketplace meet the flammability test and that children would be given increased protection:

"By providing as part of the testing procedure in the children's sleepwear standard a statistically based sampling plan for fabrics and garments, children can be given increased protection. This proposed sampling plan would also provide a framework for premarket testing, and thus assist greatly in detecting non-complying fabrics and garments before they are placed on the market."⁴

⁴ 37 FR 7628 (April 18, 1972). Department of Commerce. Children's Sleepwear Proposed Sampling Plan.

To meet the requirements of the Standards, children's sleepwear must meet the following criteria stated below and in § 1615.3(b) and § 1616.3(b):

- (1) the average char length of the sample does not exceed 17.8 cm (7.0 in), and
- (2) no individual specimen has a char length of 25.4 cm (10 in).

In 1996, the Commission published amendments to the Standards that except products of wearing apparel from the definition of sleepwear for the purposes of testing to the flammability requirements of the Standards if they are:

- (1) size 9 months and smaller;
- (2) a one-piece garment that does not exceed 64.8 cm (25.75 inches) in length or a two-piece garment that has no piece exceeding 40 cm (15.75 inches) in length;
- (3) compliant with all the applicable requirements of the Standard for the Flammability of Clothing Textiles (16 CFR part 1610 and the Standard for the Flammability of Vinyl Plastic Film (16 CFR part 1611); and
- (4) tight-fitting as defined in § 1615.1(o) and § 1616.2(m), provided the garment is labeled with its size and provided with a specified warning statement on a hangtag attached to the garment and on a label on any package in which the garment is sold.

Requirements of the Standards and Test Overview

Children's sleepwear garments subject to the Standards must follow specific sampling plans and be tested for flammability performance at several stages of manufacturing. The Standards have performance requirements for fabric, prototypes (seams and trims), and garments in production (garment production units). There are recordkeeping requirements at each stage of testing. Fabric, garment designs, and garments are accepted or rejected at each stage of production. The following summarizes the three stages of testing:

- (1) Fabric Testing. Fabrics that are promoted for use in children's sleepwear are tested in the finished state (either original state or after one laundering) and may be tested after fifty launderings⁵ (wash and dry). A Fabric Production Unit (FPU) is any quantity of fabric up to 5,000 linear yards, or 10,000 yards for Reduced Sampling, which has a specified identity that remains unchanged throughout the unit except for color and print pattern as specified in the Standards. Samples are taken from the beginning and end of the FPU.
- (2) Prototype Testing. Once a garment design is proposed, all seams and trims are tested to assess the flammability of the preproduction construction and assure that all design characteristics are acceptable. All seam types are tested. Trims are sewn on to the fabric and tested in the orientation they will be used in the final garment; however, neckline, shoulder, and sleeve trim are tested only in the vertical configuration (the most severe scenario).
- (3) Production testing. Units of production, or Garment Production Units, are "accepted or rejected on an individual unit basis" as they are produced. Garment Production Unit (GPU) testing is carried out to assess the flammability of the production garment. The

⁵ If the fabric is not tested after 50 launderings, then the garments must be laundered 50 times and then the fabric is tested.

longest seam type is tested at this stage. Tests are conducted on each GPU. The maximum number of garments in a GPU is 500 dozen (6,000 garments).

Staff Recommendations for Third Party Testing

The sampling plans in the Standards provide manufacturers with a framework for premarket testing at three stages, two of which (fabric testing and prototype testing) occur before garment construction. At the production stage, all seam types in the garment are tested during production, and failures at this juncture are generally due to inappropriate thread selection and poor seam construction. The purpose of the sampling plan in the Standards is to provide confidence to manufacturers that they are producing compliant children's sleepwear, and as noted above, to give children increased protection from burn injuries when wearing sleepwear. The fabric, the design, or the finished garment will be accepted or rejected at any stage of production.

Staff recommends that third-party testing at each stage of the sampling plans specified in the Standards. A manufacturer certifying compliance based on third party testing must follow the sampling plans for fabrics and garments in the Standards since those sampling plans define the probability of acceptance, and therefore compliance, to the high degree of statistical confidence required by the Standard. As the Standard is currently written, tests at less than all three stages cannot assure compliance to the requirements of the Standard because the Standard has acceptance or rejection criteria identified at all three stages. The tests of seams and trim at the prototype and production stages will not necessarily detect fabric that would fail the fabric test. The prototype test for seams will not detect any differences in the seams in the production garments. Similarly, tests at less than the sampling frequency specified in the Standard will not provide the same probability of acceptance to the statistical significance required by the Standard. All recordkeeping requirements, including maintaining tested specimens, would remain in effect.

In addition, staff recommends that the Commission not require third party testing to demonstrate that a product meet the exception for "tight-fitting garments" as defined by §§ 1615.1(c) and 1616.2(m), as these garments are not subject to the flammability Standards. All fabrics intended for sleepwear meeting the tight-fitting exception from 16 CFR part 1615 and 1616 must meet the flammability requirements of 16 CFR part 1610 *Standard for the Flammability of Clothing Textiles*. The staff also recommends that the presence of the required labels and hangtags for tight-fitting garments not be subject to third party testing. This would be consistent with the exemption from certification to labeling requirements under the Federal Hazardous Substances Act.⁶

II. Categories of Laboratories and Proposed Requirements

There are some accepted terms used to describe conformity assessment, depending on who conducts the assessment. Third party conformity assessment testing is testing that, except as

⁶ December 18, 2009. Press Release No. 10-083. CPSC Extends the Stay of Enforcement on Testing and Certification Requirements for Many Children's Products. <http://www.cpsc.gov/cpspub/prere1/prhtml10/10083.html>

otherwise provided, 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 are often considered to be third party laboratories. First party conformity assessment testing is 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 a signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (ILAC-MRA) (see Appendix A for more details), any of these types of laboratories can be accredited to ISO/IEC 17025. Under the ISO/IEC 17025 accreditation, conformity assessment testing laboratories (independent (third party), proprietary (first party), and governmental laboratories) must have arrangements to ensure that their management and personnel are free from any undue internal and external commercial, financial, and other pressures and influences that may adversely affect the quality of their work.

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

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

The Act specifies that a laboratory owned, managed, or controlled by a manufacturer or private labeler may request Commission accreditation to test its own products. If such laboratory desires to test products for other manufacturers the extra requirements outlined below do not apply. 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 accreditation of third party conformity assessment bodies may be conducted either by the Commission or by an independent accreditation organization designated by the Commission.

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. The staff recommends that the Commission consider ISO/IEC 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 the criteria related to undue influence.

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

Government Owned Laboratories

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

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

CPSC 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 and they meet the conditions outlined above. CPSC staff will engage the governmental entities relevant to any accreditation requests to obtain the necessary assurances.

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

The staff recommends that the Commission implement a process by which a third party laboratory must submit documentation to the CPSC that demonstrates adherence to the proposed accreditation requirements. The process for independent third party laboratories requires five steps. Firewalled laboratories and laboratories owned or controlled in whole or in part by a government must provide additional information, and firewalled laboratories must go through the additional step of approval by Commission order. The five steps of the process are:

1. All types of laboratories (third party, firewalled, governmental, combinations) submit an application and supporting documents to CPSC staff.
2. Commission staff reviews the ISO/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 by *all* applicants in Step 1 above for CPSC approval to perform certification testing must include:

1. An ISO/IEC 17025 accreditation certificate issued by an ILAC-MRA signatory accrediting body.
2. An ILAC-MRA accrediting body statement of scope that clearly identifies the regulations, requirements, and/or test methods for which accreditation is sought (the test method for the flammability of children's sleepwear is in 16 CFR part 1615 *Standard for the Flammability of Children's Sleepwear: Sizes 0 Through 6X (FF 3-71)* and 16 CFR part 1616 *Standard for the Flammability of Children's Sleepwear: Sizes 7 Through 14 (FF 5-74)*).
3. A disclosure of ownership interests, including:

- a. ten percent or more ownership 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.

IV. Proposed Lifting of the Stay of Enforcement with Respect to the Testing and Certification of the Flammability of Children's Sleepwear and Fabric or Related Material Intended or Promoted for Use in Children's Sleepwear

In the *Federal Register* of February 9, 2009 (74 FR 6396), the Commission announced that it would stay its enforcement with respect to certain testing and certification requirements in sections 14(a)(1), (a)(2), and (a)(3) of the Consumer Product Safety Act (CPSA), as amended by section 102 of the CPSIA.

In brief, sections 14(a)(1), (a)(2), and (a)(3) of the CPSA establish testing and certification requirements for most consumer products regulated by or under the statutes enforced by the Commission, including children's products.

Section 14(a)(1) of the CPSA requires every manufacturer of a product (and the private labeler of such product if such product bears a private label) that is subject to a consumer product safety rule under the CPSA, or a similar rule, ban, standard, or regulation under any other law enforced by the Commission, and which is imported for consumption or warehousing or distributed in commerce, to issue a certificate. The manufacturer must certify, based on a test of each product or upon a reasonable testing program, that the product complies with all rules, bans, standards, or regulations applicable to the product under the CPSA or any other law enforced by the Commission. The certificate must specify each such rule, ban, standard, or regulation applicable to the product.

For children's products, section 14(a)(2) of the CPSA states that, before importing for consumption or warehousing or distributing in commerce any children's product that is subject to a children's product safety rule, the manufacturer (and the private labeler if the children's product bears a private label) must submit sufficient samples of the children's product, or samples that are identical in all material respects to the product, to a CPSC-recognized third party conformity assessment body accredited under section 14(a)(3) of the CPSA ("recognized third party test laboratory"). The recognized third party test laboratory must test the children's product for compliance with such children's product safety rule. Based on the testing, the manufacturer (or private labeler) must issue a certificate that certifies that the children's product complies with the children's product safety rule based on the assessment of a recognized third party laboratory accredited to conduct such tests.

Section 14(a)(3)(A) of the CPSA states that the third party testing requirement applies to any children's product manufactured more than 90 days after the Commission has established and published a "notice of requirements" for the accreditation of third party conformity assessment bodies to assess conformity with a children's product safety rule.

On December 28, 2009, the Consumer Product Safety Commission announced its decision to revise the terms of its stay of enforcement of certain testing and certification provisions of section 14 of the CPSA as amended by section 102(a) of the CPSIA.⁷ In the decision, the Commission stated its intent to require testing and certification of certain children's products once it completes the rulemakings associated with the products, issues notices of requirements, or otherwise resolves the issues that have warranted a continuation of the stay of enforcement for the products.

Under section 14(a)(3)(A) of the CPSA, Commission approval of these accreditation requirements will make effective the third party testing and certification requirement to assess conformity with the children's product safety rules listed in section I for children's sleepwear and fabric or related material intended or promoted for use in children's sleepwear manufactured more than 90 days (the 91st day becoming the effective date for third party testing and certification) after the Commission has established and published a "notice of requirements" for the accreditation of third party conformity assessment bodies. 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, section 14(a)(3)(F) of the CPSA provides that the Commission may extend the deadline for certification by not more than 60 days.

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

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 established their own processes for third party testing to demonstrate conformity with certain mandatory and voluntary safety standards. Some of these systems may already dictate testing by third party laboratories that are accredited by an ILAC-MRA signatory in accordance with ISO/IEC 17025. It is possible that some products in the marketplace have already undergone testing earlier than the mandatory effective date (to be established by the Commission) in a way that would support certification with the subject products' respective safety standards or regulations.

For certifications of the flammability of children's sleepwear and fabric or related material intended or promoted for use in children's sleepwear, the staff recommends that the Commission allow certifications to be based upon prior testing under certain conditions. Specifically, the staff proposes that the Commission accept a certificate of compliance to the subject regulations based on testing performed by an accredited third party conformity assessment body (including a government-owned or -controlled conformity assessment body, or a firewalled conformity assessment body) if:

1. 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 at the

⁷ <http://www.cpsc.gov/businfo/frnotices/fr10/stay.html>

time of the test. For firewalled conformity assessment bodies, the firewalled conformity assessment body must be one that the Commission accredited by order at or before the time the product was tested, even though the order will not have included the test methods specified in part I of this document. 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 for 16 CFR parts 1615 and/or 1616 is accepted by the CPSC within 60 days of publication of these laboratory accreditation requirements in the *Federal Register*;
3. 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) identified earlier in part I of this document;
4. The test results show compliance with the applicable current standards and regulations; and
5. The third party conformity assessment body's accreditation remains in effect from the date of testing through the effective date for mandatory third party testing and manufacturer/private labeler certification for the subject products' respective regulations.

The staff proposes that the Commission accept children's sleepwear and fabric or related material intended or promoted for use in children's sleepwear certifications if the product⁸ was tested on or after one year prior to the date of publication of these laboratory accreditation requirements in the *Federal Register* by a laboratory whose application is accepted by the CPSC within 60 days of such publication of laboratory accreditation requirements. This policy would allow for certification of products on the basis of testing performed relatively recently by an accredited third party laboratory, thereby providing a substantial degree of assurance of compliance with the Standard. Under this approach, firms that already were getting products tested voluntarily by competent laboratories will not have to submit those same products for retesting. This approach also may help prevent testing backlogs at accredited laboratories, making it less likely that the Commission will need to postpone the effective date for certification. Manufacturers and private labelers that did not already utilize third party testing, or that based their certifications on test dates prior to the test issue dates listed above, would need to conduct third party testing by a CPSC-accepted laboratory to be able to certify products manufactured on or after the effective date.

The staff recommends that governmental laboratories be treated like 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 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 within 60 days of publication of these laboratory accreditation requirements in the *Federal Register*, testing by that laboratory conducted on or after the dates listed above can be used to support third party certification to the requirements for the subject products' respective regulations.

⁸ 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 staff recommends that laboratories owned 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) will need to consider carefully the fact that proprietary laboratories also will need to meet the conditions for firewalled conformity assessment bodies as required by the Act. If the CPSC accepts accreditation of a firewalled laboratory for testing to the Standards described in part I of this memo within 60 days of publication of these laboratory accreditation requirements in the *Federal Register*, testing by that laboratory conducted on or after the dates listed above, provided that the firewalled conformity assessment body has been accredited by order at or before the time the product was tested, can be used to support third party certification to the requirements for the subject products' respective regulations.

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

VII. Recommended Effective Date

The staff recommends that the requirements for accreditation for third party laboratories to test products for compliance with the regulations for children's sleepwear and fabric or related material intended or promoted for use in children's sleepwear 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.

VIII. Staff Recommendation for Accreditation Requirements for Third Party Laboratories to Test the Flammability of Children's Sleepwear and Fabric or Related Material Intended or Promoted for Use in Children's Sleepwear

The staff recommends that the Commission approve the staff's proposed approach for accepting accreditation of laboratories to test for compliance with the regulations for the flammability of children's sleepwear and fabric or related material intended or promoted for use in children's sleepwear. The staff recommends that the Commission approve publishing the accreditation acceptance requirements in a *Federal Register* (FR) notice as drafted by the Office of the General Counsel. The FR notice would establish the requirements for laboratories to become accredited to test for compliance with the regulations for children's sleepwear and fabric or related material intended or promoted for use in children's sleepwear.

Appendix A

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

The term “conformity assessment” describes a variety of activities that can be used to demonstrate that specified requirements relating to a product are fulfilled. This broad term is often used to describe distinct activities, such as testing, inspection, certification, as well as the accreditation of conformity assessment bodies. [Ref. 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, 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 bodies 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. [Ref. 2] ISO/IEC 17025 addresses factors relevant to a laboratory’s ability to

produce precise and 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 involvement with 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. [Ref. 3]

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

ISO/IEC 17011

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

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

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

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

Other provisions in the Standard include specifications for document control, internal audits and management reviews, preventative actions, analysis of findings and reports, and appeals processing. [Ref. 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, Germany, and the United States have three or more MRA signatory accrediting bodies.⁹

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 based on mutual evaluation and acceptance of each other's laboratory accreditation systems. Each partner in such an arrangement recognizes the other partners' accredited laboratories as if they themselves had undertaken the accreditation of the other partners' laboratories. [Ref. 5]

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

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
- [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