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

This document has been electronically approved and signed.

THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.

A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON: July 6, 2011

June 29, 2011

TO: The Commission
Todd A. Stevenson, Secretary

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

FROM: Philip L. Chao, Assistant General Counsel
Jan S. Carlson, General Attorney

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

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 toys pursuant to ASTM International's *Standard Consumer Safety Specification for Toy Safety*, F 963-08, and section 4.27 from ASTM F 963-07ε1 (toy chests), which are the consumer product safety standards for toys pursuant to section 106 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110-314.

Please indicate your vote on the following options.

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

_____ _____
(Signature) (Date)

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

_____

_____

_____

_____ _____
(Signature) (Date)

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

Billing Code CPSC-6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

CPSC Docket No. CPSC-2011-[INSERT]

Third Party Testing for Certain Children's Products; Toys: 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," "Commission," or "we") 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 ASTM International's (formerly the American Society for Testing and Materials) ("ASTM") Standard Consumer Safety Specification for Toy Safety, F 963-08 ("ASTM F 963-08"), and section 4.27 (toy chests) from ASTM International's F 963-07ε1 version of the standard ("ASTM F 963-07ε1"), which are the consumer product safety standards for toys, pursuant to section 106 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110-314. 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 ASTM F 963-08 and/or section 4.27 of ASTM F 963-07ε1 are effective upon publication of this notice in the *Federal Register*.

FOR FURTHER INFORMATION CONTACT: Richard McCallion, Team Leader for the Mechanical, Recreation, and Sports Program Area, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; e-mail RMcCallion@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 14(a)(3)(B)(vi) of the CPSA, as added by section 102(a)(2) of the CPSIA, 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 toys, pursuant to ASTM F 963-08, and for testing toy chests, pursuant to section 4.27 of ASTM F 963-07ε1. ASTM F 963-08 and section 4.27 of ASTM F 963-07ε1 are voluntary standards, but under section 106(a) of the CPSIA, they have become mandatory federal requirements, "except for section 4.2 and Annex 4 [of ASTM F 963], or any provision that restates or incorporates an existing mandatory standard or ban promulgated by the Commission or by statute." Readers may obtain a copy of ASTM F 963-08 and/or ASTM F 963-07ε1 from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA, 19428-2959; (610)-832-9500; www.astm.org.

Section 106(a) of the CPSIA states that, beginning 180 days after August 14, 2008—the date the CPSIA was enacted—ASTM F 963-07 shall be considered a consumer product safety standard issued by the Commission under section 9 of the CPSA. Under section 106(g) of the CPSIA, when ASTM proposes to revise ASTM F 963, it must notify the Commission of the proposed revision. The revised standard will be considered the consumer product safety standard effective 180 days after the date on which ASTM notified the

Commission of the revision, unless the Commission objects within the first 90 days of the 180-day period. If the Commission determines that the proposed revision does not improve the safety of a consumer product, the Commission can notify ASTM that the already-existing standard will continue to be considered the consumer product safety standard.

ASTM proposed F 963-08 as a revised standard in February 2009, and on May 13, 2009, the Commission voted to accept F 963-08 as the consumer safety standard for toys, except the revision omitting section 4.27 related to toy chests, which the Commission retained from the previous version of F 963 (ASTM F 963-07ε1). Accordingly, ASTM F 963-08 and section 4.27 of ASTM F 963-07ε1 (toy chests) are considered consumer product safety standards issued by the Commission under section 9 of the CPSA.

We note that ordinarily, when the Commission bases a mandatory requirement on a voluntary standard, we incorporate the voluntary standard by reference, in accordance with the rules of the Office of the Federal Register. See 1 CFR part 51. However, in this instance, ASTM F 963 became a consumer product safety standard by operation of law, rather than by an act of the Commission. See Public Law No. 110-314 § 106(a), (g). Therefore the Commission does not need to incorporate ASTM F 963 by reference.

We also note that certain provisions of ASTM F 963-08 and section 4.27 of ASTM F 963-07ε1 will not be subject to third party testing and therefore we will not be accepting accreditations to those excepted sections. The exceptions are as follows:

- Those sections of ASTM F 963-08 that address products outside the Commission's jurisdiction (*e.g.*, cosmetics).

- Those sections of ASTM F 963-08 that pertain to the manufacturing process and thus, cannot be evaluated meaningfully by a test of the finished product (*e.g.*, the purified water provision at section 4.3.6.1).
- Requirements for labeling, instructional literature, or producer's markings in ASTM F 963-08 or section 4.27 of ASTM F 963-07ε1. We have taken similar positions in other contexts. For example, the Commission has stated that it will not require testing and certification to the labeling requirements under the Federal Hazardous Substances Act, 15 U.S.C. 1261–1278. See 74 FR 68588, 68591 (Dec. 28, 2009) (Notice of Commission Action on the Stay of Enforcement of Testing and Certification Requirements). We also do not require third party testing for the labeling requirements for children's sleepwear under the Flammable Fabrics Act, 15 U.S.C. 1191-1204. See 75 FR 70911, 70913 (Nov. 19, 2010) (Third Party Testing for Certain Children's Products; Children's Sleepwear, Sizes 0 Through 6X and 7 Through 14: Requirements for Accreditation of Third Party Conformity Assessment Bodies).
- Those sections of ASTM F 963-08 that involve assessments that are conducted by the unaided eye and without any sort of tool or device.
- Section 4.3.8 of ASTM F 963-08, pertaining to a specific phthalate, because section 108 of the CPSIA specifically addresses phthalates and will be the subject of a separate notice of requirements.

In sum, the Commission will only require certain provisions of ASTM F 963-08 and Section 4.27 of ASTM F 963-07ε1 to be subject to third party testing and therefore we will

only accept the accreditation of third party conformity assessment bodies for testing under the following toy safety standards:

- ASTM F 963-07ε1
  - Section 4.27 - Toy Chests (except labeling and/or instructional literature requirements)

- ASTM F 963-08
  - Section 4.3.5.2, Surface Coating Materials – Soluble Test for Metals
  - Section 4.3.6.3, Cleanliness of Liquids, Pastes, Putties, Gels, and Powders (except for cosmetics and tests on formulations used to prevent microbial degradation)
  - Section 4.3.7, Stuffing Materials
  - Section 4.5, Sound Producing Toys
  - Section 4.6, Small Objects (except labeling and/or instructional literature requirements)
  - Section 4.7, Accessible Edges (except labeling and/or instructional literature requirements)
  - Section 4.8, Projections
  - Section 4.9, Accessible Points (except labeling and/or instructional literature requirements)
  - Section 4.10, Wires or Rods
  - Section 4.11, Nails and Fasteners
  - Section 4.12, Packaging Film
  - Section 4.13, Folding Mechanisms and Hinges
  - Section 4.14, Cords, Straps, and Elastics
  - Section 4.15, Stability and Overload Requirements
  - Section 4.16, Confined Spaces
  - Section 4.17, Wheels, Tires, and Axles
  - Section 4.18, Holes, Clearances, and Accessibility of Mechanisms
  - Section 4.19, Simulated Protective Devices (except labeling and/or instructional literature requirements)
  - Section 4.20.1, Pacifiers with Rubber Nipples/Nitrosamine Test
  - Section 4.20.2, Toy Pacifiers
  - Section 4.21, Projectile Toys
  - Section 4.22, Teethers and Teething Toys
  - Section 4.23.1, Rattles with Nearly Spherical, Hemispherical, or Circular Flared Ends
  - Section 4.24, Squeeze Toys
  - Section 4.25, Battery-Operated Toys (except labeling and/or instructional literature requirements)
  - Section 4.26, Toys Intended to Be Attached to a Crib or Playpen (except labeling and/or instructional literature requirements)
  - Section 4.27, Stuffed and Beanbag-Type Toys

- Section 4.30, Toy Gun Marking
- Section 4.32, Certain Toys with Spherical Ends
- Section 4.35, Pompoms
- Section 4.36, Hemispheric-Shaped Objects
- Section 4.37, Yo-Yo Elastic Tether Toys
- Section 4.38, Magnets (except labeling and/or instructional literature requirements)
- Section 4.39, Jaw Entrapment in Handles and Steering Wheels

We note that the ASTM toy safety standards cover toys intended for use by children under 14 years of age. See, *e.g.*, section 1.3 of ASTM F 963-08. However, only "children's products" are required to be third party tested in support of the children's product certificate required by section 14(a)(2) of the CPSA. Section 3(a)(2) of the CPSA defines "children's product," to mean, inter alia, "a consumer product designed or intended primarily for children 12 years of age or younger." To the extent that there are products subject to ASTM F 963-08 and/or section 4.27 of ASTM F 963-07ε1 that are not "children's products," as that term is defined in the CPSA, such products do not need to be third party tested in support of the certification required by section 14 of the CPSA.

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 safety standards 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"; however, 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 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 are "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 clear references to those sections of ASTM F

963-08 and/or 4.27 of ASTM F 963-07ε1 identified earlier in part I of this document for which the third party conformity assessment body seeks CPSC acceptance.

(Descriptions of the history and content of the ILAC-MRA approach and of the requirements of the ISO/IEC 17025:2005 laboratory accreditation standard are 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.

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 those covered by the safety standards in ASTM F 963. On December 28, 2009 the Commission published a notice in the *Federal Register* (74 FR 68588) revising the terms of the stay. One section of the December 28, 2009 notice addressed "Consumer Products or Children's Products Where the Commission Is Continuing the Stay of Enforcement Until Further Notice," due to factors such as pending rulemaking proceedings affecting the product or the absence of a notice of requirements. The ASTM F 963 testing and certification requirements were included in that section of the December 28, 2009 notice. The absence of a notice of requirements prevented the testing and certification stay from being lifted with regard to toys under ASTM F 963;

therefore, publication of this notice has the effect of lifting the stay with regard to ASTM F 963.

Accordingly, each manufacturer of a children's product covered by F 963-08 and/or section 4.27 of ASTM F 963-07ε1 (toy chests) must have any such product manufactured after [INSERT DATE 90 DAYS AFTER PUBLICATION IN FEDERAL REGISTER] tested by a third party conformity assessment body accredited to do so and must issue a certificate of compliance with applicable sections of ASTM F 963-08 and/or section 4.27 of ASTM F 963-07ε1 based on that testing. (Under the CPSA, the term "manufacturer" includes anyone who manufactures or imports a product.)

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 one or more of the ASTM F 963 toy standards 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 references to one or

more of the following sections of ASTM F 963-08, Standard Consumer Safety Specification for Toy Safety, and/or 4.27 of ASTM F 963-07ε1, the consumer product safety standard for toy chests:

- ASTM F 963-07ε1
  - Section 4.27 - Toy Chests (except labeling and/or instructional literature requirements)

- ASTM F 963-08
  - Section 4.3.5.2, Surface Coating Materials – Soluble Test for Metals
  - Section 4.3.6.3, Cleanliness of Liquids, Pastes, Putties, Gels, and Powders (except for cosmetics and tests on formulations used to prevent microbial degradation)
  - Section 4.3.7, Stuffing Materials
  - Section 4.5, Sound Producing Toys
  - Section 4.6, Small Objects (except labeling and/or instructional literature requirements)
  - Section 4.7, Accessible Edges (except labeling and/or instructional literature requirements)
  - Section 4.8, Projections
  - Section 4.9, Accessible Points (except labeling and/or instructional literature requirements)
  - Section 4.10, Wires or Rods
  - Section 4.11, Nails and Fasteners
  - Section 4.12, Packaging Film
  - Section 4.13, Folding Mechanisms and Hinges
  - Section 4.14, Cords, Straps, and Elastics
  - Section 4.15, Stability and Overload Requirements
  - Section 4.16, Confined Spaces
  - Section 4.17, Wheels, Tires, and Axles
  - Section 4.18, Holes, Clearances, and Accessibility of Mechanisms
  - Section 4.19, Simulated Protective Devices (except labeling and/or instructional literature requirements)
  - Section 4.20.1, Pacifiers with Rubber Nipples/Nitrosamine Test
  - Section 4.20.2, Toy Pacifiers
  - Section 4.21, Projectile Toys
  - Section 4.22, Teethers and Teething Toys
  - Section 4.23.1, Rattles with Nearly Spherical, Hemispherical, or Circular Flared Ends
  - Section 4.24, Squeeze Toys
  - Section 4.25, Battery-Operated Toys (except labeling and/or instructional literature requirements)

- Section 4.26, Toys Intended to Be Attached to a Crib or Playpen (except labeling and/or instructional literature requirements)
- Section 4.27, Stuffed and Beanbag-Type Toys
- Section 4.30, Toy Gun Marking
- Section 4.32, Certain Toys with Spherical Ends
- Section 4.35, Pompoms
- Section 4.36, Hemispheric-Shaped Objects
- Section 4.37, Yo-Yo Elastic Tether Toys
- Section 4.38, Magnets (except labeling and/or instructional literature requirements)
- Section 4.39, Jaw Entrapment in Handles and Steering Wheels

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 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 children's products to support the manufacturer's certification that the product complies with the applicable toy safety standards 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 in the same nation who have been accredited;
- The third party conformity assessment body's testing results are accorded no greater weight by other governmental authorities than those of other accredited third party conformity assessment bodies; and
- The third party conformity assessment body does not exercise undue influence over other governmental authorities on matters affecting its operations or on decisions by other governmental authorities controlling distribution of products based on outcomes of the third party conformity assessment body's conformity assessments.

The Commission will accept the accreditation of a governmental third party conformity assessment body if it meets the baseline accreditation requirements of part II.A of this document above, and meets the additional conditions stated here. To obtain this assurance, CPSC staff will engage the governmental entities relevant to the accreditation request.

III. How Does a Third Party Conformity Assessment Body Apply for Acceptance of Its Accreditation?

The Commission has established an electronic accreditation acceptance and registration system accessed via the Commission's Internet site at: http://www.cpsc.gov/about/cpsia/labaccred.html. The applicant provides, in English, basic identifying information concerning its location, the type of accreditation it is seeking, and electronic copies of its accreditation certificate and scope statement from its ILAC-MRA

signatory accreditation body, and firewalled third party conformity assessment body training document(s), if relevant.

Commission staff will review the submission for accuracy and completeness. In the case of baseline third party conformity assessment bodies and government-owned or government-operated conformity assessment bodies, when that review and any necessary discussions with the applicant are satisfactorily completed, the third party conformity assessment body in question is added to the CPSC's list of accredited third party conformity assessment bodies at: http://www.cpsc.gov/about/cpsia/labaccred.html. In the case of a firewalled conformity assessment body seeking accredited status, when staff's review is complete, staff transmits its recommendation on accreditation to the Commission for consideration. (A third party conformity assessment body that may ultimately seek acceptance as a firewalled third party conformity assessment body also can initially request acceptance as a third party conformity assessment body accredited for testing of children's products other than those of its owners.) If the Commission accepts a staff recommendation to accredit a firewalled conformity assessment body, the firewalled conformity assessment body will 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

children's products to support certification of compliance with the applicable toy safety standards identified earlier in part I of this document for which it has been accredited.

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

The Commission will accept a certificate of compliance with the applicable sections of Standard Consumer Safety Specification for Toy Safety, F 963-08 and/or section 4.27 (toy chests) from ASTM F 963-07ε1 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) before the Commission's acceptance of its accreditation if:

- 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 accreditation body that is a signatory to the ILAC-MRA. 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 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;

- The third party conformity assessment body's application for testing to the toy standard section(s) under which the test(s) was conducted is accepted by the CPSC on or before [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER];
- With regard to tests conducted under F 963-08, the product was tested to the applicable section(s) on or after May 13, 2009; with regard to tests conducted under section 4.27 of F 963-07ε1, the product was tested on or after August 14, 2008;
- The accreditation scope in effect for the third party conformity assessment body at the time of testing expressly included testing to the toy standard section(s) under which the test(s) was conducted;
- The test results show compliance with the applicable current toy standards; and
- The third party conformity assessment body's accreditation, including inclusion in its scope of the toy standard section(s) under which the test(s) was conducted, remains in effect through the effective date for mandatory third party testing and manufacturer certification for conformity with ASTM F 963-08 and/or section 4.27 of ASTM F 963-07ε1.

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: June 29, 2011

TO : The Commission
Todd Stevenson, Secretary

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

FROM : Richard McCallion
Mechanical, Recreational, and Sports Program Area Team Leader
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 Toys to ASTM F 963-08 and section 4.27 (toy chests) of ASTM F 963-07ε1 as Required by the Consumer Product Safety Improvement Act of 2008

I. Introduction

On August 14, 2008, the Consumer Product Safety Improvement Act (hereafter referred to as the "Act" or the "CPSIA") was signed into law [Public Law 110-314]. Section 102 of the Act mandates that third party testing be conducted for certain children's products. Before importing for consumption or warehousing or distributing in commerce any children's product that is subject to a children's product safety rule, every manufacturer of such children's product (and the private labeler of such children's product if such product bears a private label) shall: (A) submit sufficient samples of the children's product, or samples that are identical in all material respects, to a third party conformity assessment body (hereafter referred to as a third party testing laboratory) accredited under requirements to be established by the Commission to be tested for 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.[1] Section 235 of the Act defines "children's

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

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. A laboratory that is so owned, managed, or controlled, nevertheless, in certain specified circumstances, may be accredited as a third party testing laboratory. The Act specifies that a third party testing laboratory may also include a government-owned or -controlled laboratory under certain conditions.

Special provisions are established in the Act for laboratories that are owned, managed, or controlled by a manufacturer or private labeler. Such laboratories are commonly referred to as proprietary laboratories or "first party" laboratories. The Act stipulates that the Commission may accredit a proprietary laboratory as a third party testing laboratory if the Commission, by order, 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 also must 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.

Section 106 of the CPSIA establishes the provisions of the ASTM International *Standard Consumer Safety Specification for Toy Safety*, F 963, as federal consumer product safety standards, "except for section 4.2 and Annex 4, or any provision that restates or incorporates an existing mandatory standard or ban promulgated by the Commission or by statute." F 963 was formerly a voluntary standard for the purpose of providing safety requirements for toys. It is applicable to a large and diverse population of products that are defined as toys. The Commission voted in May 2009 to accept the F 963-08 revision of F 963 as the consumer safety standard, except the revision omitting section 4.27, related to toy chests, which the Commission retained from the previous version of F 963 (ASTM F 963-07ε1).

ASTM F 963 Accreditation

This memorandum presents U.S. Consumer Product Safety Commission (CPSC) staff's recommendation for establishing the criteria and process for Commission acceptance of accreditation of laboratories for testing toys pursuant to ASTM F 963-08, and section 4.27 of ASTM F 963-07ε1 (toy chest safety provisions). Staff is recommending an approach that is

similar to that approved by the Commission for laboratory accreditation requirements for the lead paint, crib, pacifier, rattles, and small parts regulations; children's metal jewelry; and other children's products.

For a third party conformity assessment body to be CPSC-accepted to test toys pursuant to ASTM F 963 standards, it must be accredited to ISO/IEC 17025-2005, *International Standard – General Requirements for the Competence of Testing and Calibration Laboratories*, by an accreditation body that is a signatory to the ILAC-MRA, and the accreditation must be accepted by the Commission. A listing of ILAC-MRA signatory accreditation bodies is available on the Internet at: http://ilac.org/membersbycategory.html.

The scope of the accreditation must include clear references that the laboratory is accredited for each of the provisions of ASTM F 963-08 and/or section 4.27 of ASTM F 963-07ε1 for which the third party conformity assessment body requests CPSC acceptance.

ASTM F 963 covers requirements and contains test methods for toys intended for use by children under 14 years of age. However, the CPSIA's third party testing requirements apply to children's products subject to a children's product safety rule, and as noted above, the CPSIA defines a children's product as one designed or intended primarily for children 12 years of age or younger. Therefore the CPSIA's third party testing requirement applies to a large subset, but not all, of the toys covered by F 963. Toys intended for consumers under age 14 that are subject to F 963 but are not children's products requiring third party testing under the CPSIA, will still be required to have a general conformance certificate.

CPSC Acceptance of ASTM F 963 Requirements

Staff recommends that certain provisions of ASTM F 963-08 and section 4.27 of ASTM F 963-07ε1 not be subject to third party testing. First, staff recommends that the Commission except from third party testing those sections of ASTM F 963-08 that address products outside the Commission's jurisdiction (*e.g.*, cosmetics). Staff also recommends excepting from third party testing, the sections of ASTM F 963-08 that pertain to the manufacturing process and thus cannot be evaluated meaningfully by a test of the finished product (*e.g.*, the purified water provision at section 4.3.6.1). We also recommend that the ASTM F 963-08 section addressing a particular phthalate in pacifiers, rattles, and teethers be excepted from third party testing because section 108 of the CPSIA specifically addresses phthalates, including the one referenced in F 963, and will be the subject of a separate notice of requirements.

Staff also recommends that the Commission not require third party testing to requirements for labeling, instructional literature, or producer's markings in ASTM F 963-08 or section 4.27 of ASTM F 963-07ε1. The Commission has taken similar positions in other contexts. For example, the Commission stated that it will not require testing and certification to the labeling requirements under the Federal Hazardous Substances Act, 15 U.S.C. 1261–1278. See 74 FR 68588, 68591 (Dec. 28, 2009) (Notice of Commission Action on the Stay of Enforcement of Testing and Certification Requirements). The Commission also does not require third party testing for the labeling requirements for children's sleepwear under the Flammable Fabrics Act, 15 U.S.C. 1191–1204. See 75 FR 70911, 70913 (Nov. 19, 2010) (Third Party Testing for Certain Children's Products; Children's Sleepwear, Sizes 0 Through 6X and 7 Through 14: Requirements for Accreditation of Third Party Conformity Assessment Bodies). Finally, staff

recommends excepting those sections of ASTM F 963-08 that involve assessments conducted by the unaided eye and without any sort of tool or device.

Specifically, third party conformity assessment bodies can request CPSC acceptance for the following sections of ASTM F 963-08 and F 963-07ε1:

- ASTM F 963-07ε1
  - Section 4.27 - Toy Chests (except labeling and/or instructional literature requirements)

- ASTM F 963-08
  - Section 4.3.5.2, Surface Coating Materials – Soluble Test for Metals
  - Section 4.3.6.3, Cleanliness of Liquids, Pastes, Putties, Gels, and Powders (except for cosmetics and tests on formulations used to prevent microbial degradation)
  - Section 4.3.7, Stuffing Materials
  - Section 4.5, Sound Producing Toys
  - Section 4.6, Small Objects (except labeling and/or instructional literature requirements)
  - Section 4.7, Accessible Edges (except labeling and/or instructional literature requirements)
  - Section 4.8, Projections
  - Section 4.9, Accessible Points (except labeling and/or instructional literature requirements)
  - Section 4.10, Wires or Rods
  - Section 4.11, Nails and Fasteners
  - Section 4.12, Packaging Film
  - Section 4.13, Folding Mechanisms and Hinges
  - Section 4.14, Cords, Straps, and Elastics
  - Section 4.15, Stability and Overload Requirements
  - Section 4.16, Confined Spaces
  - Section 4.17, Wheels, Tires, and Axles
  - Section 4.18, Holes, Clearances, and Accessibility of Mechanisms
  - Section 4.19, Simulated Protective Devices (except labeling and/or instructional literature requirements)
  - Section 4.20.1, Pacifiers with Rubber Nipples/Nitrosamine Test
  - Section 4.20.2, Toy Pacifiers
  - Section 4.21, Projectile Toys
  - Section 4.22, Teethers and Teething Toys
  - Section 4.23.1, Rattles with nearly spherical, hemispherical, or circular flared ends
  - Section 4.24, Squeeze Toys
  - Section 4.25, Battery-Operated Toys (except labeling and/or instructional literature requirements)
  - Section 4.26, Toys Intended to Be Attached to a Crib or Playpen (except labeling and/or instructional literature requirements)
  - Section 4.27, Stuffed and Beanbag-Type Toys
  - Section 4.30, Toy Gun Marking
  - Section 4.32, Certain Toys with Spherical Ends

- Section 4.35, Pompoms
- Section 4.36, Hemispheric-Shaped Objects
- Section 4.37, Yo-Yo Elastic Tether Toys
- Section 4.38, Magnets (except labeling and/or instructional literature requirements)
- Section 4.39, Jaw Entrapment in Handles and Steering Wheels

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 the product. Independent commercial laboratories and governmental laboratories are often considered to be third party laboratories. "First party conformity assessment testing" is defined as testing performed by the person or organization that provides the product (*e.g.*, a manufacturer owned laboratory that conducts testing of its own product).

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

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

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

The Act specifies that a laboratory owned or controlled by a manufacturer or private labeler may request Commission accreditation. The Commission may accredit 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 safeguards against undue influence are in place. Staff recommends that the Commission consider ISO/IEC 17025 accreditation by an ILAC-MRA signatory among the criteria for firewalled laboratories to meet the CPSIA requirements for equal or greater consumer safety and the requirements related to undue influence.

For a proprietary laboratory to be considered under the firewalled provision, staff also 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 more 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 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 that demonstrates adherence to the proposed accreditation requirements. The process for independent third party laboratories requires five steps. Firewalled laboratories and laboratories that are 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 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* by an ILAC-MRA signatory accreditation body;
2. an ILAC-MRA accreditation body *statement of scope* that clearly identifies the applicable version and specific sections of ASTM F 963 for which the laboratory is accredited (as listed earlier in Section I of this memorandum);
3. a *disclosure* of ownership interests, including:
    a. 10 percent or more ownership[2] by manufacturers or private labelers of children's products subject to the safety requirements for which the laboratory is applying to certify; and,
    b. whole or partial government interest, including indirect ownership or control through government ownership of interests in any partners of the laboratory.

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

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

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

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

Staff's recommended accreditation approach uses and builds upon existing systems of conformity assessment based on ISO/IEC standards and internationally recognized accreditation bodies. In the field of children's products, some manufacturers, importers, and/or retailers have implemented 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.

The Commission will accept a certificate of compliance to ASTM F 963 for toys based on testing performed by an accredited third party conformity assessment body (including a government-owned conformity assessment body, a government controlled conformity assessment body, and a firewalled conformity assessment body) if:

- 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 accreditation body that is a signatory to the ILAC-MRA. 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 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;

- The third party conformity assessment body's application for testing to the toy standard section under which the test was conducted is accepted by the CPSC within 60 days of publication of these laboratory accreditation requirements in the *Federal Register*;

- The product was tested on or after May 13, 2009, with respect to one or more of the toy standard sections in ASTM F 963-08 included in this notice.

- The product was tested on or after August 14, 2008, with respect to section 4.27 in ASTM F 963-07ε1 included in this notice.

- The accreditation scope in effect for the third party conformity assessment body at the time of testing expressly included testing to the toy standard section under which the test was conducted;

- The test results show compliance with the applicable current standards; and

- The third party conformity assessment body's accreditation, including inclusion in its scope, the standards described in part I of this notice, remains in effect through the effective date for mandatory third party testing and manufacturer certification for conformity with ASTM F 963-08 and section 4.27 from ASTM F 963-07ε1.

This policy would allow certification of products on the basis of testing performed since ASTM F 963-08 and section 4.27 from ASTM F 963-07ε1 became consumer product safety standards 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 by competent laboratories voluntarily will not be required to have those products retested. 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.[3] Manufacturers and private labelers that did not use third party testing already, or that based their certifications on test dates prior to the test issue date listed above, would need to conduct third party testing by a CPSC-accepted laboratory to certify products manufactured on or after the effective date.

Staff recommends that governmental laboratories be treated similarly to other third party laboratories with respect to certifications based on testing prior to the effective date. Nonetheless, manufacturers and private labelers will need to consider carefully the fact that governmental laboratories also will need to meet the conditions for governmental entities, as required by the Act. If the CPSC accepts accreditation of a governmental laboratory 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 date listed above (if all other retrospective testing criteria satisfied) can be used to support third party certification to the requirements of the listed sections of F 963.

Staff recommends that laboratories owned by a manufacturer or private labeler be treated similarly to other third party laboratories with respect to certifications based on testing prior to the effective date. Nonetheless, manufacturers and private labelers (or other parties who seek product certification) will need to consider carefully the fact that manufacturer-owned laboratories also will need to meet the conditions for firewalled conformity assessment bodies, as required by the Act. If the CPSC accepts accreditation of a firewalled laboratory for testing to the ASTM F 963 section under which the test was conducted within 60 days of publication of these laboratory accreditation requirements in the *Federal Register*, testing by that laboratory conducted on or after May 13, 2009, can be used to support third party certification to the requirements of the listed sections of F 963.

[3] 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.

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 alter that expectation. Therefore, staff does not expect such requirements to have any negative environmental impact.

VI. Recommended Effective Date

Staff recommends that the requirements for accreditation for third party laboratories to test for compliance with the mandatory standards for toys become effective upon publication of notice thereof in the *Federal Register*. Publication in the *Federal Register* is typically the means by which the public is formally advised of the activation of new mandatory requirements.

VII. Staff Recommendation for Accreditation Requirements for Third Party Laboratories to Test Toys

Staff recommends that the Commission approve staff's proposed approach for accepting accreditation of laboratories to test for compliance with ASTM F 963-08 and Section 4.27 (toy chests) from ASTM F 963-07ε1.

Staff recommends that the Commission approve publishing the accreditation acceptance requirements in a *Federal Register* (FR) notice 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 mandatory standards for toys.

Appendix A

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

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

In the context of this memorandum 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 toy safety standards 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/IEC) and the International Electrotechnical Commission (IEC) provide 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/IEC 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.

<u>ISO/IEC 17025</u>

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 testing in accordance with mandatory standards, voluntary standards, or other types of testing regimes. A laboratory's certificate of accreditation includes the statement of scope for which it is accredited.

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

To ensure continued compliance, accredited laboratories are re-examined 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 nations' accreditation bodies. The peer evaluation process provides assurance that accreditation bodies are operating in accordance with the 17011 standard. The standard provides specifications for accreditation body procedures for conducting laboratory assessments and also provides the procedures for the peer evaluation of operations among accreditation bodies.

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

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

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

International Laboratory Accreditation Cooperation (ILAC)

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

There are more than 60 ILAC-MRA signatory accreditation 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 accreditation body. Some countries have more than one accreditation organization. For example, Japan and the United States have three or more MRA signatory accreditation bodies.[4]

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

ILAC's uniform approach, based on ISO/IEC standards, allows countries to establish agreements based on mutual evaluation and acceptance of each other's laboratory accreditation systems. Each partner in such an arrangement recognizes the other partner's accredited laboratories as if they had undertaken the accreditation of the other partner's laboratories themselves.[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/IEC 9001? www.aclasscorp.com

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

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

[5] www.ilac.org

[4] The following link, http://ilac.org/membersbycategory.html contains a complete list of ILAC-MRA accrediting bodies.