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

This document has been electronically approved and signed.

BALLOT VOTE SHEET

DATE: August 4, 2010

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Kenneth R. Hinson, Executive Director
Cheryl A. Falvey, General Counsel
Philip L. Chao, Assistant General Counsel

FROM: Harleigh P. Ewell, Attorney, OGC

SUBJECT: Third Party Testing for Certain Children's Products; Youth All-Terrain Vehicles: Requirements for Accreditation of Third Party Conformity Assessment Bodies

Ballot Vote Due: August 11, 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 youth all-terrain vehicles for compliance with 16 C.F.R. part 1420.

Please indicate your vote on the following options.

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

_____ _____
(Signature) (Date)

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; Youth All-Terrain Vehicles: 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 Part 1420

Third Party Testing for Certain Children's Products; Youth All-Terrain Vehicles: 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 all-terrain vehicles (ATVs) designed or intended primarily for children 12 years of age or younger pursuant to 16 CFR part 1420, the CPSC regulations under the Consumer Product Safety Act (CPSA) relating to ATVs. 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 part 1420 are effective upon publication of this notice in the *Federal Register*.

Comments in response to this notice of requirements should be submitted by [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Comments on this notice should be captioned "Third Party Testing for Certain Children's Products; All-Terrain Vehicles: Requirements for Accreditation of Third Party Conformity Assessment Bodies."

ADDRESSES: You may submit comments, identified by Docket No. CPSC-2010-00__, by any of the following methods:

Electronic Submissions: Submit electronic comments in the following way:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (e-mail) except through http://www.regulations.gov.

Written Submissions: Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions) preferably in five copies, to: Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, Maryland 20814; telephone (301) 504-7923.

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

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

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

FOR FURTHER INFORMATION CONTACT: Richard McCallion, Program Area Team Leader, Office of Hazard Identification and Reduction, U.S. Consumer Product Safety Commission,10901 Darnestown Road, Gaithersburg, MD 20878; 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 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, as added by section 102(b) of the CPSIA).

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 can be found in part IV of this document below.

This notice provides the criteria and process for Commission acceptance of accreditation of third party conformity assessment bodies for testing pursuant to 16 CFR part 1420, *Requirements for All Terrain Vehicles*, which incorporates by reference the applicable provisions of the *American National Standard for Four Wheel All-Terrain Vehicles, ANSI/SVIA 1-2007*. 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 or younger." Although all-terrain vehicles (ATVs) are often for general use (that is, not produced specifically for use by children), some "youth ATVs" are "designed or

intended primarily for children 12 years of age or younger." The ANSI/SVIA 1-2007 standard identifies a usage category of Y (Youth Model) ATVs that consists of three subcategories: (a) Category Y-6+, for youth model ATVs intended for use by children age 6 or older; (b) Category Y-10+, for youth model ATVs intended for use by children age 10 or older; and (c) Category Y-12+, for youth model ATVs intended for use by children age 12 or older. For the purposes of this notice of requirements, the term "youth ATVs" refers to categories Y-6+ and Y-10+ in ANSI/SVIA 1-2007. Although Category Y-12+ is intended for children age 12 or older, the Commission has no information showing that Category Y-12+ ATVs are intended *primarily* for children age 12 or younger, which would be necessary for Category Y-12+ to be children's products subject to the third party testing and certification requirements in section 14(a)(2) of the CPSA. However, in determining whether a particular ATV is a children's product subject to the third party testing and certification requirements of section 14(a)(2) of the CPSA, the Commission will follow the factors set forth in section 3(a)(2) of the CPSA and will not rely solely on a statement by the manufacturer about the ATV's intended use.

The CPSC also recognizes that section 14(a)(3)(B)(vi) of the CPSA is captioned "All Other Children's Product Safety Rules," but the body of the statutory requirement refers only to "other children's product safety rules." Nevertheless, section 14(a)(3)(B)(vi) of the CPSA could be construed as requiring a notice of requirements for "all" other children's product safety rules, rather than a notice of requirements for "some" or "certain" children's product safety rules. However, whether a particular rule represents a "children's product safety rule" may be subject to interpretation, and the Commission staff is continuing to evaluate which rules, regulations, standards, or bans

are “children’s product safety rules.” The CPSC intends to issue additional notices of requirements for other rules which the Commission determines to be “children’s product safety rules.” This notice of requirements, however, relates only to all-terrain vehicles.

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 all-terrain vehicles to the requirements of 16 CFR part 1420 where the test results will be used as the basis for a certification that ATVs comply with CPSC’s requirements at 16 CFR 1420. 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.

The Commission requires baseline accreditation of each category of third party conformity assessment bodies 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 accrediting body that is a signatory to the International Laboratory Accreditation Cooperation-Mutual Recognition Arrangement (ILAC-MRA),

and the scope of the accreditation must include testing in accordance with the regulations identified earlier in part I of this document for which the third party conformity assessment body seeks to be accredited by the CPSC. (A description of the history and content of the ILAC-MRA approach and of the requirements of the ISO/IEC 17025:2005 laboratory accreditation standard is provided in the CPSC staff briefing memorandum "Third Party Conformity Assessment Body Accreditation Requirements for Testing Compliance with 16 CFR Part 1501 (Small Parts Regulations)," dated November 2008 and available on the CPSC's Web site at http://www.cpsc.gov/library/foia/foia09/brief/smallparts.pdf .)

The Commission has established an electronic accreditation registration and listing system that can be accessed via its 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 ATVs.[1] On December 28, 2009, the Commission published a notice in the *Federal Register* (74 FR 68588) revising the terms of the stay. Section II.G of the December 28, 2009, notice stated "[t]he Commission has not yet issued a notice of accreditation requirements for . . . ATVs so no third-party certificates will be required until 90 days after the Commission issues such [a] notice[ ] of requirements." As the factor preventing the stay from being lifted in the December 28, 2009 notice with regard to testing and certifications of ATVs was the absence of a notice of requirements, publication of this notice has the effect of lifting the stay with regard to 16 CFR part 1420.

[1] Two mandatory certification requirements relating to ATVs were not stayed. *See* 74 FR at 68592.

This notice of requirements is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Further, as the publication of this notice of requirements effectively lifts the stay of enforcement with regard to testing and certifications related to 16 CFR part 1420, each manufacturer of a youth ATV subject to 16 CFR part 1420 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. Further, for youth ATVs manufactured after [INSERT DATE 90 DAYS AFTER PUBLICATION IN FEDERAL REGISTER], the manufacturer must issue a certificate of compliance with 16 CFR part 1420 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, added by section 102(a)(2) of the CPSIA (15 U.S.C. 2063(a)(3)(G)).

II. Accreditation Requirements

A. Baseline Third Party Conformity Assessment Body Accreditation Requirements

For a third party conformity assessment body to be accredited to test children's products for conformity with the test methods 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 part 1420, *Requirements for All Terrain Vehicles*. 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, the type of accreditation it is

seeking, and electronic copies of its ILAC-MRA accreditation certificate and scope statement, and firewalled third party conformity assessment body training document(s), if 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 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 Commission will issue an order making the required statutory findings and the firewalled conformity assessment body will then be added to the CPSC's list of accredited third party conformity assessment bodies. In each case, the Commission will notify the third party conformity assessment body electronically of acceptance of its accreditation. All information to support an accreditation acceptance request must be provided in the English language.

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 1420, *Requirements for All Terrain Vehicles*, 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. 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 November 4, 2008 (the date that 16 CFR part 1420 was published), with respect to the regulations identified 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 regulations identified earlier in part I of this document.
- The test results show compliance with the applicable current standards and/or regulations; 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 16 CFR part 1611.

Dated: _____, 2010.

_____

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: August 4, 2010

TO : The Commission
Todd Stevenson, Secretary

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

FROM : Richard McCallion
Mechanical-Recreational 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 Youth ATVs 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]

[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 web site at http://www.cpsc.gov/businfo/frnotices/fr09/certification.pdf

Generally, under the CPSIA, a third party testing laboratory is one that is not owned, managed, or controlled by the manufacturer or private labeler of a product assessed by such testing laboratory. A laboratory that is so owned, managed, or controlled may 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 government-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 firewalled third party testing laboratory if the Commission by order makes certain findings including that the laboratory is protected from undue influence by the manufacturer or private labeler and that provisions are in place for immediate and confidential reporting to the Commission of any attempts by the manufacturer or other interested party to hide or exert undue influence over test results.

The Act provides that accreditation of third party testing laboratories may be conducted either by the Commission or by an independent accreditation organization designated by the Commission, and requires that the Commission maintain on its web site an up-to-date list of laboratories that have been accredited to assess conformity with children's product safety rules. Readers who may not be familiar with the Commission-approved process in previous phases of the agency's implementation of the CPSIA may refer to Appendix A for background information on independent accreditation organizations that have been previously designated by the Commission.

This memorandum presents the CPSC staff's recommendation for establishing accreditation requirements (using an approach that is similar to that approved by the Commission for laboratory accreditation requirements for the lead paint, crib, pacifier, and small parts regulations, children's metal jewelry, and other children's products) for laboratories wanting to ascertain the compliance of youth ATVs to the Commission's requirements at 16 CFR 1420. "Youth ATVs" are defined as the products falling within the scope of 16 CFR 1420 that are likely to be purchased primarily for children 12 years old and younger.

The test methods for youth ATVs are described in 16 CFR 1420, which incorporates by reference the applicable provisions of the American National Standard for Four Wheel All-Terrain Vehicles, ANSI/SVIA 1-2007.

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 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 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 Mutual Recognition Arrangement (ILAC-MRA) (see Appendix A for more details) signatory accrediting body, 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 accrediting signatory body serve as the baseline criterion for CPSC acceptance of <u>any</u> laboratory (e.g., commercial third party, governmental, or manufacturer owned). The staff also recommends certain additional criteria as directed by the CPSIA, depending on the type of laboratory.

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

The Act specifies that a laboratory owned, managed, 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. 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 those related to undue influence.

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

The 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 would require

five steps (firewalled laboratories and laboratories that are owned or controlled in whole or in part by a government require an additional step):

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 explained in Section II above).
3. Staff makes a decision to approve or disapprove the application, or staff may request more information.
    a. For firewalled laboratories, staff may request more information and then make 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 web site (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 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:
    a. For youth ATVs, the scope document must cite 16 CFR 1420.
3. A *disclosure* of ownership or controlling interests, including:
    a. ten 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.

If the applicant seeks approval as 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

[2] This ten percent or greater criterion is also used by the Federal Energy Regulatory Commission [Standards of Conduct for Transmission Providers, Order No. 2004, 105 FERC P61,248 at 62,299 (2003)] and the Federal Communications Commission [47 C.F.R. section 1.2112] as the criterion for potential control by an affiliated business entity.

exert undue influence over test results can be immediately and confidentially reported to the Commission.

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

The staff's recommended accreditation approach utilizes and builds upon existing systems of conformity assessment based on ISO/IEC standards and internationally recognized accrediting bodies. In the field of children's products, some manufacturers, importers, and/or retailers have put in place their own processes for third party testing to demonstrate conformity with certain mandatory and voluntary safety standards. 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 youth ATVs, the staff recommends that the Commission allow certifications to be based on prior testing under certain conditions. Specifically, the staff proposes that the Commission accept certifications if:

1. the product[3] was tested by a laboratory that was ISO/IEC 17025 accredited by an ILAC-MRA signatory accrediting body at the time of the test;
2. the laboratory's application is accepted by CPSC at least 30 days prior to the date that the Commission terminates the current stay of enforcement for the testing and certification requirements that was originally announced in the Federal Register on February 9, 2009 (74 FR 6396) for youth ATVs;
3. the product was tested on or after the date of publication of 16 CFR 1420 in the Federal Register (Nov. 14, 2008);
4. the accreditation scope in effect for the laboratory at the time of the test expressly included the applicable test methods in the list above; and
5. the test results show compliance with the applicable *current* standards and regulations.

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 who were already voluntarily getting products tested by competent laboratories will not have to have those same products retested. This approach also may help prevent testing backlogs at accredited laboratories, making it less likely that the Commission will have to postpone the effective date for certification.[4] Manufacturers and private labelers that did not already utilize third party

[3] The CPSIA requires that certification be based on testing of sufficient samples of the product, or samples that are identical in all material respects to the product.

[4] In accordance with the CPSIA, if the Commission determines that an insufficient number of third party laboratories have been accredited to permit certification for a children's product safety rule under the Act's accreditation schedule, the Commission may extend the deadline for certification to such rule by not more than 60 days.

testing, or that based their certifications on test dates prior to Nov. 14, 2008, would need to conduct third party testing by a CPSC recognized laboratory in order 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 acceptance by the Commission of the governmental laboratory's accreditation. 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 by at least 30 days prior to the date that the Commission terminates the current stay of enforcement for the testing and certification requirements for youth ATVs, testing by that laboratory conducted on or after that date can be used to support third party certification to the requirements for the subject product's regulation.

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 acceptance by the Commission of the firewalled laboratory's accreditation. 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 by at least 30 days prior to the date that the Commission terminates the current stay of enforcement for the testing and certification requirements for youth ATVs, testing by that laboratory conducted on or after the date of publication of the mandatory regulations can be used to support third party certification to the requirements for the subject products' respective regulations.

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

VI. Recommended Effective Date

The staff recommends that the requirements for accreditation for third party laboratories to test for compliance with the mandatory regulations for youth ATVs 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 Youth ATVs

The staff recommends that the Commission approve the staff's proposed approach for accepting accreditation of laboratories to test for compliance with the mandatory regulations for youth ATVs in 16 CFR 1420.

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 (provided separately under restricted cover). The FR notice would establish the requirements for laboratories to become accredited to test for compliance with the mandatory regulations for youth ATVs. In addition, the FR notice would solicit comments from interested parties on the established approach for laboratory accreditation associated with the subject products and on the overall approach for accreditation.

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 to the Commission on accreditation, "third party conformity assessment body" is synonymous with "third party testing laboratory." For proposed CPSC requirements for accreditation of testing laboratories, the CPSC staff recommends allowing certain testing laboratories to test products for compliance with the requirements established by the Code of Federal Regulations if they belong to recognized accreditation organizations.

The rapidly growing global demand for conformity assessment entities that can facilitate the acceptance of products across nations' borders has resulted in the establishment of international organizations and the development of international standards related to all aspects of conformity assessment. The International Laboratory Accreditation Cooperation (ILAC) was formed in 1977 to promote international acceptance of test results performed by accredited laboratories. A series of standards developed by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) provides specifications for organizations that conduct conformity assessment activities. The ISO/IEC is a specialized system for worldwide standardization. Technical committees comprised of members from across the globe (including the United States) collaborate to develop these conformity assessment standards to facilitate acceptance of testing results between countries. These standards were developed expressly to be used by accreditation bodies that have entered into mutual recognition arrangements (MRAs) with equivalent bodies in other countries. The most relevant ISO/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 such items as testing in accordance with mandatory standards, voluntary standards, or other types of testing regimes. A laboratory's certificate of accreditation includes the statement of scope for which it is accredited.

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

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

ISO/IEC 17011

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

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

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

The standard requires that an accreditation body be a registered legal entity. A governmental accreditation body is deemed to be a legal entity on the basis of its governmental status. A government is responsible for identifying the accreditation body in such a way that there is no conflict of interest with governmental conformity assessment bodies (such as 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 over 60 ILAC-MRA signatory accrediting bodies located throughout the world. This includes MRA signatory organizations in Australia, Canada, China, many countries in the European Union, Japan, Mexico, the United States and several other countries. Many countries have one ILAC-MRA signatory accrediting body. Some countries have more than one accrediting organization. For example, Japan, Germany, and the United States have three or more MRA signatory accrediting bodies.[5]

The evaluation of an accreditation body to establish its qualifications to be a signatory involves a team of peers (generally senior staff of experienced accreditation bodies) who conduct evaluations in accordance with ISO/IEC 17011. The evaluations include audits at the headquarters 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 themselves had undertaken the accreditation of the other partner's laboratories. [5]

References

[1] ISO/IEC 17000:2004 Conformity Assessment – Vocabulary and General Principles.

[2] White paper: Should Laboratories be Accredited to ISO/IEC 17025 or Certified to ISO/IEC 9001? www.aclasscorp.com

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

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

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

[5] www.ilac.org