The contents of this document will be discussed at the Commission Meeting/ Briefing scheduled for March 21, 2012.

**UNITED STATES**
**CONSUMER PRODUCT SAFETY COMMISSION**
**BETHESDA, MD 20814**

This document has been electronically approved and signed.

**A DECISION MEETING ON THIS MATTER IS SCHEDULED ON: April 4, 2012**

**DATE:** March 14, 2012

**TO:** The Commission
Todd A. Stevenson, Secretary

**THROUGH:** Kenneth R. Hinson, Executive Director

**FROM:** Cheryl A. Falvey, General Counsel
David M. DiMatteo, Attorney, OGC

**SUBJECT: Proposed Rule: Requirements Pertaining to Third Party Conformity Assessment Bodies**

The Office of the General Counsel is providing for Commission consideration the attached draft proposed rule. It would establish the requirements pertaining to third party conformity assessment bodies that test children's products for the purpose of the certification required by section 14(a)(2) of the Consumer Product Safety Act (CPSA), as amended by section 102(a) of the Consumer Product Safety Improvement Act of 2008 (CPSIA). In addition, the proposed rule would establish the general requirements concerning third party conformity assessment bodies, such as the requirements and procedures for CPSC acceptance of the accreditation of a third party conformity assessment body, and it would address adverse actions against CPSC-accepted third party conformity assessment bodies. The proposed rule also would amend the audit requirements for third party conformity assessment bodies, and it would amend the Commission's regulation on inspections at 16 CFR § 1118.2(a).

Please indicate your vote on the following options:

I. Approve publication of the proposed rule in the *Federal Register*.

_____ _____
(Signature) (Date)



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II. Approve publication of the proposed rule in the *Federal Register,* with changes. (Please specify.)

_____

_____

_____

_____ _____
(Signature) (Date)

III. Do not approve publication of the proposed rule in the *Federal Register*.

_____ _____
(Signature) (Date)

IV. Take other action. (Please specify.)

_____

_____

_____

_____ _____
(Signature) (Date)

Attachments: Draft Final Rule titled, "Requirements Pertaining to Third Party Conformity Assessment Bodies"; Briefing Memorandum from Randy Butturini and DeWane J. Ray, Office of Hazard Identification and Reduction, to the Commission and Todd Stevenson, titled, "Requirements Pertaining to Third Party Conformity Assessment Bodies."



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Billing Code CPSC-6355-01-P

**CONSUMER PRODUCT SAFETY COMMISSION**

**16 CFR Parts 1112 and 1118**

**CPSC Docket No. CPSC-2011-[INSERT]**

**Requirements Pertaining to Third Party Conformity Assessment Bodies**

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Notice of Proposed Rulemaking.

**SUMMARY:** The Consumer Product Safety Commission ("CPSC," "Commission," or "we") is issuing a proposed rule that would establish the requirements pertaining to the third party conformity assessment bodies (or "laboratories") that are authorized to test children's products in support of the certification required by section 14(a)(2) of the Consumer Product Safety Act (CPSA), as amended by section 102(a) of the Consumer Product Safety Improvement Act of 2008 (CPSIA). The proposed rule would establish the general requirements concerning third party conformity assessment bodies, such as the requirements and procedures for CPSC acceptance of the accreditation of a third party conformity assessment body, and it would address adverse actions against CPSC-accepted third party conformity assessment bodies. The proposed rule also would amend the audit requirements for third party conformity assessment bodies and would amend the Commission's regulation on inspections at 16 CFR § 1118.2(a).

**DATES:** Comments related to the Paperwork Reduction Act aspects of the instructional literature and marking requirements of the proposed rule should be directed to the Office of Information and Regulatory Affairs, OMB, Attn: CPSC Desk Officer, FAX: 202-395-6974, or e-mailed to oira_submission@omb.eop.gov. Other comments in response to this notice of proposed rulemaking must be received by [INSERT DATE 75 DAYS AFTER PUBLICATION



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IN THE FEDERAL REGISTER]. **ADDRESSES:** You may submit comments, identified by Docket No. CPSC-2011-[INSERT] 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, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. Do not submit confidential business information, trade secret information, or other sensitive or protected information (such as a Social Security Number) electronically; if furnished at all, such information should be submitted in writing.

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

**FOR FURTHER INFORMATION CONTACT:** Randy Butturini, Project Manager, Office of Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; 301-504-7562; e-mail: RButturini@cpsc.gov.

**SUPPLEMENTARY INFORMATION:**



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## I. Background: Statutory Provisions

Section 14(a)(1) of the CPSA (15 U.S.C. 2063(a)(1)), as amended by the CPSIA (Public Law 110-314, 122 Stat. 3016), requires that the manufacturer and the private labeler, if any, of a product that is subject to an applicable consumer product safety rule under the CPSA, or any similar rule, ban, standard, or regulation under any other Act enforced by the CPSC, issue a General Conformity Certificate. The General Conformity Certificate certifies "based on a test of each product or upon a reasonable testing program, that such product complies with all rules, bans, standards, or regulations applicable to the product under this Act or any other Act enforced by the Commission," and it specifies each rule, ban, standard, or regulation applicable to the product. 15 U.S.C. 2063(a)(1)(A).

Section 14(a)(2) of the CPSA states that, for 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 if the children's product bears a private label) shall submit sufficient samples of the product, or samples that are identical in all material respects to the product, to an accredited third party conformity assessment body (or, "laboratory") to be tested for compliance with such children's product safety rule. Section 14(a)(2)(B) of the CPSA requires the manufacturer or private labeler, based on such testing, to issue a certificate ("Children's Product Certificate") certifying that such product complies with the children's product safety rule. Section 14(h) of the CPSA clarifies that, irrespective of certification, the product in question must actually comply with all applicable rules, regulations, standards, or bans enforced by the CPSC.

Section 14(a)(3) of the CPSA establishes various timelines for accreditation of the laboratories that may conduct third party tests of children's products and requires the Commission to publish "a notice of the requirements for accreditation of third party conformity



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assessment bodies to assess conformity" with specific laws or regulations. Under section 14(a)(3)(A) of the CPSA, the requirement for a manufacturer or private labeler of a children's product subject to a children's product safety rule to issue a certificate based on third party testing does not commence until "more than 90 days" after the Commission publishes a notice of requirements pertaining to the regulation or standard to which the children's product is subject.

The Commission has published several notices of requirements in the *Federal Register. See, e.g.,* 73 FR 54564 (September 22, 2008) (Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity with Part 1303 of Title 16, Code of Federal Regulations); 74 FR 45428 (September 2, 2009) (Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity with Parts 1203, 1510, 1512, and/or 1513 and Section 1500.86(a)(7) and/or (a)(8) of Title 16, Code of Federal Regulations); 75 FR 70911 (November 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). We invited public comment on most, but not all, notices of requirements. In section III of this preamble, we summarize and respond to those comments. Section 14(a)(3)(C) of the CPSA provides that the Commission may either accredit laboratories itself or may designate an independent accreditation organization to conduct the accreditations. Section 14(a)(3)(E) of the CPSA requires that the Commission maintain on its website an up-to-date list of entities that have been accredited to assess conformity with children's product safety rules.

Section 14(i)(1) of the CPSA requires the Commission to establish "requirements for the periodic audit of third party conformity assessment bodies as a condition for the continuing accreditation of such conformity assessment bodies" under section 14(a)(3)(C) of the CPSA.



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Section 14(e) of the CPSA addresses Commission withdrawal and suspension of the accreditation (or its acceptance of the accreditation) of a laboratory.

Section 14(f)(2)(A) of the CPSA defines a "third party conformity assessment body" to mean a conformity assessment body that is not owned, managed, or controlled by the manufacturer or private labeler of a product assessed by the laboratory, unless such a laboratory has satisfied certain statutory criteria. Section 14(f)(2)(D) of the CPSA provides that a laboratory owned, managed, or controlled by a manufacturer or private labeler may be accepted by the Commission if the Commission makes certain findings, by order, concerning the laboratory's protections against undue influence by the manufacturer, private labeler, or other interested parties. In that case the laboratory is considered "firewalled." Similarly, section 14(f)(2)(B) of the CPSA lists five criteria that a conformity assessment body owned or controlled in whole or in part by a government (or "governmental laboratory") must satisfy for its accreditation to be accepted by the CPSC.

This proposed rule, if finalized, would establish the requirements related to CPSC acceptance of the accreditation of a laboratory for purposes of testing children's products under section 14 of the CPSA. The proposed requirements would be largely the same as the requirements that the CPSC has been using since the CPSIA's passage in August 2008. Among other things, the proposed rule also would delineate how a laboratory may voluntarily discontinue its participation with the CPSC, and it would establish the procedures for the suspension and/or withdrawal of CPSC acceptance of the accreditation of a laboratory. This proposed rule also would amend our rule titled, "Audit Requirements for Third Party Conformity Assessment Bodies" ("audit final rule"), which implements section 14(i)(1) of the CPSA, and is



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published elsewhere in this issue of the *Federal Register*. Finally, the proposed rule would make particular conforming amendments to 16 CFR § 1118.2(a).

## II. Background: The CPSC Third Party Conformity Assessment Body Program, to Date

We published 19 notices of requirements between August 14, 2008 and August 14, 2011.

The notices of requirements established the criteria and process for CPSC acceptance of accreditation of laboratories for testing children's products under section 14 of the CPSA. Each notice of requirements was specific to particular CPSC rules, bans, standards, or regulations, and/or it was specific to a standard established by the CPSIA. We have published the following notices of requirements:

- Third Party Testing for Certain Children's Products; Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity With Part 1303 of Title 16, Code of Federal Regulations, 73 FR 54564 (Sept. 22, 2008).
- Third Party Testing for Certain Children's Products; Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity With Part 1508, Part 1509, and/or Part 1511 of Title 16, Code of Federal Regulations, 73 FR 62965 (Oct. 22, 2008).
- Third Party Testing for Certain Children's Products; Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity With Part 1501 of Title 16, Code of Federal Regulations, 73 FR 67838 (Nov. 17, 2008).



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- Accreditation Requirements for Third Party Conformity Assessment Bodies to Test to the Requirements for Lead Content in Children's Metal Jewelry as Established by the Consumer Product Safety Improvement Act of 2008, 73 FR 78331 (Dec. 22, 2008).
- Third Party Testing for Certain Children's Products; Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity With Parts 1203, 1510, 1512, and/or 1513 and Section 1500.86(a)(7) and/or (a)(8) of Title 16, Code of Federal Regulations, 74 FR 45428 (Sept. 2, 2009).
- Third Party Testing for Certain Children's Products; Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity With the Limits on Total Lead in Children's Products, 74 FR 55820 (Oct. 29, 2009).
- Third Party Testing for Certain Children's Products; Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity With Part 1505 and/or § 1500.86(a)(5) of Title 16, Code of Federal Regulations, 75 FR 22746 (April 30, 2010).
- Third Party Testing for Certain Children's Products; Infant Bath Seats: Requirements for Accreditation of Third Party Conformity, 75 FR 31688 (June 4, 2010); correction, 75 FR 33683 (June 15, 2010).
- Third Party Testing for Certain Children's Products; Infant Walkers: Requirements for Accreditation of Third Party Conformity Assessment Bodies, 75 FR 35282 (June 21, 2010).
- Third Party Testing for Certain Children's Products; Carpets and Rugs: Requirements for Accreditation of Third Party Conformity Assessment Bodies, 75 FR 42315 (July 21, 2010).



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- Third Party Testing for Certain Children's Products; Vinyl Plastic Film: Requirements for Accreditation of Third Party Conformity Assessment Bodies, 75 FR 42311 (July 21, 2010).
- Third Party Testing for Certain Children's Products; Mattresses, Mattress Pads, and/or Mattress Sets: Requirements for Accreditation of Third Party Conformity Assessment Bodies, 75 FR 51020 (Aug. 18, 2010).
- Third Party Testing for Certain Children's Products; Clothing Textiles: Requirements for Accreditation of Third Party Conformity Assessment Bodies, 75 FR 51016 (Aug. 18, 2010).
- Third Party Testing for Certain Children's Products; Youth All-Terrain Vehicles: Requirements for Accreditation of Third Party Conformity Assessment Bodies, 75 FR 52616 (Aug. 27, 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, 75 FR 70911 (Nov. 19, 2010).
- Third Party Testing for Certain Children's Products; Full-Size Baby Cribs and Non-Full-Size Baby Cribs: Requirements for Accreditation of Third Party Conformity Assessment Bodies, 75 FR 81789 (Dec. 28, 2010).
- Third Party Testing for Certain Children's Products; Toddler Beds: Requirements for Accreditation of Third Party Conformity Assessment Bodies, 76 FR 22030 (April 20, 2011).



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- Third Party Testing for Certain Children's Products; Toys: Requirements for Accreditation of Third Party Conformity Assessment Bodies, 76 FR 46598 (Aug. 3, 2011).
- Third Party Testing for Certain Children's Products; Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity With the Limits on Phthalates in Children's Toys and Child Care Articles, 76 FR 49286 (Aug. 10, 2011).

The notices of requirements explained the three types of third party conformity assessment bodies contemplated by section 14 of the CPSA: (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 ("independent" laboratories); (2) "firewalled" conformity assessment bodies (those that are owned, managed, or controlled by a manufacturer or private labeler of the children's product); and (3) third party conformity assessment bodies owned or controlled, in whole or in part, by a government ("governmental laboratories").

The notices of requirements have stated that, for a third party conformity assessment body to be accredited to test children's products under section 14 of the CPSA, it must be accredited 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). A listing of ILAC-MRA signatory accreditation bodies is available on the Internet at: http://ilac.org/membersbycategory.html. The



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scope of the laboratory's accreditation must include testing to a specific regulation or test method that has been the subject of a notice of requirements.

(A description of the history and content of the ILAC-MRA approach and of the requirements of the ISO/IEC 17025:2005 laboratory accreditation standard is provided in the CPSC staff briefing memorandum, "Third Party Conformity Assessment Body Accreditation Requirements for Testing Compliance with 16 CFR Part 1501 (Small Parts Regulations)," dated November 2008, and available on the CPSC's website at: http://www.cpsc.gov/library/foia/foia09/brief/smallparts.pdf.)

The notices of requirements have stated that the CPSC maintains on its website an up-to-date listing of laboratories whose accreditation it has accepted, and the scope of each accreditation. Once we add a laboratory to that list, the laboratory may begin testing children's products to any test method or regulation included in the laboratory's scope of accreditation on the CPSC list, to support a Children's Product Certificate.

In addition to the baseline accreditation requirements, the notices of requirements have provided that firewalled laboratories must submit to the CPSC, copies, in English, of their training documents, showing how employees are trained that they may notify the CPSC immediately of any attempt by the manufacturer, private labeler, or other interested party to hide or exert undue influence over the laboratory's test results. Employees also must be trained that their report of alleged undue influence may be reported to the CPSC confidentially. (The notices of requirements stated that firewalled applicants must submit "training documents showing how employees are trained to notify the CPSC immediately and confidentially of any attempt . . . to hide or exert undue influence." To be more consistent with the statute, we are hereby describing this requirement as a need for the firewalled applicant to train employees that they may notify the



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CPSC immediately, and that a report to the CPSC may be confidential. The laboratory must have established procedures to ensure that an employee may report an allegation of undue influence to the CPSC and may do so confidentially. *See* 15 U.S.C. 2063(f)(2)(D)(ii)(III). Submission of training documents evidencing such policies is required. Additionally, the statute imposes a duty on the laboratory to have procedures in place to ensure that the CPSC is notified immediately of any attempt at undue influence, *see* 15 U.S.C. 2063(f)(2)(D)(ii). However, we do not interpret the statute as requiring an individual employee to contact the CPSC. Accordingly, the change in phrasing increases consistency with the statute.) These additional requirements have applied to any laboratory in which a manufacturer or private labeler of a children's product to be tested by the laboratory owns an interest of 10 percent or more.

With regard to governmental laboratories, the notices of requirements have reiterated the five criteria from section 14(f)(2)(B) of the CPSA that must be satisfied for the CPSC to accept the accreditation of a governmental laboratory:

- 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 whose accreditation has been accepted by the CPSC;



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- The third party conformity assessment body's testing results are accorded no greater weight by other governmental authorities than those of other third party conformity assessment bodies whose accreditation has been accepted by the CPSC; 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 notices of requirements have explained that CPSC staff will engage the governmental entities relevant to the accreditation request to obtain assurances that the statutory criteria are satisfied.

The notices of requirements also have explained that we have established an electronic accreditation acceptance and registration system accessed via the CPSC's website site at: http://www.cpsc.gov/about/cpsia/labaccred.html. CPSC Form 223, the application form for laboratories seeking CPSC acceptance of their accreditation, may be accessed, completed, and submitted online. The applicant must provide, in English, basic identifying information concerning its location, the type of accreditation it is seeking, electronic copies of its certificate and scope statement from an ILAC-MRA signatory accreditation body, and firewalled laboratory training document(s), if relevant.

As explained in the notices of requirements, CPSC staff reviews the submission for accuracy and completeness. In the case of independent and governmental laboratories, when that review and any necessary discussions with the applicant are completed, we will add any accepted laboratory to the CPSC's list of accepted laboratories. This list can be found at: http://www.cpsc.gov/about/cpsia/labaccred.html. In the case of a firewalled laboratory, when



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CPSC staff's review is complete, CPSC staff transmits its recommendation on acceptance of accreditation to the Commission (meaning, in this instance, the Commissioners) for consideration. If the Commission accepts a CPSC staff recommendation to accept the accreditation of a firewalled laboratory, we will add the firewalled laboratory to the CPSC's list of accepted laboratories. In each case, we notify the laboratory electronically of our acceptance of its accreditation.

The notices of requirements have become effective on publication, meaning that as soon as the notices of requirements publish, laboratories could apply to the CPSC for acceptance of their accreditation. In most cases, the requirement for a manufacturer or private labeler of a children's product subject to a children's product safety rule to issue a certificate of compliance, based on third party testing with that rule, commences for products manufactured more than 90 days after publication of the notice of requirements that pertains to that rule.

In most cases, the standard or test method specified in a notice of requirements was either already in effect, or became effective upon publication of the notice of requirements. (There were four notices of requirements that published the same day as a final rule establishing the safety standard specified in the notice: the notices of requirements for infant bath seats, infant walkers, cribs, and toddler beds. In those cases, the safety standard took effect six months after publication. *See* 75 FR 31688 (June 4, 2010), correction, 75 FR 33683 (June 15, 2010); 75 FR 35282 (June 21, 2010); 75 FR 81789 (Dec. 28, 2010); 76 FR 22030 (Apr. 20, 2011)). Our approach to third party conformity assessment uses and builds upon existing systems of conformity assessment, based on ISO/IEC standards and internationally recognized accreditation bodies. Some manufacturers of children's products subject to children's product safety rules have put in place their own processes for third party testing to demonstrate conformity with



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certain mandatory and voluntary safety standards. As we were publishing the notices of requirements, we were aware that some manufacturers may already have been testing their products at laboratories that were accredited by an ILAC-MRA signatory accreditation body in accordance with ISO/IEC 17025:2005. Thus, it was possible that when a particular notice of requirements published, some products in the marketplace had already undergone testing (*i.e.*, earlier than the mandatory effective date of third party testing) in a way that would support certification with the respective children's product safety rule(s). Therefore, most notices of requirements included provisions allowing Children's Product Certificates to be based on testing performed by a ISO/IEC 17025:2005-accredited laboratory prior to the CPSC's acceptance of its accreditation. This practice is sometimes referred to as allowing "retrospective" testing. In the notices of requirements, we prescribed particular circumstances under which retrospective testing could support a Children's Product Certificate. For example, we required that the product be tested by a laboratory that was, at the time of product testing, accredited to ISO/IEC 17025:2005 by an ILAC-MRA signatory; the accreditation scope in effect at the time of testing had to include testing to the regulation or test method identified in the notice; and we placed constraints on how far back in time the retrospective testing could have occurred. In several of the initial notices of requirements, we did not allow any retrospective testing by firewalled laboratories. Later, we allowed retrospective testing by firewalled laboratories if the firewalled laboratory had already been accepted by an order of the Commission for testing to a children's product safety rule specified in an earlier notice of requirements.

## III. Comments on the Notices of Requirements and the Commission's Responses



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The Commission has established requirements for accreditation of third party conformity assessment bodies ("laboratories") for certain children's product safety rules in accordance with section 102(a)(2) of the CPSIA. Most notices of requirements provided an opportunity for public comment. Below, we describe and respond to the comments submitted in response to the notices of requirements that published before August 14, 2011. As of August 14, 2011, 17 notices of requirements have been published in the *Federal Register.* Table 1 lists the notices of requirements.

**Table 1: Notices of Requirements Issued with Comments Received**

| **Regulation or Product(s)** | ***Federal Register* citation** | **Regulations.gov Docket Number** |
|---|---|---|
| Part 1303/Lead Paint | 73 FR 54564, (September 22, 2008) (Revision notice at 76 FR 18645 (April 5, 2011)) | CPSC-2008-0033 |
| Parts 1508, 1509, 1511/Full-size cribs, non-full-size cribs, and pacifiers | 73 FR 62965, (October 22, 2008) | CPSC-2008-0038 |
| Part 1501/Small parts | 73 FR 67838, (November 17, 2008) | CPSC-2008-0050 |
| Lead content in children's metal jewelry | 73 FR 78331 (December 22, 2008) | CPSC-2008-0049 |
| Parts 1203,1510, 1512, 1513, sec. 1500.86(a)(7) and (a)(8)/Bicycle helmets, dive sticks, rattles, bicycles, and | 74 FR 45428, (September 2, 2009) | CPSC-2009-0067 |



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| bunk beds | | |
| Total lead in children's (metal and non-metal) products | 74 FR 55820, (October 29, 2009) | CPSC-2009-0090 |
| Part 1505, sec. 1500.86(a)(5)Electrically operated toys/articles and clacker balls | 75 FR 22746, (April 30, 2009) | CPSC-2010-0035 |
| Part 1215/Infant bath seats | 75 FR 31688, (June 4, 1020), (Correction notice at 75 FR 33683 (June 15, 2010)) | CPSC-2010-0064 |
| Part 1216/Infant walkers | 75 FR 35282, (June 21, 2010) | CPSC-2010-0066 |
| Part 1611/Vinyl plastic film | 75 FR 42311 (July 21, 2010) | CPSC-2010-0079 |
| Parts 1630 and 1631/ Carpets and rugs | 75 FR 42315 (July 21, 2010) | CPSC-2010-0078 |
| Part 1610/Clothing Textiles | 75 FR 51016 (August 18, 2010) (Revision notice at 76 FR 22608 (April 22, 2011) | CPSC-2010-0086 |
| Parts 1632 & 1633/ Mattresses, Mattress Pads, and Mattress Sets | 75 FR 51020 (August 18, 2010) Revision notice at 75 FR 72944 (November 29, 2010) | CPSC-2010-0085 |



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| Part 1420/ATVs[1] | 75 FR 52616 (August 27, 2010) (Extension notice at 75 FR 76708 (December 9, 2010) | CPSC-2010-0090 |
| Parts 1615 and 1616/Children's Sleepwear | 75 FR 70911 (November 19, 2010) | None |
| Parts 1219 and 1220/Full-Size Baby Cribs and Non-Full-Size Baby Cribs | 75 FR 81789 (December 28, 2010) | CPSC-2009-0064 |
| Part 1217/Toddler Beds | 76 FR 22030 (April 20, 2011) | CPSC-2009-0064 |
| ASTM F 963-08, and section 4.27 of ASTM F 963-07 for toy chests (CPSIA Section 106) | 76 FR 46598 (August 3, 2011) | CPSC–2011–0050 |
| CPSC–CH–C1001–09.3 | 76 FR 49286 (August 10, 2011) | CPSC-2011-0052 |

A summary of each of the commenters' topics is presented, and each topic is followed by our response. For ease of reading, each comment will be prefaced by a numbered "Comment"; and each response will be prefaced by a corresponding numbered "Response." Each "Comment" is numbered to help distinguish between different topics. The number assigned to each comment is for organizational purposes only, and does not signify the comment's value, or importance, or the order in which it was received. Comments on similar topics are grouped together.

[1] We note that recently we published a final rule in the *Federal Register*, revising 16 CFR part 1420. The final rule makes American National Standard, ANSI/SVIA–1–2010, the new mandatory standard for ATVs. Consequently, proposed § 1112.15(b)(9) would refer to the ANSI/SVIA–1–2010 safety standard for all-terrain vehicles for purposes of our acceptance of laboratory accreditation.



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## *A. Comments on Baseline Accreditation Requirements*

(*Comment 1*) - Some commenters supported the use of International Standards Organization/International Electrotechnical Commission (ISO/IEC) 17025:2005 standard on testing and calibration laboratories and the International Laboratory Accreditation Cooperation – Mutual Recognition Arrangement (ILAC-MRA) because this helps establish an internationally recognized consortium for organizations qualified to provide accreditation services. A commenter recommended that the CPSC conduct periodic reviews and revise the accreditation requirements to ensure that the highest standards for laboratory accreditation are being followed. The commenter suggested that if ISO/IEC 17025:2005 is superseded by a more stringent standard, then the CPSC should adopt the more stringent standard.

*(Response 1)* - Section 14(a)(3)(D) of the CPSA states: "[t]he Commission shall periodically review and revise the accreditation requirements established under subparagraph (B) to ensure that the requirements assure the highest conformity assessment body quality that is feasible." If a new version of ISO/IEC 17025:2005 is adopted by the ISO, the CPSC will review the new requirements and determine whether the new version would improve the CPSC's laboratory program. Any change to the requirements for CPSC-accepted third party conformity assessment bodies will be pursued as an amendment to 16 CFR part 1112.

(*Comment 2*) - Multiple commenters suggested that the Commission consider accepting laboratory accreditation from the National Environmental Laboratory Accreditation Conference (NELAC). A commenter noted that NELAC follows the ISO/IEC 17025:2005 standard and is similar to the American Association of Laboratory Accreditation (A2LA), an ILAC-MRA signatory accreditation body. The National Environmental Laboratory Accreditation Program (NELAP) implements the NELAC standards.



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Another commenter recommended that the CPSC accept the accreditation of laboratories accredited by the American Industrial Hygiene Association (AIHA), which is accredited to ISO/IEC 17011:2004, but was not an ILAC-MRA signatory (at the time the comment was submitted). The AIHA accredits laboratories to ISO/IEC 17025:2005 for the National Lead Laboratory Accreditation Program (NLLAP), administered by the U.S. Environmental Protection Agency (EPA). One commenter stated that, by not including AIHA-accredited laboratories, there are not a sufficient number of laboratories in the United States to handle the volume of testing required by the CPSIA. Multiple commenters recommended that accreditation bodies that are part of the National Cooperation for Laboratory Accreditation (NACLA) be recognized by the CPSC, and thus, enable the laboratories accredited by NACLA members to provide test results for lead in paint that can be used as a basis of issuing a Children's Product Certificate. The NACLA does not rely on mutual recognition among accreditation bodies, but it has a Recognition Council to recognize accreditation bodies. NACLA members follow the provisions of ISO/IEC 17011:2004 and accredit laboratories to ISO/IEC 17025:2005.

(*Response 2*) - In September 2010, AIHA became an ILAC-MRA signatory. Laboratories accredited by AIHA, after becoming an ILAC-MRA signatory, may apply for CPSC acceptance of their accreditation. Therefore, the comment that the Commission should make AIHA a CPSC-designated accreditation body is moot. Currently, NACLA and NELAC are not signatories to the ILAC-MRA. NACLA and NELAC are domestic organizations that do not have recognition arrangements with foreign countries.

The CPSA, as amended by the CPSIA, directs the CPSC to establish and publish notices of requirements for accreditation of third party conformity assessment bodies to assess conformity with a children's product safety rule to which such children's product is subject. The



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CPSA provides that accreditation of third party laboratories may be conducted by the Commission or by an independent accreditation organization designated by the Commission.

In consideration of the timelines established by the CPSA and the fact that children's consumer products are manufactured for the U.S. market in nations throughout the world, we identified several objectives for a laboratory accreditation program that could accomplish the implementation of the CPSA. These objectives were:

1) Designate the core elements of a CPSC accreditation program to an entity that is established and has acceptance on a multinational level. The entity should follow internationally recognized standards for assessing the competence of laboratories and for the processes and standards used by accreditation bodies that evaluate such laboratories;

2) Designate one entity that immediately could bring on board, on a multinational level, the largest number of accreditation bodies that could begin the process of accrediting laboratories in accordance with the CPSC specific requirements for a children's product safety rule; and

3) Avoid designation to accreditation programs or entities that are recognized only in a specific region, nation, or locality. The reasons for this objective are to: (a) keep the program as simple as possible for use by manufacturers, private labelers, importers, laboratories, and other interested parties; (b) avoid any perceived notions of barriers to fair trade practices; (c) establish a program that is manageable within agency resources; and (d) maintain a degree of consistency in the procedures used by the designated accreditation bodies.

The Commission will continue to designate accreditation bodies that are signatories to the ILAC-MRA. We believe that the laboratory accreditation requirements approved by the Commission are consistent with the direction of the CPSA and meet the objectives outlined above.

We recognize that there are other laboratory accreditation organizations or accreditation bodies. Some of these organizations may adhere to similar procedures and standards (but with some distinctions) as those established in the ILAC-MRA signatory program. However,



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expanding CPSC designations to such organizations would not meet all of the objectives outlined above.

Regarding laboratory testing capacity for lead in paint, we are not aware of any evidence indicating that insufficient CPSC-accepted laboratory testing capacity for lead in paint exists. If lead in paint testing capacity becomes an issue in the future, the CPSC will address the situation.

(*Comment 3*) - A commenter recommended that laboratories "be specifically CPSC accepted based on accreditation which the [ILAC-MRA] system, on its own, may not ensure." The commenter stated that this would secure the impartiality of certification better. The commenter opposed limiting accreditation bodies to ILAC-MRA signatories because there is no reciprocity with ILAC-MRA countries to accept accreditations from the Occupational Safety and Health Administration (OSHA), the American National Standards Institute, or the Standards Council of Canada.

(*Response 3*) - With regard to the commenter's suggestion that there are standards or norms which the ILAC-MRA system "on its own, may not ensure," the commenter did not specify what the ILAC-MRA system fails to ensure. Accordingly, we are unable to respond meaningfully to that portion of the comment. As for the impartiality of certification, we note that the CPSA does not require conformity assessment bodies to issue certificates. Instead, section 14(a)(2) of the CPSA assigns responsibility for certifying to "every manufacturer of [a children's product subject to a children's product safety rule] (and the private labeler of such children's product if such children's product bears a private label)."

The topic of reciprocity is addressed in the response to Comment 7.

(*Comment 4*) - A commenter responding to the notice of requirements for accreditation of laboratories to assess conformity with 16 CFR part 1505 (electrically operated toys or other



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electrically operated articles intended for use by children) stated that many requirements of the regulation would not be evaluated by laboratory testing, but rather, would be evaluated via inspection, auditing, and construction review. For example, the fulfillment of requirements in §§ 1505.3, pertaining to labeling, 1505.4, regarding manufacturing requirements, and 1505.5, related to electrical design and performance, generally would not be evaluated by what is commonly understood as "laboratory testing." The commenter suggested using ISO/IEC 17020:1998, *General criteria for the operation of various types of bodies performing inspection,* as the accreditation requirements for these activities. The commenter said that the CPSC could supplement ISO/IEC 17020:1998 criteria with additional specific requirements for individuals performing these activities to ensure that individuals possess engineering education, training, and experience to evaluate compliance effectively.

(*Response 4*) - Section 14(a)(2) of the CPSA requires manufacturers of any children's product subject to a children's product safety rule to submit the product for third party testing. As structured by the CPSA, certification of compliance with children's product safety rules is based on product testing (not manufacturing facility inspection) at a third party conformity assessment body (laboratory). A third party conformity assessment body conducts all of the performance tests in the standard. The portions of the standard, rule, ban, or regulation that do not use testing are attested to by the manufacturer when it issues a Children's' Product Certificate for the product.

Inspection, as intended by ISO/IEC 17020:1998, is generally used for individual items or very small production volumes. Conformity assessment is used for assuring compliance to established standards and is applicable to larger production volumes. At this time, we decline to recommend adopting the suggestion of using ISO/IEC 17020:1998.



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(*Comment 5*) - One commenter urged the Commission to consider third party certification of products (as opposed to third party testing) by certification bodies accredited to ISO/IEC 17065, *General Requirements for Bodies Operating Product Certification Systems*. The commenter stated that third party certification includes actions taken by the certifying body to ensure continuing conformance. The commenter suggested that requiring third party certification and marking would be less costly and more effective. The commenter urged the CPSC to consider the principles of product certification outlined in the American National Standards Institute (ANSI) document, *National Conformity Assessment Principles for the United States*.

Another commenter asked that the CPSC consider alternative criteria for accreditation to allow for organizations that are accredited to Standard ISO/IEC 17065.

(*Response 5*) - With regard to the suggestion that the Commission consider third party certification of products, section 14(a)(2) of the CPSA specifically states that samples of the children's product are submitted to a third party conformity assessment body for testing (not for certification), and that the manufacturer or private labeler of the children's product issue the certificate that certifies that the product complies with the applicable children's product safety rules. That responsibility cannot be delegated to another party. Thus, certification of a children's product by a third party certification body does not meet the requirements of the CPSA.

With regard to the commenter's suggestion that the CPSC consider including alternative criteria for accreditation to allow CPSC acceptance of accreditations to ISO/IEC 17065, ISO/IEC 17065 has not (as of the date of this proposed rule) been finalized. This draft standard is still in development as a revision to ISO Guide 65:1996, *General Requirements for Bodies Operating*



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*Product Certification Systems*. Because ISO/IEC 17065 has not been finalized, we cannot evaluate whether this standard would meet the requirements of the CPSA. If we assume that the provisions of ISO Guide 65:1996 are maintained in ISO/IEC 17065, § 1.2 of ISO Guide 65:1996 states that the certification system used by the certification body may include one of more of a list of evaluation techniques. Included in that list are methods that do not involve testing for compliance to the applicable children's product safety rules. Section 14(a)(2)(B) of the CPSA requires Children's Product Certificates to be based on testing. Because ISO Guide 65:1996 allows for product certification without testing, certification by organizations that are accredited to ISO Guide 65:1996 may not include the required testing and cannot be used for children's product certification purposes.

With regard to the ANSI document, *National Conformity Assessment Principles for the United States*, this document mirrors many widely-accepted concepts and processes used by conformity assessment bodies and certification bodies. For example, provisions in the ANSI document regarding testing competency and protection of a customer's data are mirrored in ISO/IEC 17025:2005 and ISO Guide 65:1996. However, the principles in the ANSI document are more closely related to product certification, and thus, are not appropriate for laboratories involved in support of children's product certification by the manufacturer. For example, conformity assessment principle number 12 in the ANSI document states: "As appropriate, conformity assessment bodies undertake reasonable surveillance procedures to ensure continued product conformity and protection of their mark." Surveillance procedures and certification marks are activities typically undertaken by certification bodies, not laboratories conducting tests. Thus, we decline to recommend adopting the suggestion of using the ANSI document because it relates to certification activities not undertaken by testing.



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(*Comment 6*) - Some commenters supported the use of ISO/IEC 17025:2005 as an accreditation tool but emphasized the importance of ensuring that the scope of accreditation applies only to the testing for which the conformity assessment body has demonstrated competence.

(*Response 6*) – We agree with the commenters. Every conformity assessment body applying for CPSC acceptance of their accreditation must submit a statement of scope that lists explicitly the CPSC regulation(s) and/or test method(s) for which they are applying.

(*Comment 7*) - Multiple commenters suggested adopting reciprocity provisions as a part of laboratory accreditation requirements. Reciprocity, in this context, means that if the CPSC accepts the accreditation of foreign laboratories to test consumer products for compliance to the requirements of section 14 of the CPSA, the host country of the foreign laboratory must provide similar treatment to U.S.-based laboratories. Possible reciprocity provisions could include a statement that, in reviewing a laboratory's application, the CPSC will take into consideration whether the host country of the applicant provides similar accreditation for U.S.-based laboratories in their markets. Another possible reciprocity policy would require that the countries of non-U.S.-based laboratories that wish for their accreditation to be accepted by the CPSC, offer recognition to U.S-based laboratories for that country's certification programs.

One commenter stated that a reciprocity provision would benefit U.S. manufacturers because reciprocity would allow for streamlined testing requirements and protocols across international markets and would also keep manufacturers from sending testing samples to multiple testing facilities around the world in order to "shop" for passing testing results. Another commenter stated that without reciprocity provisions, U.S.-based laboratories are damaged by not having access to other countries' conformity assessment systems. The commenter



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recommended that the CPSC amend its proposed accreditation requirements to include reciprocity provisions identical to those used by OSHA under its Nationally Recognized Testing Laboratory (NRTL) program.

One commenter stated that, without reciprocity provisions, the product safety scheme will lack the necessary shared interest in quality oversight to make it a functioning program.

(*Response 7*) – We decline to adopt reciprocity as a criterion in the CPSC third party conformity assessment body program, although we are aware that the other federal laboratory recognition programs contain such a provision. At this time, we have not determined that reciprocity promotes consumer safety. The mission of this agency is to protect the public against unreasonable risks of injury from consumer products. One way we accomplish that mission is by implementing the CPSIA's requirement that products subject to children's product safety rules be third party tested. Thus, our interest, in this instance, is to establish an effective and efficient laboratory program through which we recognize laboratories that are competent to conduct these third party tests.

As for the comment regarding shared interest in quality oversight, to the extent that the commenter is suggesting that reciprocity provisions are necessary for the CPSC's laboratory program to function, the commenter did not describe how or why having reciprocal testing-body recognition is necessary to implementing section 14 of the CPSA. We use accreditation by an ILAC-MRA signatory accreditation body to an international standard, ISO/IEC 17025:2005, and additional information, to determine whether to accept the accreditation of an applicant laboratory. Sections 1.4 and 1.6 of ISO/IEC 17025:2005 specifically refer to the quality management system of the laboratory. Laboratories accredited to ISO/IEC 17025:2005 must implement a quality management system, appoint a staff member as quality manager, and



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continually improve the effectiveness of its management system through the use of quality policy, quality objectives, audit results, and other factors. None of these quality oversight items requires reciprocity between nations.

### *B. Comments on Firewalled/Governmental Laboratories and Undue Influence*

(*Comment 8*) - One commenter stated the belief that validation of a laboratory's independence is critical to the success of all CPSC safety initiatives, including program development for third party testing of children's products. The commenter pointed to OSHA's NRTL program and ISO Guide 65:1996 as a means to underscore the critical role of independence. ISO Guide 65:1996 details the requirements of operating without a conflict of interest and includes several requirements concerning organizational structure to protect impartiality and to prevent conflict of interest. The commenter suggested that the Commission should consider the requirements of Clause 4.2 of ISO Guide 65:1996 and look to OSHA's NRTL program as an example of the level of inquiry that should be required, the type of requirements that should be implemented, and to ensure impartiality and prevent conflict of interest.

The commenter noted that these issues deserve special emphasis for proprietary (firewalled) and governmental laboratories. Under the CPSC's laboratory accreditation requirements that were published in the notices of requirements and that are provided in additional detail in this proposed rulemaking, firewalled and governmental laboratories are required to demonstrate particular undue influence safeguards, as specified in the CPSA, in addition to the requirements of the ISO/IEC 17025:2005 standard.



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(*Response 8*) - The OSHA program and ISO Guide 65:1996 are tailored to certification bodies/programs and not to laboratories that conduct tests. Under the structure of third party testing required by the CPSA (as amended by the CPSIA), product certification elements (certifying compliance with a CPSC rule) are the responsibility of the manufacturer or private labeler. The certifying manufacturer or private labeler must support its certificate of compliance with testing by a CPSC-accepted laboratory (referred to in the CPSA as third party conformity assessment body). There are international standards written specifically for different areas related to conformity assessment (*e.g*., inspection activities, certification programs, laboratories). Because the CPSA requires the CPSC to establish requirements for entities that conduct product testing, the CPSC programs require the ISO/IEC standard that is specifically applicable to testing laboratories (ISO/IEC 17025:2005). ISO/IEC 17025:2005 has provisions that require the laboratory to have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity. A third party laboratory must demonstrate that it is impartial and that its personnel are free from any undue commercial, financial, and other pressures that might influence their technical judgment. ILAC-MRA signatory accreditation bodies assess laboratories to these criteria during laboratory assessments.

In addition, the CPSA requires that firewalled and governmental laboratories satisfy certain criteria, which include protections against undue influence. The CPSC implements those criteria, such that firewalled and governmental laboratory applicants must submit additional materials that address undue influence safeguards. For a full description of the additional application materials, see discussion of proposed § 1112.13(b) and (c) in section IV, B.2 of the preamble.



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The criteria for safeguards against undue influence are addressed by the proposed CPSC requirements, and there should not be additional criteria based on programs or standards that are not specific for laboratories that conduct tests.

(*Comment 9*) - One commenter urged the CPSC to "differentiate between what are authentic, third party conformity assessment bodies from manufacturer-owned, firewalled labs." The commenter stated that such differentiation would be consistent with widely used terminology in the manufacturing communities and would reflect the structure of the laboratories better.

(*Response 9*) – We interpret the commenter as addressing our use of the term "third party conformity assessment body" to refer to any of the three types of laboratories accepted by the CPSC (independent, firewalled, and governmental). To many in the consumer product industry, a "third party conformity assessment body" corresponds only to an independent laboratory.

Section 14(f) of the CPSA defines and discusses the term "third party conformity assessment body" to include all three types of laboratories. Accordingly, the notices of requirements, and this proposed rule, describe all laboratories whose accreditation has been accepted by the Commission as "third party conformity assessment bodies," whether they are independent, governmental, or firewalled.

(*Comment 10*) - The notices of the requirements for accreditation of third party conformity assessment bodies require firewalled laboratory applicants to submit copies of training documents showing how employees are trained to notify the CPSC 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. Some commenters suggested that the Commission develop standards for these training



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documents. A commenter noted that standards for impartiality are addressed in ISO Guide 65:1996, which, as a starting place, could be used for this purpose. A commenter also suggested that the CPSC, in developing standards for training documents, consider other standards or best practices that are protective of laboratory and test result integrity.

(*Response 10*) - The CPSA includes a provision that requires all CPSC-accepted firewalled laboratories to establish procedures to ensure that employees may report immediately and confidentially allegations of undue influence to the CPSC, 15 U.S.C. § 2063(f)(2)(D). The notices of requirements have required firewalled laboratory applicants to submit copies, in English, of their training documents showing how employees are trained on those procedures. This proposed rule would continue that requirement.

A team of CPSC staff reviews applications from firewalled laboratories, including the submission of training documents. If the team concludes that the application materials satisfy the statutory requirements for acceptance as a firewalled conformity assessment body, the team recommends the applicant for Commission acceptance. Thus far, the training documents submitted by firewalled laboratory applicants have indicated clearly whether section 14(f)(2)(D) of the CPSA has been satisfied. However, the CPSC will consider this suggestion as we review future applications from firewalled laboratories. Should we determine that establishing standards for training documents would be helpful, we will consider the criteria for impartiality in other standards and best practices.

We note that accreditation bodies play a role in ensuring impartiality of firewalled laboratories as well. Section 4.1.5(b) of ISO/IEC 17025:2005 requires that the laboratory "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



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quality of their work." Note 2 under § 4 of ISO/IEC 17025:2005, *Management Requirements*, states:

> If the laboratory wishes to be recognized as a third party laboratory, it should be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgment. The third party testing or calibration laboratory should not engage in any activities that may endanger the trust in its independence of judgment and integrity in relation to its testing or calibration activities.

The accreditation body evaluates the laboratory regarding this provision during the initial assessment and during each reassessment. Thus, the firewalled laboratory's accreditation body also evaluates the policies and procedures by which the laboratory avoids activities that would diminish confidence in its impartiality.

To the extent that these commenters also intended to suggest that the CPSC apply standards to the training documents submitted by government laboratory applicants, we note that, to date, the CPSC has not requested that governmental laboratory applicants submit training documents. Nor are we proposing in this rule that governmental laboratory applicants submit training documents to the CPSC. Sections 14(f)(2)(D)(ii)(II) and (III) of the CPSA specifically require that applicants for firewalled status have established procedures to ensure that, *inter alia*, the CPSC is notified immediately of any attempt at undue influence and that allegations of undue influence may be reported to the CPSC confidentially. To implement those provisions, we require firewalled applicants to submit training documents so that we can ensure that these safeguards have been communicated to employees. The statute does not require governmental laboratories to have established policies that involve employees notifying the CPSC immediately and confidentially of an attempt at undue influence. Thus, we are not requiring training documents from governmental laboratory applicants in support of such requirements. Instead, the CPSIA established five criteria that each governmental applicant must satisfy to have its



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accreditation accepted by the CPSC. To implement those criteria, the proposed rule would require a governmental laboratory applicant to submit responses to a questionnaire, a description of its relationship with other entities, an attestation, and the laboratory's undue influence policy. For more information on those requirements, see the discussion of proposed § 1112.13(c) in section IV.B.2 of the preamble.

(*Comment 11*) - Some commenters recommended that the Commission establish safeguards to ensure that employees who are engaged in conformity assessment activities are not rewarded for positive outcomes of testing.

(*Response 11*) – We agree that a third party conformity assessment body should not reward an employee for a "passing" test result. The notices of requirements have required, and this proposed rule would continue requiring, that CPSC-accepted laboratories be accredited to the provisions in ISO/IEC 17025:2005 by a signatory to the ILAC-MRA. Section 4.1.5(b) of ISO/IEC 17025:2005 states that the laboratory shall "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." The laboratory's accreditation body checks for conformance to this section of ISO/IEC 17025:2005 during initial accreditation and each reassessment. Therefore, we consider the commenters' suggestion to be addressed already in the ISO/IEC 17025:2005 requirements, and therefore, additional CPSC requirements are not warranted.

(*Comment 12*) - One commenter, who responded to several notices of requirements, suggested that we require applicants, including the firewalled and governmental laboratories, to submit the evidence used to validate the fulfillment of § 4.1.5(b) of ISO/IEC 17025:2005, as part of their application to the CPSC to assure impartiality and avoid undue influence. The



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commenter argued that this information is particularly necessary because the requirements for firewalled laboratories to submit documents related to staff training on undue influence "are not sufficient on their own to pro-actively assure the Commission about the impartiality of a firewalled (or government) laboratory." The commenter contended that requiring evidence of the fulfillment of § 4.1.5(b) of ISO/IEC 17025:2005 would drive accreditation bodies and laboratories to pay more specific attention to ISO/IEC 17025:2005 § 4.1.5(b); promote consistency; and provide the CPSC with a means of monitoring compliance.

(*Response 12*) – We believe that requiring applicants to submit records used to validate the fulfillment of § 4.1.5(b) of ISO/IEC 17025:2005 to the CPSC is unnecessary. It is the role of the laboratory's accreditation body to evaluate whether a laboratory satisfies the requirements of ISO/IEC 17025:2005; it would be duplicative for the CPSC to perform the same evaluation. Accreditation bodies have the expertise to evaluate laboratories to all provisions of ISO/IEC 17025:2005, including § 4.1.5(b).

With regard to the suggestion that, if the CPSC required submission of the evidence of compliance with § 4.1.5(b) of ISO/IEC 17025:2005, accreditation bodies and laboratories would pay more specific attention to that requirement, we believe that accreditation bodies garner significant attention from laboratories. If a laboratory failed to meet the requirements of ISO/IEC 17025:2005 to the satisfaction of its accreditation body, the laboratory could lose its accreditation and a potentially significant portion of its business.

With regard to the suggestion that submission of the records used to validate fulfillment of ISO/IEC 17025:2005 § 4.1.5(b) would promote consistency among laboratories, we respond that currently, we do not perceive any need to do so. The Commission has decided to designate laboratory accreditation to ILAC-MRA signatories, per section 14(a)(3)(C) of the CPSA. At this



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time, we are not aware that this designation has resulted in problems regarding undue influence. Requiring submission of the records used to validate the fulfillment of ISO/IEC § 4.1.5(b) would impose a burden on the CPSC and laboratories, without corresponding benefit. Finally, we note that fulfillment of the requirements of ISO/IEC 17025:2005 § 4.1.5(b) may be achieved in a number of ways. Decreasing variability in how laboratories fulfill that requirement would not necessarily increase protection against undue influence.

With regard to the suggestion that the submission of records used to validate fulfillment of ISO/IEC 17025:2005 § 4.1.5(b) would promote consistency among accreditation bodies, the ILAC-MRA evaluation process of an accreditation body involves a team of peer review members drawn from multiple accreditation bodies located around the world. This multi-member team arrangement tends to harmonize how the requirements of § 4.1.5(b) of ISO/IEC 17025:2005 are fulfilled around a common set of principles shared by the globally distributed team members.

With regard to the suggestion that requiring the submission of evidence of the fulfillment of ISO/IEC 17025:2005 § 4.1.5(b) to the CPSC would provide us with a means of monitoring compliance, we do not agree. Records related to accreditation assessments and reassessments are maintained by the accreditation bodies and the laboratories. The final rule on the audit requirements (implementing § 14(i)(1) of the CPSA) requires a third party conformity assessment body to retain records relating to the last three reassessments conducted by the accreditation body and make such records available to the CPSC upon request. Records of nonconformities related to safeguards against undue influence (or any ISO/IEC 17025:2005 requirement) and the corrective actions must be made available to the CPSC upon request.



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Accordingly, we already have a means of monitoring compliance with this and every other provision in ISO/IEC 17025:2005.

With regard to the commenter's particular concern with firewalled and governmental laboratories, CPSC acceptance of these types of laboratories requires the submission and evaluation of additional information specifically dealing with avoiding undue influence. Proposed §§ 1112.13(b) and (c) provide details of the additional documentation we would require for CPSC acceptance of the accreditation of firewalled and governmental laboratories.

The proposed rule would require these additional application materials from firewalled and government laboratories because we expect that they will provide us with helpful information concerning the structure and independence of these applicants.

(*Comment 13*) - Another commenter similarly pointed out that independent laboratories can "easily" satisfy ISO/IEC 17025:2005 § 4.1.5(b) but stated that the application of this requirement to firewalled and governmental laboratories "poses issues of commercial, financial, and political pressures." The commenter suggested that the CPSC impose "additional audit requirements and accreditation decisions" on firewalled and government laboratories, and that the CPSC require from such applicants "additional application information . . . which should include, but not be limited to, extensive public disclosure of both manufacturer and/or government laboratory personnel involved in the testing of the relevant product(s)."

(*Response 13*) - The commenter did not specify what additional audit requirements or accreditation decisions it thought the CPSC should impose. However, with regard to this commenter's recommendation that the CPSC require additional application materials from firewalled and governmental applicants, as explained in the response to Comment 10, the proposed rule would require such materials.



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We decline the suggestion to require extensive public disclosure of manufacturer and/or government laboratory personnel. We consider that mandating such disclosure would constitute an invasion of personal privacy that would be unwarranted when balanced against the public interest in the information. *See Horowitz v. Peace Corps*, 428 F.3d 271 (D.C. Cir. 2005) ("we must balance the private interest involved [namely, 'the individual's right of privacy'] against the public interest").

(*Comment 14*) - Some commenters suggested that the sampling frequency of firewalled laboratories should be double that of independent conformity assessment bodies. Although it was not clear from the submissions, these commenters may have been suggesting that the government laboratories also test twice as many samples as independent laboratories.

(*Response 14*) - Section 14(a)(2) of the CPSA requires that a manufacturer of a children's product subject to a children's product safety rule submit "sufficient samples of the children's product, or samples that are identical in all material respects to the product," to a third party conformity assessment body for testing. Under the requirement of the statute, then, it is the manufacturer, as opposed to the laboratory, who determines what sample is provided to the laboratory for testing, and the agency has no authority to transfer responsibility for determining sample size to the laboratories. The CPSC has addressed the sufficiency of the number of samples required under section 14(a)(2) of the CPSA in the final rule, *Testing and Labeling Pertaining to Product Certification*. 76 FR 69482 (November 8, 2011).

(*Comment 15*) - Some commenters also suggested that firewalled laboratories be required to meet additional requirements, such as:

- Public disclosure that the manufacturer has a financial interest or ownership stake in the laboratory;



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- Submission of materials that identify whether employee compensation or annual bonuses (including stock options) are tied to the financial performance of the controlling manufacturer;
- Submission of detailed protocols by which the engineering staff of the firewalled laboratory do not either transfer from or transfer to the manufacturer's staff, or otherwise look to the manufacturer for career advancement; and
- Evidence that employees are required to participate, and regularly pass, third party ethics and compliance audits and programs intended to detect and protect against undue influence. The International Federation of Inspection Agencies (IFIA) Compliance Code was mentioned as a possible standard. Employees should also be required to submit to any programs established by the manufacturer/firewalled laboratory, including training, reporting, monitoring, investigating, and enforcement, intended to protect against and detect undue influence.

(*Response 15*) - With regard to the suggestion that the CPSC require firewalled laboratories to publicly disclose that the manufacturer has a financial interest or ownership stake in the laboratory, section 14(f)(2)(D) of the CPSA provides that a firewalled laboratory may be accepted by the Commission only if the Commission, by order, makes certain findings concerning the firewalled laboratory. The orders of the Commission accepting the accreditation of firewalled laboratories are public and are posted on the CPSC's website. Accordingly, there is public disclosure of each firewalled laboratory applicant at the time the Commission votes on whether to accept the firewalled laboratory's accreditation. (*See, e.g.*, http://www.cpsc.gov/library/foia/foia10/brief/firewalled.pdf).

With regard to the suggestions that firewalled laboratories be required to identify whether employee compensation or annual bonuses (including stock options) are tied to the financial performance of the controlling manufacturer, and that the CPSC require submission of detailed protocols by which the engineering staff of the firewalled laboratory do not either transfer from or transfer to the manufacturer's staff or otherwise look to the manufacturer for career advancement, we do not believe that such information would be dispositive. The core concern is whether the testing process will be tainted, and this concern drives the provisions that were in the



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notices of requirements, as well as the provisions in this proposed rule, which seek to ensure that the testing process is protected against undue influence. As explained in the response to Comment 16, we are proposing to expand the definition of "firewalled laboratory," and we are requiring more information from those entities about safeguards against undue influence.

As we have noted in the responses to Comments 10 and 11, § 4.1.5(b) of ISO/IEC 17025:2005 requires that the laboratory have arrangements to ensure that it is free from undue influence. The accreditation body evaluates the laboratory's fulfillment of this provision at the initial accreditation and at each reassessment. Further, section 14(f)(2)(D)(ii) of the CPSA requires the Commission, by order, to find that the conformity assessment body has established procedures to ensure that its test results are protected from undue influence by the manufacturer, private labeler, or other interested party. Because multiple entities are evaluating the means by which the firewalled laboratory avoids undue influence by the manufacturer, additional application requirements for firewalled applicants are not seen as necessary at this time. At a future date, we may consider additional requirements for firewalled laboratories in response to evidence that the prevailing requirements are not effective.

Finally, as for the suggestion that we require evidence that employees are required to participate, and regularly pass, third party ethics and compliance audits and to submit to any programs established by the manufacturer/firewalled laboratory intended to detect and protect against undue influence, we decline to adopt this suggestion. Under the proposed rule, a firewalled laboratory applicant would be required to submit, among other things, copies of training documents, including a description of the training program content), showing how employees are trained to notify the CPSC immediately and confidentially of any attempt by the manufacturer, private labeler, or other interested party to hide or exert undue influence over the



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third party conformity assessment body's test results; and training records (including training dates, location, and the name and title of the individual providing the training), listing the staff members who received the required training. At this time, we believe that requiring these training records sufficiently addresses our interest in ensuring that firewalled laboratory personnel are adequately trained in detecting and protecting against undue influence. Again, however, we will continue to consider this suggestion, and if additional requirements concerning undue influence-related training of laboratory personnel would be helpful, we may recommend adopting additional training requirements in the future.

(*Comment 16*) - Other commenters expressed concern about the situation in which a laboratory and a manufacturer are owned by the same parent company. The commenter urged the Commission to expand the definition of "firewalled laboratories" to cover common parentage of laboratories.

The commenter suggested further that the definition of "firewalled laboratories" be extended to include laboratories that do 50 percent or more of their business with a single manufacturer or private labeler of children's products.

(*Response 16*) - We agree that if a laboratory and a manufacturer share a common corporate parent, and the laboratory intends to test the manufacturer's children's products for certification purposes, the laboratory should be considered a firewalled laboratory. The proposed rule would address the situation of common parentage in the definition of a "firewalled laboratory." The proposed rule would have an applicant attest to whether it satisfies any aspect of the definition of a "firewalled laboratory." One attestation concerns common parentage; the applicant would need to attest to whether it is affiliated with a manufacturer or private labeler of the children's product. "Affiliated with" would mean that the conformity assessment body is in



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the same ownership network as a manufacturer or private labeler of the children's product, with the exception that "affiliated with" does not include a manufacturer or private labeler of the children's product that is owned, managed or controlled by the conformity assessment body.

We considered the potential controlling effect of manufacturers with a significant part of a laboratory's business, and concluded that evaluating such a factor would be challenging administratively and difficult to verify. Variables such as the time period and types of products to consider could have a significant impact on any calculation of a percentage of a laboratory's business.

However, the proposed rule would address management and/or control of a laboratory by a manufacturer or private labeler by including in the definition of "firewalled laboratory," laboratories over which a manufacturer or private labeler has the ability to appoint a majority of the laboratory's senior internal governing body; the ability to appoint the presiding official of the laboratory's senior internal governing body; or the ability to hire, dismiss, or set the compensation level of laboratory personnel. Another proposed aspect of this definition would be to deem "firewalled," a laboratory that is under contract to a manufacturer or private labeler, such that the contract limits explicitly the services that the laboratory may perform for other customers or limits explicitly which or how many other entities may be customers of the laboratory.

(*Comment 17*) - A commenter suggested that, as a requirement for accreditation, we consider accrediting only manufacturer-controlled laboratories that agree that their entire organization, including the firewalled laboratories, will be held strictly liable for defective products. For foreign governmental laboratories, the commenter suggested that we require, as a condition of accreditation, that any foreign governmental lab that seeks to test and certify



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products be required to agree to submit to the jurisdiction of U.S. regulatory agencies and U.S. courts without asserting claims of sovereign immunity or other defenses seeking to limit their liability.

(*Response 17*) - We decline to adopt the commenter's suggestions. The statutes enforced by the Commission are structured to assign liability to culpable persons or entities. To the extent that by "entire organization," the commenter means that the manufacturer owns, manages, or controls the firewalled laboratory, potential liability already exists under the statutes enforced by the Commission. It would be redundant to require the laboratory to agree to such liability as a condition of becoming accepted by the CPSC. To the extent that the commenter intends to suggest that the firewalled laboratory itself be held liable, we do not have the authority to assign liability to an entity that is not already culpable under the law.

With regard to the suggestion that we require foreign governmental laboratories to agree to submit to the jurisdiction of U.S. regulatory agencies and courts without asserting claims of sovereign immunity, or asserting other bases for limiting their liability, such actions are beyond the scope of our laboratory accreditation authority.

(*Comment 18*) - One commenter advised the Commission to "consider the liability implications that may arise from accrediting a firewalled or foreign governmental laboratory in the event that one of those laboratories permits an unsafe product [to] enter the U.S. marketplace, as well as the legal remedies thereto."

(*Response 18*) - We interpret the commenter as expressing concern that there may be obstacles to the CPSC holding CPSC-accepted firewalled and foreign governmental laboratories legally accountable for the tests they conduct. Section 14(f) of the CPSA establishes that firewalled and governmental laboratories may be accredited by the Commission to conduct third



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party tests of children's products. We wish to assure this commenter that we pursue available legal remedies against entities that permit unsafe products to enter the U.S. marketplace. We also note that, under the proposed rule, the Commission would be able to withdraw its acceptance of a laboratory on such grounds as the laboratory failed to comply with the requirements of subpart B of the proposed rule, and/or if the laboratory succumbs to undue influence.

(*Comment 19*) - One commenter suggested that we require assessments of a laboratory's independence and freedom from undue influence annually, or at least require that these assessments coincide with other reassessment and surveillance visits.

(*Response 19*) - We agree that a laboratory's independence should be reassessed on a regular basis. The final rule on audit requires that the reassessment portion of an audit, which is conducted by the accreditation body, include an examination of the laboratory's management system to ensure that the laboratory is free from any undue influence.

In addition to a laboratory's reassessment visits, surveillance visits can be conducted by accreditation bodies during the period between reassessments. Surveillance visits are assessments that are conducted for a particular purpose, such as to follow up on a previously observed problem or to ensure that a newly accredited laboratory has implemented necessary procedures. Surveillance visits may or may not be conducted for purposes of reviewing the impartiality of a laboratory, and thus, may or may not involve a reassessment of a laboratory's impartiality.

(*Comment 20*) - A commenter suggested that there is no objective basis for assessing the additional application materials submitted by governmental conformity assessment bodies.



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(*Response 20*) - We interpret the commenter's suggestion as urging the Commission to issue objective standards for assessing these applications. Section 14(f)(2) of the CPSA, as amended by section 102 of the CPSIA, establishes five criteria which, in addition to the baseline requirements, a third party conformity assessment body owned or controlled, in whole, or in part, by a government must satisfy. These criteria are:

> (i) 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;
> (ii) the entity's testing results are not subject to undue influence by any other person, including another governmental entity;
> (iii) the entity is not accorded more favorable treatment than other third party conformity assessment bodies in the same nation who have been accredited under this section;
> (iv) the entity's testing results are accorded no greater weight by other governmental authorities than those of other third party conformity assessment bodies accredited under this section; and
> (v) 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.

15 U.S.C. 2063 (f)(2)(B) of the CPSA.

In order for us to evaluate whether a governmental laboratory applicant satisfies the statutory criteria, we have developed a standard questionnaire and requests for documentation that each governmental laboratory applicant is asked to complete. The questionnaire accompanies the proposed rule as part of the CPSC's Paperwork Reduction Act package, and the required documents are described in proposed § 1112.13(c)(2). In addition, CPSC staff reviews governmental laboratory applications using a standardized review document that provides grounds and reasoning for a finding relative to each of the five statutory criteria. These standardizations provide increased objectivity to the application review process, and the questionnaire and documentation requirements are being published via this proposed rule.



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(*Comment 21*) - Some commenters that are foreign governments contended that, rather than assess additional application materials before acting on a governmental laboratory application, we should accept each governmental laboratory applicant, unless there is evidence that the applicant fails to satisfy the statutory criteria. The commenters argued that our approach is not fair and is inconsistent with the principal of impartiality expressed in the statutory criterion, which requires that the applicant laboratory "is not accorded more favorable treatment than other third party conformity assessment bodies in the same nation who have been accredited."

The commenters also argued that our approach violates the "mutual recognition principle of conformity assessment procedures" under the international treaty, "Agreement on Technical Barriers to Trade" (TBT Agreement). The commenters also invoked article 6.3 of the TBT Agreement, which encourages members to negotiate agreements for the mutual recognition of conformity assessments, and the commenters suggested additional consultations on these issues.

One commenter raised several issues under the World Trade Organization's TBT Agreement. The commenter stated that Article 2.4 of the TBT Agreement requires members to use relevant international standards (if they exist) as a basis for their technical regulations and said that ISO 9239-1, *Reaction to fire tests for floorings – Part 1: Determination of the burning behavior using a radiant heat source,* ISO 9239-2, *Reaction to fire tests for floorings – Part 2: Determination of flame spread at a heat flux level of 25 kW/m2,* and ISO 6925, *Textile floor coverings – Burning behavior – Tablet test at ambient temperature*, "contain specifications to fire tests for floorings." The commenter said that these international standards "would be an effective and appropriate means for the fulfillment of the objective pursued by CPSC."



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Finally, another commenter referred to Article 5.1.2 of the TBT Agreement to state that "conformity assessment procedures shall not be more strict than necessary to give the Importing Member adequate confidence that products conform to the applicable technical regulations or standards." The commenter also cited Articles 2.4, 2.5, 2.9.3, 5.4, and 5.6.3 of the TBT Agreement and asked us to "identify parts, if any, of the new regulation which in substance deviate from relevant international standards and to explain why such deviation has become necessary."

(*Response 21*) - To the extent that these commenters are suggesting that our approach has been partial to nongovernmental laboratory applicants, we acknowledge that there are criteria imposed by the CPSIA that apply only to governmental laboratory applicants. We have chosen to determine whether the criteria are satisfied before acting on each application. Similarly, we have not accepted any firewalled laboratory applicant without determining first that it satisfies the statutory criteria relevant to that type of laboratory (*see* section (f)(2)(D) of the CPSA). We have chosen to defer action on governmental and firewalled laboratory applications until we determine that the statutory criteria are satisfied because we want to ensure that CPSC-accepted third party conformity assessment bodies have the structures and practices required by the statute to avoid undue influence, or any other interference with, or compromise to, the integrity of the testing process. This is consistent with the goal of the CPSIA that children's products that enter the U.S. marketplace have been tested by a competent and unbiased laboratory.

We do not agree that this approach is unfair. Because neither governmental nor firewalled laboratories are independent entities, both are potentially subject to undue influence from the organizations to which they are connected, which have interests beyond product testing. The CPSIA imposes additional requirements on firewalled and government laboratories so that



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only laboratories that are arranged to avoid undue influence sufficient to satisfy the statutory criteria may be accepted. We remain committed to implementing the conformity assessment program established by the CPSIA fairly and with the primary goal of product safety in mind.

The notices of requirements have not contradicted the TBT Agreement. We are willing to accept laboratories recognized by foreign governments if the laboratories satisfy the statutory requirements, including the five statutory criteria listed above (as long as the laboratory satisfies the baseline criteria) in the case of laboratories owned or controlled in whole, or in part, by a government. In fact, we have accepted the accreditations of several governmental laboratories, and we have applied the same statutory criteria to governmental laboratories, regardless of whether the governmental laboratory was located in a foreign country or in the United States. (Indeed, we note that the definition of "government participation" in section 14(f)(2)(B) of the CPSA (for purposes of a "third party conformity assessment body") is not limited to foreign governments.) The CPSC consults extensively with laboratories seeking to become accepted to test products under section 14 of the CPSA. We remain open to further consultation on these issues with any interested laboratory applicant.

With respect to specific articles in the TBT Agreement, the commenter addressing Article 2.4 of the TBT agreement may have misinterpreted the notice of requirements. The notice of requirements simply establishes the conditions under which the CPSC will accept the accreditation of a third party conformity assessment body to test a children's product for compliance with a particular children's product safety rule. The notice of requirements does not affect the regulations pertaining to the children's product itself.

Similarly, the commenter addressing Article 5.1.2 of the TBT agreement may have misinterpreted the notice of requirements. This commenter was responding to the notice of



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requirements pertaining to 16 CFR part 1630, *Standard for the Surface Flammability of Carpets and Rugs (FF 1-70)* and/or part 1631, *Standard for the Surface Flammability of Small Carpets and Rugs (FF 2-70)* (See 75 FR 42315 (July 21, 1010)). The notice of requirements for 16 CFR parts 1630 and/or 1631, however, did not affect or alter the standards established or test methods required in 16 CFR parts 1630 and/or 1631. It simply informed laboratories of the process and requirements by which they could apply to test children's products according to the test method detailed in parts 1630 and/or 1631. A laboratory that has been ISO/IEC 17025:2005-accredited by an ILAC-MRA signatory to conduct flammability tests for floor coverings pursuant to a standard other than 16 CFR parts 1630 and/or 1631 that has similar test methods would likely not find it difficult to expand its accreditation scope with its accreditation body to include 16 CFR parts 1630 and/or 1631 and subsequently apply to the CPSC to test children's products subject to these regulations.

Moreover, consistent with Article 5.1.2 of the TBT Agreement, the notices of requirements have not established procedures and requirements for laboratories that are more strict than necessary to give the CPSC adequate confidence that children's products tested by CPSC-accepted laboratories conform to applicable CPSC standards, regulations, rules, or bans. We are unclear which relevant international standards the commenter would like us to compare the notices of requirements and explain why differences between the two are necessary. To the extent that the commenter is asking for differences between various substantive safety standards, we again note that the notices of requirements do not affect the underlying consumer product safety standard or children's product safety rule.



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### *C. Comments on the Suspension and/or Withdrawal of CPSC's Acceptance of Conformity Assessment Bodies*

(*Comment 22*) - Some commenters suggested that if a third party conformity assessment body tested a product later found to be noncompliant with the applicable rules, that conformity assessment body should lose its accreditation temporarily. (We interpret "lose accreditation" to mean a loss of the CPSC's acceptance of their accreditation.) The commenters suggested varying loss schedules, depending on the type of laboratory, with increasing periods of suspension for repeat offenses. For firewalled and government laboratories, the commenters suggested that acceptance of their accreditation should be lost for three months after the first offense, six months after the second offense, one year after the third offense, and permanent loss for four offenses over a 2-year period. For independent laboratories, the commenters suggested a written warning after the first offense, a 1-month loss after the second offense, a 3-month loss after the third offense, and upon the fourth offense, the CPSC would reevaluate the laboratory's practices, and the accreditation body would conduct a reassessment.

(*Response 22*) – We decline to adopt the suggestion that laboratories lose CPSC acceptance of their accreditation (either for a specified time or permanently) after noncompliant products associated with the laboratories' test reports are found in the marketplace. Factors independent of the laboratory may have led to the presence of noncompliant products. For example, poor process control by the manufacturer after certification could lead to some noncompliant products being produced after the laboratory had tested compliant samples. As another example, a manufacturer may have made a material change to the product that affected the product's compliance, without sending samples for testing to a laboratory. Setting a



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withdrawal schedule based solely on the presence of noncompliant products would risk holding laboratories responsible for factors beyond their control and about which they had no knowledge.

In addition, we are not adopting a graduated system of penalties because we consider it preferable to deal with laboratory infractions on a case-by-case basis.

(*Comment 23*) - Some commenters suggested that we establish a defined system for "de-listing" a third party conformity assessment body "for just cause." (We interpret "de-listing" to mean that the CPSC withdraws its acceptance of the laboratory's accreditation and removes the laboratory from the listing of accepted laboratories on the CPSC website http://www.cpsc.gov/cgi-bin/labsearch). The commenter provided examples of what would constitute "just cause":

- Evidence of conflict of interest or where there is undue influence by a manufacturer, a common parent company, or other party, that could have affected test results;
- A laboratory has been found to be incompetent to conduct required testing due to personnel or laboratory equipment changes; or
- A laboratory has a record of repeatedly certifying products that are later identified as noncompliant.

(*Response 23*) – We agree with the commenter that there should be greater clarity of what conduct or circumstances are sufficient for the agency to withdraw its acceptance of the accreditation of a third party conformity assessment body. Subpart D of the proposed rule would address adverse actions that the CPSC may take against a laboratory. These adverse actions would include: withdrawing CPSC acceptance of a laboratory's accreditation and removing the laboratory from the CPSC website listing of accepted laboratories. Proposed § 1112.47 would establish three basic grounds for withdrawal, which would include a manufacturer, private labeler, or governmental entity exerting undue influence on the laboratory or otherwise



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interfering with or compromising the integrity of the testing process. Proposed § 1112.41 would establish the procedures for withdrawal.

## *D. Comments on Specific Notices of Requirements*

### 1. Lead Content in Children's Metal Jewelry

(*Comment 24*) - Another commenter requested an exclusion in the CPSC test method for determining total lead in children's metal products (including children's metal jewelry). The commenter suggested that samples of electroplated jewelry—for which the electroplating is a metal excluded from testing for lead (such as gold or silver)—not be required to contain the electroplating when tested. The commenter suggested the following change to procedures A.2 and B.2:

> Component parts of children's products, including metal jewelry items, generally weigh several grams or more, and an aliquot (with no paint or similar surface coating, but including any electroplated or other coating which is considered to be part of the substrate, excluding precious or other metals exempt from testing) will have to be obtained.

(*Response 24*) – We decline to make the suggested change to the CPSC test method, CPSC-CH-E1001-08, because test methods are an inappropriate place to list testing exclusions. The test method is limited to describing how to conduct a test, not whether a material should be tested.

The commenter is correct that an excluded material, such as gold of at least 10 karats, does not require testing for lead. On August 26, 2009, the Commission published in the *Federal Register*, a list of materials determined not to contain lead and excluded them from testing (74



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FR, 43031). This created a new section, § 1500.91 of the *Hazardous Substances and Articles: Administration and Enforcement Regulations*.

If the commenter submits samples for testing without the electroplating, those test results, combined with the exclusion for a plating material (such as gold greater than 10 karats) could be used as the basis for issuing a Children's Product Certificate for a finished product consisting of units from the same lot or batch as the samples, plus the electroplating. However, once the electroplating occurs, the combination of the base material and the electroplating are considered one component part. If finished product samples are submitted for testing, the electroplating must be part of the tested specimen.

(*Comment 25*) - A commenter urged the CPSC to consider X-ray fluorescence (XRF) spectrometry as a valid testing option to screen for products with very low lead levels; more precise testing would be required if the uncertainty range of the instrument included the lead concentration limit.

Another commenter urged the CPSC to consider the use of a specific XRF technology, energy dispersive- X-ray fluorescence spectrometry (EDXRF), as a validated method for the testing of lead in substrates of consumer products. The commenter referred to interlaboratory testing that compared EDXRF technology to "wet chemistry" techniques (Inductively Coupled Plasma and Atomic Absorption Spectrometry) to measure lead in multiple substrates. The commenter opined that the economic and other benefits of using EDXRF over "wet chemistry" may be even more pronounced with application to the nondestructive measurement of lead in the substrate of product samples.

(*Response 25*) - The CPSC has accepted the use of certain types of XRF testing but only for certain polymeric materials and for paints. The CPSC test method, CPSC-CH-E1002-08 (and



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its revision, CPSC-CH-E1002-8.1), *Standard Operating Procedure for Determining Total Lead (Pb) in Non-Metal Children's Products*, includes an option for the use of XRF for the analysis of lead in certain polymeric materials. *See* 74 FR 55820 (Oct. 29, 2009) (notice of requirements for total lead in children's products); *see also* 76 FR 6765 (Feb. 8, 2011) (notice extending the stay of enforcement pertaining to total lead content in children's products [except for metal components of children's metal jewelry] until December 31, 2011). ASTM International, formerly the American Society for Testing and Materials (ASTM) test method, F2853-10, *Standard Test Method for Determination of Lead in paint Layers and Similar Coatings or in Substrates and Homogeneous Materials by Energy Dispersive X-Ray Fluorescence Spectrometry Using Multiple Monochromatic Excitation Beams*, can be used for the analysis of lead content in paints (16 CFR part 1303). See 76 FR 18645 (Apr. 5, 2011) (revision to notice of requirements for lead paint).

This proposed rule also would allow the use of XRF to determine the lead content of glass materials, crystals, and certain metals. We will continue to evaluate improvements to technology and methods on an ongoing basis.

2. Total Lead in Children's (Metal and Non-Metal) Products

(*Comment 26*) - A commenter suggested that we expand the use of XRF beyond polymeric materials, to test paints and thin film coatings for the purposes of a manufacturer, importer, or retailer's providing certification. Another commenter said we should allow the XRF method described in ASTM F2853-10 to be used to measure lead content in multiple substrates, in addition to homogeneous polymeric materials.

(*Response 26*) - On April 5, 2011, we published a notice revising the requirements for accreditation of laboratories to test for lead in paint. In that notice, the Commission approved the



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use of ASTM International (formerly the American Society for Testing Materials, ASTM) test method, F2853-10, *Standard Test Method for Determination of Lead in paint Layers and Similar Coatings or in Substrates and homogeneous Materials by Energy Dispersive X-Ray Fluorescence Spectrometry Using Multiple Monochromatic Excitation Beams*, for the analysis of lead content in paint. We have not determined that other XRF technologies are as effective, precise, or reliable as the methods described in the notice of requirements for compliance determinations of paints.

Additionally, the proposed rule (at proposed § 1112.15(b)(26), (27), and (28)) would allow the use of XRF to determine the lead content of glass materials, crystals, and certain metals. We will continue to evaluate improvements to technology and methods on an ongoing basis.

(*Comment 27*) - Another commenter suggested that, in addition to using a cryogenic mill for sample preparation, we should allow the test specimen to be cut into small representative pieces, with a maximum length in any dimension of 2.0 millimeters. The commenter also suggested a procedural change in the test method for determining lead in metals (CPSC-CH-E1001-08). The suggested change calls for the tester to observe when no particles are visible in one step and omits a heating period in another step.

(*Response 27*) - New revisions, dated June 21, 2010, of CPSC test methods: CPSC-CH-E1001-08.1 and CPSC-CH-E1002-08.1 have been posted on the CPSC's website. In test method CPSC-CH-E1002-08.1, the commenter's suggestion has been implemented. The sample preparation method instructs the tester to:



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Cut the test specimen into small pieces. Hard-to-digest plastics may need to be cryomilled to get finer powder. The minimum size is left to the discretion and flexibility of the tester for the material being evaluated.

With regard to the suggested change in test method CPSC-CH-E1001-08, we do not have sufficient proof that the method of not heating the acid to 60 degrees C (in step 6 of the Hot Block method), or using a longer time period, would result in consistent measurements. In addition to the Hot Block Method, we allow another testing method, based on the EPA's method 3051A2, which uses microwave digestion. Both methods are allowed in the revised test method, CPSC-CH-E1001-08.1.

3. 16 CFR part 1303 – Lead in Paint

(*Comment 28*) - Two commenters noted that the absence of a specified testing method in 16 CFR part 1303, *Ban of Lead-Containing Paint and Certain Consumer Products Bearing Lead-Containing Paint*, leads to uncertainty and confusion among accreditation bodies and laboratories about which testing methods are adequate for meeting the requirements of the standard.

(*Response 28*) - We addressed these comments in a notice published in the *Federal Register* on April 5, 2011, in which we amended the notice of requirements for testing for lead paint (*see* 76 FR 18645). The notice of requirements listed the test methods that are approved for compliance determination: CPSC-CH-E1003-09, CPSC-CH-E1003-09.1 and/or ASTM F2853-10 (which uses a specific type of XRF technology).

(*Comment 29*) - A commenter encouraged us to continue to ensure that the current ASTM F40 Committee (Declarable Substances in Materials) review process of a proposed standard method for lead in paint using traditional XRF technologies undergoes the same rigorous



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scientific and statistical requirements as we used during the ASTM F2853-10 standard method development process.

(*Response 29*) – We will continue to evaluate improvements to technology and methods on an ongoing basis. We have not determined that other XRF technologies are as effective, precise, or reliable as the methods described in the notice of requirements for determination of the lead content in paint.

4. 16 CFR parts 1630 and 1631 - Carpets and Rugs

(*Comment 30*) - A commenter requested that we continue the stay with respect to handmade "Oriental" carpets. The regulation at 16 CFR §1630.2(b) states: "[o]ne of a kind, carpet or rug, such as an antique, an Oriental, or a hide, may be excluded from testing under this Standard pursuant to conditions established by the Consumer Product Safety Commission." There is a corresponding regulation applying to small carpets and rugs at 16 CFR § 1631.2(b). The commenter noted that we have not established such conditions, and encouraged us to do so. Pending the establishment of the conditions, the commenter sought a continuation of the stay.

(*Response 30*) - We decline to continue (or reinstitute) the stay for handmade "Oriental" carpets. With regard to children's products, publication of the notice of requirements regarding carpets and rugs on July 21, 2010 had the effect of lifting the stay. With regard to non-children's products, we announced the lifting of this stay, effective January 26, 2011. 75 FR 81236, December 27, 2010. The CPSIA was enacted in August 2008; the carpets and rugs industry had ample opportunity to prepare for the law's testing and certification requirements.

In the years since the flammability regulations at 16 CFR parts 1630 and 1631 were promulgated, we have handled, on an individual basis, requests for exclusion of one-of-a-kind carpets or rugs. The commenter is correct that we have not formally established the conditions



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under which a carpet or rug would be excluded under 16 CFR §§ 1630.2(b) and/or 1631.2(b), but such matters are outside the scope of this rulemaking.

(*Comment 31*) - Some commenters recommended that we support and approve the testing of flammability of carpets and rugs by laboratories accredited by the National Voluntary Laboratory Accreditation Program (NVLAP). One commenter added that this should also include "internal" laboratories. The commenters expressed the opinion that that the existing procedures (testing methods, protocols, and recordkeeping requirements) in FF 1-70 (16 CFR part 1630) and FF 2-70 (16 CFR part 1631) are effective in protecting consumers and children and that no additional safety benefit is gained by "different testing protocols." One commenter expressed the belief that the requirement for accreditation of third party conformity assessment bodies to assess conformity with 16 CFR parts 1630 and/or 1631 will only add costs, with no additional safety benefits, for children's carpet and rug products.

(*Response 31*) - It is common for U.S. laboratories that test carpets and rugs in accordance with 16 CFR part 1630 and/or 1631 to be ISO/IEC 17025:2005-accredited by NVLAP. Because NVLAP is a signatory to the ILAC-MRA, it may be a Commission-designated accreditation body, as prescribed in the notices of requirements. Several NVLAP-accredited laboratories have been accepted and posted on our website for testing to 16 CFR parts 1630 and 1631. Worldwide, there are more than 25 CPSC-accepted laboratories for 16 CFR part 1630 and/or 16 CFR part 1631 (with several different ILAC-MRA accreditation bodies represented). Thus, NVLAP accreditation is not inconsistent with CPSC acceptance of third party conformity assessment bodies (laboratories) for testing to 16 CFR parts 1630 and/or 1631.

In response to the commenter who asked that we allow internal laboratories that are accredited by NVLAP, we interpret the comment as referring to laboratories that are owned by



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carpet or rug manufacturers. In these cases, the notice of requirements allows NVLAP accreditation to serve as a "baseline" requirement for CPSC acceptance. However, in accordance with the CPSA (as amended by the CPSIA), laboratories that are owned by a manufacturer of a product that is subject to the regulation for which it conducts tests must meet additional criteria for Commission acceptance as a firewalled third party conformity assessment body.

As for the commenters suggesting that the implementation of different testing protocols will provide no safety benefit, the notice of requirements makes no changes to the flammability test methods that appear in 16 CFR parts 1630 and 1631. The commenters may be referring to the language in section 14(a)(2) of the CPSA (as amended by the CPSIA) that the manufacturer "must submit sufficient samples of the children's product, or samples that are identical in all material respects to the product," for testing by a CPSC-accepted third party conformity assessment body, and/or the CPSA language in section 14(i)(2)(B) related to Commission rulemaking for a continued testing program (including periodic and random sample testing, and compliance labeling). These "testing protocols" are required for children's carpets and rugs by the CPSIA and the recently issued final rule *Testing and Labeling Pertaining to Product Certification*, (76 FR 69482 (November 8, 2011) (to be codified at 16 CFR part 1107)).

(*Comment 32*) - One commenter asked whether conformity assessment bodies in its country that were accredited by a signatory to the ILAC-MRA and accredited to ISO 9239-1, 9239-2, and 6925 "fulfill the requirements listed in 16 CFR parts 1630 and 1631" or whether there are additional requirements that a conformity assessment body must meet to have CPSC accept its accreditation.



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(*Response 32*) - The purpose of the CPSC's laboratory program is to authorize laboratories to conduct CPSC tests capable of supporting a Children's Product Certificate. Although there may be other product standards and test methods in existence, the purpose of this program is limited to conducting third party tests of children's products under section 14 of the CPSA. A laboratory must be accredited by an ILAC-MRA signatory to ISO/IEC 17025:2005 and must have the relevant CPSC regulation or test method in its scope of accreditation to apply successfully for CPSC acceptance of its accreditation. ISO 9239-1, 9239-2, and 6925 all specify methods for assessing the burning behavior of floorings and/or floor coverings. The CPSC regulations at 16 CFR parts 1630 and 1631 assess the surface flammability of carpets and rugs. To the extent that a laboratory was accredited to ISO/IEC 17025:2005, but it did not have 16 CFR part 1630 and/or 1631 in its scope of accreditation, it would not be eligible for acceptance by the CPSC to test children's products under 16 CFR part 1630 and/or 1631. The CPSC standards contain specific test methods for assessing compliance with CPSC requirements. Because other test methods do not assess for compliance with CPSC requirements, accreditation to such other test methods is not sufficient for CPSC acceptance of accreditation.

(*Comment 33*) - One commenter, a government agency, said that the notice of requirements raised serious concerns for the textile industry in its country and "may imply new additional costly requirements."

(*Response 33*) - We believe that the commenter may have misinterpreted the notice of requirements. The regulations pertaining to carpets and rugs have been in place for several decades, and the notice of requirements did not alter those regulations. To the extent that the commenter is expressing concern over the cost of third party testing for children's products, such a comment is beyond the scope of the proposed rulemaking because this proposed rule would



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establish requirements for laboratories, and it would not address testing costs associated with manufacturers.

5. Requirements for Electrically Operated Toys or Other Electrically Operated Articles Intended for Use by Children

(*Comment 34*) - A commenter suggested that we should accept evaluation results from certification bodies recognized by the U.S. Occupational Safety & Health Administration (OSHA) as a Nationally Recognized Testing Laboratory (NRTL) with UL 696 in their scope of recognition. According to the commenter, the requirements in UL 696 are "nearly identical" to those in 16 CFR part 1505.

(*Response 34*) - As explained more fully above in the response to Comment 2, in order to ensure a consistent, global approach toward CPSC acceptance of accredited laboratories, we have decided to consider acceptance only of laboratories accredited by ILAC-MRA signatory accreditation bodies.

In addition, and as explained in the response to Comment 31, concerning carpets and rugs, a laboratory that wishes to conduct tests upon which a manufacturer of a children's product subject to a particular rule may base a certificate of compliance, must have that particular rule listed in its scope of accreditation. This requirement ensures that the laboratory understands the CPSC regulation and test methods associated with the regulation and has been evaluated as competent to conduct that testing. Although UL 696 has been revised to be consistent with 16 CFR 1505, an NRTL laboratory with UL 696 in its scope of recognition must be accredited to ISO/IEC 17025:2005 by an ILAC-MRA signatory accreditation body to 16 CFR part 1505 before the laboratory may apply to the CPSC for acceptance of that accreditation.



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6. 16 CFR parts 1632 and 1633 – Mattresses, Mattress Pads, and Mattress Sets

(*Comment 35*) - One commenter urged us to adopt a longer implementation period for third party testing under 16 CFR part 1632 and to broaden this notice of requirements' retrospective testing provisions.

(*Response 35*) - We already responded to this comment in a notice published in the *Federal Register* on November, 29, 2010 (75 FR 72944), in which we revised the retrospective testing provision applicable to third party testing under 16 CFR parts 1632 and 1633.

7. 16 CFR part 1420 - Youth All-Terrain Vehicles (ATVs)

(*Comment 36*) - One commenter supported our publication of the notice of requirements for ATVs, and they specifically offered support for the "CPSC's analysis to determine whether an ATV is intended for a child and not just rely[ing] on what the ATV industry/manufacture[r] states that it is." Some commenters expressed safety concerns with ATVs. Two commenters (49A, 51C) suggested that the CPSC include Y–12+ model ATVs in the "youth ATV" category, along with the Y–6+ and the Y–10+ models. One commenter claimed that the CPSC is excluding the Y–12+ model from the category "youth ATV." The commenter stated that because the models are intended to be used by 12 year olds, they should fall under the scope of the CPSIA's definition of a "children's product." Both commenters noted that because the T model ATV is intended for children 14 years old and older, the Y–12+ model will be used primarily by children 12 and 13 years old.

(*Response 36*) - Section 232 of the CPSIA required us to establish the American National Standard for Four-Wheel All-Terrain Vehicles Equipment Configuration, and Performance



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Requirements developed by the Specialty Vehicle Institute of America (American National Standard ANSI/SVIA–1–2007) as a mandatory standard for four-wheel all-terrain vehicles.

This standard includes "Category Y" classifications, which are for off-road use by operators under age 16. These categories are: Y–6+, intended for use by children age 6 or older; Y–10+, intended for use by children age 10 or older; Y–12+, intended for use by children age 12 or older; and T, intended for use by children age 14 or older *with adult supervision,* and by persons age 16 or older. While we appreciate the comment that a significant percentage of the riders of the Y–12+ model will be children 12 years old, and *not* the children who are older than 12, no data were provided to support that statement.

We do not have data to indicate which portion of the "12 or older" category represents the rider of Y–12+ ATV models most. The CPSIA defines a "children's product" in § 3(a)(2) of the CPSA as:

> (2) CHILDREN'S PRODUCT.--The term "children's product" means a consumer product designed or intended primarily for children 12 years of age or younger. In determining whether a consumer product is primarily intended for a child 12 years of age or younger, the following factors shall be considered:
>
> (A) A statement by a manufacturer about the intended use of such product, including a label on such product if such statement is reasonable.
>
> (B) Whether the product is represented in its packaging, display, promotion, or advertising as appropriate for use by children 12 years of age or younger.
>
> (C) Whether the product is commonly recognized by consumers as being intended for use by a child 12 years of age or younger.



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(D) The Age Determination Guidelines issued by the Commission staff in September 2002, and any successor to such guidelines.

We cannot categorically include Y–12+ model ATVs as "youth ATVs" because the age range for that model includes children over the age of 12; however, the definition of a "children's product" is limited to products designed or intended primarily for children 12 years of age or younger. When it is unclear whether a product should be considered a children's product, we will apply the four factors. Different manufacturers may mark, package, and market their ATVs as primarily intended for children older than 12, or as primarily intended for 12 year olds. We will determine on a per-model basis, using the four factors listed above, whether a particular model Y–12+ ATV is primarily intended for use by children 12 years of age or younger (and is therefore considered a children's product in need of third party testing to support a certification). Indeed, some commenters commended the CPSC for applying the four statutory factors, rather than relying solely on the manufacturer's statements regarding whether an ATV is intended for a child.

The commenter is incorrect that we have excluded Y–12+ model ATVs from third party testing. In the notice of requirements that appeared in the *Federal Register* on August 27, 2010, we stated: "for the purposes of this notice of requirements, the term 'youth' ATVs *at a minimum* refers to categories Y–6+ and Y–10+ in ANSI/SVIA 1 -2007." (*See* 75 FR at 52616; emphasis added). Thus, we have indicated that the Y–12+ model may be considered for inclusion as a product that must meet third party testing requirements. Again, it will depend upon application of the four factors to a particular model.

On August 12, 2011, the President signed into law Public Law 112-28 (PL 112-28), which amended the CPSIA in several respects. One provision in PL 112-28 created an exception



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from the lead limits for off-highway vehicles. Consequently, ATVs, recreational off-highway vehicles, and snowmobiles are no longer subject to the lead limits in section 101 of the CPSIA. We also note that recently, a final rule revising 16 CFR part 1420, in which American National Standard ANSI/SVIA–1–2010 will become the new mandatory standard effective April 30, 2012, was published in the *Federal Register*. *See* 77 FR 12197 (February 29, 2012) . This standard, which pertains to ATVs, is an updated version of the standard that was the subject of the notice of requirements that appeared in the *Federal Register* of August 27, 2010 (75 FR 52616).

(*Comment 37*) - One commenter requested that we extend the date on which ATV manufacturers must begin third party testing and certification. The commenter further requested that we consider additional forms of relief if there continues to be an insufficient number of CPSC-accepted laboratories.

(*Response 37*) - We responded to this comment in notices published in the *Federal Register* on December 9, 2010 (75 FR 76709) and February 1, 2011 (76 FR 5565), in which we first extended, and then conditionally stayed, third party testing for youth ATVs.

Additionally, as noted in the response to Comment 36, all-terrain vehicles, recreational off-highway vehicles, and snowmobiles are no longer subject to the lead limits in section 101 of the CPSIA.

8. Toys and ASTM F 963

*(Comment 38)* – Two entities submitted letters before we published the notice of requirements pertaining to ASTM F-963-08 (76 FR 46598 (August 3, 2011)), and these letters were placed in the administrative record as comments. For convenience, we will refer to the entities as commenters. (We did receive a third submission, but it appeared to be from a



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laboratory seeking to be listed as a third party conformity assessment body, rather than a comment on the notices of requirements.)

One commenter urged us to refrain from issuing a notice of requirements to ASTM F 963 because it said that requiring third party testing would "dramatically and permanently harm small batch toymakers." The commenter sought an indefinite stay of enforcement of the third party testing requirements for ASTM F 963 or delayed publication of the notice of requirements. The commenter cited testing costs, the impact of a third party testing requirement relative to the production of toys for the holiday season, the complexity of ASTM F 963, and congressional consideration of changes to the CPSIA.

Another commenter expressed concern about "potential confusion in the marketplace that may result from a lack of coordination between timing of the effective date" of a third party testing requirement and revisions to the ASTM F 963 toy standard. It recommended that we set the effective date of third party testing requirements to coincide with an expected revision of the toy standard and the date on which the revision would become a mandatory standard (as provided by section 106 of the CPSIA). It also urged us to clarify that, in cases where requirements overlap between versions of the standard, manufacturers do not need to test to demonstrate compliance with both standards. The commenter also sought flexibility on the acceptance of retrospective testing because, it explained, delays in our acceptance of third party conformity assessment body accreditation could force "redundant testing" on manufacturers who seek to test to new or revised standards before their effective date.

*(Response 38)* – With respect to the request to refrain from issuing the notice of requirements or to issue an indefinite stay of enforcement, we note that the notice of requirements with regard to ASTM F-963 published in the *Federal Register* on August 3, 2011



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(76 FR 46598), and therefore, this comment is moot. Thus, the request to refrain from issuing the notice of requirements is moot. We also decline to issue an indefinite stay of enforcement. We note, however, that the notice of requirements, as well as changes resulting from Public Law 112-28, have addressed some of the commenter's concerns. For example, in the notice of requirements pertaining to ASTM F-963, the Commission stated that it would "stay enforcement of the testing and certification requirements of section 14 of the CPSA with respect to toys subject to ASTM F 963 until December 31, 2011" (76 FR at 46601). Public Law 112-28 also provided some relief, specifically to small batch manufacturers, through the creation of a new section 14(i)(4) of the CPSA, which establishes "special rules" for small batch manufacturers that would result in alternative testing requirements or exemptions from third party testing.

As for the second commenter's concern about effective dates, revisions to the toy standard, and potentially "redundant" testing, we are sensitive to potential disruptions and confusion that may result when standards are revised. The notice of requirements acknowledges that we anticipated another revision to ASTM F-963 and invited comment on "how to make the transition in testing requirements as clear and efficient as possible should the standard change" (76 FR at 46599). The enactment of Public Law 112-28 has magnified the need to develop policies with respect to transitions in testing requirements when standards change, because Public Law 112-28 revised section 104 of the CPSIA to establish a process for subsequent revisions to voluntary standards for durable infant and toddler products. The resulting process is similar to that under section 106 of the CPSIA (which pertains to toys and ASTM F-963). The issuance of future notices of requirements, relative to revised or changing standards, is complicated further by the fact that, after August 14, 2011, all notices of requirements are subject



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to the rulemaking requirements in 5 U.S.C. 553 and 601 through 612 of the Administrative Procedures Act.

Nevertheless, we agree that "redundant" testing should not be necessary when the relevant provision in the toy standard has not changed, or not changed in a manner that would affect how testing is conducted between revisions. For example, assume that a provision in the 2008 version of the standard imposed a particular test on a toy. If the standards organization revised the standard in 2011, such that a provision in the revised 2011 standard imposes the same test as the 2008 standard or a "functionally equivalent" test to the 2008 standard on the toy, then we believe it would be unnecessary to require manufacturers to take toys that had been tested to the 2008 standard and retest them to the 2011 standard. (By "functionally equivalent," we mean that the standards organization has made certain changes in the revised standard, as compared to the earlier standard, but the changes are not substantial, and they do not affect the associated conformance testing.) Similarly, we believe that it is unnecessary, and contrary to public policy, to expect third party conformity assessment bodies that have been accredited to conduct that particular test under the 2008 standard, to cease testing until they are reaccredited to the 2011 standard. Therefore, in those situations where the provisions in a revised toy standard are equivalent or functionally equivalent to the provisions in the earlier standard, we will continue to accept the accreditation of those third party conformity assessment bodies, and manufacturers should continue to have their toys tested and to issue certificates based on such testing. Third party conformity assessment bodies whose accreditation we had accepted to the 2008 standard should notify us when they become accredited to the 2011 standard by submitting an application through Form 223 on the CPSC website, and we will update our listing accordingly.

9. Phthalates



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*(Comment 39)* – One commenter expressed appreciation for our inclusion of two test methods for phthalates (a revised CPSC test method and a Chinese test method) in the notice of requirements, but they asked us to allow for other "proven internal test methods." The commenter explained that testing laboratories may modify existing test methods or develop their own methods for testing for phthalates; accordingly, they assert that restricting the notice of requirements to two test methods could result in manufacturers retesting products and testing backlogs at test laboratories. The commenter said we should allow other methods "as long as it can be shown that these are equivalent to the CSPC methods." The commenter said that equivalency could be shown through side-by-side comparisons with the CPSC method, method validation data, participation in interlaboratory studies, or other requirements established by the CPSC.

Another commenter supported our inclusion of the revised CPSC test method and Chinese test method, but they asked that we consider Health Canada's test method for total phthalate content in PVC products. The commenter said that recognizing the Canadian test method would reduce redundant testing further, by enabling firms to certify compliance with U.S. and Canadian phthalate requirements using one test.

*(Response 39)* – We are receptive to considering other test methods and to adding those methods to a notice of requirements. Indeed, as our own experience with phthalates testing demonstrates, we have revised or refined our test method several times and added the Chinese test method to the notice of requirements for phthalates testing. Parties who believe that our accreditation criteria should be expanded to include a specific test method should contact us; or, alternatively, they should use the petition process at 16 CFR part 1051, to ask us to amend this rule (assuming that this rule is finalized). The commenter did not indicate a specific test method



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that we should allow to be used to determine phthalate concentrations. Thus, we cannot determine equivalency to our existing test methods.

With respect to the Canadian test method, we assume that the commenter is referring to *Determination of Phthalates in Polyvinyl Chloride Consumer Products*, Health Canada test method C-34. We share the desire to reduce the testing burden, where possible, through harmonization; and we developed CSPC test method CPSC-CH-C1001-09.3 (and its predecessors), specifically including the Health Canada Method C-34 for determining phthalates, as well as many other methods that were deemed acceptable as optional means of extraction and analysis of the phthalates in samples. Thus, tests by a CPSC-accepted testing laboratory using the C-34 test method are allowed for children's product certification purposes.

*(Comment 40)* – Two commenters sought clarification of what materials need to be tested for phthalates. One commenter referred to our "Statement of Policy: Testing of Component Parts with Respect to Section 108 of the CPSIA" (dated August 7, 2009) ("Statement of Policy") to point out that the Statement of Policy gave examples of materials that do not normally contain phthalates and would not require testing or certification. The commenter then said that the notice of requirements caused confusion because a joint statement by a majority of the Commissioners indicated that the notice of requirements did not expand the universe of materials or products to be tested or certified and that the Statement of Policy remained in effect, yet the notice of requirements did not reflect the Statement of Policy. Thus, the commenter asked us to revise the notice of requirements to "specifically list all plastic materials that are known not to contain phthalates, including, but not limited to, those identified in the (Statement of Policy)…." The commenter also provided a list of more than 30 plastic materials that it said are known not to contain phthalates.



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The second commenter also referred to the Statement of Policy, but they asked that we revise the Statement of Policy to "make it clear . . . that the excluded material list compiled, is not exhaustive and similar, related or other such materials may not require testing and may be added in the future." The commenter said, however, that "it is likely impossible to create an exhaustive list of *all* materials that may not include phthalates and therefore may not require testing" (emphasis in original).

*(Response 40)* – While we recognize the commenters' desire for greater clarification with respect to materials that may or may not contain phthalates, the principal purpose of a notice of requirements is to establish the criteria under which we will accept the accreditation of a third party conformity assessment body. In this instance, the notice of requirements identified the two test methods to which third party conformity assessment bodies should be accredited, and any information describing the materials that normally do not contain phthalates was intended to provide helpful guidance, rather than establish accreditation criteria. We acknowledge that the Statement of Policy discussed materials or products that are not known to contain phthalates and that the notice of requirements referred to the Statement of Policy and other previous CPSC documents; but that portion of the notice of requirements was intended to inform interested parties about those prior CPSC documents and to indicate that they remain in effect.

With respect to expanding the list of materials that may or may not contain phthalates and whether such a list should be part of a notice of requirements, we will consider whether additional guidance on materials containing or not containing phthalates should be developed. We decline, however, to include such a list in a notice of requirements or this rulemaking. Our experience indicates that when a regulation or document attempts to provide a list of examples, often the list is construed to be exhaustive or definitive, resulting in multiple requests to amend



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the rule or revise the document to add or delete items from the list. Given our scarce resources, and for the reasons mentioned in this response, we do not believe it would be prudent to include as part of this rulemaking, a list of materials containing phthalates or a list of materials known not to contain phthalates.

*(Comment 41)* – One commenter discussed Public Law 112-28 and the exception it created for inaccessible component parts containing phthalates. In brief, section 5 of Public Law 112-28 amended section 108 of the CPSIA to create an exclusion for "inaccessible component parts." The commenter sought clear direction from us about "how the phthalate standard will apply to inaccessible components" and asked that we "immediately amend the Statement of Policy to clarify that inaccessible components are exempt from the phthalate standard and therefore exempt from third party testing."

*(Response 41)* – We published the Statement of Policy and the notice of requirements before Public Law 112-28 was enacted. Thus, issues concerning implementation of the phthalates provision in Public Law 112-28 and revisions to the Statement of Policy are outside the scope of the notice of requirements and this rulemaking. Further, the notice of requirements establishes the criteria and process for CPSC acceptance of accreditation of laboratories for testing children's products under section 14 of the CPSA. Determination of which component parts require testing is outside the scope of a notice of requirements.

*(Comment 42)* – One commenter said that because phthalates are added intentionally to some plastics, paints, and other materials and are not ubiquitous environmental contaminants, manufacturers of products "produced exclusively from materials on the phthalate exclusion list (or other materials not likely to contain phthalates)" are "generally able to be certain that they are not intentionally adding phthalates and that phthalate-containing materials are not present in their



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factories." The commenter asked that we "explicitly recognize such knowledge as a reasonable basis for certifying compliance" with the phthalates limits and "allow self-certification by such entities."

*(Response 42)* – We decline to revise the notice of requirements or draft this rule to incorporate the commenter's suggestion. Section 14(a)(2) of the CPSA is clear that, with respect to children's products, a manufacturer must certify the product based upon testing by a third party conformity assessment body accredited under section 14(a)(3) of the CPSA. Self-certification based upon a manufacturer's knowledge would not be consistent with section 14(a)(2) of the CPSA.

## *E. Miscellaneous Comments*

(*Comment 43*) - One commenter agreed with the notice of requirements for 16 CFR part 1505, *Requirements for Electrically Operated Toys or other Electrically Operated Articles Intended for Use by Children*, and 16 CFR § 1500.86(a)(5) (Clacker Balls) and suggested that officials be sent to manufacturer sites (domestic and foreign) to conduct audits to see that the tests are performed properly and to ensure that the manufacturers do perform all steps of the tests submitted by them to the accredited agencies.

(*Response 43*) - The commenter may have misunderstood the notice of requirements. The tests to assess compliance are performed at laboratories, not at manufacturing sites (unless a manufacturing site has a firewalled laboratory). If the commenter is referring to firewalled laboratories or third party laboratories, in general, we have designated accreditation bodies that are signatories to the ILAC-MRA to conduct accreditation of third party conformity assessment bodies to be accepted by the Commission. ILAC-MRA signatories visit independent and



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firewalled laboratories during initial assessments and regular reassessments to assess the laboratory's continued compliance to the requirements of ISO/IEC 17025:2005. In every assessment and reassessment, the accreditation body must demonstrate that it has adequately assessed all of the laboratory's technical competencies and management systems competencies (as prescribed in ISO/IEC 17025:2005) associated with its scope of testing.

(*Comment 44*) - Most notices of requirements included provisions allowing certificates of compliance to be based on testing performed by an accredited third party conformity assessment body before the Commission accepts the laboratory's accreditation. This practice is sometimes referred to as allowing "retrospective" testing. In the notices of requirements, we prescribed particular circumstances under which retrospective testing could support a Children's Product Certificate. For example, we stated that the product should be tested by a third party conformity assessment body that was, at the time of product testing, ISO/IEC 17025:2005 accredited by an ILAC-MRA signatory accreditation body; the accreditation scope in effect at the time of testing had to include testing to the regulation or test method identified in the notice; and we placed constraints on how far back in time the retrospective testing could occur. Initially, we did not allow any retrospective testing by firewalled laboratories. Later, we allowed retrospective testing by firewalled laboratories, if the firewalled laboratory had already been accepted by an order of the Commission for testing to a test method or regulation specified in an earlier notice of requirements.

A commenter, in response to an earlier notice of requirements, supported the position of not allowing any retrospective testing by firewalled laboratories. This commenter viewed the position of not allowing any retrospective testing by firewalled laboratories as a way to reduce



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any possible conflicts of interest and to ensure that no undue influence occurred in the certification process.

(*Response 44*) - If we have already accepted a laboratory as firewalled, we consider the laboratory to have shown previously that it has policies and procedures in place consistent with laboratory independence and impartiality. We will monitor this policy, and, if necessary, revise it in future rulemakings. We note that because retrospective testing issues arise only when a third party testing requirement for a particular rule or standard begins, this proposed rule would not address retrospective testing.

(*Comment 45*) - Some commenters argued that the CPSA, as amended by the CPSIA, does not require third party testing of children's products that are subject to a regulation of general applicability (*e.g.*, 16 CFR § 1610, *Standard For the Flammability of Clothing Textiles*). In the view of these commenters, the only children's products for which third party testing is required are those children's products subject to a regulation whose reach is limited to children's products (*e.g.*, 16 CFR §§ 1615, 1616, *Standard for the Flammability of Children's Sleepwear*). One commenter stated that the safety of children's products subject to rules of general applicability can be assured via the General Comformity Certificates that are required for non-children's products under section 14(a)(1) of the amended CPSA.

Some of the commenters who disagreed that the amended CPSA requires third party testing of children's products subject to rules of general applicability asserted that, even if the Commission views the text of the statute as requiring third party testing for such products, we should, nevertheless, use our implementing authority under section 3 of the CPSIA to limit the third party testing requirement to rules of limited applicability—that is, rules applicable solely to



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children's products. Similarly, one commenter urged the Commission to use authority granted in section 14(b) of the CPSA to "assess the necessity of third party testing on a case-by-case basis."

One commenter argued that we have been inconsistent in describing what constitutes a "children's product safety rule." The commenter noted that in the proposed rule on "Testing and Labeling Pertaining to Product Certification," we stated: "[c]urrently, the rule on children's bicycle helmets is the only children's product safety rule that contains requirements for a reasonable testing program." 75 Fed. Reg. 28336, 28348 (May 20, 2010). Because the FFA regulations, such as 16 CFR part 1610, *Standard for the Flammability of Clothing Textiles*, contain reasonable testing programs, the commenter asserted that we must not consider FFA regulations to be children's product safety rules. The commenter argued that we should offer the reasonable testing program requirements in 16 CFR part 1610 the same treatment we have afforded all children's product safety rules with existing reasonable testing programs (*e.g.*, bicycle helmets).

(*Response 45*) - Section 14(a)(2) of the CPSA requires manufacturers and private labelers of a children's product subject to a children's product safety rule to certify that their children's product complies with the relevant children's product safety rule. Section 14(f)(1) of the CPSA defines "children's product safety rule" as "a consumer product safety rule under this Act 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." 15 U.S.C. § 2063(f)(1).

Thus, the statute defines a "children's product safety rule" to mean a consumer product safety rule. The Commission has taken the position that the statute requires third party testing to support a certification of a children's product if that children's product is subject to a consumer



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product safety rule. A "consumer product safety rule" becomes a "children's product safety rule"—not when the product subject to the rule is limited to children's products—but rather, when the product subject to the rule includes children's products.

With regard to the comment that a General Conformity Certificate would adequately assure the safety of children's products, we again refer to the statute. Section 14(a)(2) of the CPSA states that a certification based on third party testing is required for "any children's product that is subject to a children's product safety rule." General Conformity Certificates are required for non-children's products and are not required to be based on third party testing. However, Public Law 112-28 allows small batch manufacturers to use alternative testing requirements once the Commission has identified such testing requirements, or they are allowed an exemption if the Commission determines that no alternative testing requirement is available or economically practicable.

As for the comment regarding section 3 of the CPSIA, the statute gives us some latitude in implementing the CPSIA, but it does not authorize us to avoid implementing the statute altogether. Courts have held that an agency's authority to implement a new statute does not encompass avoiding the statutory obligation itself. *See U.S. v. Markgraf*, 736 F.2d 1179, 1183 (7th Cir. 1984) ("An administrative agency cannot abdicate its responsibility to implement statutory standards under the guise of determining that inaction is the best method of implementation."). *See also Friends of the Earth, Inc. v. EPA*, 446 F.3d 140, 145 (D.C. Cir. 2006) (An administrative agency may not avoid the plain language of a statute by asserting that its preferred approach would be better policy; nor can a court "set aside a statute's plain language simply because the agency thinks it leads to undesirable consequences in some applications.")



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Finally, the comment regarding inconsistency in determining what is a children's product safety rule was submitted in response to the notice of requirements for clothing textiles, which was published on August 18, 2010—several months after publication of the proposed rule on "Testing and Labeling Pertaining to Product Certification." The publication of the clothing textiles notice of requirements clearly indicates that the Commission decided that the clothing textiles standard is a children's product safety rule. In fact, the Commission reaffirmed its position when it revised the clothing textiles notice of requirements on April 22, 2011. *See* 76 FR 22608. The Commission also issued other FFA-related notices of requirements subsequent to the publication of the proposed rule on "Testing and Labeling Pertaining to Product Certification." *See, e.g.*, 75 FR 42311 (July 21, 2011). Accordingly, we consider the quoted sentence in the preamble to the proposed rule on "Testing and Labeling Pertaining to Product Certification" to be in error because, as shown by subsequent CPSC actions, FFA regulations may be children's product safety rules and the subject of a notice of requirements.

(*Comment 46*) - Some commenters expressed concern over the cost of third party testing. One commenter noted, in particular, that for regulations under the Flammable Fabrics Act (FFA), 15 U.S.C. 1191–1204, the tests involve hazards, which could result in "required testing of additional samples, longer lead times for testing, and added expenses." Some commenters urged a thorough cost-benefit analysis of the CPSC's rules related to testing and certification, component parts, and/or the notices of requirements. Some of these commenters argued that the additional cost of third party testing carries no benefit because third party testing does not enhance product safety.

Another commenter stated that "[r]equiring third party testing further triggers compliance" with requirements under the two recent notices of proposes rulemaking (NPRs),



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*Testing and Labeling Pertaining to Product Certification* (to be codified at 16 C.F.R § 1107) (75 Fed. Reg. 28336 (May 20, 2010) and *Conditions and Requirements for Testing Component Parts of Consumer Products* (to be codified at 16 CFR § 1109) (75 Fed. Reg. 28208 (May 20, 2010)). The commenter opined that "these regulatory burdens dilute the focus from . . . ensuring that the product is safe and compliant with regulatory standards."

**(***Response 46*) -We are sensitive to testing cost concerns and note that Public Law 112-28 expressly required us to seek public comment on opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation and listed seven issues for public comment. In the *Federal Register* of November 8, 2011 (76 FR 65956), we invited comment on the seven issues and on opportunities to reduce the cost of third party testing requirements. The comment period for the notice ended on January 23, 2012, and we will address the comments in a separate proceeding.

However, with respect to conducting cost-benefit analyses for the rules identified in the comment, the CPSIA did not require us to conduct such analyses. We also note that we issued final rules on "Testing and Labeling Pertaining to Product Certification" (76 FR 69482 (November 8, 2011)) and "Conditions and Requirements for Relying on Component Part Testing or Certification, or Another Party's Finished Product Testing or Certification, to Meet Testing and Certification Requirements" (76 FR 69546 (November 8, 2011)). The preamble to the final rule on "Testing and Labeling Pertaining to Product Certification" summarized and responded to a similar comment on cost-benefit analyses (*see* 76 FR at 69484 (comment 2 and response)).

Yet, with respect to the comment that a notice of requirements somehow "triggers compliance" with these two rules, we disagree. A notice of requirements establishes the criteria



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under which we will accept the accreditation of a third party conformity assessment body to test children's products for compliance to a children's product safety rule. Section 14(a)(3)(A) of the CPSA states that the third party testing requirement applies to any children's product manufactured more than 90 days after we have established and published the notice of requirements. Section 14(i)(2) of the CPSA creates the obligation for continuing testing. In any event, the final rule on "Testing and Labeling Pertaining to Product Certification" does not become effective until February 8, 2013. The final rule on "Conditions and Requirements for Relying on Component Part Testing or Certification, or Another Party's Finished Product Testing or Certification, to Meet Testing and Certification Requirements," while effective on December 8, 2011, pertained to the conditions and requirements under which passing component part test reports, certification of component parts of consumer products, or finished product testing or certification procured or issued by another party, can be used to meet, in whole or in part, the testing and certification requirements of sections 14(a) and 14(i) of the CPSA. As such, component part testing as described by that final rule is voluntary, rather than mandatory.

**(***Comment 47*) - One commenter asserted that requiring manufacturers of children's clothing textiles subject to the FFA regulations at 16 CFR part 1610, *Standard for the Flammability of Clothing Textiles*, to issue certifications based on third party testing "bypasses the entire FFA rulemaking process." The commenter argued that section 4(b) of the FFA requires that regulations or amendments to regulations be based on certain findings that the CPSC has not made, and argued that we have effectively amended part 1610 to require third party testing of children's clothing textiles. The commenter stated that when the test methods in part 1610 were promulgated, and "[i]n accordance with Section 4(b) of the FFA," the CPSC hosted several meetings attended by industry and testing representatives, who worked



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cooperatively to develop test methods that the representatives and CPSC agreed were appropriate to assess compliance with the flammability standards. The commenter stated that the third party testing requirements, along with the requirements proposed in the testing and labeling and component parts NPRs, "entirely undermine this cooperative effort."

This commenter also asserted that the testing requirements in part 1610 are sufficient for children's products subject to those regulations, and that requiring third party testing does not provide additional assurance of the product's ability to pass the applicable product safety standard. The commenter asked the Commission to hold a public meeting if we do not agree that the testing regime under part 1610 is sufficient for the industry to demonstrate compliance with the standard.

(*Response 47*) - The purpose of the *Standard for the Flammability of Clothing Textiles* is to keep dangerously flammable textiles and garments made of these textiles out of commerce. The standard provides methods of testing the flammability of clothing and textiles intended to be used for clothing by classifying fabrics into three classes of flammability based on their speed of burning. The CPSC has not amended 16 CFR part 1610 by implementing the third party testing requirements of section 14 of the CPSA.

Section 4 of the FFA prescribes the process for promulgating a regulation under that statute. Section 4(b) of the FFA requires, in relevant part, that each FFA "standard, regulation, or amendment thereto . . . be based on findings that such standard, regulation, or amendment thereto is needed to adequately protect the public against unreasonable risk of the occurrence of fire leading to death, injury, or significant property damage, is reasonable, technologically practicable, and appropriate." 15 U.S.C. 1193(b). Section 4(b) of the FFA does not mandate consultation with industry. It requires findings in support of an FFA regulation. The fact that



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industry representatives cooperated with the CPSC when part 1610 was promulgated does not mean that the CPSC, in implementing section 14(a)(3)(B)(vi) of the CPSA, must host meetings before issuing a notice of requirements. Therefore, we decline the commenter's suggestion to hold a public meeting on this matter.

With regard to the commenter's assertion that tests conducted under part 1610 sufficiently assure compliance with the standard, and therefore, third party testing is not necessary, we note that, absent the CPSIA, a manufacturer of a clothing textile was not required to conduct the test prescribed by part 1610 at all. If the manufacturer wished to issue an FFA guaranty that the product complied with part 1610, then the manufacturer had to conduct the tests prescribed by part 1610, but that testing was entirely optional.

(*Comment 48*) - One commenter stated that the Commission should have allowed 60 days for the comments to be submitted in response to the notices of requirements, noting that the TBT Committee has recommended 60-day comment periods. This commenter also observed that the notice of requirements was effective on publication; thus, there was no opportunity to comment prior to the notice taking effect.

(*Response 48*) - The notices of requirements that invited public comments have all contained a 30-day comment period and have all been effective upon publication. Nevertheless, this proposed rule provides a 75-day comment period. The public may comment on all aspects of the proposal, even those parts that were previously included in the notices of requirements.



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## *F. Comments Considered Out of Scope*

Several commenters raised issues that were not present in the notices of requirements and are not directly relevant to this proposed rule; such issues, therefore, are outside the scope of this rulemaking.

(*Comment 49*) - One commenter recommended that we address the procedures for filing certificates of compliance, including who "owns" the certificate and what is the required retention period for certificates.

(*Response 49*) - This issue is outside the scope of this rulemaking because neither the notices of requirements, nor this proposed rule, concern the requirements or processes for certificates of compliance. We note that the recently issued final rule, *Testing and Labeling Pertaining to Product Certification* (76 FR 69482 (November 8, 2011) (to be codified at 16 CFR part 1107)), addresses the length of time manufacturers are required to keep records of certificates of compliance.

(*Comment 50*) - One commenter suggested that we specify what will be considered "sufficient samples" of a children's product to submit for third party testing. The commenter was concerned that different laboratories would require different sampling schedules, and they suggested that manufacturers might choose to use laboratories that require the least onerous sampling schedule. The commenter recommended that we prescribe a specific, testing schedule based on a statistical scheme for sample product runs of the children's products. The commenter also suggested that the number of samples selected for testing should be based on the size and duration of the production run of the children's product.

(*Response 50*) - The proposed rule is limited to establishing the requirements for conformity assessment bodies in order for their test results to be used for children's product



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certification purposes. The certifier, not the laboratory, determines what constitutes a sufficient number of samples to test for certification. The recently issued final rule on *Testing and Labeling Pertaining to Product Certification* (76 FR 69482 (November 8, 2011) (to be codified at 16 CFR part 1107)), addresses sample size issues to a certain extent, and we also issued a proposed rule pertaining to "representative samples" (76 FR 69586 (November 8, 2011)), pursuant to Public Law 112-28.

(*Comment 51*) - One commenter stated: "component or raw material testing is another major concern," and they urged that "allowing for reasonable component testing is a critical need to avoid a crushing financial burden on small businesses."

(*Response 51*) - This rulemaking is limited to the requirements related to the accreditation of third party conformity assessment bodies. Whether and under what circumstances component parts of children's products may be third party tested separately in support a certificate of compliance is not related to the criteria and process for CPSC acceptance of the accreditation of third party conformity assessment bodies. The recently issued final rule, *Conditions and Requirements for Relying on Component Part Testing or Certification, or Another Party's Finished Product Testing or Certification, to Meet Testing and Certification Requirements* (76 FR 69546 (November 8, 2011) (to be codified at 16 CFR part 1109)), should address the commenter's concerns.

(*Comment 52*) - Some commenters described their opinions concerning whether third party testing of children's products for lead content should be required. Overall, the commenters supported third party testing in this context.

(*Response 52*) - Section 101 of the CPSIA established the lead content limits for children's products. Section 14(a)(2)(A) of the CPSA requires manufacturers of children's



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products to submit samples of a children's product to a third party conformity assessment body for testing as a basis for certifying the children's product. These comments refer to the statutory requirements and are beyond the scope of this proposed rulemaking.

(*Comment 53*) - In response to the notice of requirements for accreditation of third party conformity assessment bodies to assess conformity of youth products under the CPSC regulation on ATVs (16 CFR part 1420), one commenter urged that children younger than the age at which one can legally drive traditional motor vehicles should not be allowed to operate ATVs. In the view of this commenter, ATVs have become a serious public health concern for children. The commenter described study findings and statistics in support of his view.

(*Response 53*) - The notice of requirements related to ATVs provided the criteria and processes for CPSC acceptance of the accreditation of laboratories that will be able to conduct the third party tests of youth ATVs that may support manufacturers' certificates of compliance with 16 CFR part 1420. Therefore, the question of whether children should be allowed to operate ATVs is beyond the scope of the ATV notice of requirements and the proposed rule.

(*Comment 54*) - Several commenters remarked on the cost of complying with the lead content requirements in the context of small businesses selling handcrafted items. One commenter remarked that handcrafted, one-of-a-kind items cannot each be destructively tested. The commenter suggested that our regulations mirror California's Lead-Containing Jewelry Law, AB 2901. Another commenter asked if the regulations had exceptions to the testing requirements. Another commenter stated that the testing costs will tend to decrease consumer options because small manufacturers will not be able to stay in business. The commenter's main concern was that all "units" of children's items must be tested for lead content and phthalates,



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and that relying on testing by suppliers is not sufficient. The commenter offered the following suggestions:

1. Waive the testing requirements for small-volume manufacturers, such as those with less than $1 million in revenue in the United States.
2. If a waiver is not possible, provide free testing to small businesses that produce children's products.
3. Allow third party certification of components from manufacturers to be used as a basis for a finished product certificate.

(*Response 54*) - The scope of this proposed rule is limited to the requirements related to the accreditation of third party conformity assessment bodies. This rulemaking does not address the requirements related to the testing and certification of consumer products. Therefore, these comments are beyond the scope of this proposed rule.

Additionally, one provision in PL 112-28 directs us to seek public comment on seven specific issues, including:

- the extent to which modification of the certification requirements may have the effect of reducing redundant third party testing by or on behalf of two or more importers of a product that is substantially similar or identical in all material respects;
- the extent to which products with a substantial number of different components subject to third party testing may be evaluated to show compliance with an applicable rule, ban, standard, or regulation by third party testing of a subset of such components selected by a third party conformity assessment body;
- the extent to which manufacturers with a substantial number of substantially similar products subject to third party testing may reasonably make use of sampling procedures that reduce the overall test burden without compromising the benefits of third party testing; and
- other techniques for lowering the cost of third party testing consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.



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Recently, we published a *Federal Register* notice seeking public comment on issues regarding reducing the testing burden for children's product certifiers. *See Application of Third Party Testing Requirements; Reducing Third Party Testing Burdens* (76 FR 69596 (November 8, 2011)). Public Law 112-28 also requires us to review the public comments, and it states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

(*Comment 55*) - One commenter raised concerns that the third party testing requirements would create a competitive advantage for the larger firms and drive many small businesses out of the market. The commenter recommended that the law (presumably the CPSIA) be amended to focus on manufacturers directly linked to the production of unsafe products for children and penalize them, as opposed to penalizing the small business community.

(*Response 55*) - The commenter may have misunderstood the purpose of a notice of requirements. A notice of requirements establishes the accreditation requirements for laboratories to test for compliance to specific rules, bans, standards, or regulations. It does not establish requirements for manufacturers, other than establishing a date by which children's products must be certified based on third party testing results. Therefore, issues pertaining to statutory amendments, the effects of third party testing on small businesses, and penalties for manufacturers, are all beyond the scope of this proposed rule.

As discussed in the response to Comment 49, we have published a notice in the *Federal Register* (76 FR 69596) seeking public comment on issues regarding reducing the testing burden for children's product certifiers. Further, Public Law 112-28 created a new section 14(i)(4) of



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the CPSA to provide for special rules for small batch manufacturers. The provision contemplates the possible development of alternative testing requirements for "covered products" made by "small batch manufacturers" and defines the terms "covered product" and small batch manufacturer." The provision also provides for possible exemptions of small batch manufacturers from the third party testing requirements and imposes certain limits on third party testing requirements.

## IV. Description of the Proposed Rule

The proposed rule would consist of four subparts. Subpart A, "Purpose and Definitions," is created by the audit final rule published elsewhere in this issue of the *Federal Register*. This proposed rule would add to subpart A, a section describing the purpose of part 1112; it would amend two definitions contained in the audit final rule; and it would add several new definitions. In addition, the audit final rule reserved a subpart B in part 1112; this proposed rule would create subpart B, which would contain the principal requirements for third party conformity assessment bodies, including how a laboratory may obtain CPSC acceptance of its accreditation. Subpart C addresses audits, and it is the core of the audit final rule (published elsewhere in this issue of the *Federal Register*). The proposed rule, however, would add a provision to subpart C, addressing the timing of audits. The proposed rule also would create a subpart D, addressing adverse actions that we may take against CPSC-accepted third party conformity assessment bodies. Finally, the proposed rule would make limited changes to § 1118.2, the Commission's regulation on the conduct and scope of inspections, to conform with part 1112.

At the outset, we note that section 14(f)(2)(D) of the CPSA requires that the acceptance of the accreditation of a firewalled laboratory occur by order of the Commission. Consistent



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with this provision, the Commission considers that any removal of the acceptance of the accreditation of a firewalled laboratory (whether by suspension or withdrawal) also must occur by order of the Commission. The Commission may delegate other functions and powers described in this part to CPSC staff, under 16 CFR § 1000.11. (Due to this distinction between functions that the Commission as a body of appointed Commissioners must discharge, and other functions that the agency may discharge via staff activity, from this point forward in this preamble, we attempt to distinguish between the Commission as a body ("Commission") and the CPSC as an agency ("CPSC").)

*A. Subpart A – Purpose and Definitions*

1. Proposed § 1112.1 – Purpose

Proposed § 1112.1 would describe the major topics addressed in part 1112. It would note that the part defines the term "third party conformity assessment body" and describes the types of third party conformity assessment bodies whose accreditations are accepted by the CPSC to test children's products under section 14 of the CPSA. It would note that part 1112 describes the requirements and procedures for becoming a CPSC-accepted third party conformity assessment body; the audit requirement applicable to third party conformity assessment bodies; how a third party conformity assessment body may voluntarily discontinue participation as a CPSC-accepted third party conformity assessment body; the grounds and procedures for withdrawal or suspension of CPSC acceptance of accreditation of a third party conformity assessment body; and how an individual may submit information alleging grounds for adverse action.

2. Proposed § 1112.3 – Definitions

The proposed rule would add a sentence preceding the definitions, to clarify that the definitions in this section apply for purposes of this part.



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(i) Revised Definitions

Proposed § 1112.3 would amend two definitions that appear in the audit final rule, which published elsewhere in this issue of the *Federal Register*. The two definitions to be amended are:

*Audit*: An audit of a CPSC-accepted laboratory consists of two parts: the reassessment portion, which is conducted by the accreditation body, and the examination portion, which is conducted by the CPSC. Currently, the definition of audit describes the examination portion as:

> "The resubmission of the "Consumer Product Conformity Assessment Body Acceptance Registration Form" (CPSC Form 223) by the third party conformity assessment body and the Consumer Product Safety Commission's ("CPSC's") examination of the resubmitted CPSC Form 223. If the third party conformity assessment body is owned, managed, or controlled by a manufacturer or private labeler (also known as a "firewalled" conformity assessment body) or is a government-owned or government-controlled conformity assessment body, the CPSC's examination may include verification to ensure that the entity continues to meet the appropriate statutory criteria pertaining to such conformity assessment bodies."

To this portion of the definition, the proposed rule would add the words, "and accompanying documentation" twice, after each mention of the CPSC Form 223. The proposed rule would delete the second sentence and replace it with the following two sentences:

> "Accompanying documentation includes the baseline documents required of all applicants in § 1112.13(a), the documents required of firewalled applicants in § 1112.13(b)(2), and/or the documents required of governmental applicants in § 1112.13(c)(2)."

Documents beyond the baseline documents are required of firewalled and governmental applicants so that the CPSC's examination may include verification to ensure that the entity continues to meet the appropriate statutory criteria pertaining to such third party conformity assessment bodies. These changes would clarify which materials must be submitted at audit. As the purpose of the audit is to confirm that the laboratory continues to meet the requirements of CPSC acceptance, all laboratories would be required to submit the baseline documentation.



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*CPSC*: The audit final rule defines "CPSC" to mean the U.S. Consumer Product Safety Commission. The proposed rule would discuss certain tasks that must be accomplished by the actual Commission body, as opposed to the CPSC as an agency. Thus, to distinguish between the Commission, as a body, as opposed to the agency, as a whole, the proposed rule, for purposes of part 1112 only, would revise the definition of "CPSC" to mean the U.S. Consumer Product Safety Commission as an agency.

(ii) New Definitions

Proposed § 1112.3 would create the following nine definitions:

*Accept accreditation*: The proposed rule would define this term consistent with its use in section 14 of the CPSA. *See, e.g.,* 15 U.S.C. 2063(e)(1). It would mean that the CPSC has positively disposed of an application by a third party conformity assessment body to test children's products pursuant to a particular children's product safety rule, for purposes of the testing required in section 14 of the CPSA.

*Commission*: We would define "Commission" to mean the body of Commissioners appointed to the U.S. Consumer Product Safety Commission. In contrast, the agency as a whole will be referred to, in this part, as the CPSC.

*CPSA*: We would define this acronym to mean the Consumer Product Safety Act, 15 U.S.C. 2051–2089.

*Notice of requirements*: We would define this term consistent with how it is used in section 14 of the CPSA and with how we have used the term to date. It would mean a publication that provides the minimum qualifications necessary for a laboratory to become CPSC-accepted to test children's products pursuant to a particular children's product safety rule.



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*Scope*: The testing and accreditation community typically use the word "scope" or "scope of accreditation" to mean the entire list of testing services for which a laboratory has been granted accreditation, which usually includes many test methods and standards beyond those related to CPSC rules. For purposes of this part, we would define this term slightly differently. In part 1112, "scope" would mean the range of particular children's product safety rules and/or test methods to which a laboratory has been accredited and for which it may apply for CPSC acceptance of its accreditation.

*Suspend*: The proposed rule would define this term consistent with its use in section 14(e) of the CPSA, which this proposed rule would implement. "Suspend" would mean that the CPSC has removed its acceptance, for purposes of the testing of children's products required in section 14 of the CPSA, of a laboratory's accreditation due to the laboratory's failure to cooperate in an investigation under this part.

*Third party conformity assessment body*: We propose to define this term to mean a testing laboratory.

We developed this definition from the use of the term "third party conformity assessment body" in section 14 of the CPSA. The CPSA contains a lengthy definition of this term, which includes the conditions placed on governmental and firewalled laboratories. For ease of understanding, we propose to define the term more succinctly, but our definition is consistent with the term's use throughout the CPSA.

In particular, we note that the statutory definition of this term states that a governmental laboratory that satisfies certain conditions may be considered a third party conformity assessment body. The statutory definition also states that a conformity assessment body that is owned, managed, or controlled by a manufacturer or private labeler may be accepted as a third party



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conformity assessment body by the Commission if it satisfies certain conditions. Section 14 of the CPSA consistently refers to CPSC-accepted laboratories collectively as "third party conformity assessment bodies."

We are aware that the term "third party conformity assessment body," by virtue of the words "third party," commonly refers to a laboratory that is entirely independent of the entity supplying the product to be tested and independent of any entity interested in the product. However, because this rule implements section 14 of the CPSA, which refers to all CPSC-accepted laboratories as "third party conformity assessment bodies," the proposed rule would follow the statute's convention on this point.

We also are aware that, in the laboratory industry, the term "third party conformity assessment body" is understood to include entities other than testing laboratories. However, the proposed rule would use the term as it is used in the CPSA, which is as a testing laboratory.

Finally, we note that, in the preamble to this rule, for ease of reference, and for the convenience of the reader, we use the word "laboratory" interchangeably with "third party conformity assessment body." In the regulatory text, for clarity, we only use the full term, "third party conformity assessment body."

*Undue influence*: We have developed a definition for undue influence after reviewing similar definitions used by other federal agencies and some laboratories, and with the goal of having a broad enough definition that the myriad sources and methods of undue influence that could arise in this context would be captured by the definition. The proposed rule would define "undue influence" to mean that a manufacturer, private labeler, governmental entity, or other interested party affects a laboratory, such that commercial, financial, and other pressures compromise the integrity of its testing processes or results.



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*Withdraw*: The proposed rule would define this term consistent with its use in section 14(e) of the CPSA. The proposal would define "withdraw" to mean that the CPSC removes its prior acceptance of a laboratory's accreditation pursuant to a particular children's product safety rule for purposes of the testing of children's products required in section 14 of the CPSA.

*B. Subpart B – General Requirements Pertaining to Third Party Conformity Assessment Bodies*

Proposed subpart B would establish the foundation for the CPSC third party conformity assessment body program with respect to basic topics, such as when and how a laboratory may apply to the CPSC for acceptance of its accreditation, and how a laboratory can voluntarily discontinue its participation with the CPSC. The proposed subpart also would define the three types of laboratories, create various obligations for CPSC-accepted laboratories, such as recordkeeping responsibilities, and institute certain limitations, such as limits on the ability to subcontract test work conducted, on CPSC-accepted laboratories. Proposed subpart B also would include details on how we will respond to each application and how we will publish information concerning which laboratories have had their accreditation accepted.

1. Proposed § 1112.11 – What Are the Types of Third Party Conformity Assessment Bodies?

Proposed § 1112.11 would describe, for purposes of part 1112, the three types of third party conformity assessment bodies: independent, firewalled, and governmental. Proposed § 1112.11(a) would describe an "independent laboratory" as a third party conformity assessment body that is neither owned, managed, or controlled by a manufacturer or private labeler of a children's product to be tested by the laboratory, nor owned or controlled, in whole or in part, by a government.



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Section 14(f)(2) of the CPSA defines a "firewalled third party conformity assessment body" as one that is owned, managed, or controlled by a manufacturer or private labeler. We note that section 14(f)(2)(D) of the CPSA clearly states that a firewalled laboratory is one "owned, managed, or controlled by a manufacturer or private labeler (emphasis added)." Therefore, we do not consider a laboratory to be firewalled if the laboratory owns, manages, or controls a manufacturer or private labeler.

We note that, for purposes of determining whether a laboratory is considered firewalled, we propose to interpret "manufacturer" to include a trade association. Like a manufacturer, an association of manufacturers is in a position to exert undue influence on a laboratory owned, managed, or controlled by the association. The undue influence may come in the form of an expectation that special consideration will be given to the test results of association members or reports of attempted undue influence by an association member are discouraged.

The proposed rule would consider a laboratory "firewalled" if: it is owned, managed, or controlled by a manufacturer or private labeler of a children's product; that children's product is subject to a CPSC children's product safety rule which the laboratory requests CPSC acceptance to test; and the laboratory intends to test such children's product made by the owning, managing, or controlling entity for the purpose of supporting a Children's Product Certificate. A laboratory would be considered to be "owned, managed, or controlled" by a manufacturer or private labeler if one (or more) of four characteristics apply.

The first circumstance that would result in a laboratory being characterized as firewalled is closely related to the method we have been using in the notices of requirements to identify firewalled laboratories. Under proposed § 1112.11(b)(1)(ii)(A), if the manufacturer or private labeler of the children's product holds a 10 percent or greater ownership interest, whether direct



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or indirect, in the laboratory, the laboratory would be considered firewalled. In this context, indirect ownership interest would be calculated by successive multiplication of the ownership percentages for each link in the ownership chain.

We propose to maintain the 10 percent threshold ownership amount because it is our estimation that a manufacturer or private labeler that possesses a less than 10 percent ownership interest in a laboratory, and that does not otherwise exercise management or control of the laboratory, presents a low risk of exercising undue influence over the laboratory. In addition, our experience using this threshold over the past three years indicates that applicants easily understand it and have been able to supply such information. We note that the Federal Communications Commission also uses a 10 percent ownership threshold in its ownership disclosure requirements for applications. See 47 CFR § 1.2112.

The difference in the proposed rule from current practice is the addition of indirect ownership. Proposed § 1112.11(b)(1)(ii)(A) would include indirect ownership because an entity that owns a manufacturer or private labeler which, in turn, owns a laboratory, has the same potential for conflict of interest concerning the independence of the testing process as a manufacturer or private labeler who owns a laboratory directly. We propose to determine whether an indirect owner holds a 10 percent interest in a laboratory by multiplying the percentages of ownership in each owning entity. For example, if Company X is a manufacturer of a children's product and owns 25 percent of the stock in Company Y, and Company Y owns 50 percent of Laboratory Z, then Company X would own (indirectly) 12.5 percent of Laboratory Z (0.25 x 0.50 = 0.125). Because Company X holds more than a 10 percent indirect ownership interest in Laboratory Z, if Laboratory Z wishes to apply to the CPSC for acceptance of its accreditation to test children's products made by Company X, Laboratory Z would be considered



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an applicant for firewalled status. This approach to calculating indirect ownership is used by some other Federal agencies. *See, e.g.,* 42 CFR 420.202 (Medicare regulations concerning ownership or control disclosure requirements); 47 CFR 1.2112 (FCC regulations concerning ownership disclosure requirements).

The second circumstance, in proposed § 1112.11(b)(1)(ii)(B), that would signify a firewalled laboratory is when the laboratory and a manufacturer or private labeler of the children's product are owned by the same parent entity. In this instance, the manufacturer would not be a 10 percent owner of the laboratory, either directly or indirectly; but the interests of both entities would converge in a common parent. In such a case, the parent company would hold the interests of the manufacturer, and the laboratory should be properly firewalled to ensure its testing processes are independent.

The third circumstance, in proposed § 1112.11(b)(1)(ii)(C), which would result in firewalled status is when a manufacturer or private labeler of the children's product has the ability to appoint a majority of the laboratory's senior internal governing body (including, but not limited to, a board of directors); the ability to appoint the presiding official (including, but not limited to, the chair or president) of the laboratory's senior internal governing body; and/or the ability to hire, dismiss, or set the compensation level for laboratory personnel. The ability to appoint the president or a majority of the senior internal governing body, or to make personnel decisions, indicates management and/or control of the laboratory.

The fourth circumstance, at proposed § 1112.11(b)(1)(ii)(D), that would result in firewalled status is when the laboratory is under a contract to a manufacturer or private labeler of the children's product and the contract explicitly limits the services the laboratory may perform for other customers and/or explicitly limits which or how many other entities may also be



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customers of the laboratory. In this instance, the terms of the contract would grant the manufacturer or private labeler such a significant interest in the work of the laboratory that the Commission would consider that interest to be controlling.

To date, the list of CPSC-accepted laboratories maintained on the CPSC website has not indicated which laboratories have firewalled status. Because this proposed rule would expand the definition of "firewalled laboratory" to include laboratories not only owned, but also those managed or controlled by a manufacturer or private labeler, we invite comments on whether the website listing should include an indication of firewalled status. Do manufacturers looking for a laboratory via the CPSC website want to know whether a laboratory is firewalled? Are there other interests in identifying a laboratory as firewalled on our website? Do laboratories with firewalled status perceive disadvantages to being identified as such?

According to section 14(f)(2)(B) of the CPSA, a "governmental" laboratory is one "owned or controlled in whole or in part by a government." Proposed § 1112.11(c) would implement that definition. For purposes of this part, we would consider "government" to include any unit of a national, territorial, provincial, regional, state, tribal, or local government. "Government" would include domestic, as well as foreign governmental entities.

Proposed § 1112.11(c) would consist of six characteristics, any one of which triggers governmental laboratory status. The legal framework for government ownership or control of a laboratory will vary across the world's jurisdictions, as will the potential for undue influence as a direct or indirect result of that government's ownership or control. The government of the laboratory in question may exercise control, based on the rule of law or otherwise, out of proportion to its ownership stake in a laboratory or to the laboratory's official independent status within the government organizational structure—a situation that Congress foresaw when it



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specified "in whole or in part" in section 14(f)(2)(B) of the CPSA. For that reason, the proposed rule would describe those ways that a government could reasonably be seen to have a means of operational control over a laboratory that has a financial or organizational connection to that government.

The first characteristic that would indicate governmental status is that a governmental entity holds a 1 percent or greater ownership interest, whether direct or indirect, in the laboratory. Selecting 1 percent as an ownership threshold is a practical matter of selecting the smallest whole number as an expression of ownership "in part." Indirect ownership interest would be calculated for these purposes in the same way as we propose to calculate it for purposes of indirect ownership of a firewalled laboratory, which is by successive multiplication of the ownership percentages for each link in the ownership chain. For example, if Government A is a joint venture partner with Company B, such that Government A owns 20 percent of Company B, and Company B holds a 10 percent interest in Laboratory C, then Government A would indirectly own 2 percent of Laboratory C. Therefore, Laboratory C is considered a governmental laboratory.

The second characteristic that would indicate governmental status is that a governmental entity provides any direct financial investment or funding (other than fee for work) to the laboratory. We consider that this circumstance would trigger governmental status because operational control of an enterprise may be affected by control or influence over its resources.

The third proposed governmental characteristic would mirror the third characteristic of firewalled status: a governmental entity has the ability to appoint a majority of the laboratory's senior internal governing body (such as but not limited to a board of directors); the ability to appoint the presiding official of the laboratory's senior internal governing body (such as but not



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limited to chair or president); and/or the ability to hire, dismiss, or set the compensation level for laboratory personnel. The ability to appoint the president or a majority of the senior internal governing body, or to make personnel decisions, indicates control, at least in part, of the laboratory.

The fourth characteristic, at proposed § 1112.11(c)(4), would consider a laboratory to be governmental if any of the laboratory's management or technical personnel are government employees. This direct involvement by the government in the operation of the laboratory would represent control in part.

The fifth characteristic, at proposed § 1112.11(c)(5), which would signify a governmental laboratory is if the laboratory has a subordinate position to a governmental entity in its external organizational structure. We would except the circumstance where the only relationship the laboratory has with the governmental entity is that of a regulated entity. In that sense, most laboratories in existence are associated administratively with a government, and we do not consider the existence of governmental regulations applicable to a laboratory to establish governmental control. (For example, the fact that a laboratory may be subject to certain employment requirements or subject to tax regulations does not establish that the laboratory is a government laboratory.) Instead, we intend to consider those laboratories that are organizationally a part of, or formally linked to, the government to be governmental laboratories. In those cases, even if the government is not an owner, it has the means of controlling the laboratory.

Finally, the sixth characteristic, at proposed § 1112.11(c)(6), would list situations in which government control of a laboratory is evident via the authority the government has over the laboratory. We propose that if a government can determine, establish, alter, or otherwise



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affect the laboratory's testing outcomes, its budget or financial decisions, its organizational structure or continued existence, or whether the laboratory may accept particular offers of work, then the laboratory would be considered governmental.

2. Proposed § 1112.13 – How Does a Third Party Conformity Assessment Body Apply for CPSC Acceptance?

Proposed § 1112.13 would describe how a third party conformity assessment body may apply for CPSC acceptance of its accreditation. We propose to use the authority granted in section 14(a)(3)(C) of the CPSA to designate signatories to the ILAC-MRA to accredit laboratories to ISO/IEC 17025:2005. For a laboratory to be able to conduct tests under section 14 of the CPSA, however, the CPSC must affirmatively accept that laboratory's accreditation.

Proposed § 1112.13(a) would relate the initial baseline requirements applicable to all laboratory applicants. The proposed baseline requirements are substantially similar to the baseline requirements in the notices of requirements, although the application form (CPSC Form 223) would be revised to correspond with other changes in the proposed rule. The first baseline requirement would be a completed application, CPSC Form 223. On a revised CPSC Form 223, the laboratory would attest to certain facts and characteristics concerning its business, which would determine whether the applicant is independent, firewalled, or governmental. If the laboratory is considered firewalled or governmental, the online CPSC Form 223 will prompt the laboratory to submit the requisite additional documentation. On a revised CPSC Form 223, the laboratory also would attest that it has read, understood, and agrees to the regulations in this part. Proposed § 1112.13(a) also would require that the laboratory update its CPSC Form 223 whenever any information previously supplied on the form changes.



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The second baseline criteria would be an accreditation certificate. Each laboratory would be required to be accredited to ISO/IEC Standard 17025:2005, "General requirements for the competence of testing and calibration laboratories." Because we are proposing to require compliance with a standard that is already published, we must incorporate that standard by reference into these regulations. The proposed rule would note that the Director of the *Federal Register* approved the incorporation by reference of ISO/IEC 17025:2005 in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. It would note that readers may obtain a copy of ISO/IEC 17025:2005 from the International Organization for Standardization (ISO), 1, ch. de la Voie-Creuse, Case postale 56, CH-1211 Geneva 20, Switzerland; Telephone +41 22 749 01 11, Fax +41 22 733 34 30; http://www.iso.org/iso/catalogue_detail.htm?csnumber=39883. Readers may also inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301–504–7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741– 6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

The proposed rule would require accreditation by an accreditation body that is a signatory to the ILAC-MRA. All laboratories also would be required to furnish their statement of scope, and it would have to clearly identify the CPSC rule(s) and/or test method(s) for which CPSC acceptance is sought.

Proposed § 1112.13(b) would state the additional requirements for firewalled laboratories. Section 14(f)(2)(D) of the CPSA mandates that a laboratory only may be accepted as firewalled if the Commission, by order, finds that:



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> (i) [Acceptance] of the conformity assessment body would provide equal or greater consumer safety protection than the manufacturer's or private labeler's use of an independent third party third party conformity assessment body; and
> (ii) [T]he conformity assessment body has established procedures to ensure that --
>
> (I) [I]ts test results are protected from undue influence by the manufacturer, private labeler, or other interested party;
> (II) [T]he 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) [A]llegations of undue influence may be reported confidentially to the Commission.

15 U.S.C. 2063(f)(2)(D).

To evaluate whether a laboratory satisfies these criteria, the proposed rule would require that a laboratory seeking CPSC-accepted firewalled status submit copies of various documents to the CPSC. First, the proposed rule would require the laboratory to submit copies of certain established policies and procedures. The laboratory would need to submit its policies and procedures that explain how test results are protected from undue influence by the manufacturer, private labeler, or other interested party. The purpose of reviewing such documents would be to assess whether the laboratory has established the necessary written procedures to preserve its independence from the manufacturer or private labeler. We also would require the laboratory to submit copies of established policies and procedures, indicating that the CPSC will be notified immediately of any attempt to hide or exert undue influence over test results, and policies and procedures explaining that an allegation of undue influence may be reported confidentially to the CPSC. The purpose of reviewing these documents is to ensure that the laboratory has written procedures in place that address when and how the CPSC will be notified of any attempt at undue influence.

Second, the proposed rule would require an applicant laboratory seeking firewalled status to supply copies of training documents, including a description of the training program content,



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showing how employees are trained on the three policies just described. We propose to require this training annually. If an employee receives such training only once, the employee may forget the information over the course of time, or the importance of the information would not be reinforced. In addition, the issue of staff turnover presents a risk that new employees would not receive the training. An annual training requirement would address these risks.

Third, proposed § 1112.13(b)(2) would require training records listing the staff members who received the training and bearing their signatures. The training records would include training dates, location, and the name and title of the individual providing the training. We propose to require the submission of these training-related documents so that we may assess whether the laboratory is sufficiently and effectively communicating to its employees the need to protect the testing process from undue influence, and that the employees may notify the CPSC immediately and confidentially of any attempt by a manufacturer, private labeler, or other interested party to hide or exert undue influence over test results.

Proposed § 1112.13(b)(2)(iv) and (v) would require firewalled laboratory applicants to submit two organizational charts. One chart would be an organizational chart(s) of the laboratory itself. It would include the names of all personnel, both temporary and permanent, and their reporting relationship within the laboratory. The other organizational chart would identify the reporting relationships of the laboratory within the broader organization (using both position titles and staff names). Finally, we also would require a list of all laboratory personnel with reporting relationships outside of the laboratory. The list would identify the name and title of the relevant laboratory employee(s) and the names, titles, and employer(s) of all individuals outside of the laboratory to whom they report. The organizational charts and the list of



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employees with outside reporting relationships would help us determine the degree to which the laboratory is independent of the manufacturer or private labeler.

If the Commission determines that the firewalled-specific documents indicate that the laboratory has sufficient safeguards against and procedures concerning undue influence in place, and the laboratory satisfies the baseline criteria, including ISO/IEC 17025:2005 accreditation by an ILAC-MRA signatory body, then the Commission will consider that the applicant laboratory would provide equal consumer safety protection than the manufacturer's or private labeler's use of an independent laboratory.

Proposed § 1112.13(c) would state the additional accreditation requirements applicable to governmental laboratories. Section 14(f)(2)(B) of the CPSA mandates that the Commission may accept the accreditation of a governmental laboratory if:

> (i) [T]o 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;
> (ii) [T]he entity's testing results are not subject to undue influence by any other person, including another governmental entity;
> (iii) [T]he entity is not accorded more favorable treatment than other third party conformity assessment bodies in the same nation who have been accredited under [section 14];
> (iv) [T]he entity's testing results are accorded no greater weight by other governmental authorities than those of other accredited third party conformity assessment bodies accredited under [section 14]; and
> (v) [T]he 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.

15 U.S.C. 2063(f)(2)(B).

To evaluate whether a laboratory satisfies these criteria, the proposed rule would require a governmental laboratory to submit a description that can be in the form of a diagram, which illustrates relationships with other entities, such as government agencies and joint venture partners. Such a document would give us basic information concerning the nature of the



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relationship between the laboratory and the government. In addition, we would require the laboratory and the relevant governmental entity to each respond to a questionnaire. The questionnaires are designed to elicit information related to the five statutory criteria.

Third, we would require a governmental laboratory to submit a copy of an executed memorandum that addresses undue influence. The purpose of the memorandum is to provide affirmative and continuous communication to the laboratory staff concerning the management policies regarding undue influence, and the staff's responsibilities in implementing the policies. The memorandum would be on company letterhead, from the senior management of the laboratory, and directed to all laboratory staff. The memorandum must be in the primary written language used for business communications in the area in which the laboratory is located, and, if that language is not English, then the laboratory must provide an English translation. The memorandum would need to be displayed prominently at the laboratory for as long as the laboratory is accepted by the CPSC.

The proposed rule would require the memorandum to state certain policies. It would require that the memorandum state that the laboratory's policy is to reject undue influence. We also would have the memorandum require employees to report immediately, to their supervisor or some other designated laboratory official, any attempt at undue influence. It would require the memorandum to state that the laboratory will not tolerate violations of the undue influence policy.

The fourth and final document to be required from governmental laboratory applicants would be an attestation. We would require a senior official of the governmental laboratory, who has the authority to make binding statements of policy on behalf of the laboratory, to attest to several statements related to the application, including that the laboratory does not receive and



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will not accept favorable treatment from any governmental entity with regard to products for export to the United States that are subject to CPSC jurisdiction. Among other things, the senior official of the governmental laboratory would have to attest that the information in the laboratory's application continues to be accurate, unless the laboratory notifies the CPSC otherwise. Thus, the senior official would be acknowledging a duty to inform the CPSC if any information submitted as part of the application has changed. As another example, the proposal would require the senior official to attest that the laboratory will not conduct CPSC tests in support of a Children's Product Certificate for products produced by a governmental entity that has any ownership or control of the laboratory. The attestation gives us an additional level of assurance that is unique to intergovernmental relationships.

Finally, the proposed rule would state that, if our approval of a governmental laboratory application is dependent upon a recently changed circumstance in the relationship between the laboratory and the governmental entity, and/or a recently changed policy of the related governmental entity, we may require the relevant governmental entity to attest to the details of the new relationship or policy. Such a provision would enable us to verify the changed circumstance prior to our acceptance of the governmental laboratory.

Proposed § 1112.13(d) would state that if a laboratory satisfies both the criteria for governmental status and the criteria for firewalled status, such a laboratory would be required to apply under both categories.

Proposed § 1112.13(e) would require that all application materials be in English. Proposed § 1112.13(f) would require that CPSC Form 223 and all required accompanying documentation be submitted electronically via the CPSC website. We have established an electronic application system accessed via our Internet site at:



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http://www.cpsc.gov/about/cpsia/labaccred.html. Proposed § 1112.13(g) would reserve the authority to require additional information from an applicant laboratory to determine whether the laboratory meets the relevant criteria. This provision would allow us to gather additional information if the initial information supplied by an applicant laboratory was insufficient. This paragraph also would state that we may, before acting on an application, verify the accreditation certificate and statement of scope directly from the accreditation body.

Finally, proposed § 1112.13(h) would provide that a laboratory may retract an application at any time before the CPSC has acted on it. We would note, however, that a retraction would not end or nullify any enforcement action that the CPSC is authorized to pursue.

3. Proposed § 1112.15 – When Can a Third Party Conformity Assessment Body Apply for CPSC Acceptance for a Particular CPSC Rule and/or Test Method?

Proposed § 1112.15(a) would state, consistent with section 14(a)(3) of the CPSA, that a laboratory may apply to the CPSC for acceptance of its accreditation to test a children's product to a particular CPSC rule and/or test method once the Commission has published the requirements for accreditation of third party conformity assessment bodies to assess conformity with that rule and/or test method. A laboratory would be able to apply for acceptance to more than one CPSC rule and/or test method at a time. Alternatively, a laboratory also would be able to apply separately for various CPSC rules and/or test methods. A laboratory would only be authorized to issue test results for purposes of section 14 of the CPSA for tests that fall within the CPSC rules and/or test methods for which its accreditation has been accepted by the CPSC.

Proposed § 1112.15(b) would list the rules and test methods for which the Commission has published the requirements for accreditation of laboratories. The list is current through August 10, 2011. When any final rule resulting from this proposed rule publishes, we intend to



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add to this list those CPSC rules and/or test methods for which we have published proposed requirements between October 1, 2011 and the date of the final rule. After any final rule publishes, additions or revisions to this list would be proposed as amendments to this section.

Some notices of requirements contained unique provisions related to exactly what a laboratory's statement of scope must indicate for the CPSC to accept that accreditation. Those unique provisions are included in this list.

In the *Federal Register* of September 20, 2011, we published a proposed rule to establish a safety standard for play yards. *See* 76 FR 58167, (September 20, 2011). The standard would be codified at 16 CFR part 1221. We are working on a final rule to establish a safety standard for play yards and hope to issue it in the near future. Consequently, proposed § 1112.15(b)(7) would include 16 CFR part 1221 among the list of CPSC rules and/or test methods for accreditation for third party conformity assessment bodies. If, however, the Commission does not issue a final rule to establish a safety standard for play yards, we will revise § 1112.15(b) accordingly, as part of this rulemaking process.

We have included the notice of requirements for the safety standard for portable bedrails at proposed § 1112.15(b)(8) in the list because we have published a final rule establishing the safety standard for bed rails (16 CFR part 1224) in the *Federal Register*. *See* 77 FR 12182 (February 29, 2012).

We will accept retrospective testing for 16 CFR part 1224 under certain circumstances. For the tests contained in 16 CFR part 1224, testing before the effective date of 16 CFR part 1112 will be accepted, if the following conditions are met:

- The children's product was tested by a third party conformity assessment body accredited to ISO/IEC 17025:2005 by a signatory to the ILAC-MRA at



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the time of the test. The scope of the third party conformity body accreditation must include testing in accordance with 16 CFR part 1224. For firewalled third party conformity assessment bodies, the firewalled third party conformity assessment body must be one that the Commission, by order, has accredited on or before the time that the children's product was tested, even if the order did not include the tests contained in 16 CFR part 1224. For governmental third party conformity assessment bodies, the governmental third party conformity assessment body must be one whose accreditation was accepted by the Commission, even if the scope of accreditation did not include the tests contained in 16 CFR part 1224.

- The third party conformity assessment body's application for acceptance of its accreditation is accepted by the CPSC on or after [insert date of publication in *Federal Register*] and before the effective date of 16 CFR part 1112.
- The test results show compliance with 16 CFR part 1224.
- The children's product was tested on or after the date of publication in the *Federal Register* of the final rule for 16 CFR part 1224, and before the effective date of 16 CFR part 1112.
- The testing laboratory's accreditation remains in effect through the effective date of 16 CFR part 1112.

Additionally, the notice of requirements pertaining to 16 CFR part 1303, Ban of Lead-Containing Paint and Certain Consumer Products Bearing Lead-Containing Paint, is listed at proposed § 1112.15(b)(9). According to our initial notice of requirements for part 1303 (73 FR



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54564 (Sept. 22, 2008)), in order for us to accept a laboratory to test children's products for conformity with the lead-paint ban, the laboratory's scope of accreditation had to include 16 CFR part 1303 (73 FR 54565). Part 1303 does not contain a test method. We received comments from the public, asking us to specify test methods to ensure that accreditation bodies are able to determine the acceptable technologies and methods for lead analyses. On April 5, 2011, we published a revision to the notice of requirements for part 1303 to specify particular test methods, one or more of which laboratories must have in their scope of accreditation in order for us to accept their accreditation to test for conformity with the lead paint ban.

Proposed § 1112.15(b)(9) would contain the approved test methods and explain how we will phase in the requirement of one or more of these test methods on laboratories' statements of scope. In brief, laboratories whose accreditations for part 1303 we had already accepted were given two years to reapply with accreditation documents that specify one or more of the approved test methods. New laboratory applicants could continue to apply with merely "16 CFR part 1303" in their statement of scope for one year after we revised the notice of requirements. After April 5, 2012, laboratories newly applying to test for compliance with the lead paint ban must have one of the approved test methods on their statement of scope.

Proposed § 1112.15(b)(10) would reference 16 CFR part 1420, Safety Standard for All-Terrain Vehicles. We note that recently, we published a final rule in the *Federal Register*, revising 16 CFR part 1420. *See* 77 FR 12197 (February 29, 2012). The final rule makes American National Standard, ANSI/SVIA–1–2010, the new mandatory standard for ATVs, and the new standard is effective April 30, 2012, replacing the previous standard, which was designated ANSI/SVIA-1-2007. For purposes of testing youth ATVs, however, ANSI/SVIA 1-2010 is functionally equivalent to ANSI/SVIA 1-2007 because the changes specified in the 2010



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edition do not substantially change the requirements applicable to, nor do they affect the associated conformance testing of youth ATVs. Consequently, the Commission is continuing its acceptance of accreditation of the third party conformity assessment body to test youth ATVs. (As of February 7, 2012, we had accepted the accreditation of a single third party conformity assessment body to test youth ATVs.) Thus, the third party conformity assessment body should test youth ATVs for compliance with ANSI/SVIA 1-2010, as incorporated by reference in 16 CFR part 1420. Based on such testing, manufacturers of youth ATVs should issue certificates under section 14(a)(2) of the CPSA.

Third party conformity assessment bodies that are accredited to test youth ATVs to the 2007 version of the ATV standard for children's product certification purposes do not need to become reaccredited to the 2010 revision before the next time their accreditation body reassesses them to the ATV standard. However, they may elect to do so. Third party conformity assessment bodies, whose accreditation to test to the 2007 version of the ATV standard has previously been accepted by the CPSC, must be accredited to the 2010 revision of the ATV standard when reassessed by their accreditation body, and submit a Form 223 with the applicable accompanying documents to the CPSC in order to continue to have their accreditation to the ATV standard accepted. We will revise our listing of the third party conformity assessment body when it becomes accredited to the ATV standard and the CPSC accepts their application for accreditation.

For third party conformity assessment bodies that applied for CPSC acceptance of accreditation to the 2007 version of the ATV standard before we accepted the 2010 revision of the ATV standard as a mandatory standard, and the CPSC accepts that accreditation, test results from the third party conformity assessment body can be used for children's product certification



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purposes until the third party conformity assessment body is reassessed by its accreditation body to the ATV standard. If the third party conformity assessment body wishes to have its accreditation continue to be accepted by the CPSC after it is reassessed by its accreditation body, it must become accredited to the 2010 revision of the standard and submit a new Form 223 with accompanying documents to the CPSC, requesting acceptance of its accreditation to the 2010 revision of the standard.

New third party conformity assessment body applicants that apply for CPSC acceptance on or after [insert date of publication in the *Federal Register*] must be accredited to the 2010 revision when applying for CPSC acceptance of their accreditation to test youth ATVs.

We also note four revisions to our lead-content test methods. Proposed § 1112.15(b)(27) and (28), Lead Content in Children's Metal Jewelry and Limits on Total Lead in Children's Products: Children's Metal Products, would contain two proposed revisions. First, the notices of requirements related to testing for lead content in children's metal jewelry (73 FR 78331 (Dec. 22, 2008)) and total lead in children's products (74 FR 55821 (Oct. 29, 2009)) each listed the test method numbered CPSC-CH-E1001-08 as the required test method for testing for lead in children's metal products (including metal jewelry). We revised that test method in June 2010. The revised method allows for some alternative, simplified procedures for certain portions of the test method. Second, we propose allowing the use of XRF spectrometry to determine the lead content in certain metals. The option of using the revised test methods would be reflected in proposed § 1112.15(b)(27) and (28). Accordingly, the proposed rule would provide that, to be considered for CPSC-acceptance of accreditation to test for lead in children's metal products (including metal jewelry), an applicant laboratory may have either Test Method CPSC-CH-E1001-08 (the original test method) and/or Test Method CPSC-CH-E1001-08.1 (the revised test



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method allowing alternative, simplified procedures) and/or the proposed revision of the test method, Test Method CPSC-CH-E1001-08.2 (allowing the use of XRF for certain metals) in its scope of accreditation.

Third, proposed § 1112.15(b)(29), Limits on Total Lead in Children's Products: Non-Metal Children's Products, also would contain a proposed revision relative to the original notice of requirements. The notice of requirements related to testing for total lead in children's products (74 FR 55821 (Oct. 29, 2009)) listed the test method numbered CPSC-CH-E1002-08 as the required test method for testing for lead in non-metal children's products. We revised that test method in June 2010; the revised method allows for some alternative, simplified procedures for certain portions of the test method. Fourth, we propose allowing the use of XRF to determine the lead content in glass materials and crystals. This option would be reflected in proposed § 1112.15(b)(29). Accordingly, the proposed rule would state that, to be considered for CPSC acceptance of accreditation to test for lead in non-metal children's products, an applicant laboratory may have Test Method CPSC-CH-E1002-08 (the original test method) and/or Test Method CPSC-CH-E1002-08.1 (the revised test method allowing alternative, simplified procedures) and/or Test Method CPSC-CH-E1002-08.2 (allowing the use of XRF for glass materials and crystals) in its scope of accreditation.

We have identified a potential opportunity to reduce the testing burdens for certification of conformity related to the new requirements in ASTM F 963-11. Among the changes in ASTM F 963-11, are changes in the requirements and test methods for eight elements of interest: antimony, arsenic, barium, cadmium, chromium, lead, mercury, and selenium. ASTM F 963-11 extends the requirements from prior versions (which had limits for these elements in surface coatings) to consider, in addition, these elements in substrates. For substrates and surface



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coatings, ASTM F 963-11 limits soluble migration of each of these elements when tested in dilute acid. Additionally, a new optional screening test is established in section 8.3.1 ASTM F 963-11, which is based on the total concentration of those elements, determined by digesting the samples completely, in hot, concentrated, strong acids, using methods based on CPSC test methods for lead content.

ASTM F 963-11 allows the screening test from section 8.3.1 to be performed on a toy to establish that the total concentration of each of the eight elements of interest is lower than each of the soluble limits for those elements. For example, a toy that has only 10 ppm of each of those elements could not possibly leach more than the soluble limits for any of the elements (which are all greater than 10 ppm); and thus, the solubility test could be skipped. In another example, a toy that contained 2,000 ppm barium would not pass the screening test for barium and would require solubility testing according to section 8.3 to determine how much barium would leach out (compared to the limit of 1,000 ppm soluble barium).

We recognize that firms potentially could reduce testing costs if a single test would meet the screening test of section 8.3.1 of ASTM F 963-11 and the CPSIA lead content requirements for paint, metals, or nonmetals. The methods provided in section 8.3.1 of ASTM F 961-11 refer to CPSC test methods, but with a prescribed modification. The CPSC test methods for lead in paint (http://www.cpsc.gov/about/cpsia/CPSC-CH-E1003-09_1.pdf), lead in nonmetals (http://www.cpsc.gov/about/cpsia/CPSC-CH-E1002-08_1.pdf), and lead in metals (http://www.cpsc.gov/about/cpsia/CPSC-CH-E1001-08_1.pdf) each allow for modifications based on sound chemical judgment and knowledge. CPSC staff tested a variety of well-characterized paint, metal, and nonmetal materials, and based upon the results and our professional judgment and experience, we found that the modifications detailed in section 8.3.1.2



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of ASTM F 963-11 represent sound chemical judgment to improve the recovery of antimony in certain samples. In addition, we believe that they are acceptable for use for lead in paint, lead in metals, and lead in nonmetals and are considered to be within the existing scope of allowable changes to the CPSC methods. Because these modifications are considered acceptable, a CPSC-accepted testing laboratory accredited to the CPSC method for lead in paint, CPSC-CH-E1003-09, for example, could test the paint from a toy, according to CPSC-CH-E1003-09, with the modifications provided in section 8.3.1.2 of ASTM F 963-11, and still fulfill the requirements of CPSC-CH-E1003-09 to certify lead content and use the same testing to determine the screening levels for the other elements of interest. Because samples that fail the screening may pass section 4.3.5 solubility limits, a testing laboratory must be accredited in ASTM F 963-11, Section 8.3 to have its test results used to demonstrate compliance with the limits given in section 4.3.5. In the example above, the testing for lead in paint, with the modifications, could be used to determine if the elements of interest pass the screening test and the toy can be certified to section 4.3.5, without additional testing; paints exceeding screening limits for any of the elements of interest would have to be tested according to section 8.3 for heavy element solubility.

Proposed § 1112.15(b)(30) would reference the limits on phthalates in children's toys and child care articles. The notice of requirements pertaining to phthalates approved of two test methods, at least one of which must be included in a laboratory's accreditation scope document in order for us to accept the laboratory to test for the limits on phthalates, and both test methods are included in proposed § 1112.15(b)(30).

The notice of requirements pertaining to toys also contained unique provisions related to exactly what a laboratory's statement of scope must indicate for the CPSC to accept that



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accreditation. Pursuant to section 106 of the CPSIA, the provisions of ASTM International's (formerly the American Society for Testing and Materials) ("ASTM") Standard Consumer Safety Specification for Toy Safety, F 963, are considered to be consumer product safety standards issued by the Commission. For reasons explained in the notice of requirements, *see* 76 FR 46598, 46599 through 46600 (Aug. 3, 2011), only certain provisions of ASTM F 963 are subject to third party testing requirements. We will accept the accreditation of laboratories only to those sections of ASTM F 963 that are subject to third party testing requirements. The list of sections of ASTM F 963 for which laboratories may apply for CPSC acceptance, which must each be specifically referenced in the laboratories' scope documents, was contained in the notice of requirements and is reproduced in proposed § 1112.15(b)(31).

Additionally, proposed § 1112.15(b)(31) would reflect recent revisions to the ASTM F 963 standard. On February 15, 2012, the Commission, pursuant to section 106(g) of the CPSIA, accepted the revised toy standard (ASTM F 963-11) as a consumer product safety standard. 77 FR 10358, (February 22, 2012). ASTM F 963-11 is, in many ways, equivalent or functionally equivalent to ASTM F 963-08. For example, in the notice of requirements that we issued on August 3, 2011, some 23 sections in ASTM F 963-08 remain unchanged in ASTM F 963-11, and another seven sections in ASTM F 963-11 are functionally equivalent to their earlier counterparts in ASTM F 963-08. (By "functionally equivalent," we mean that the standards organization made certain changes in the revised standard compared to the earlier standard , but the changes are not substantial and do not affect the associated conformance testing.) Consequently, the Commission is continuing its acceptance of accreditation of third party conformity assessment bodies for those provisions in ASTM F 963-11 that are equivalent or functionally equivalent to their corresponding provisions in ASTM F 963-08. The third party



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conformity assessment bodies should test toys for compliance with ASTM F 963-11, and based on such testing, manufacturers should issue certificates under section 14(a)(2) of the CPSA.

Third party conformity assessment bodies that are accredited to test to provisions of ASTM F 963-08 that are equivalent or functionally equivalent for children's product certification purposes do not need to become reaccredited to the ASTM F 963-11 revision before the next time their accreditation body reassesses them to ASTM F 963 toy standard. However, they may elect to do so. Third party conformity assessment bodies whose accreditation to test to ASTM F 963-08 has previously been accepted by the CPSC must be accredited to the ASTM F 963-11 revision when reassessed by their accreditation body, and they must submit a Form 223 with the applicable accompanying documents to the CPSC in order to continue to have their accreditation to ASTM F 963-11 accepted. We will revise our listing of the third party conformity assessment body when it becomes accredited to the ASTM F 963-11 standard and the CPSC accepts their application for accreditation.

For third party conformity assessment bodies that applied for CPSC acceptance of accreditation to ASTM F 963-08 before the Commission accepted ASTM F 963-11 as a mandatory standard, and before we accepted that accreditation, test results from the third party conformity assessment body for those provisions of ASTM F 963-08 that are equivalent or functionally equivalent to ASTM F 963-11, can be used for children's product certification purposes until the third party conformity assessment body is reassessed by its accreditation body to the ASTM F 963 toy standard. If the third party conformity assessment body wishes to have its accreditation continue to be accepted by the CPSC after it is reassessed by its accreditation body, it must become accredited to the ASTM F 963-11 and submit a new Form 223 with



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accompanying documents to the CPSC, requesting acceptance of its accreditation to the 2011 revision of the standard.

New third party conformity assessment body applicants that apply for CPSC acceptance on or after [insert date of publication in the *Federal Register*] must be accredited to the ASTM F 963-11 revision when applying for CPSC acceptance of their accreditation to test toys under ASTM F 963.

ASTM F 963-11, however, did make substantial changes to certain provisions in ASTM F 963-08 or added new testing or requirements. These changes are seen in the following sections of ASTM F 963-11:

- Section 4.3.5.1(2), Surface Coating Materials – Soluble Test for Metals;
- Section 4.3.5.2, Toy Substrate Materials;
- Section 4.15, Stability and Overload Requirements;
- Section 4.37, Yo-Yo Elastic Tether Toys; and
- Section 4.39, Jaw Entrapment in Handles and Steering Wheels.

Therefore, proposed § 1112.15(b)(30) would add section 4.3.5.1(2) from ASTM F 963-11, "Surface Coating Materials – Soluble Test for Metals," and section 4.3.5.2, "Toy Substrate Materials," to the list of provisions in ASTM F 963 that require third party testing. The proposed rule, like the earlier notice of requirements for ASTM F 963-08, would continue to list section 4.15, "Stability and Overload Requirements," section 4.37, "Yo-You Elastic Tether Toys," and section 4.39, "Jaw Entrapment in Handles and Steering Wheels"; but third party conformity assessment bodies should understand that these sections in ASTM F 963-11 are not equivalent to ASTM F 963-08. Furthermore, if we had accepted the third party conformity assessment body's accreditation to sections 4.15, 4.37, or 4.39 of ASTM F 963-08, the third party conformity



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assessment body should become accredited to, and apply for, CPSC acceptance for its accreditation under sections 4.15, 4.37, and 4.39 of ASTM F 963-11.

Proposed § 1112.15(b)(31) would establish and codify those provisions of ASTM F 963-11 that would require accreditation and third party testing. However, we are aware that another revision to ASTM F 963 may occur (see http://news.consumerreports.org/baby/2012/01/revised-toy-safety-standards-are-in-the-works.html. If after the proposed rule is published in the *Federal Register*, the Commission receives a revision to ASTM F 963-11 from ASTM and subsequently accepts the revision, we will (assuming that we issue a final rule) revise § 1112.15(b)(30) in the final rule to reflect the most current version of ASTM F 963 approved by the Commission in lieu of ASTM F 963-11.

We will accept testing on children's products conducted by a third party conformity assessment body accepted by the Commission for those sections of ASTM F 963-08 that are considered equivalent or functionally equivalent to ASTM F 963-11, as discussed above. For those tests in ASTM F 963-11 that have no equivalent or functionally equivalent test in ASTM F 963-08, testing before the effective date of ASTM F 963-11 will be accepted, if the following conditions are met:

- The children's product was tested by a third party conformity assessment body accredited to ISO/IEC 17025:2005 by a signatory to the ILAC-MRA at the time of the test. The scope of the third party conformity assessment body accreditation must include the tests contained in the applicable nonequivalent section of ASTM F 963-11. For firewalled third party conformity assessment bodies, the firewalled third party conformity assessment body must be one that the Commission, by order, has accredited, on or before the time that the



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children's product was tested, even if the order did not include the nonequivalent tests contained in ASTM F 963-11. For governmental third party conformity assessment bodies, the governmental third party conformity assessment body must be one whose accreditation was accepted by the Commission, even if the scope of accreditation did not include the tests for the nonequivalent tests contained in ASTM F 963-11.

- The third party conformity assessment body's application for acceptance of its accreditation is accepted by the CPSC on or after [insert date of publication in the Federal Register] and before the effective date for 16 CFR part 1112.
- The test results show compliance with the nonequivalent section(s) of ASTM F 963-11.
- The children's product was tested on or after February 22, 2012, and before the effective date of 16 CFR part 1112.
- The third party conformity assessment body's accreditation remains in effect through the effective date of 16 CFR part 1112.

4. Proposed § 1112.17 -- How Will the CPSC Respond to Each Application?

Proposed § 1112.17 would establish the procedures related to CPSC action on a third party conformity assessment body's application for CPSC acceptance of its accreditation.

Proposed § 1112.17(a) would state that CPSC staff will review each application, and they may contact applicant laboratories with questions or to request submission of missing information.



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Proposed § 1112.17(b), consistent with section 14(f)(2)(D) of the CPSA, would state that an application from a firewalled laboratory will be accepted by order of the Commission, if the Commission makes certain findings that are required by the statute; the required findings are enumerated. We intend that CPSC staff will act on applications from independent and governmental laboratories, as long as such action is consistent with a proper delegation of authority from the Commission.

Proposed § 1112.17(c) would state that the CPSC will communicate its decision on each application, in writing, to the applicant; the written decision may be by electronic mail.

5. Proposed § 1112.19 -- How Does the CPSC Publish Information Identifying Third Party Conformity Assessment Bodies That Have Been Accepted?

In accordance with section 14(a)(3)(E) of the CPSA, proposed § 1112.19 would provide that the CPSC will maintain on its website an up-to-date listing of third party conformity assessment bodies whose accreditations have been accepted, and the scope of each acceptance. We would update the listing regularly to account for changes of information and status, such as the addition of CPSC rules and/or test methods to a scope of accreditation; changes to accreditation certificates; or a new address. In addition, we propose to update the listing to indicate changes in status, such as if a laboratory voluntarily discontinues its participation with the CPSC, or if the CPSC suspends or withdraws our acceptance of the accreditation of a laboratory (which we discuss later in this document).

6. Proposed § 1112.21 -- May a Third Party Conformity Assessment Body Use Testing Methods Other Than Those Specified in the Relevant CPSC Rule and/or Test Method?

Proposed § 1112.21 would require a CPSC-accepted laboratory to use only a test method specified by the CPSC for a particular CPSC rule and/or test method, for any test conducted for



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purposes of section 14 of the CPSA. The proposed rule would require laboratories to use a CPSC-specified test method(s) for several reasons. First, a specified test method firmly establishes how to generate test results that are acceptable to the CPSC as indicative of compliance, so there may be a common understanding between laboratories and the CPSC. Second, by specifying the test method, greater consistency among tests conducted at different laboratories is established. Variations between laboratory tests are reduced. Finally, it serves as a common procedure that accreditation bodies can use to evaluate a laboratory for a particular CPSC rule and/or test method. By evaluating to a CPSC-specified test method, the accreditation bodies can determine whether the laboratory meets competency requirements to carry out that particular test.

7. Proposed § 1112.23 -- May a CSPC-Accepted Third Party Conformity Assessment Body Subcontract Work Conducted for Purposes of Section 14 of the CPSA?

The purpose of having each third party conformity assessment body satisfy CPSC requirements in order for its accreditation to be eligible for acceptance is to promote competent and consistent test results across laboratories. Proposed § 1112.23(a) would prohibit subcontracting of tests conducted for purposes of section 14 of the CPSA, unless the subcontract is to a CPSC-accepted laboratory. In addition, the CPSC's acceptance of the scope of accreditation of the subcontracting laboratory must include the test being subcontracted. For example, in order for Laboratory A to subcontract the test for lead-containing paint to Laboratory B, Laboratory B would need to have had its accreditation to 16 CFR part 1303 (lead-containing paint) accepted by the CPSC. In this example, we would refer to Laboratory A as the prime contractor, and Laboratory B would be the subcontractor.



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Any violation of this provision would constitute compromising the integrity of the testing process and could be grounds for withdrawal of the CPSC's acceptance of the accreditation of the prime- and/or sub- contracting laboratory under proposed § 1112.47. Given this restriction and staff's concerns about compromising the integrity of the testing process, we request comment as to whether subcontracting ought to be allowed and, if so, under what circumstances. For example, for what reasons should subcontracting of the preparation of samples for flammability testing, such as laundering or dry cleaning, be allowed? We are also interested in comments regarding subcontracting under other CPSC regulations and the relationship between subcontracting and the technical competence and protection against undue influence of the third party testing program as a whole. Under what conditions could we allow the CPSC-accepted laboratory to vouch for the independence and technical competence of its subcontractors and their testing processes without requiring accreditation of the subcontractor by a signatory to the ILAC-MRA? How would subcontracting affect the recordkeeping requirements of this rule?

Proposed § 1112.23(b) would state that the provisions of part 1112 apply to all CPSC-accepted laboratories, even if they are a prime contractor and/or a subcontractor.

8. Proposed § 1112.25 -- What Are a Third Party Conformity Assessment Body's Recordkeeping Responsibilities?

Proposed § 1112.25 would require third party conformity assessment bodies to retain certain records related to the tests conducted for purposes of section 14 of the CPSA. We are aware that ISO/IEC 17025:2005 contains some recordkeeping provisions of its own. For example, section 4.13 of ISO/IEC 17025:2005 addresses "control of records" and requires a laboratory to retain technical records "for a defined period." However, proposed § 1112.25 would impose additional recordkeeping responsibilities beyond those established in ISO/IEC



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17025:2005. Additional requirements are necessary because we have an interest in being able to investigate a noncompliant product and/or whether grounds exist for adverse action against a third party conformity assessment body. For example, if a product that fails to comply with a children's product safety rule is present in the market, and the product was tested by a CPSC-accepted laboratory, we would have an interest in reviewing the test records related to that product. Additionally, ISO/IEC 17025:2005 does not specify a record-retention period, which means different laboratories could retain their records for different periods of time. If we pursue an investigation, the records we would require in proposed § 1112.25 are those that would help us conduct that investigation. Some records, such as a report furnished to a customer where the report differs from the test record, may not be retained by some laboratories under ISO/IEC 17025:2005. Therefore, we would impose these recordkeeping requirements in addition to those imposed via ISO/IEC 17025:2005.

Proposed § 1112.25(a) would state that all required records must be legible. In terms of particular records, we would first require that all test reports and technical records related to tests conducted for purposes of section 14 of the CPSA be maintained for a period of at least five years from the date the test was conducted. We propose a 5-year retention period because the statute of limitations on civil penalties under the CPSA is five years. *See* 28 U.S.C. 2462. Next, the proposed rule would require that, in the case of a test report for a test conducted by a CPSC-accepted laboratory acting as a sub-contractor, the prime contractor's test report must clearly identify which test(s) was performed by a CPSC-accepted laboratory acting as a subcontractor(s), and the test report from the CPSC-accepted laboratory acting as a subcontractor must be appended to the prime contractor's test report.



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Proposed § 1112.25(a) would require that, where a report for purposes of section 14 of the CPSA provided by the laboratory to a customer is different from the test record, the laboratory also must retain the report provided to the customer for a period of at least five years from the date the test was conducted. Finally, the proposed rule also would require any and all laboratory internal documents describing testing protocols and procedures (such as instructions, standards, manuals, guides, and reference data) that have applied to a test conducted for purposes of section 14 of the CPSA be retained for a period of at least five years from the date such test was conducted.

Proposed § 1112.25(b) would state that, upon request by the CPSC, the laboratory must make any and all of the records required by this section available for inspection, either in hard copy or electronic form, within 48 hours. We would require that, if the records are not in English, copies of the original records be made available to the CPSC within 48 hours, and an English translation of the records be made available by the laboratory within 30 calendar days of the date we requested an English translation.

9. Proposed § 1112.27 -- Must a Third Party Conformity Assessment Body Allow CPSC Inspections Related to Investigations?

Proposed § 1112.27 would require that each CPSC-accepted third party conformity assessment body allow an officer or employee duly designated by the Commission to enter its facility and conduct an inspection as a condition of the continued CPSC-acceptance of its accreditation. Such inspections would not be routine and/or for the purpose of confirming that the laboratory satisfies accreditation requirements. We intend that audits (addressed in subpart C of part 1112) be the vehicle by which we confirm that a laboratory continues to satisfy the requirements necessary for our acceptance of its accreditation. Rather, such inspections would



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be limited to inspections related to a CPSC investigation into whether a ground exists for adverse action against a third party conformity assessment body. An ability to enter and inspect a laboratory would help us investigate circumstances, such as an allegation of undue influence or the presence in the market of a product that fails to comply with a children's product safety rule, yet is accompanied by a certificate based on a passing third party test result. In those cases, our investigation may need to include the laboratory so that we could attempt to obtain facts relevant to the case at hand.

We would conduct such inspections in accordance with 16 CFR 1118.2, *Conduct and Scope of Inspections*. Failure to cooperate with such an inspection would constitute failure to cooperate with an investigation and would be grounds for suspension under proposed § 1112.45.

10. Proposed § 1112.29 -- How Does a Third Party Conformity Assessment Body Voluntarily Discontinue its Participation with the CPSC?

Proposed § 1112.29(a) would provide that a third party conformity assessment body may voluntarily discontinue participation as a CPSC-accepted laboratory at any time and for any portion of its scope that is accepted by the CPSC. It also would provide the procedural requirements for such voluntary discontinuance.

To voluntarily discontinue its participation as a CPSC-accepted laboratory, the laboratory would have to notify us in writing. This notification may be sent electronically. The notice would have to include the name, address, phone number, and electronic mail address of the laboratory and the person responsible for submitting the request. The notice also would need to include the scope of the discontinuance; the beginning date for the discontinuance; a statement that the laboratory understands that it must reapply for acceptance of the accreditation scope for



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which it is requesting discontinuance; and verification that the person requesting the discontinuance has the authority to make such a request on behalf of the laboratory.

Proposed § 1112.29(b) would state that we may verify the information submitted in a notice of voluntary discontinuance.

Proposed § 1112.29(c) would explain that, either upon receipt of a notice for voluntary discontinuance as a CPSC-accepted third party conformity assessment body or after verifying the information in a notice, we will update our website to indicate that we no longer accept the accreditation of the third party conformity assessment body as of the date provided and for the scope indicated in the notice.

Proposed § 1112.29(d) would note that we may begin or continue an investigation related to an adverse action under this part, or any other legal action, despite the voluntary discontinuation of a laboratory.

*C. Subpart C – Audit Requirements for Third Party Conformity Assessment Bodies*

1. Proposed § 1112.35(b) – When Must an Audit be Conducted?

As explained in the audit final rule published elsewhere in this issue of the *Federal Register*, for purposes of part 1112, an audit consists of two parts. The first part, known as "reassessment," is an examination by an accreditation body to determine whether the third party conformity assessment body meets or continues to meet the conditions for accreditation. The second part, which we refer to as "examination," is the resubmission of the "Consumer Product Conformity Assessment Body Acceptance Registration Form" (CPSC Form 223) and accompanying documentation by the laboratory, and the CPSC's examination of the resubmitted materials.



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The reassessment portion of an audit is conducted, at a minimum, at the frequency established by its accreditation body. Proposed § 1112.35(b) would establish when the examination portion of an audit must be conducted.

Proposed § 1112.35(b)(1) would have each laboratory submit a new CPSC Form 223 and applicable accompanying documentation, no less than every two years. The proposed rule would begin the implementation of this provision by assigning an audit date to each CPSC-accepted laboratory. The initial audit date, which will be assigned based on such factors as when the laboratory was last accepted by the CPSC, and the expiration date of the laboratory's ISO/IEC 17025:2005 certificate, will be no sooner than three months, and no later than two years, after any final rule resulting from this proposed rule is published. Laboratories that were not previously CPSC-accepted laboratories and that apply to the CPSC after the publication of a final rule resulting from this proposed rule will be issued an audit date based upon the date of CPSC acceptance of accreditation as posted on the CPSC website.

Proposed § 1112.35(b)(2) would note that proposed § 1112.13(a)(1) would require a third party conformity assessment body to submit a new CPSC Form 223 whenever the information supplied on the form changes. If the third party conformity assessment body submits a new CPSC Form 223 to provide updated information, the third party conformity assessment body may elect to have the new CPSC Form 223 satisfy the audit requirement of proposed § 1112.35(b)(1). If the laboratory also intends to satisfy the audit requirement of proposed § 1112.35(b)(1), it would need to indicate that intent clearly when it submits a CPSC Form 223. In addition, the laboratory would need to upload all applicable accompanying documentation.

Proposed § 1112.35(b)(3) would state that, at least 30 days before the date by which a third party conformity assessment body must submit a CPSC Form 223 for audit purposes, we



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will notify the body, in writing, of the impending audit deadline. The notice may be delivered by electronic mail. A laboratory may request an extension of the deadline for the examination portion of the audit, but it must indicate how much additional time is requested, and it also must explain why such an extension is warranted. The CPSC will notify the laboratory whether its request for an extension has been granted.

*D. Subpart D – Adverse Actions: Types, Grounds, Allegations, Procedural Requirements, and Publication*

Proposed subpart D would implement section 14(e) of the CPSA. It would establish whether, when, and how we may deny a third party conformity assessment body's application and suspend and/or withdraw a previously-granted acceptance of a laboratory's accreditation. It also would establish how a person may submit to the CPSC information alleging a ground for adverse action, including an allegation of undue influence. This subpart also would address the publication of adverse actions.

1. Proposed § 1112.41 -- What Are the Possible Adverse Actions the CPSC May Take Against a Third Party Conformity Assessment Body?

Proposed § 1112.41 would list the potential adverse actions we may take against a third party conformity assessment body. Proposed § 1112.41(a) lists the possible actions: denial of acceptance of accreditation; suspension of acceptance of accreditation; or withdrawal of acceptance of accreditation. These actions will each be discussed further below, in relation to the proposed sections that address each possible action.

Proposed § 1112.41(b) would state that withdrawal of acceptance of accreditation can be on a temporary or permanent basis, and the CPSC may immediately withdraw its acceptance in accordance with § 1112.53 of this part.



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2. Proposed § 1112.43 -- What Are the Grounds for Denial of an Application?

Proposed § 1112.43(a) would list the bases for denying an application for acceptance of accreditation from a third party conformity assessment body. There would be three reasons for denying an application.

First, proposed § 1112.43(a)(1) would state that we may deny a laboratory's application if the laboratory failed to submit a complete application. We would state that all information and/or attestations required by CPSC Form 223 are necessary components of an application. We also would state that all accompanying documentation required in connection with an application is a necessary component of an application. We would provide notice of a deficiency and would deny an application if the laboratory failed to correct the deficiency within 30 days.

Proposed § 1112.43(a)(2) would provide the second basis upon which we would be able to deny an application. The proposed rule would address the submission of false or misleading information concerning a material fact(s) on either an application, any materials accompanying an application, or on any other information provided to the CPSC related to a laboratory's ability to become or to remain a CPSC-accepted laboratory. A fact would be considered material if its inclusion in the application, any materials accompanying an application, or on any other information provided to the CPSC, would have resulted in the application's denial.

Third, proposed § 1112.43(a)(3) would state that we may deny an application if the applicant laboratory failed to satisfy the necessary requirements described in § 1112.13, such as ISO/IEC 17025:2005 accreditation by an ILAC-MRA signatory accreditation body for the scope for which acceptance of accreditation is being sought.

Proposed § 1112.43(b) would state that the CPSC's denial of an application will follow the process described in § 1112.51 of this part.



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3. Proposed § 1112.45 -- What Are the Grounds for Suspension of CPSC Acceptance?

Section 14(e)(3) of the CPSA states that the Commission may suspend the accreditation of a conformity assessment body if it fails to cooperate with the Commission in an investigation under section 14 of the CPSA. Proposed § 1112.45 would implement that statutory provision.

The procedures relevant to adverse actions would be addressed in proposed § 1112.51, which we will describe and discuss more fully below. For current purposes, however, we note that proposed § 1112.51(a) would provide that the CPSC may investigate when it is aware that grounds for an adverse action may exist. For example, if we receive an allegation of undue influence concerning a CPSC-accepted laboratory, we may (depending on the strength of the allegation) launch an investigation. As another example, if a product was present in the market that failed to comply with a children's product safety rule, yet is supported by a certificate based on a CPSC-accepted laboratory's passing test result, we may investigate whether the laboratory is, in fact, conducting tests according to a CPSC-required test method. Under proposed § 1112.51(a)(4), we would provide written notice to a laboratory upon commencement of an investigation.

Section 1112.45(a) would state that we may suspend our acceptance of a laboratory's accreditation for any portion of its CPSC scope when the laboratory fails to cooperate with an investigation under section 14 of the CPSA. The proposed rule would state further that a third party conformity assessment body "fails to cooperate" when it does not respond to CPSC inquiries or requests, or responds in a manner that is unresponsive, evasive, deceptive, or substantially incomplete, or when the laboratory fails to cooperate with an investigatory inspection under proposed § 1112.27.



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If we determine that a laboratory is not cooperating with an investigation, under proposed § 1112.51(b), we would provide an initial notice of adverse action to the laboratory. This initial notice would state that the CPSC proposes to suspend the laboratory, and it would specify the actions the laboratory would need to take to avoid suspension. Proposed § 1112.45(b) would state that suspension will last until the laboratory complies, to our satisfaction, with required actions, as outlined in the initial notice described in proposed § 1112.51(b), or until we withdraw our acceptance of the laboratory.

Proposed § 1112.45(c) would provide that we will lift the suspension of CPSC acceptance if we determine that the third party conformity assessment body is cooperating sufficiently with the investigation. The suspension would lift as of the date of our written notification to the laboratory, which may be by electronic mail, indicating that we are lifting the suspension.

4. Proposed § 1112.47 -- What Are the Grounds for Withdrawal of CPSC Acceptance?

Proposed § 1112.47 would establish the grounds upon which we may withdraw acceptance of the accreditation of a third party conformity assessment body for any portion of its CPSC scope.

The first ground for withdrawal would be that a manufacturer, private labeler, governmental entity, or other interested party has exerted undue influence on such conformity assessment body, or otherwise interfered with, or compromised, the integrity of the testing process. Proposed § 1112.3 would define "undue influence" to mean that a manufacturer, private labeler, governmental entity, or other interested party affects a third party conformity assessment body, such that commercial, financial, or other pressures compromise the integrity of its testing processes or results. Undue influence can take many forms. For example, it would be



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undue influence if a laboratory director instructs laboratory personnel to alter a test report to indicate a passing result, rather than a failing result, because a customer has exerted pressure on the laboratory director by threatening to withdraw its business if the laboratory report indicates a failing result. Another example of undue influence would be if a manager of a firewalled laboratory asks a laboratory technician not to report a failing test result because it would delay a large shipment of products. Similarly, in the case of a firewalled laboratory, a manufacturing manager who urges the laboratory to complete the testing promptly and "cut corners" on the normal testing procedures so that the factory can ship product to meet a production quota for the month, would be attempting to apply undue influence. In the governmental laboratory context, undue influence might take the form of a government official influencing a laboratory to report falsely that a sample passed a test in order to facilitate exports.

The second ground for withdrawal, at proposed § 1112.47(b), would be that the third party conformity assessment body failed to comply with an applicable protocol, standard, or requirement under proposed subpart C of this part. This provision implements section 14(e)(1)(B) of the CPSA.

The third ground for withdrawal, at proposed § 1112.47(c), would state that we may withdraw our acceptance of the accreditation of a laboratory if the laboratory fails to comply with any provision in subpart B of this part. As a reminder, proposed subpart B would establish the general requirements pertaining to third party conformity assessment bodies, such as requirements, processes, and timing related to applying for CPSC acceptance, recordkeeping requirements, and limitations on subcontracting. Thus, examples of failure to comply with subpart B would include a laboratory that loses its ISO/IEC 17025:2005 accreditation (either for the entire laboratory or for any portion of its CPSC scope) or has such accreditation suspended; a



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firewalled laboratory that fails to continue to satisfy the relevant statutory criteria; or a laboratory that fails to use, in relation to a test conducted for purposes of section 14 of the CPSA, a CPSC-specified test method.

5. Proposed § 1112.49 -- How May a Person Submit Information Alleging Grounds for Adverse Action, and What Information Should Be Submitted?

Proposed § 1112.49(a) would allow any person to submit information alleging that one or more of the grounds for adverse action exists. The information may be submitted in writing or electronically. Any request for confidentiality would need to be indicated clearly in the submission.

Proposed § 1112.49(a) also would list the information to be included in a submission alleging grounds for adverse action. First, the submission should include the name and contact information of the person making the allegation. Second, the submission should identify the laboratory against whom the allegation is being made, as well as any officials or employees of the laboratory relevant to the allegation, in addition to contact information for those individuals. Third, a person alleging a ground for adverse action should identify any manufacturers, distributors, importers, private labelers, or governmental entities relevant to the allegation, along with any officials or employees of the manufacturers, distributors, importers, private labelers, and/or governmental entities relevant to the allegation, as well as contact information for those individuals. Fourth, a submission should include a description of acts and/or omissions to support each asserted ground for adverse action. Generally, the submission should describe, in detail, the basis for the allegation that grounds for adverse action against a laboratory exists. In addition to a description of the acts and omissions and their significance, a description may include: dates, times, persons, companies, governmental entities, locations, products, tests, test



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results, equipment, supplies, frequency of occurrence, and negative outcomes. When possible, the submission should attach documents, records, photographs, correspondence, notes, electronic mails, or any other information that supports the basis for the allegations. Finally, a submission of grounds for adverse action should include a description of the impact of the acts and/or omissions, where known.

Proposed § 1112.49(b) would state that, upon receiving the information, we would review the information to determine if it is sufficient to warrant an investigation. We may deem the information insufficient to warrant an investigation if the information fails to address adequately the categories of information outlined in paragraph (a) of this section.

6. Proposed § 1112.51 -- What Are the Procedures Relevant to Adverse Actions?

Proposed § 1112.51 would describe the process by which we may deny an application from a laboratory, suspend our acceptance of the accreditation of a laboratory, withdraw our acceptance of the accreditation of a laboratory on a temporary or permanent basis; and/or immediately temporarily withdraw our acceptance of the accreditation of a laboratory.

Proposed § 1112.51(a)(1) would state that investigations, for purposes of part 1112, are investigations into grounds for an adverse action against a third party conformity assessment body. Proposed § 1112.51(a)(2) would explain that we would use our *Procedures for Investigations, Inspections, and Inquiries*, 16 CFR part 1118, subpart A, to investigate under this part.

Proposed § 1112.51(a)(3) would provide that an investigation under this part may include: any act we may take to verify the accuracy, veracity, and/or completeness of information received in connection with an application for acceptance of accreditation; a



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submission alleging grounds for an adverse action; or any other information we receive, which relates to a laboratory's ability to become or remain a CPSC-accepted laboratory.

Proposed § 1112.51(a)(4) would state that we would begin an investigation by providing written notice, which may be electronic, to the laboratory. The notice would inform the laboratory that we have received information sufficient to warrant an investigation, and it would describe the information received by the CPSC, as well as describe our investigative process. The notice also would inform the laboratory that failure to cooperate with a CPSC investigation is grounds for suspension.

Proposed §1112.51(a)(5) would state that any notice sent by the CPSC under proposed § 1112.35(b)(3) informing the third party conformity assessment body that it must submit a CPSC Form 223 for audit purposes, constitutes a notice of investigation for purposes of this section. The examination portion of an audit under § 1112.33(c) of this part (which we have finalized elsewhere in this issue of the *Federal Register*) constitutes an investigation for purposes of this section.

Failure to cooperate in an investigation under this part is grounds for the CPSC to suspend its acceptance of the accreditation of a laboratory under proposed § 1112.45. In addition, we note that section 19(a)(13) of the CPSA makes it unlawful for any person to make a material misrepresentation to an officer or employee of the Commission in the course of an investigation.

Proposed § 1112.51(b) would state that if, after investigation, we determine that grounds for adverse action exist, and we propose to take an adverse action against a laboratory, we would notify the laboratory, in writing, which may be electronic, about the proposed adverse action. If the proposed adverse action is suspension or withdrawal, the CPSC's notice formally would



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begin a proceeding to suspend or withdraw our acceptance of its accreditation, as described in section 14(e) of the CPSA. The notice would contain the CPSC's proposed adverse action; specify grounds on which the proposed adverse action is based; and provide findings of fact to support the proposed adverse action. This notice also would contain, when appropriate, specific actions a third party conformity assessment body must take to avoid an adverse action. For example, if a laboratory submitted an incomplete application, we would notify the laboratory of the deficiencies that the laboratory would need to remedy to avoid denial of the application. Also, when the proposed adverse action is withdrawal, the notice would contain consideration of the criteria set forth in proposed § 1112.51(d)(1).

The notice in proposed § 1112.51(b) also would contain the time period by which a laboratory has to respond to the notice. In general, the notice would inform the laboratory that it has 30 calendar days to respond. A laboratory may request an extension of the response time, but it must explain why such an extension is warranted and indicate the amount of additional time needed for a response. Finally, the notice would state that, except under proposed § 1112.53 (which we discuss below in section IV.D.7 of this preamble), a CPSC-accepted laboratory would be able to continue to conduct tests for purposes of section 14 of the CPSA until a Final Notice of adverse action is issued.

Proposed § 1112.51(c) would address how the laboratory may respond to the initial notice. The proposed rule would require the laboratory's response to be in writing, which may be by electronic mail, and in English.

Responses contemplated under proposed § 1112.51(c) could include, but would not be limited to, an explanation or refutation of material facts upon which the CPSC's proposed action is based, supported by documents or a sworn affidavit; results of any internal review of the



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matter, and action(s) taken as a result; or a detailed plan and schedule for an internal review. Proposed § 1112.51(c) would explain that the response is the laboratory's opportunity to state its case that the ground(s) for adverse action does not exist, or explain why the CPSC should not pursue the proposed adverse action, or any portion of the proposed adverse action. If a laboratory responds to the notice in a timely manner, we would review the response, and, if necessary, conduct further investigation to explore or resolve issues bearing on whether grounds exist for adverse action, and the nature and scope of the proposed adverse action. If a laboratory does not submit a response to the notice in a timely manner, we would be able to proceed to a Final Notice, as described in proposed § 1112.51(e), without further delay.

Proposed § 1112.51(d) would address the adverse action proceeding. Proposed § 1112.51(d)(1) would reiterate the factors that we must consider in any proceeding to withdraw under section 14(e)(2)(A) of the CPSA. The proposed rule would state that we will consider the gravity of the laboratory's action or failure to act, including: whether the action or failure to act resulted in injury, death, or the risk of injury or death; whether the action or failure to act constitutes an isolated incident or represents a pattern or practice; and whether and when the third party conformity assessment body initiated remedial action.

Proposed § 1112.51(d)(2) would state that, in all cases, we would review and take under advisement, the response provided by the third party conformity assessment body. Except for cases under proposed § 1112.51(d)(3), we would determine what action is appropriate under the circumstances. Proposed § 1112.51(d)(3) would clarify that any suspension or withdrawal of a firewalled laboratory would occur by order of the Commission. We consider this provision to be consistent with section 14(f)(2)(D) of the CPSA and its requirement that the accreditation of a firewalled laboratory may be accepted by Commission order only.



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Proposed § 1112.51(d)(4) would reiterate section 14(e)(2)(B)(i) of the CPSA, and would state that the CPSC may withdraw its acceptance of the accreditation of a laboratory on a permanent or temporary basis. Proposed § 1112.51(d)(5) would reiterate section 14(e)(2)(B)(ii) of the CPSA and would state that, if we withdraw our acceptance of the accreditation of a laboratory, we may establish requirements for the reacceptance of the laboratory's accreditation. Any such requirements would be related to the reason(s) for the withdrawal.

Proposed § 1112.51(e) would detail the Final Notice. If, after reviewing a laboratory's response to a notice, and conducting additional investigation, where necessary, we determine that grounds for adverse action exist, we would send a Final Notice to the laboratory, in writing, which may be electronic. The Final Notice would state the adverse action that we are taking, the specific grounds on which the adverse action is based, and the findings of fact that support the adverse action. When the adverse action is withdrawal, the Final Notice would address the consideration of the criteria as set forth in proposed § 1112.51(d)(1) and would state whether the withdrawal is temporary or permanent, and, if the withdrawal is temporary, the duration of the withdrawal. The Final Notice would inform the laboratory that its accreditation is no longer accepted by the CPSC as of the date of the Final Notice of denial, suspension, or withdrawal for any specified portion(s) of its CPSC scope. The Final Notice also would inform the laboratory that the CPSC website will be updated to reflect adverse actions taken against a previously CPSC-accepted laboratory. Finally, the Final Notice would inform the laboratory whether it may submit a new application.

Proposed § 1112.51(f) would state that, upon receipt of a Final Notice, a third party conformity assessment body, as applicable, may submit a new application (if the Final Notice indicated such) or file an Administrative Appeal.



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Proposed § 1112.51(g) would address Administrative Appeals. Except for cases covered in proposed § 1112.51(g)(2), a laboratory could file an Administrative Appeal with the Office of the Executive Director. The Administrative Appeal would need to be sent by mail within 30 calendar days of the date on the Final Notice; proposed § 1112.51(g) would provide the appropriate mailing and electronic mail addresses. The proposed rule would require all appeals to be in English; to explain the nature and scope of the issues appealed from in the Final Notice; and describe, in detail, the reasons why the laboratory believes that no grounds for adverse action exist.

The Executive Director would issue a Final Decision within 60 calendar days of receipt of an Administrative Appeal. If the Executive Director's Final Decision would require more than 60 calendar days, he or she would notify the third party conformity assessment body that more time is required, state the reason(s) why more time is required, and, if feasible, include an estimated date for a Final Decision to issue.

Proposed § 1112.51(g)(2) would address the circumstance in which the Commission has suspended or withdrawn its acceptance of the accreditation of a firewalled laboratory. Because suspensions and withdrawals of firewalled laboratories must occur by order of the Commission, Administrative Appeals, in these cases, would be filed with the Commission. The Administrative Appeal would need to be sent to the Office of the Secretary by mail within 30 calendar days of the date on the Final Notice.. The proposed rule would require all appeals to be in English, to explain the nature of the issues appealed in the Final Notice, and to describe in detail the reasons why the laboratory believes that no ground(s) exist for adverse action.

7. Proposed § 1112.53 -- Can the CPSC Immediately Withdraw its Acceptance of the Accreditation of a Third Party Conformity Assessment Body?



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Under proposed § 1112.51(b)(7) a CPSC-accepted third party conformity assessment body generally would be able to continue to conduct tests for purposes of section 14 of the CPSA during an investigation and the procedures leading up to an adverse action, until a Final Notice of adverse action is issued. Proposed § 1112.53 would establish a means of immediately and temporarily withdrawing the accreditation of a laboratory in the rare circumstance that it would be in the public interest to remove our acceptance of the laboratory while we pursue an investigation and potential adverse action against the laboratory under proposed § 1112.51.

Section 12 of the CPSA addresses imminent hazards. Proposed § 1112.53 would use section 12 of the CPSA as a guide. We do not foresee many circumstances under which we would be so concerned with the testing conducted by a CPSC-accepted laboratory that we would need to stop the laboratory from conducting third party tests of children's products while we investigate and proceed against the laboratory. However, because any such circumstances would endanger the public, the proposed rule would enable us to do exactly that in certain prescribed conditions and after following particular procedures.

Proposed § 1112.53(a) would state that, when it is in the public interest to protect health and safety, and notwithstanding any other provision of this part, we would be able to immediately and temporarily withdraw our acceptance of a laboratory's accreditation for any portion of its CPSC scope while we pursue an investigation and potential adverse action. Proposed § 1112.53(a)(1) would define "in the public interest to protect health and safety" to mean that the CPSC has credible evidence that: (1) the integrity of test(s) being conducted under a scope for which we have accepted the laboratory's accreditation have been affected by undue influence or otherwise interfered with or compromised; and (2) any portion of a CPSC scope for which we have accepted the laboratory's accreditation involve a product(s) which, if



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noncompliant with CPSC rules, bans, standards, and/or regulations, constitutes an imminently hazardous consumer product under section 12 of the CPSA.

Proposed § 1112.53(a)(2) would state that, when presented with an allegation that, if credible, would result in immediate and temporary withdrawal of CPSC acceptance of a third party conformity assessment body's accreditation, the investigation and adverse action procedures described in § 1112.51 apply, except that instead of the timeframes described in § 1112.51, the following timeframes would apply when the CPSC pursues immediate and temporary withdrawal: The Initial Notice will generally inform the third party conformity assessment body that it has 7 calendar days to respond; an administrative appeal of a Final Notice of immediate and temporary withdrawal will be timely if filed within 7 calendar days of the date of the Final Notice.

Proposed § 1112.53(b) would state that, if the laboratory is already the subject of an investigation or adverse action process, the immediate and temporary withdrawal would remain in effect until either we communicate in writing that the immediate and temporary withdrawal has been lifted, the investigation concludes and we do not propose an adverse action, or the adverse action process concludes with denial, suspension, or withdrawal. Under proposed § 1112.53(c), if the laboratory is not already the subject of an investigation or adverse action process under § 1112.51, an investigation under § 1112.51(a) would be launched based on the same information that justified the immediate and temporary withdrawal.

8. Proposed § 1112.55 – Will the CPSC Publish Adverse Actions?

Proposed § 1112.55 would state that, immediately following a final adverse action, we would be able to publish the fact of a final adverse action, the text of a final adverse action, or a summary of the substance of a final adverse action. In addition, after issuance of a final adverse



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action, we would amend our website listing of CPSC-accepted laboratories to reflect the nature and scope of such adverse action.

E. *Proposed § 1118.2 – Conduct and Scope of Inspections*

The Commission's regulations on investigations, inspections, and inquiries under the CPSA are located at 16 CFR part 1118. Subpart A of part 1118 prescribes CPSC procedures for investigations, inspections, and inquiries. Section 1118.2 addresses topics such as how the CPSC conducts an inspection, which sites the CPSC has authority to inspect, and what the CPSC may view or obtain during an inspection.

The proposed rule would amend § 1118.2(a) in two ways. First, it would include third party conformity assessment bodies as entities that we may inspect. This amendment is necessary to conform with the inspection provision at proposed § 1112.27. Second, it would remove the word "consumer" before the word "product" throughout paragraph (a), for accuracy. Some children's products regulated by the Commission and that are required by the CPSA to be third party tested are not regulated primarily under the CPSA. For example, some toys are regulated under the Federal Hazardous Substances Act, 15 U.S.C. 1261–1278. To be consistent with the inspection provision at proposed § 1112.27, the references to "product" must be broad enough to include more than just products subject to CPSA safety standards.

Normally, we would use the plain language "must" rather than "shall" when describing mandatory requirements in a rule. However, because we are amending one paragraph of a section that was drafted using "shall," we will continue to use "shall" in this paragraph, to avoid any potential confusion that might arise from the appearance of inconsistent terminology within § 1118.2.



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## V. Regulatory Flexibility Act

### *A. Introduction*

The Regulatory Flexibility Act (RFA), 5 U.S.C. chapter 6, requires the agency to evaluate the economic impact of this proposed rule on small entities. The RFA defines "small entities" to include small businesses, small organizations, and small governmental jurisdictions. Section 603 of the RFA requires the CPSC to prepare an initial regulatory flexibility analysis and make it available to the public for comment when the notice of proposed rulemaking is published. The initial regulatory flexibility analysis must describe the impact of the proposed rule on small entities and identify any alternatives that may reduce the impact. Specifically, the initial regulatory flexibility analysis must contain:

1. [A] description of the reasons why action by the agency is being considered;
2. [A] succinct statement of the objectives of, and legal basis for, the proposed rule;
3. [A] description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
4. [A] description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities subject to the requirements and the type of professional skills necessary for the preparation of reports or records;
5. [A]n identification, to the extent possible, of all relevant Federal rules which may duplicate, overlap, or conflict with the proposed rule.

5 U.S.C. 603(b).

Additionally, the initial regulatory flexibility analysis must contain a description of any significant alternatives to the proposed rule that accomplish the stated objectives of the proposed rule while minimizing the economic impact on small entities.

### *B. Reasons the Commission is Considering the Proposed Rule*

Section 14(a)(2)of the CPSA requires that a manufacturer or private labeler of a children's product subject to a children's product safety rule submit samples of the product to a



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CPSC-accepted third party conformity assessment body for testing for compliance with the rule. Based on the testing, the manufacturer or private labeler must issue a certificate that certifies that the children's product complies with the applicable children's product safety rule(s). This proposed rule would codify, inter alia, the requirements and process by which a laboratory may apply for CPSC acceptance of its accreditation, the process for a laboratory to voluntarily discontinue providing testing to support a children's product certification, and the procedures by which the CPSC may suspend or withdraw its acceptance of the accreditation of a laboratory.

*C. Objectives of and Legal Basis for the Proposed Rule*

The primary objective of the proposed rule is to codify the requirements pertaining to laboratories, including the requirements and processes related to obtaining CPSC acceptance of their accreditation. Codifying the requirements related to obtaining CPSC acceptance of accreditation will make it easier for interested parties to locate the requirements because, from September 2008 through August 2011, the CPSC has issued 19 notices of requirements pertaining to specific regulations or test methods. This rule would compile the requirements in a single location.

The proposed rule also would establish the grounds for and procedures by which the CPSC could suspend or withdraw its acceptance of the accreditation of a laboratory. Additionally, where the required test method(s) is not specified in a children's product safety rule, provisions in the proposed rule (§ 1112.15, § 1112.17) would formally establish the test method(s) that laboratories must use to assess conformity with the particular rule.

The legal bases of the rule are found in section 14 of the CPSA, as amended by section 102 of the CPSIA, and section 3 of the CPSIA. Section 3 of the CPSIA grants the CPSC the authority to issue regulations to implement the CPSIA and the amendments made by the CPSIA.



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Section 14(a)(3) of the CPSA provides the authority for the CPSC to establish the accreditation requirements for laboratories. Section 14(e) of the CPSA provides the authority for the CPSC to suspend and/or withdraw the acceptance of the accreditation of a laboratory.

*D. Description and Estimate of the Number of Small Entities to Which the Proposed Rule Would Apply*

This proposed rule would apply to laboratories that intend to offer their testing services to manufacturers and private labelers of children's products for purposes of supporting a certification that the products conform to applicable children's product safety rules. The proposed rule would not impose any requirements on laboratories that do not intend to provide these services.

Although there are 5,041 firms classified as "testing laboratories" (NAICS code 54138) in the United States,[2] only a small subset of these laboratories are expected to provide third party conformity assessments of children's products for purposes of section 14(a)(2)of the CPSA. As of August 29, 2011, the CPSC has accepted the accreditation of 87 laboratories located in the United States.[3] This number could increase somewhat over the next year or so as the remaining notices of requirements for accreditation are issued and the stays of enforcement of the requirements for third party testing that the Commission issued pending clarification of the regulations and testing requirements, are lifted. Of the laboratories located in the United States with CPSC-accepted accreditations, 12 are owned by large, foreign-based companies and 22 are large, U.S.-based companies. The remaining 53 laboratories (about 61 percent) could be small

[2] Based on 2007 data from the U.S. Census Bureau that was compiled by the U.S. Small Business Administration (available at http://www.sba.gov/advo/research/us_rec07.txt).

[3] CPSC has recognized the accreditations of at least 346 (if using the date of Aug 17, 2011) testing laboratories worldwide. However, most of the laboratories are located in other countries. Only domestic firms are relevant for purposes of the RFA.



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firms, according to the criteria established by the U.S. Small Business Administration (SBA), which for a laboratory is revenue of less than $12 million annually.

*E. Projected Reporting, Recordkeeping, and other Compliance Requirements*

1. Accreditation Requirements

The proposed rule would establish the requirements for CPSC acceptance of the accreditation of a laboratory. The rule would apply only to laboratories that intend to provide third party testing of children's products in support of the certification required by section 14(a)(2) of the CPSA. The proposed rule would not impose any requirements on laboratories that do not intend to provide these services.

The proposed rule would require that, as a condition of CPSC acceptance of its accreditation, the laboratory must be accredited to the Standard ISO/IEC 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). The scope of the accreditation must list the CPSC safety rule(s) and/or test method(s) for which acceptance is sought. This aspect of the proposed rule would simply codify the existing conditions for CPSC acceptance of accreditation, which have been stated in every notice of requirements published by the CPSC.

The proposed rule would require that laboratories provide the CPSC with their accreditation certificate and scope documents. These records are normally generated during the accreditation process and can be provided to the CPSC electronically. The application form for the CPSC acceptance of accreditation is CPSC Form 223. This is an electronic application form and all of the information that is required to be supplied on the form should be readily available



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to the laboratory. The professional skills required to complete CPSC Form 223 and the related documents are skills that a competent, accredited laboratory would be expected to have.

The proposed rule also would require firewalled laboratories to submit additional materials. The additional documents would provide evidence that, despite the fact that the laboratory is managed, owned, or controlled by a manufacturer or private labeler, the testing process is independent of that relationship. The acceptance of a firewalled laboratory's accreditation would occur only by Commission order after it has made certain findings. The additional documents required to support the findings include:

(i) The laboratory's policies and procedures that explain:

(A) How the third party conformity assessment body will protect its test results from undue influence by the manufacturer, private labeler, or other interested party;

(B) That the CPSC will be notified immediately 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; and

(C) That allegations of undue influence may be reported confidentially to the CPSC;

(ii) Training documents, including a description of the training program content, showing how employees are trained annually on the policies and procedures described above.

(iii) Training records listing the staff members who received the required training identified in subparagraph (i). The records must include training dates, location, and the name and title of the individual providing the training;

(iv) An organizational chart(s) of the laboratory that includes the names of all laboratory personnel, both temporary and permanent, and their reporting relationship within the laboratory;

(v) An organizational chart(s) of the broader organization that identifies the reporting relationships of the laboratory within the broader organization (using both position titles and staff names); and

(vi) A list of all laboratory personnel with reporting relationships outside of the laboratory. The list must identify the name and title of the relevant laboratory employee(s) and the names, titles, and employer(s) of all individuals outside of the laboratory to whom they report.



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The proposed rule also would establish requirements for CPSC acceptance of the accreditation of laboratories that are owned or controlled by a government. The additional requirements for this type of laboratory include a description, which may be in the form of a diagram, that illustrates relationships with other entities, such as government agencies and joint venture partners, and answering questions that will be used by the CPSC to determine whether it meets the statutory requirements for acceptance of its accreditation. The laboratory must also provide a copy of an executed memorandum addressed to all staff members and displayed for staff reference stating the laboratory policy to reject undue influence over its testing results by any outside person or entity. The memorandum must add that employees are required to report immediately to their supervisor or other designated official about any attempts to gain undue influence and that the laboratory will not tolerate violations of its undue influence policy. Further, a senior officer of the laboratory must make attestations regarding the continuing accuracy of the conditions and policies of the laboratory.

Laboratories that are owned by foreign governments do not meet the definition of a "small entity" under the Regulatory Flexibility Act. To date, we have accepted one application from a domestic governmental laboratory.

There are no fees payable to the CPSC associated with applying for CPSC acceptance of accreditation. The costs of obtaining ISO/IEC 17025:2005 accreditation by a signatory to the ILAC-MRA typically include a one-time application fee, an annual fee for each field in which the laboratory is accredited, and an assessment fee. These charges will vary somewhat among accreditation bodies; but representative charges, based on the published fee schedule of one accreditation body, are $800 for the initial application fee, $1,300 per field for the annual fee,



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and $135 per hour per assessor. A representative of an accreditation body stated that assessments can take from 1 to 5 days, with 2.5 days being about average.

Based on the above discussion, a laboratory seeking accreditation in one field of testing can expect to pay around $4,800 in fees. The cost could be higher if the assessment takes more than 2.5 days. If the laboratory is seeking accreditation in more than one field, such as chemical and mechanical testing, the cost will be higher because there will be additional fees for each field, and the assessment will likely take more time. In addition, the laboratory can be expected to be charged for the cost of the assessor's travel, lodging, and meals while conducting the assessment. There will be some cost to the laboratory in terms of personnel to prepare documents for the assessment and to work with the assessors during the assessment.

If a laboratory is already accredited to ISO/IEC 17025:2005 by an accreditation body that is a signatory to the ILAC-MRA, and the laboratory is simply seeking to expand its scope of accreditation to include specific CPSC tests, the cost to the laboratory will be substantially less. In some cases, if the laboratory's scope already includes closely related tests, the accreditation body might be willing to add the CPSC tests to the scope without additional charges. In other cases, there could be some administrative or assessment charges, but these would be less than would be required for a full initial assessment.

For most product safety rules, the required test methods were specified in the regulation that established the safety rule. However, in the case of the requirements limiting the lead content of children's products, the test methods have been specified in the notices of requirements for accreditation, because the limits on acceptable lead were established in law via the CPSIA. The proposed rule would expand the list of acceptable test methods for measuring lead content to include the use of XRF for measuring the lead content of glass materials, crystals,



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and certain metals. Because XRF can be significantly less expensive than other approved test methods, such as inductively coupled plasma or atomic absorption spectrometry, this provision could lower the laboratories testing costs. Some or all of the cost reductions could be passed onto the consumer product manufacturers in the form of lower testing prices.

ISO/IEC 17025:2005 has requirements for the periodic reassessment of accredited laboratories. We are addressing these requirements in the separate but related rulemaking on periodic audits.

2. Recordkeeping Requirements

The proposed rule would require that laboratories maintain certain records associated with the testing conducted for purposes of section 14(a)(2) of the CPSA for at least five years. The retention requirement would apply to all test reports and technical records, records related to subcontracted tests, and customer reports, if different from the test record, if related to tests conducted for purposes of section 14(a)(2) of the CPSA. Additionally, all internal documents describing testing protocols and procedures (such as instructions, standards, manuals, guides, and reference data) that have applied to a test conducted for purposes of section 14(a)(2)of the CPSA must be retained for a period of at least five years from the date such test was conducted. Upon a request by the CPSC, the laboratory must make the records available to the CPSC within 48 hours. If the records are not in English, the proposed rule would require that the laboratory provide the CPSC with copies of the non-English record available to the CPSC within 48 hours, and the laboratory must make an English translation available within 30 days of a request to do so. All records must be legible, but they can be in electronic format or hardcopy, so long as they are readily retrievable.

3. Grounds and Procedures for Adverse Actions Against CPSC-Accepted Laboratories



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The proposed rule also would establish the grounds and procedures that the CPSC would use to take adverse actions against a laboratory. Adverse actions would include: denying the acceptance of the laboratory's accreditation, suspending the acceptance of the laboratory's accreditation for a period of time, or withdrawing the acceptance of the laboratory's accreditation on a temporary or permanent basis. Grounds for these adverse actions would include: a failure to comply with CPSC requirements, failure to cooperate with the CPSC during an investigation, and allowing a manufacturer or other party to exert undue influence on the testing process. Among other things, the rule would establish the requirements for the notices that the CPSC must provide a laboratory before taking an adverse action, the time limits for responses by the laboratory to the notice, and the laboratory's appeal rights.

During an investigation of an allegation, some costs would be incurred by the laboratory for things such as making employees available for interviews with CPSC investigators, providing the CPSC with documents or records requested by the investigators, and allowing CPSC investigators access to its facilities. The cost incurred would depend upon the scope of the investigation. If the CPSC proposed an adverse action against the laboratory, the laboratory could incur some cost in preparing a reply to the notice, if it chooses to reply. The number of investigations of laboratories that the CPSC will open is not known.

4. Summary

Laboratories that intend to provide third party testing services for purposes of section 14(a)(2) of the CPSA will incur some costs to obtain CPSC acceptance of their accreditation. The costs would be low for laboratories that are already accredited to ISO/IEC 17025:2005 by a body that is an ILAC-MRA signatory. If the laboratory is not already accredited to ISO/IEC 17025:2005 by an ILAC-MRA signatory, it can expect to incur fees of around $4,800. The fees



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could be higher if the laboratory sought accreditation in more than one field of testing or the assessment took more than 2.5 days. If the CPSC opened an investigation of the laboratory, the laboratory would likely incur some costs in connection with the investigation.

As noted, the requirements in this proposed rule would apply only to those laboratories that intend to provide third party testing services for purposes of section 14(a)(2) of the CPSA. The only laboratories that are expected to provide those services are those that expect to receive sufficient revenue from providing the testing to justify accepting the requirements as a business decision. Laboratories that do not expect to receive sufficient revenue from these services to justify accepting these requirements would not be expected to pursue accreditation for this purpose. Therefore, one would not expect the requirements to have a significant adverse impact on a substantial number of laboratories.

*F. Federal Rules that Duplicate, Overlap, or Conflict with the Proposed Rule*

We have not identified any federal rules that duplicate, overlap, or conflict with the proposed rule.

*G. Significant Alternatives Considered*

The RFA directs agencies to describe significant alternatives to the proposed rule that would minimize the significant economic impacts on small entities, while accomplishing the agency's objectives. We considered two alternatives to provisions in the proposed rule. One alternative was for the CPSC to accept the accreditation of laboratories that had been accredited by bodies other than just those that are signatories to the ILAC-MRA. The second alternative involved accepting XRF test methods for determining lead content in paint, children's metal jewelry, and children's metal products.

1. Accepting Accreditations by Bodies that are Not ILAC-MRA Signatories



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Comments were received in response to several notices of requirements that the CPSC should accept the accreditation of laboratories that had been accredited by organizations or accreditation bodies that are not signatories to the ILAC-MRA. Some of the organizations not affiliated with the ILAC-MRA, that were suggested by commenters, are the American Industrial Hygiene Association (AIHA), the National Lead Laboratory Accreditation Program (NLLAP), the National Environmental Laboratory Accreditation Conference (NELAC), and accreditation bodies that are members of the National Cooperation for Laboratory Accreditation (NACLA).

If we accepted the accreditation of laboratories that were accredited by these other organizations, it would reduce the cost of obtaining CPSC acceptance for those laboratories that are accredited by the non- ILAC-MRA bodies. Under the proposed rule, to gain CPSC acceptance of their accreditation, these laboratories would have to seek additional accreditation by a body that is a signatory to the ILAC-MRA. It is not known how many laboratories that are accredited by nonsignatories to the ILAC-MRA intend to offer conformity assessment testing services to manufacturers or private labelers of children's products for purposes of section 14(a)(2) of the CPSA.

We recognize that there are other laboratory accreditation organizations or accreditation body cooperations, and we realize that some of these organizations may adhere to similar rules and standards (but with some distinctions) as those established in the ILAC-MRA signatory program. However, CPSC designations to such organizations would not meet all of the objectives we had when we established, as a baseline accreditation requirement, accreditation by a body that was a signatory to the ILAC-MRA. Moreover, we sought to designate a program that operated and was accepted on a broad, multinational level and that could immediately bring on board a large number of accreditation bodies and avoid designating accreditation programs or



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entities that were recognized only in specific regions, nations, or localities. In the absence of establishing conditions for accreditation bodies, any person or entity can claim to be able to accredit laboratories to ISO/IEC 17025:2005, regardless of their qualifications to do so. It should also be noted that the AIHA, one of the suggested alternative accreditation bodies, is now a signatory to the ILAC-MRA.

2. Alternative Test Methods for Lead

The CPSC has received a number of requests to allow more extensive use of XRF analysis in testing related to lead because XRF analysis is significantly less expensive than the other test methods for lead content.

Based on its continuing research of testing methodologies, the Commission has approved the use of certain XRF methods for determining the lead content of homogenous polymer components and paints, and the proposed rule would allow, in addition, the use of certain XRF methods for determining the lead content of glass materials, crystals, and certain metals. However, for other materials, CPSC staff has not determined that XRF is as effective, precise, and reliable as the approved methods. Therefore, the proposed rule does not expand the approved use of XRF to cover all materials or substances. We continue to evaluate improvements in technology and methods on an ongoing basis.

3. Other Potential Alternatives

The RFA directs agencies to consider some specific alternatives to a proposed rule including:

1. The establishment of different compliance or reporting requirements for small entities or timetables that take into account the resources available to small entities;
2. Clarification, consolidation, or simplification of compliance and reporting requirements for small entities;
3. Use of performance rather than design standards; and
4. Exemption for certain or all small entities from coverage of the rule, in whole or part.



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Other than the alternatives specifically discussed above (regarding accreditation by bodies that are not signatories to the ILAC-MRA and alternative testing methods for lead content), we did not identify any significant alternatives that also would meet the agency's objectives and fulfill its obligations under the CPSA, as amended by the CPSIA. However, we welcome comments suggesting other alternatives that could reduce the burden on small entities, while fulfilling the agency's objectives.

## VI. Paperwork Reduction Act

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (PRA). We describe the provisions in this section of the document with an estimate of the annual reporting burden. Our estimate includes the time for completing the application to become a CPSC-accepted laboratory (CPSC Form 223), including uploading the accompanying documents that would be required under this rule; for complying with the proposed recordkeeping requirements; for submitting the information that would be necessary to discontinue voluntarily as a CPSC-accepted laboratory; and for supplying the accompanying documents that would be required at audit.

In particular, we invite comments on the following: (1) Whether the collection of information is necessary for the proper performance of the CPSC's functions, including whether the information will have practical utility; (2) the accuracy of the CPSC's estimate of the burden of the proposed collection of information, including the validity of the method and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to reduce the burden of the collection of information on respondents, including through



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the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Requirements Pertaining to Third Party Conformity Assessment Bodies

Description: The proposed rule would establish the requirements pertaining to the laboratories that are authorized to test children's products in support of the certification required by section 14(a)(2) of the CPSA, as amended by section 102(a) of the CPSIA. The proposed rule would establish the general requirements concerning third party conformity assessment bodies, such as the requirements and procedures for CPSC acceptance of the accreditation of a laboratory, and it also would address adverse actions against CPSC-accepted laboratories. In addition, the proposed rule would amend the audit requirements for laboratories.

Description of Respondents: Testing laboratories.

We estimate the burden of this collection of information as follows: There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimates are based on the following: A laboratory desiring to have its accreditation accepted by the CPSC first must submit an application, CPSC Form 223. CPSC Form 223 is already an OMB-approved collection of information, control number 3041-0143, which expires on July 31, 2013. In that approved collection, we estimated that it would take respondents (applicant laboratories) one hour to complete the form, which includes uploading the "baseline documentation" required of all applicants: the accreditation certificate, and statement of scope.

The proposed rule, if finalized as written, would necessitate changes to CPSC Form 223. For purposes of this PRA estimate, we assume the rule will be finalized as written. To estimate the paperwork burden associated with the application, we are beginning with the 1-hour time estimate already approved under control number 3041-0143, and adding to the one hour



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estimate, the time we estimate it will take or an applicant laboratory to comply with the application requirements that would be newly imposed as a result of this rule.

The proposed rule would require applicant laboratories to attest to a variety of facts concerning their ownership and legal relationships, to determine whether the laboratory should be considered an applicant for firewalled or governmental status. Each characteristic contained in § 1112.11(b) that indicates a firewalled laboratory, would be reflected in a statement to which an applicant laboratory would need to attest with a "yes" or "no" answer. Similarly, each characteristic indicating a governmental laboratory, as contained in § 1112.11(c), would be reflected in a statement to which an applicant laboratory would need to attest with a "yes" or "no" answer. We surveyed less than nine CPSC-accepted laboratories, and we asked them how long it took them to complete the attestation portion of the current CPSC Form 223. The average of the estimates provided was three minutes. This proposed rule would expand significantly the list of characteristics indicating "governmental" or "firewalled" status, as compared to the current CPSC Form 223. We estimate that the additional attestation requirements will take applicants five times longer than the current attestation section on CPSC Form 223. Accordingly, we estimate that it would take applicants an additional 15 minutes to complete CPSC Form 223. Thus, the total time estimated to comply with proposed § 1112.13(a) is 75 minutes per respondent. Based on our experience with the laboratory program to date, we estimate that there will be a total of 450 laboratories whose accreditations are accepted by the CPSC after an initial period of about four years. To predict the annual burden, we divided the number of laboratories by the initial period, to arrive at an estimated 113 laboratories per year with the 75-minute burden.



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Proposed § 1112.13(a)(1) would require CPSC-accepted laboratories to submit a new CPSC Form 223 whenever information previously submitted on the form changes. Based on our experience operating the laboratory program, to date, only about 1 percent of laboratories per year need to update their information, and the information changes, thus far, have been limited to items such as a contact name. A laboratory will not need to fill out an entirely new CPSC Form 223 to submit new information; the laboratory can access its existing CPSC Form 223 via the laboratory application program on the CPSC website and change only those elements that are in need of updating. We estimate that it will take a laboratory that needs to update its information 15 minutes to do so.

The proposed rule, at § 1112.13(b)(2), would require applicant firewalled laboratories to submit six documents concerning their relationship to the manufacturer in addition to their policies on undue influence. First, an applicant firewalled laboratory must submit their established policies and procedures addressing undue influence; that the CPSC will be notified immediately if there is an attempt at undue influence; and that allegations of undue influence may be reported confidentially to the CPSC. Because applicant laboratories must be accredited to ISO/IEC 17025:2005, we know that the laboratories already have certain policies and procedures in place concerning undue influence. However, those policies and procedures will not address reporting attempts at undue influence to the CPSC and that such reports to the CPSC may be confidential. Therefore, we estimate that a laboratory will need to amend its policies and procedures to include these CPSC-related topics. Based on our experience with firewalled laboratory applications, to date, we estimate that it will take applicants two hours to develop these additional policies. The experience of CPSC staff working on firewalled laboratory applications indicates that often applicants choose to submit draft amended policies and



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procedures for feedback prior to finalizing the documents. To err on the side of overestimating, rather than underestimating the burden, we will assume that all firewalled applicants will submit draft documents, and we estimate that applicants will spend an additional hour revising and finalizing those documents after CPSC staff's initial review. Therefore, we estimate that laboratories will spend 3 hours creating these policies and procedures.

In terms of the time it will take an applicant to upload the policies and procedures once they exist, we estimate eight minutes. This estimate is based partly on the results of a survey of fewer than nine laboratories that we asked to estimate the amount of time it took to upload the baseline documents (accreditation certificate and statement of scope). On average, it took an applicant four minutes to locate and upload the two documents. Again, based on our experience with firewalled laboratory applicants, to date, we estimate that the required policies and procedures will be reflected in two documents (*e.g.*, a quality manual and a procedures guide), each of which will take the estimated four minutes to locate and upload into the CPSC laboratory application system. To account for submitting a draft version first, to be followed by a final version, we doubled the 4 minute estimate.

The second submission that the proposed rule would require of firewalled applicants is training documents showing how employees are trained annually on the policies and procedures just described (*see* § 1112.11(b)(2)(i)). Again, laboratories will already have training documents, but those documents will need to be amended to reflect CPSC-related policies (*e.g.*, laboratory staff may report allegations of undue influence confidentially to the CPSC). Following the same reasoning that we applied to laboratories that amend their policies and procedures, we estimate that it will take an applicant firewalled laboratory three hours to create the necessary training documents. Following the same reasoning that we applied to the time it would take to upload the



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policies and procedures, we estimate that it will take a firewalled laboratory applicant eight minutes to locate and upload the necessary training documents.

The third submission the proposed rule would require firewalled laboratory applicants to furnish training records showing that laboratory staff were trained on the policies and procedures described above (*see* § 1112.11(b)(2)(i)). While we understand that laboratories maintain training records in the normal course of doing business, we acknowledge that it is unlikely that all laboratories routinely maintain records that include all of the elements that would be required under this rule. For example, while some laboratories may have employees sign in at each training, other laboratories may not. As another example, while some laboratories may record who conducted the training, others may not. To account thoroughly for the burden that would be imposed by this rule, we estimate that it will take each laboratory one hour to create the training records that would be required under this rule; this one hour is intended to account for any detail of the training that a laboratory would record for compliance with this rule that the laboratory otherwise would not record.

In terms of the time it takes to locate and upload the training records, we assume that some laboratories will maintain the requisite information in more than two documents. Based on the survey results described previously, which indicated that it took an average of four minutes for respondents to locate and upload two documents, we estimate that the burden associated with locating and uploading the training documents requirement is four minutes.

The fourth submission required of firewalled laboratory applicants is an organizational chart of the laboratory. We assume that a laboratory will already have such a document, so the time it would take to comply with this requirement merely would be the time it would take to locate and upload the chart. Based on the earlier estimate of four minutes for two documents and



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because this is only one document, we estimate the burden associated with this requirement to be two minutes.

Similarly, the fifth submission required of firewalled laboratory applicants is an organizational chart of the broader organization, indicating how the laboratory fits into the manufacturing company structure. Again, we assume that the laboratory will already have access to such a document that exists in the normal course of the manufacturer's and laboratory's business. Therefore, the only burden associated with this proposed requirement would be the time it takes for the laboratory to locate and upload the chart. Based on the same reasoning applied for the last organizational chart, we estimate the burden associated with submitting the broader organization's chart to be two minutes.

The sixth submission that would be required of firewalled laboratory applicants is a list of laboratory staff that have reporting relationships outside the laboratory. We assume, for PRA purposes, that this document has not been created in the normal course of the laboratory's business. We do not anticipate that there will be many laboratory employees with outside reporting relationships. Thus, we estimate that this will be a short list. Based on similar lists we have seen from prior firewalled laboratory applicants, we estimate that it will take a laboratory one hour to create this list. Using the same reasoning as applied already, we estimate that it will take a laboratory two minutes to locate and upload this document.

Therefore, based on the above analysis, we estimate that it will take a firewalled laboratory applicant about 8.4 hours to comply with the proposed requirements in § 1112.13(b)(2) (188 min. for policies and procedures + 188 min. for training documents + 64 min. for training records + 2 min. for laboratory organizational chart + 2 min. for broader



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organizational chart + 62 min. for the list of staff with outside reporting relationship = 506 min.; 506 min./60 min. in each hour = 8.4 hours).

Proposed § 1112.13(c)(2) addresses the four additional application requirements for governmental laboratories. The first requirement would be that a governmental laboratory applicant must submit a description, which may be in the form of a diagram, which illustrates the laboratory's relationships with other entities, such as government agencies and joint ventures. Based on the response from a governmental laboratory whose accreditation is accepted by the CPSC, the time required for this is estimated at one hour.

Second, a governmental laboratory applicant would be required to respond to a questionnaire concerning the criteria for governmental laboratories; the criteria are statutory in origin, but they appear at § 1112.13(c)(1) of the proposed rule. Based on our experience with governmental laboratory applications, to date, we estimate that it takes each applicant one hour to respond to this questionnaire.

Third, proposed § 1112.13(c)(2)(iii) would require a governmental laboratory applicant to submit a copy of an executed memorandum addressing undue influence. Our experience with governmental laboratory applicants suggests that it will take 0.5 hours to complete the memorandum. Therefore, we tentatively assign an estimate of 0.5 hours to complete this task.

Fourth, a senior officer of the governmental laboratory applicant would be required to attest to facts and policies concerning the applicant. Our experience with governmental laboratory applicants suggests that it will take 0.5 hours to complete the attestation. Therefore, we tentatively assign an estimate of 0.5 hours to complete this task.

Therefore, the total time we estimate that it will take for a governmental laboratory applicant to comply with the proposed requirements in § 1112.13(c)(2), is 3 hours (1 hour for



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the laboratory relationships description + 1 hour for responding to the questionnaire + 0.5 hours to complete the memorandum addressing undue influence + 0.5 hours for the attestation of facts and policies = 3 hours).

Proposed § 1112.25(a) addresses recordkeeping requirements. We would require that laboratories maintain all test reports and technical records related to tests conducted for purposes of section 14 of the CPSA for at least five years. It is our understanding that laboratories maintain these records in the normal course of their business. However, we would also require that when a test conducted for purposes of section 14 of the CPSA is subcontracted, the prime contractor's report must clearly identify which test(s) was performed by a CPSC-accepted laboratory acting as a subcontractor, and the test from the subcontractor must be appended to the prime contractor's report. We assume, for PRA purposes, that those requirements may not be satisfied in the normal course of a laboratory's business. Based upon responses received from laboratories we surveyed, we estimate that on average, a laboratory conducts 10,188 tests for purposes of section 14 of the CPSA annually. Based on our experience with the laboratory program, to date, we estimate that 5 percent of laboratories will subcontract tests to other CPSC-accepted laboratories. It is difficult to estimate exactly how many tests will be subcontracted, but for current purposes, we will estimate that of the laboratories that subcontract, they will subcontract 25 percent of their tests. To comply with the proposed recordkeeping requirements related to subcontracted tests, we estimate that a laboratory will spend five minutes locating and amending a test report to indicate clearly that one of the test(s) supporting the test report has been subcontracted. We estimate that it will take 2 minutes for the laboratory to append the subcontracted report to the main report (either electronically append, or append hard copies of the reports [*e.g.*, staple]). Therefore, we estimate that it will take a laboratory seven minutes to



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comply with this proposed recordkeeping requirement. Given the number of laboratories that have already been accepted by the CPSC, and based on our experience with the rate of new successful applications, we predict that the total number of laboratories will be 450. Five percent of 450 laboratories is 23 laboratories. Twenty-five percent of 10,188 tests are 2,547 tests. If 23 laboratories subcontract 2,547 tests per year, that is a total of 58,581 subcontracted tests per year. Seven minutes times 58,581 subcontracted tests produces an estimate of 410,067 minutes, or approximately 6,834 hours per year, to comply with the recordkeeping requirement proposed at § 1112.25(a)(2).

Proposed § 1112.25(a)(3) would require that if a laboratory, after conducting a test, chooses to send a report to the customer different from the laboratory test report, the laboratory must maintain the report sent to the customer for five years. Any report that falls within this requirement would be a report that the laboratory has created in the normal course of its business, and thus, is not part of the burden associated with this proposed rule.

We also would require laboratories to maintain any and all internal documents describing testing protocols and procedures, such as instructions and manuals, for a period of five years. Again, these documents would exist as part of the laboratory's normal business activity so that it would not be part of the burden imposed by this proposed rule.

Proposed § 1112.29(a) would explain that a CPSC-accepted laboratory may voluntarily discontinue its participation with the CPSC at any time, by submitting a written notice to the CPSC, and the proposed rule would detail the information that must be included in the notice. In the three years that we have been operating the laboratory program, six laboratories have voluntarily discontinued their participation with us. To err on the side of overestimating, rather than inaccurately underestimating the burden, we will assume that six laboratories will



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voluntarily discontinue their participation each year. We propose to require five elements for the voluntary discontinuance notice, including the name of, and contact information for, the laboratory, scope of the discontinuance, and the beginning date of the discontinuance. Based on our experience with the laboratory program, to date, we estimate that it would take a laboratory one hour to prepare and send this notice of discontinuance. Because we estimate that six laboratories per year will submit such a notice, the total annual burden associated with § 1112.29(a) is estimated to be six hours per year.

The last section of this proposed rule that imposes paperwork burdens is a section related to audits. The final audit rule appears elsewhere in this issue of the *Federal Register*. Here, we are proposing to amend the definition of "audit," to include in the definition the requirement that all laboratories submit at audit, whatever accompanying documentation would be required if they were submitting an initial application. Because the CPSC portion of the audit is required no less than once every two years, we estimate that 50 percent of laboratories will go through an audit each year. Based on the number of independent laboratories that have already been accepted by the CPSC and our experience with the rate of new successful applications, we predict that the total number of independent laboratories will be 365. Half of those, or 183 laboratories, will be audited annually. As noted above, based on results from a survey of fewer than nine laboratories, it takes applicants an average of four minutes to locate and upload their accreditation certificate and statement of scope. Therefore, we estimate that independent labs will spend approximately 12.2 hours complying with this proposed amendment annually (183 laboratories x 4 minutes = 732 min. annually; 732 min./60 minutes per hour=12.2 hours).

With regard to the burden associated with proposed § 1112.13(b)(2), we estimated that it would take a firewalled laboratory applicant 8.4 hours to submit the accompanying



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documentation required with their initial application for CPSC acceptance. Seven hours of that time was allotted for laboratories to create documents specifically required for testing children's products for purposes of section 14 of the CPSA. The laboratories will not need to create those documents again at audit, however. Therefore, instead of the three hours we estimated that firewalled laboratories would spend developing the policies and procedures that would be required under § 1112.13(b)(2)(i), we estimate, for audit purposes, that laboratories will spend one hour reviewing and updating those policies and procedures. Similarly, instead of the three hours we projected that laboratories would need for developing the training documents under § 1112.13(b)(2)(ii), we estimate that laboratories will spend one hour reviewing and updating those documents at audit. Instead of the one hour we estimated laboratories would spend creating the list of employees with outside relationships that would be required under § 1112.13(b)(2)(vi), we estimate laboratories will spend 20 minutes reviewing and updating that list at audit. Accordingly, instead of the 506 minutes we estimated that a firewalled laboratory would spend in support of submitting the accompanying documentation at the time of their initial application for CPSC acceptance, we estimate that a laboratory will spend 226 minutes in support of submitting the accompanying documentation at audit (506 min. – 120 min. for policies and procedures – 120 min. for training documents – 40 min. for list of employees and outside interests = 226 min.). Based on the number of firewalled laboratories that have already been accepted by the CPSC and our experience with the rate of new successful applications, we predict that the total number of firewalled laboratories will be 35. Half of those, or 18, will be audited annually. If half of the firewalled laboratories spend 226 minutes to comply with this aspect of audit annually, that is an annual paperwork burden of 4,068 minutes, or 68 hours (18



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laboratories x 226 minutes = 4,068 minutes annually; 4,068 minutes/60 minutes per hour = approximately 68 hours).

With regard to the burden associated with proposed § 1112.13(c)(2), we estimated that it would take a governmental laboratory applicant three hours to submit the accompanying documentation required when they initially apply for CPSC acceptance. We estimated that one hour would be required to develop a description, which may be in the form of a diagram, which illustrates the laboratory's relationships with other entities, such as government agencies and joint ventures. The laboratories will not need to create the diagrams or documents again at audit, however. Therefore, instead of the one hour we estimated that governmental laboratories would spend developing a description or diagram that would be required under § 1112.13(c)(2), we estimate, for audit purposes, that laboratories will spend 10 minutes reviewing and updating the description or diagram. Similarly, instead of the one hour estimated for responding to the questionnaire that would be required under § 1112.13(c)(1), we estimate laboratories that will spend 20 minutes reviewing the document at audit. Instead of the 30 minutes we estimated that laboratories would spend creating a memorandum addressing undue influence that would be required under § 1112.13(c)(2)(iii), we estimate laboratories will spend 20 minutes reviewing and updating that memorandum at audit. A CPSC-accepted governmental laboratory stated that it took 30 minutes to complete the attestation at audit. Instead of the 30 minutes we estimated that a senior official would spend developing an attestation to facts and policies concerning the applicant, as required under § 1112.13(c)(2)(iv), we estimate that laboratories will spend 10 minutes reviewing the attestation. Accordingly, instead of the 180 minutes we estimated that a governmental laboratory would spend in support of submitting the accompanying documentation at the time of their initial application, we estimate that a laboratory will spend 60 minutes in



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support of submitting the accompanying documentation at audit (10 min. reviewing the description or diagram + 20 min. reviewing the questionnaire + 20 min. reviewing the undue influence memorandum + 10 min. reviewing the attestation = 60 minutes). Based on the number of governmental laboratories that have already been accepted by the CPSC, as well as our experience with the rate of new successful applications, we predict that the total number of governmental laboratories will be 50. Half of those, or 25, will be audited annually. If 25 laboratories spend 60 minutes to comply with this aspect of audit annually, that is an annual paperwork burden of 1,500 minutes, or about 25 hours (25 laboratories x 60 minutes = 1500 minutes annually; 1500 minutes / 60 minutes per hour = 25 hours).

Therefore, we estimate that the total paperwork burden associated with our proposed amendment to the definition of audit will be about 105 hours.

Finally, we estimate that the total paperwork burden associated with this rule will be 7,202 hours. Table 2 summarizes the estimates and the total paperwork burden associated with this rule.

Table 2 – Estimated Annual Reporting Burden

| 16 CFR Section (Proposed) | Number of Respondents | Frequency of Responses, Percent | Total Annual Responses | Minutes per Response | Total Burden, in Hours |
|---|---|---|---|---|---|
| § 1112.13(a), Baseline documents - CPSC Form 223 and Uploading Accreditation Certificate and Statement of Scope | 450 | 25% per year, for 4 years | 113 | 75 minutes | 141 hours per year |
| § 1112.13(a)(1), | 450 | 1% per year | 5 | 15 minutes | 1.25 hours per year |



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| Laboratory update of CPSC Form 223, whenever any information previously supplied on the form changes | | | | | |
| 1112.13(b)(2), Additional requirements for firewalled applicants (6 documents to upload) | 35 | 25% per year, for 4 years | 9 | 506 minutes (8.4 hours) | 76 hours per year |
| § 1112.13(c)(2), Additional requirements for governmental lab applicants (4 requirements - upload description/diagram; respond to questionnaire; execute and submit copy of memorandum; and complete the attestation) | 50 | 25% per year, for 4 years | 13 | 180 minutes (3 hours) | 39 hours per year |
| § 1112.25(a)(2), Recordkeeping requirements for subcontracted test reports | 23 (5% of 450 laboratories) | 25% of tests subcontracted per year (10,188 tests per year, per laboratory) | 58,581 tests per year that are subcontracted | 7 minutes | 6,834 hours per year |
| § 1112.29(a), Submit notification of | 6 | 100% | 6 | 60 minutes | 6 hours per year |



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| voluntary discontinuance in writing, include 5 items | | | | | |
| § 1112.35, Adding "and accompanying documentation" to the definition of Audit<br><br>A. Independent (baseline documents)<br><br>B. Firewalled laboratories<br><br>C. Governmental laboratories | A. 365 Independent laboratories<br><br>B. 35 Firewalled laboratories<br><br>C. 50 Governmental laboratories | 50% per year | A. 183 Independent laboratories<br><br>B. 18 Firewalled laboratories<br><br>C. 25 Governmental laboratories | A. 4 minutes<br><br>B. 226 minutes<br><br>C. 60 minutes | A. 12.2 hours per year (732 minutes per year)<br><br>B. 68 hours per year (4068 minutes per year)<br><br>C. 25 hours per year (1,500 minutes per year) |
| | | | | TOTAL BURDEN | 7,202 hours |

In compliance with the PRA, we have submitted the information collection requirements of this rule to OMB for review. Interested persons are requested to fax comments regarding information collection by [insert date 30 days after date of publication in the FEDERAL REGISTER], to the Office of Information and Regulatory Affairs, OMB (see ADDRESSES).

## VII. Environmental Considerations

The proposed rule falls within the scope of the Commission's environmental review regulations at 16 CFR § 1021.5(c)(1), which provide a categorical exclusion from any requirement for the agency to prepare an environmental assessment or environmental impact statement for product certification rules.



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## VIII. Executive Order 12988

Executive Order 12988 (February 5, 1996), requires agencies to state in clear language the preemptive effect, if any, of new regulations. The proposed regulation would be issued under authority of the CPSA and CPSIA. The CPSA provision on preemption appears at section 26 of the CPSA. The CPSIA provision on preemption appears at section 231 of the CPSIA. The preemptive effect of this rule would be determined in an appropriate proceeding by a court of competent jurisdiction.

## IX. Effective Date

The Commission proposes that any final rule based on this proposed rule become effective 60 days after its date of publication in the *Federal Register*.

The requirements for CPSC acceptance of the accreditation of a third party conformity assessment body under the final rule may differ from the requirements currently in effect. In particular, CPSC Form 223 may change, as may the accompanying documents required with an application. The Commission proposes to begin applying any new application requirements, including requirements for accompanying documents, the first time after the publication of the final rule that a laboratory submits a CPSC Form 223. For CPSC-accepted laboratories, their first submission of CPSC Form 223 after the 1112 final rule publishes would likely occur at audit.

## List of Subjects in 16 CFR Part 1112

Consumer protection, Third party conformity assessment body, Audit, Administrative practice and procedure; Reporting and recordkeeping requirements.



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For the reasons discussed in the preamble, the Consumer Product Safety Commission proposes to amend 16 CFR part 1112 and 16 CFR § 1118.2(a) to read as follows:

## PART 1112 – REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

1. The authority citation for part 1112 continues to read as follows:

Public Law 110-314, Sec. 3, 122 Stat. 3016, 3017 (2008); 15 U.S.C. 2063.

2. Amend part 1112 by adding § 1112.1 to read as follows:

**§ 1112.1 Purpose.**

This part defines the term "third party conformity assessment body" and describes the types of third party conformity assessment bodies that are accepted by the CPSC to test children's products under section 14 of the CPSA. It describes the requirements and procedures for becoming a CPSC-accepted third party conformity assessment body; the audit requirement applicable to third party conformity assessment bodies; how a third party conformity assessment body may voluntarily discontinue participation as a CPSC-accepted third party conformity assessment body; the grounds and procedures for withdrawal or suspension of CPSC acceptance of the accreditation of a third party conformity assessment body; and how an individual may submit information alleging grounds for adverse action.



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3. Amend § 1112.3 by:

a. Adding a sentence to precede the definitions, as set forth below;

b. Revising the definitions of "Audit" and "CPSC," as set forth below, and

c. Adding the definitions, "Accept accreditation," "Commission," "CPSA," "Notice of requirements," "Scope," "Suspend," "Third party conformity assessment body," "Undue Influence," and "Withdraw," as set forth below.

**§ 1112.3 Definitions.**

The following definitions apply for purposes of this part:

"*Accept accreditation*" means that the CPSC has positively disposed of an application by a third party conformity assessment body to test children's products pursuant to a particular children's product safety rule, for purposes of the testing required in section 14 of the CPSA.

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"*Audit*" means a systematic, independent, documented process for obtaining records, statements of fact, or other relevant information, and assessing them objectively to determine the extent to which specified requirements are fulfilled. An audit, for purposes of this part, consists of two parts:

(1) An examination by an accreditation body to determine whether the third party conformity assessment body meets or continues to meet the conditions for accreditation (a process known more commonly as a "reassessment"); and

(2) The resubmission of the "Consumer Product Conformity Assessment Body Acceptance Registration Form" (CPSC Form 223) and accompanying documentation by the third party conformity assessment body and the Consumer Product Safety Commission's



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("CPSC's") examination of the resubmitted CPSC Form 223 and accompanying documentation. Accompanying documentation includes the baseline documents required of all applicants in § 1112.13(a), the documents required of firewalled applicants in § 1112.13(b)(2), and/or the documents required of governmental applicants in § 1112.13(c)(2).

"*Commission*" means the body of Commissioners appointed to the Consumer Product Safety Commission.

"*CPSA*" means the Consumer Product Safety Act, 15 U.S.C. 2051–2089.

"*CPSC*" means the Consumer Product Safety Commission as an agency.

"*Notice of requirements*" means a publication that provides the minimum qualifications necessary for a third party conformity assessment body to become accepted to test children's products for conformity with a particular children's product safety rule.

*****

"*Scope*" means the range of particular CPSC safety rules and/or test methods to which a third party conformity assessment body has been accredited and for which it may apply for CPSC acceptance.

"*Suspend*" means the CPSC has removed its acceptance, for purposes of the testing of children's products required in section 14 of the CPSA, of a third party conformity assessment body's accreditation for failure to cooperate in an investigation under this part.

"*Third party conformity assessment body*" means a testing laboratory.

"*Undue influence*" means that a manufacturer, private labeler, governmental entity, or other interested party affects a third party conformity assessment body, such that commercial, financial, or other pressures compromise the integrity of its testing processes or results.



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"*Withdraw*" means the CPSC removes its prior acceptance of a third party conformity assessment body's accreditation pursuant to a particular children's product safety rule for purposes of the testing of children's products required in section 14 of the CPSA.

4. Amend part 1112 by adding subpart B, to read as follows:

**Subpart B -- General Requirements Pertaining to Third Party Conformity Assessment Bodies**

Sec.



**Subpart B -- General Requirements Pertaining to Third Party Conformity Assessment Bodies**

**§ 1112.11 What Are the Types of Third Party Conformity Assessment Bodies?**

(a) *Independent*. Independent third party conformity assessment bodies are third party conformity assessment bodies that are neither owned, managed, or controlled by a manufacturer



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or private labeler of a children's product to be tested by the third party conformity assessment body, nor owned or controlled in whole or in part by a government;

(b) *Firewalled*. A third party conformity assessment body must apply for firewalled status if:

(1) It is owned, managed, or controlled by a manufacturer or private labeler of a children's product;

(i) For purposes of determining whether a third party conformity assessment body is firewalled, "manufacturer" includes a trade association.

(ii) A manufacturer or private labeler is considered to own, manage, or control a third party conformity assessment body if any one of the following characteristics applies:

(A) The manufacturer or private labeler of the children's product holds a 10 percent or greater ownership interest, whether direct or indirect, in the third party conformity assessment body. Indirect ownership interest is calculated by successive multiplication of the ownership percentages for each link in the ownership chain;

(B) The third party conformity assessment body and a manufacturer or private labeler of the children's product are owned by a common "parent" entity;

(C) A manufacturer or private labeler of the children's product has the ability to appoint a majority of the third party conformity assessment body's senior internal governing body (such as, but not limited to, a board of directors), the ability to appoint the presiding official (such as, but not limited to, the chair or president) of the third party conformity assessment body's senior internal governing body, and/or the ability to hire, dismiss, or set the compensation level for third party conformity assessment body personnel; or



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(D) The third party conformity assessment body is under a contract to a manufacturer or private labeler of the children's product that explicitly limits the services the third party conformity assessment body may perform for other customers and/or explicitly limits which or how many other entities may also be customers of the third party conformity assessment body.

(2) The children's product is subject to a CPSC children's product safety rule that the third party conformity assessment body requests CPSC acceptance to test; and

(3) The third party conformity assessment body intends to test such children's product made by the owning, managing, or controlling entity for the purpose of supporting a Children's Product Certificate.

(c) *Governmental*. Governmental third party conformity assessment bodies are owned or controlled, in whole or in part, by a government. For purposes of this part, "government" includes any unit of a national, territorial, provincial, regional, state, tribal, or local government, and a union or association of sovereign states. "Government" also includes domestic, as well as foreign entities. A third party conformity assessment body is "owned or controlled, in whole or in part, by a government" if any one of the following characteristics applies:

(1) A governmental entity holds a 1 percent or greater ownership interest, whether direct or indirect, in the third party conformity assessment body. Indirect ownership interest is calculated by successive multiplication of the ownership percentages for each link in the ownership chain;

(2) A governmental entity provides any direct financial investment or funding (other than fee for work);

(3) A governmental entity has the ability to appoint a majority of the third party conformity assessment body's senior internal governing body (such as, but not limited to, a



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board of directors); the ability to appoint the presiding official of the third party conformity assessment body's senior internal governing body (such as, but not limited to, chair or president); and/or the ability to hire, dismiss, or set the compensation level for third party conformity assessment body personnel;

(4) Third party conformity assessment body management or technical personnel include any government employees;

(5) The third party conformity assessment body has a subordinate position to a governmental entity in its external organizational structure (not including its relationship as a regulated entity to a government regulator); or

(6) Apart from its role as regulator, the government can determine, establish, alter, or otherwise affect:

(i) The third party conformity assessment body's testing outcomes;

(ii) The third party conformity assessment body's budget or financial decisions;

(iii) Whether the third party conformity assessment body may accept particular offers of work; or

(iv) The third party conformity assessment body's organizational structure or continued existence.

**§ 1112.13 How Does a Third Party Conformity Assessment Body Apply for CPSC Acceptance?**

(a) *Baseline Requirements*. Each third party conformity assessment body seeking CPSC acceptance must:



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(1) Submit a completed Consumer Product Conformity Assessment Body Registration Form ("CPSC Form 223" or "Application"). In submitting a CPSC Form 223, the third party conformity assessment body must attest to facts and characteristics about its business that will determine whether the third party conformity assessment body is independent, firewalled, or governmental. The third party conformity assessment body also must attest that it has read, understood, and agrees to the regulations in this part. The third party conformity assessment body must update its CPSC Form 223 whenever any information previously supplied on the form changes.

(2) Submit the following documentation.

(i) (A) Accreditation Certificate. The third party conformity assessment body must be accredited to the ISO/ IEC Standard 17025:2005(E), "General requirements for the competence of testing and calibration laboratories."

(B) The accreditation must be by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation-Mutual Recognition Arrangement (ILAC-MRA).

(ii) Statement of Scope. The third party conformity assessment body's accreditation must include a statement of scope that clearly identifies each CPSC rule and/or test method for which CPSC acceptance is sought. Although a third party conformity assessment body may include more than one CPSC rule and/or test method in its scope in one application, it must submit a new application if the CPSC has already accepted the third party conformity assessment body for a particular scope, and the third party conformity assessment body wishes to expand its acceptance to include additional CPSC rules and/or test methods.

(b) *Additional Requirements for Firewalled Third Party Conformity Assessment Bodies*.



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(1) A third party conformity assessment body may be accepted as a firewalled third party conformity assessment body if the Commission, by order, makes the findings described in § 1112.17(b).

(2) For the Commission to evaluate whether an applicant firewalled third party conformity assessment body satisfies the criteria listed in § 1112.17(b), and in addition to the baseline accreditation requirements in paragraph (a) of this section, a firewalled third party conformity assessment body applying for acceptance of its accreditation must submit copies of:

(i) The third party conformity assessment body's established policies and procedures that explain:

(A) How the third party conformity assessment body will protect its test results from undue influence by the manufacturer, private labeler, or other interested party;

(B) That the CPSC will be notified immediately 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; and

(C) That allegations of undue influence may be reported confidentially to the CPSC;

(ii) Training documents, including a description of the training program content, showing how employees are trained annually on the policies and procedures described in subparagraph (i) of this section;

(iii) Training records, including a list and corresponding signatures, of the staff members who received the training identified in subparagraph (ii) of this section. The records must include training dates, location, and the name and title of the individual providing the training;



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(iv) An organizational chart(s) of the third party conformity assessment body that includes the names of all third party conformity assessment body personnel, both temporary and permanent, and their reporting relationship within the third party conformity assessment body;

(v) An organizational chart(s) of the broader organization that identifies the reporting relationships of the third party conformity assessment body within the broader organization (using both position titles and staff names); and

(vi) A list of all third party conformity assessment body personnel with reporting relationships outside of the third party conformity assessment body. The list must identify the name and title of the relevant third party conformity assessment body employee(s) and the names, titles, and employer(s) of all individuals outside of the third party conformity assessment body to whom they report;

(c) *Additional Requirements for Governmental Third Party Conformity Assessment Bodies*.

(1) The CPSC may accept a governmental third party conformity assessment body if the CPSC determines that:

(i) To the extent practicable, manufacturers or private labelers located in any nation are permitted to choose third party conformity assessment bodies that are not owned or controlled by the government of that nation;

(ii) The third party conformity assessment body's testing results are not subject to undue influence by any other person, including another governmental entity;

(iii) 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;



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(iv) 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

(v) 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.

(2) For the CPSC to evaluate whether a governmental third party conformity assessment body satisfies the criteria listed in subparagraph (1), and in addition to the baseline accreditation requirements in paragraph (a), a governmental third party conformity assessment body seeking CPSC-accepted status must submit:

(i) A description illustrating the relationships with other entities, such as government agencies and joint ventures partners. The description may be in the form of a diagram;

(ii) Responses to questionnaires. The CPSC will provide a governmental third party conformity assessment body applicant with a questionnaire and will provide a separate questionnaire to the affiliated governmental entity;

(iii) A copy of an executed memorandum addressing undue influence;

(A) The memorandum must be:

(1) Addressed to all staff of the third party conformity assessment body;

(2) On company letterhead;

(3) From senior management;



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(4) In the primary written language used for business communication in the area where the third party conformity assessment body is located; if that language is different than English, an English translation of the executed memorandum must also be provided to the CPSC;

(5) Displayed prominently for staff reference for as long as the accreditation of the third party conformity assessment body is accepted by the CPSC; and

(B) The memorandum must state that:

(1) The policy of the laboratory is to reject undue influence by any manufacturer, private labeler, governmental entity, or other interested party, regardless of that person or entity's affiliation with any organization;

(2) Employees are required to report immediately to their supervisor or any other official designated by the third party conformity assessment body about any attempts to gain undue influence; and

(3) The third party conformity assessment body will not tolerate violations of the undue influence policy.

(iv) Attestation. A senior officer of the governmental third party conformity assessment body, who has the authority to make binding statements of policy on behalf of the third party conformity assessment body, must attest to the following:

(A) The third party conformity assessment body seeks acceptance as a governmental third party conformity assessment body under the CPSC's program of requirements for the testing of children's products;

(B) The official intends the attestation to be considered in support of any and all applications made by this third party conformity assessment body for acceptance of its



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accreditation by the CPSC, including future applications related to additional CPSC rules and/or test methods;

(C) The attestation, and any other document submitted in support of the application, is accurate in its representation of current conditions or policies at the third party conformity assessment body, to the best of the official's knowledge, information, and/or belief. The information in the attestation, and any other document submitted in support of the application, will be understood by the CPSC as continuing in its accuracy in every respect, until and unless notice of its revocation by an authorized officer of the third party conformity assessment body is received by the CPSC. The official understands that acceptance by the CPSC carries with it the obligation to comply with 16 CFR part 1112, in order to remain on the CPSC's list of accepted third party conformity assessment bodies. The attestation is submitted as a condition of acceptance of this laboratory as a governmental third party conformity assessment body by the CPSC.

(D) The word "government" in the attestation refers to any government (central, provincial, municipal, or other) in this third party conformity assessment body's country or administrative area and includes state-owned entities, even if those entities do not carry out governmental functions.

(E) With regard to consumer products to be distributed in commerce in the United States and subject to CPSC third party testing requirements, the third party conformity assessment body does not receive, and will not accept from any governmental entity, treatment that is more favorable than that received by other third party conformity assessment bodies in the same country or administrative area, which have been accepted as accredited for third party testing by the CPSC. More favorable treatment for a governmental third party conformity assessment body



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includes, but is not limited to, authorization to perform essential export-related functions, while competing CPSC-accepted laboratories in the same country or administrative area are not permitted to perform those same functions.

(F) With regard to consumer products to be sold in the United States and subject to CPSC third party testing requirements, the third party conformity assessment body's testing results are not accorded greater weight by any governmental entity that may be evaluating such results for export control purposes, compared to other third party conformity assessment bodies in the same country or administrative area, which have been accepted as accredited for third party testing by the CPSC.

(G) The third party conformity assessment body has an expressed policy, known to its employees, that forbids attempts at undue influence over any government authorities on matters affecting its operations.

(H) When a governmental third party conformity assessment body is owned or controlled by a governmental entity that also has any ownership or control over consumer product production, the senior officer of the applicant third party conformity assessment body must attest that the third party conformity assessment body will not conduct CPSC tests in support of a Children's Product Certificate for products for export to the United States that have been produced by an entity in which that governmental entity holds such ownership or control until it has applied for and been accepted by the Commission as, a dual governmental-firewalled third party conformity assessment body.

(v) Governmental Entity Attestation. In the event that the CPSC determines that its ability to accept a governmental third party conformity assessment body's application is dependent upon a recently changed circumstance in the relationship between the third party



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conformity assessment body and a governmental entity, and/or a recently changed policy of the related governmental entity, the CPSC may require the relevant governmental entity to attest to the details of the new relationship or policy.

(d) *Dual firewalled and governmental status*. A third party conformity assessment body that meets both the firewalled and the governmental criteria must submit applications under both firewalled and governmental categories.

(e) *English language*. All application materials must be in English.

(f) *Electronic submission*. The CPSC Form 223 and all accompanying documentation must be submitted electronically via the CPSC website.

(g) *Clarification and verification*. The CPSC may require additional information to determine whether the third party conformity assessment body meets the relevant criteria. In addition, the CPSC may verify accreditation certificate and scope information directly from the accreditation body before approving an application.

(h) *Retraction of Application*. A third party conformity assessment body may retract a submitted CPSC Form 223 any time before the CPSC has acted on the submission. A retraction will not end or nullify any enforcement action that the CPSC is otherwise authorized by law to pursue.

(i) The Director of the *Federal Register* approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of ISO/IEC 17025:2005(E) from the International Organization for Standardization (ISO), 1, ch. de la Voie-Creuse, Case postale 56, CH-1211 Geneva 20, Switzerland; Telephone +41 22 749 01 11, Fax +41 22 733 34 30; http://www.iso.org/iso/catalogue_detail.htm?csnumber=39883. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room



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820, 4330 East West Highway, Bethesda, MD 20814, telephone 301–504–7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741– 6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

**§ 1112.15 When Can a Third Party Conformity Assessment Body Apply for CPSC Acceptance for a Particular CPSC Rule and/or Test Method?**

(a) Once the CPSC publishes the requirements for accreditation to a particular CPSC rule and/or test method, a third party conformity assessment body may apply to the CPSC for acceptance to that scope of accreditation. An application may be made for acceptance of accreditation to more than one CPSC rule and/or test method. Once accepted by the CPSC, a third party conformity assessment body may apply at any time to expand the scope of its acceptance to include additional CPSC rules or test methods. A third party conformity assessment body may only issue test results for purposes of section 14 of the CPSA that fall within a scope for which the CPSC has accepted the third party conformity assessment body's accreditation.

(b) The CPSC has published previously, or in the cases of 16 CFR part 1221, 16 CFR part 1224, and ASTM F 963-11 for the first time, the requirements for accreditation for third party conformity assessment bodies to assess conformity with the following CPSC rules and/or test methods:

(1) 16 CFR part 1203, Safety Standard for Bicycle Helmets;

(2) 16 CFR part 1215, Safety Standard for Infant Bath Seats;

(3) 16 CFR part 1216, Safety Standard for Infant Walkers;



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(4) 16 CFR part 1217, Safety Standard for Toddler Beds;

(5) 16 CFR part 1219, Safety Standard for Full-Size Baby Cribs;

(6) 16 CFR part 1220, Safety Standard for Non-Full-Size Baby Cribs;

(7)16 CFR part 1221, Safety Standard for Play Yards;

(8) 16 CFR part 1224, Safety Standard for Portable Bedrails;

(9) 16 CFR part 1303, Ban of Lead-Containing Paint and Certain Consumer Products Bearing Lead-Containing Paint;

(i) For its accreditation to be accepted by the Commission to test to 16 CFR part 1303, a third party conformity assessment body must have one or more of the following test methods referenced in its statement of scope:

(A) CPSC Standard Operating Procedure for Determining Lead (Pb) in Paint and Other Similar Surface Coatings, CPSC-CH-E1003-09 and/or CPSC-CH-E1003-09.1;

(B) ASTM F 2853-10, "Standard Test Method for Determination of Lead in Paint Layers and Similar Coatings or in Substrates and Homogenous Materials by Energy Dispersive X-Ray Fluorescence Spectrometry Using Multiple Monochromatic Excitation Beams."

(ii) The original notice of requirements pertaining to 16 CFR part 1303 did not require reference to any particular test method. *See* 73 FR 54564 (Sept. 22, 2008). In order to give third party conformity assessment bodies sufficient time to amend their scope of accreditation to include one or more of the test methods listed in subparagraph (i),

(A) Third party conformity assessment bodies that were listed on the CPSC's website as accepted to 16 CFR part 1303 on April 5, 2011 (the date when the CPSC published the revision to the notice of requirements in the *Federal Register*, *see* 76 FR 18646) have until April 5, 2013,



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to reapply and be accepted by the Commission with an statement of scope that includes one or more of the test methods listed in subparagraph (i);

(B) Third party conformity assessment bodies that were not listed on the CPSC website as accepted to 16 CFR part 1303 on April 5, 2011, and apply for acceptance to 16 CFR part 1303 on or before April 5, 2012, have the option to apply without reference to one or more of the test methods listed in subparagraph (i);

(C) Third party conformity assessment bodies that were not listed on the CPSC website as accepted to 16 CFR part 1303 on April 5, 2011, and apply for acceptance after April 5, 2012, must have one or more of the test methods listed in subparagraph (i) on their statement of scope.

(10) 16 CFR part 1420, Safety Standard for All-Terrain Vehicles;

(11) 16 CFR 1500.86(a)(5), Exceptions from Classification as a Banned Toy or Other Banned Article for Use by Children (Clacker Balls);

(12) 16 CFR 1500.86(a)(7) and (8), Exceptions from Classification as a Banned Toy or Other Banned Article for Use by Children (Dive Sticks and Similar Articles);

(13) 16 CFR part 1501, Method for Identifying Toys and Other Articles Intended for Use by Children Under 3 Years of Age Which Present Choking, Aspiration, or Ingestion Hazards Because of Small Parts;

(14) 16 CFR part 1505, Requirements for Electrically Operated Toys or Other Electrically Operated Articles Intended for Use by Children;

(15) 16 CFR part 1510, Requirements for Rattles;

(16) 16 CFR part 1511, Requirements for Pacifiers;

(17) 16 CFR part 1512, Requirements for Bicycles;

(18) 16 CFR part 1513, Requirements for Bunk Beds;



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(19) 16 CFR part 1610, Standard for the Flammability of Clothing Textiles;

(20) 16 CFR part 1611, Standard for the Flammability of Vinyl Plastic Film;

(21) 16 CFR part 1615, Standard for the Flammability of Children's Sleepwear: Sizes 0 Through 6X (FF 3–71);

(22) 16 CFR part 1616, Standard for the Flammability of Children's Sleepwear: Sizes 7 Through 14 (FF 5-74);

(23) 16 CFR part 1630, Standard for the Surface Flammability of Carpets and Rugs (FF 1-70);

(24) 16 CFR part 1631, Standard for the Surface Flammability of Small Carpets and Rugs (FF 2-70);

(25) 16 CFR part 1632, Standard for the Flammability of Mattresses and Mattress Pads (FF 4-72, amended);

(26) 16 CFR part 1633, Standard for the Flammability (Open Flame) of Mattress Sets;

(27) Lead Content in Children's Metal Jewelry. For its accreditation to be accepted by the Commission to test for lead content in children's metal jewelry, a third party conformity assessment body must have one or more of the following test methods referenced in its statement of scope:

(i) CPSC Test Method CPSC-CH-E1001-08, "Standard Operating Procedure for Determining Total Lead (Pb) in Children's Metal Products (Including Children's Metal Jewelry); and/or the June 21, 2010, revision of that test method (Test Method CPSC-CH-E1001-08.1); and/or



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(ii) Section I, "Screening Test for Total Pb Analysis," from CPSC "Standard Operating Procedure for Determining Lead (Pb) and its Availability in Children's Metal Jewelry," dated February 3, 2005;

(28) Limits on Total Lead in Children's Products: Children's Metal Products. For its accreditation to be accepted by the Commission to test for total lead content in children's metal products, a third party conformity assessment body must have one or more of the following test methods referenced in its statement of scope: CPSC Test Method CPSC-CH-E1001-08, "Standard Operating Procedure for Determining Total Lead (Pb) in Children's Metal Products (Including Children's Metal Jewelry); and/or the June 21, 2010, revision of that test method (Test Method CPSC-CH-E1001-08.1) and/or the revision of that test method ((Test Method CPSC-CH-E1001-08.2);

(29) Limits on Total Lead in Children's Products: Non-Metal Children's Products. For its accreditation to be accepted by the Commission to test for lead content in non-metal children's products, a third party conformity assessment body must have one or more of the following test methods referenced in its statement of scope: CPSC Test Method CPSC-CH-E1002-08, "Standard Operating Procedure for Determining Total Lead (Pb) in Non-Metal Children's Products;" and/or the June 21, 2010 revision of that test method (Test Method CPSC-CH-E1002-08.1) and/or the revision of that test method ((Test Method CPSC-CH-E1002-08.2); and

(30) Limits on Phthalates in Children's Toys and Child Care Articles. For its accreditation to be accepted by the Commission to test for phthalates in children's toys and child care articles, a third party conformity assessment body must have one or more of the following test methods referenced in its statement of scope:



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(i) CPSC Test Method CPSC-CH-1001-09.3, "Standard Operating Procedure for Determination of Phthalates;" and/or

(ii) GB/T 22048-2008, "Toys and Children's Products – Determination of Phthalate Plasticizers in Polyvinyl Chloride Plastic;"

(31) ASTM International's *Standard Consumer Safety Specification for Toy Safety*, F 963-11, and section 4.27 (toy chests) from ASTM International's *Standard Consumer Safety Specification for Toy Safety*, F 963-07ε1. The CPSC only requires certain provisions of ASTM F 963–11 and Section 4.27 of ASTM F 963–07ε1 to be subject to third party Testing; and therefore, the CPSC only accepts the accreditation of third party conformity assessment bodies for testing under the following toy safety standards:

(i) ASTM F 963–07ε1; Section 4.27—Toy Chests (except labeling and/or instructional literature requirements)

(ii) ASTM F 963–11

(A) Section 4.3.5.1(2), Surface Coating Materials—Soluble Test for Metals

(B) Section 4.3.5.2,Toy Substrate Materials

(C) 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)

(D) Section 4.3.7, Stuffing Materials

(E) Section 4.5, Sound Producing Toys

(F) Section 4.6, Small Objects (except labeling and/or instructional literature requirements)

(G) Section 4.7, Accessible Edges (except labeling and/or instructional literature requirements)



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(H) Section 4.8, Projections (except bath toy projections)

(I) Section 4.9, Accessible Points (except labeling and/or instructional literature requirements)

(J) Section 4.10, Wires or Rods

(K) Section 4.11, Nails and Fasteners

(L) Section 4.12, Plastic Film

(M)Section 4.13, Folding Mechanisms and Hinges

(N) Section 4.14, Cords, Straps, and Elastics

(O) Section 4.15, Stability and Overload Requirements

(P) Section 4.16, Confined Spaces

(Q) Section 4.17, Wheels, Tires, and Axles

(R) Section 4.18, Holes, Clearances, and Accessibility of Mechanisms

(S) Section 4.19, Simulated Protective Devices (except labeling and/or instructional literature requirements)

(T) Section 4.20.1, Pacifiers with Rubber Nipples/Nitrosamine Test

(U) Section 4.20.2, Toy Pacifiers

(V) Section 4.21, Projectile Toys

(W) Section 4.22, Teethers and Teething Toys

(X) Section 4.23.1, Rattles with Nearly Spherical, Hemispherical, or Circular Flared Ends

(Y) Section 4.24, Squeeze Toys

(Z) Section 4.25, Battery-Operated Toys (except labeling and/or instructional literature requirements)



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(AA) Section 4.26, Toys Intended to Be Attached to a Crib or Playpen (except labeling and/or instructional literature requirements)

(BB) Section 4.27, Stuffed and Beanbag-Type Toys

(CC) Section 4.30, Toy Gun Marking

(DD) Section 4.32, Certain Toys with Nearly Spherical Ends

(EE) Section 4.35, Pompoms

(FF) Section 4.36, Hemispheric-Shaped Objects

(GG) Section 4.37, Yo-Yo Elastic Tether Toys

(HH) Section 4.38, Magnets (except labeling and/or instructional literature requirements)

(II) Section 4.39, Jaw Entrapment in Handles and Steering Wheels

(c) The Director of the *Federal Register* approves the incorporations by reference in this section in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy of the standards incorporated in this section at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301–504–7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741– 6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(1) ASTM F 2853-10, "Standard Test Method for Determination of Lead in Paint Layers and Similar Coatings or in Substrates and Homogenous Materials by Energy Dispersive X-Ray Fluorescence Spectrometry Using Multiple Monochromatic Excitation Beams."

(2) GB/T 22048-2008, "Toys and Children's Products – Determination of Phthalate Plasticizers in Polyvinyl Chloride Plastic."



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**§ 1112.17 How Will the CPSC Respond to Each Application?**

(a) The CPSC staff will review each application and may contact the third party conformity assessment body with questions or to request submission of missing information.

(b) The application of a firewalled third party conformity assessment body will be accepted by order of the Commission, if the Commission finds that:

(1) Acceptance of the accreditation of the third party conformity assessment body would provide equal or greater consumer safety protection than the manufacturer's or private labeler's use of an independent third party third party conformity assessment body; and

(2) The third party conformity assessment body 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 CPSC 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 CPSC.

(c) The CPSC will communicate its decision on each application in writing to the applicant, which may be by electronic mail.

**§ 1112.19 How Does the CPSC Publish Information Identifying Third Party Conformity Assessment Bodies That Have Been Accepted?**

The CPSC 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 acceptance. The CPSC will update the listing regularly to account for changes, such as the addition of new CPSC rules and/or test methods to its scope of accreditation, changes to accreditation certificates, new



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addresses, as well as changes to the status of a third party conformity assessment body due to voluntary discontinuance, suspension, and/or withdrawal.

**§ 1112.21 May a Third Party Conformity Assessment Body Use Testing Methods Other Than Those Specified in the Relevant CPSC Rule and/or Test Method?**

If the CPSC has specified a test method, a third party conformity assessment body must use that test method for any tests conducted for purposes of section 14 of the CPSA.

**§ 1112.23 May a CSPC-Accepted Third Party Conformity Assessment Body Subcontract Work Conducted for Purposes of Section 14 of the CPSA?**

(a) A CPSC-accepted third party conformity assessment body (which, for purposes of this section, also will be referred to as the prime contractor) may only subcontract work conducted for purposes of section 14 of the CPSA to other third party conformity assessment bodies that have been accepted by the CPSC for the scope necessary for the subcontracted work. Violation of this provision constitutes compromising the integrity of the testing process and may be grounds for withdrawal of the CPSC's acceptance of the accreditation of the prime and/or subcontracting third party conformity assessment body.

(b) The provisions of this part apply to all CPSC-accepted third party conformity assessment bodies, even if they are a prime contractor and/or a subcontractor.

**§ 1112.25 What Are a Third Party Conformity Assessment Body's Recordkeeping Responsibilities?**



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(a) The third party conformity assessment body must maintain the following records, which must be legible:

(1) All test reports and technical records related to tests conducted for purposes of section 14 of the CPSA must be maintained for a period of at least five years from the date the test was conducted;

(2) In the case of a test report for a test conducted by a CPSC-accepted third party conformity assessment body acting as a subcontractor, the prime contractor's test report must clearly identify which test(s) was performed by a CPSC-accepted third party conformity assessment body acting as a subcontractor(s), and the test report from the CPSC-accepted third party conformity assessment body acting as a subcontractor must be appended to the prime contractor's test report.

(3) Where a report, for purposes of section 14 of the CPSA, provided by the third party conformity assessment body to a customer is different from the test record, the third party conformity assessment body also must retain the report provided to the customer for a period of at least five years from the date the test was conducted.

(4) Any and all third party conformity assessment body internal documents describing testing protocols and procedures (such as instructions, standards, manuals, guides, and reference data) that have applied to a test conducted for purposes of section 14 of the CPSA must be retained for a period of at least five years from the date such test was conducted.

(b) Upon request by the CPSC, the third party conformity assessment body must make any and all of the records required by this section available for inspection, either in hard copy or electronic form, within 48 hours. If the records are not in the English language, the third party conformity assessment body must make copies of the original (non-English language) available



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to the CPSC within 48 hours, and they must make an English translation of the records available to the CPSC within 30 calendar days of the date the CPSC requested an English translation.

**§ 1112.27 Must a Third Party Conformity Assessment Body Allow CPSC Inspections Related to Investigations?**

A third party conformity assessment body, as a condition of the continued CPSC-acceptance of its accreditation, must allow an officer or employee duly designated by the CPSC to enter and inspect the third party conformity assessment body for purposes of an investigation under this part. The CPSC will conduct such inspections in accordance with 16 CFR § 1118.2. Failure to cooperate with such an inspection constitutes failure to cooperate with an investigation and is grounds for suspension under § 1112.45.

**§ 1112.29 How Does a Third Party Conformity Assessment Body Voluntarily Discontinue its Participation with the CPSC?**

(a) A third party conformity assessment body may voluntarily discontinue participation as a CPSC-accepted third party third party conformity assessment body at any time and for any portion of its scope that is accepted by the CPSC. The third party conformity assessment body must notify the CPSC, in writing, which may be electronic. The notice must include:

(1) Name, address, phone number, electronic mail address for the third party conformity assessment body and the person responsible for submitting the request;

(2) Scope of the discontinuance;

(3) Beginning date for the discontinuance;



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(4) Statement that the third party conformity assessment body understands that it must reapply for acceptance of the accreditation scope for which it is requesting discontinuance; and

(5) Verification that the person requesting the discontinuance has the authority to make such a request on behalf of the third party conformity assessment body.

(b) The CPSC may verify the information submitted in a notice of voluntary discontinuance.

(c) Upon receipt of a notice from a third party conformity assessment body that it wishes to discontinue voluntarily as a CPSC-accepted third party conformity assessment body, or after verifying the information in a notice, the CPSC will update its website to indicate that the CPSC no longer accepts the accreditation of the third party conformity assessment body for the scope indicated, as of the date provided in the notice.

(d) Notwithstanding a third party conformity assessment body's voluntary discontinuance as a CPSC-accepted third party conformity assessment body, the CPSC may begin or continue an investigation related to an adverse action under this part, or other legal action.

5. Amend § 1112.35 by adding paragraph (b) to read as follows:

**§ 1112.35 When Must an Audit Be Conducted?**

*****

(b) For the examination portion of the audit, which is conducted by the CPSC:

(1) Each third party conformity assessment body must submit a CPSC Form 223 for audit purposes no less than every two years. When a CPSC Form 223 is submitted for audit purposes,



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the third party conformity assessment body must submit any accompanying documentation that would be required if it were a new application.

(2) Under § 1112.13(a)(1), a third party conformity assessment body must submit a new CPSC Form 223 whenever the information supplied on the form changes. In the event that the third party conformity assessment body submits a new CPSC Form 223 to provide updated information, the third party conformity assessment body may elect to have the new CPSC Form 223 satisfy the requirement of paragraph (b)(1) of this section. If the third party conformity assessment body intends to have the new CPSC Form 223 treated as its submission for audit purposes, the third party conformity assessment body must make that intention clear upon submission, and it must submit any accompanying documentation that would be required if it were a new application.

(3) At least 30 days prior to the date by which a third party conformity assessment body must submit a CPSC Form 223 for audit purposes, the CPSC will notify the body in writing, which may be electronic, of the impending audit deadline. A third party conformity assessment body may request an extension of the deadline for the examination portion of the audit, but it must indicate how much additional time is requested and explain why such an extension is warranted. The CPSC will notify the third party conformity assessment body whether its request for an extension has been granted.

6. Amend part 1112 by adding subpart D to read as follows:

**Subpart D – Adverse Actions: Types, Grounds, Allegations, Procedural Requirements, and Publication**

Sec.



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**Subpart D – Adverse Actions: Types, Grounds, Allegations, Procedural Requirements, and Publication**

**§ 1112.41 What Are the Possible Adverse Actions the CPSC May Take Against a Third Party Conformity Assessment Body?**

(a) Potential adverse actions against a third party conformity assessment body include:

(1) Denial of Acceptance of Accreditation;

(2) Suspension of Acceptance of Accreditation; or

(3) Withdrawal of Acceptance of Accreditation.

(b) Withdrawal of acceptance of accreditation can be on a temporary or permanent basis, and the CPSC may immediately withdraw its acceptance in accordance with § 11123.53 of this part.

**§ 1112.43 What Are the Grounds for Denial of an Application?**

(a) The CPSC may deny an application for any of the following reasons:



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(1) Failure to complete all information, and/or attestations, and/or failure to provide accompanying documentation, required in connection with an application within 30 days after notice of a deficiency by the CPSC;

(2) Submission of false or misleading information concerning a material fact(s) on an application, any materials accompanying an application, or on any other information provided to the CPSC related to a third party conformity assessment body's ability to become or to remain a CPSC-accepted third party conformity assessment body; or

(3) Failure to satisfy necessary requirements described in § 1112.13, such as ISO/IEC 17025:2005 accreditation by a ILAC-MRA signatory accreditation body for the CPSC scope for which acceptance of accreditation is being sought.

(b) The CPSC's denial of an application will follow the process described in § 1112.51 of this part.

**§ 1112.45 What Are the Grounds for Suspension of CPSC Acceptance?**

(a) The CPSC may suspend its acceptance of a third party conformity assessment body's accreditation for any portion of its scope when the third party conformity assessment body fails to cooperate with an investigation under section 14 of the CPSA. A third party conformity assessment body "fails to cooperate" when it does not respond to CPSC inquiries or requests, or it responds in a manner that is unresponsive, evasive, deceptive, or substantially incomplete, or when it fails to cooperate with an investigatory inspection under § 1112.27.

(b) Suspension lasts until the third party conformity assessment body complies, to the satisfaction of the CPSC, with required actions, as outlined in the notice described in §



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1112.51(b), or until the CPSC withdraws its acceptance of the third party conformity assessment body.

(c) If the CPSC determines that the third party conformity assessment body is cooperating sufficiently with the CPSC's investigation, the CPSC will lift the suspension. The suspension will lift as of the date of the CPSC's written notification to the third party conformity assessment body that the CPSC is lifting the suspension. The written notification may be by electronic mail.

**§ 1112.47 What Are the Grounds for Withdrawal of CPSC Acceptance?**

(a) A manufacturer, private labeler, governmental entity, or other interested party has exerted undue influence on such third party conformity assessment body or otherwise interfered with or compromised the integrity of the testing process.

(b) The third party conformity assessment body failed to comply with an applicable protocol, standard, or requirement under subpart C of this part.

(c) The third party conformity assessment body failed to comply with any provision in subpart B of this part.

**§ 1112.49 How May a Person Submit Information Alleging Grounds for Adverse Action, and What Information Should Be Submitted?**

(a) *Initiating Information*. Any person may submit information to the Commission, such as by writing to the U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, or by sending electronic mail to: labaccred@cpsc.gov. The submission must allege that one or more of the grounds for adverse action set forth in this part exists. Any



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request for confidentiality must be indicated clearly in the submission. The submission should include:

(1) Contact information, including a name and/or a method by which the CPSC may contact the person providing the information;

(2) Identification of the third party conformity assessment body against whom the allegation is being made, identification of any officials or employees of the third party conformity assessment body relevant to the allegation, and contact information for such individuals.

(3) Identification of any manufacturers, distributors, importers, private labelers, and/or governmental entities relevant to the allegation. The submission also should identify any officials or employees of the manufacturers, distributors, importers, private labelers, or governmental entities relevant to the allegation, and contact information for such individuals.

(4) Description of acts and/or omissions to support each asserted ground for adverse action. Generally, the submission should describe, in detail, the basis for the allegation that grounds for adverse action against a third party conformity assessment body exists. In addition to a description of the acts and omissions and their significance, a description may include: dates, times, persons, companies, governmental entities, locations, products, tests, test results, equipment, supplies, frequency of occurrence, and negative outcomes. When possible, the submission should attach documents, records, photographs, correspondence, notes, electronic mails, or any other information that supports the basis for the allegations;

(5) Description of the impact of the acts and/or omissions, where known.

(b) *Review of Initiating Information*. Upon receiving the information, the CPSC will review the information to determine if it is sufficient to warrant an investigation. The CPSC may



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deem the information insufficient to warrant an investigation if the information fails to address adequately the categories of information outlined in paragraph (a) of this section above.

**§ 1112.51 What Are the Procedures Relevant to Adverse Actions?**

(a) *Investigation*.

(1) Investigations under this part are investigations into grounds for an adverse action against a third party conformity assessment body.

(2) The Commission will use its *Procedures for Investigations, Inspections, and Inquiries*, 16 CFR part 1118, subpart A, to investigate under this part.

(3) An investigation under this part may include any act the CPSC takes to verify the accuracy, veracity, and/or completeness of information received in connection with an application for acceptance of accreditation, a submission alleging grounds for an adverse action, or any other information received by the CPSC that relates to a third party conformity assessment body's ability to become or remain a CPSC-accepted third party conformity assessment body.

(4) The CPSC will begin an investigation under this part by providing written notice, which may be electronic, to the third party conformity assessment body. The notice will inform the third party conformity assessment body that the CPSC has received information sufficient to warrant an investigation, and it will describe the information received by the CPSC and the CPSC's investigative process. The notice also will inform the third party conformity assessment body that failure to cooperate with a CPSC investigation is grounds for suspension under § 1112.45.



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(5) The notice sent by the CPSC under § 1112.35(b)(3) informing the third party conformity assessment body that it must submit a CPSC Form 223 for audit purposes, which may be electronic, constitutes notice of investigation for purposes of this section. The examination portion of an audit under § 1112.33(c) constitutes an investigation for purposes of this section.

(b) *Initial Notice*. If, after investigation, the CPSC determines that grounds for adverse action exist and proposes to take an adverse action against a third party conformity assessment body, the CPSC will notify the third party conformity assessment body, in writing, which may be electronic, about the proposed adverse action. If the proposed adverse action is suspension or withdrawal, the notice formally begins a proceeding to suspend or withdraw, as described in section 14(e) of the CPSA. The notice will contain:

(1) The proposed adverse action;

(2) Specific grounds on which the proposed adverse action is based;

(3) Findings of fact to support the proposed adverse action;

(4) When appropriate, specific actions a third party conformity assessment body must take to avoid an adverse action;

(5) When the proposed adverse action is withdrawal, consideration of the criteria set forth in paragraph (d)(1) of this section;

(6) The time period by which a third party conformity assessment body has to respond to the notice. In general, the notice will inform the third party conformity assessment body that it has 30 calendar days to respond. A third party conformity assessment body may request an extension of the response time, but they must explain why such an extension is warranted and the amount of additional time needed for a response; and



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(7) Except under § 1112.53, a CPSC-accepted third party conformity assessment body may continue to conduct tests for purposes of section 14 of the CPSA until a Final Notice of adverse action is issued.

(c) *Third Party Conformity Assessment Body Response to Initial Notice.* A third party conformity assessment body's response must be submitted in writing, in English, and may be in the form of electronic mail. The response may include, but is not limited to, an explanation or refutation of material facts upon which the Commission's proposed action is based, supported by documents or sworn affidavit; results of any internal review of the matter and action(s) taken as a result; or a detailed plan and schedule for an internal review. The written response must state the third party conformity assessment body's reasons why the ground(s) for adverse action does not exist, or for why the CPSC should not pursue the proposed adverse action, or any portion of the proposed adverse action. If a third party conformity assessment body responds to the notice in a timely manner, the CPSC will review the response, and, if necessary, investigate further to explore or resolve issues bearing on whether grounds exist for adverse action and the nature of the proposed adverse action. If a third party conformity assessment body does not respond to the notice in a timely manner, the CPSC may proceed without further delay to a Final Notice, as described in paragraph (e) of this section.

(d) *Proceeding*.

(1) In any proceeding to withdraw the CPSC's acceptance of a third party conformity assessment body's accreditation, the CPSC will consider the gravity of the third party conformity assessment body's action or failure to act, including:

(i) Whether the action or failure to act resulted in injury, death, or the risk of injury or death;



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(ii) Whether the action or failure to act constitutes an isolated incident or represents a pattern or practice; and

(iii) Whether and when the third party conformity assessment body initiated remedial action.

(2) In all cases, the CPSC will review and take under advisement the response provided by the third party conformity assessment body. Except for cases under subparagraph (3) of this section, the CPSC will determine what action is appropriate under the circumstances.

(3) If, after reviewing and taking under advisement the response provided by a CPSC-accepted firewalled third party conformity assessment body, the CPSC staff concludes that suspension or withdrawal of CPSC acceptance of accreditation is appropriate, staff will transmit their recommendation to the Commission for consideration. Any suspension or withdrawal of CPSC acceptance of accreditation of a firewalled third party conformity assessment body (including immediate and temporary withdrawal under § 1112.53) will be by order of the Commission.

(4) The CPSC may withdraw its acceptance of the accreditation of a third party conformity assessment body on a permanent or temporary basis.

(5) If the CPSC withdraws its acceptance of the accreditation of a third party conformity assessment body, the CPSC may establish conditions for the reacceptance of the accreditation of the third party conformity assessment body, under section 14(e)(2)(B)(ii) of the CPSA. Any such conditions would be related to the reason(s) for the withdrawal.

(e) *Final Notice.* If, after reviewing a third party conformity assessment body's response to a notice and conducting additional investigation, where necessary, the CPSC determines that



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grounds for adverse action exist, it will send a Final Notice to the third party conformity assessment body, in writing, which may be electronic. The Final Notice will state:

(1) The adverse action that the CPSC is taking;

(2) Specific grounds on which the adverse action is based;

(3) Findings of fact that support the adverse action;

(4) When the adverse action is withdrawal, consideration of the criteria as set forth in paragraph (d)(1) of this section;

(5) When the adverse action is withdrawal, whether the withdrawal is temporary or permanent, and if temporary, the duration of the withdrawal;

(6) The third party conformity assessment body's accreditation is not accepted by the Commission as of the date of the Final Notice of denial, suspension, or withdrawal, for specified portion(s) of its CPSC scope. The CPSC website will be updated to reflect adverse actions to any previously CPSC-accepted third party conformity assessment bodies; and

(7) Whether the third party conformity assessment body may submit a new application.

(f) *Possible Actions After Final Notice*. Upon receipt of a Final Notice, a third party conformity assessment body, as applicable, may:

(1) If the Final Notice indicates such, the third party conformity assessment body may submit a new application; or

(2) File an Administrative Appeal.

(g) *Administrative Appeal*. (1) Except for subparagraph (2) of this section below, the third party conformity assessment body may file an Administrative Appeal with the Office of the Executive Director.



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(i) The Administrative Appeal must be sent, by mail, within 30 calendar days of the date on the Final Notice to: the Office of the Executive Director, Room 812, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, or by electronic mail to: cpsc-os@cpsc.gov.

(ii) All appeals must be in writing, in English.

(iii) All appeals must explain the nature and scope of the issues appealed from in the Final Decision, and must describe in detail the reasons why the third party conformity assessment body believes that no ground(s) for adverse action exist.

(iv) If an Administrative Appeal is timely filed, the Executive Director will issue a Final Decision within 60 calendar days of receipt. If the Executive Director's Final Decision requires more than 60 calendar days, he or she will notify the third party conformity assessment body that more time is required, state the reason(s) why more time is required, and, if feasible, include an estimated date for a Final Decision to issue.

(2) In the case that the Commission has suspended or withdrawn its acceptance of the accreditation of a firewalled third party conformity assessment body, the firewalled third party conformity assessment body may file an Administrative Appeal with the Commission.

(i) The Administrative Appeal must be sent, by mail, within 30 calendar days of the date on the Final Notice to: the Office of the Secretary, Room 820, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, or by electronic mail to: cpsc-os@cpsc.gov.

(ii) All appeals must be in writing, in English.



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(iii) All appeals must explain the nature of the issues appealed from in the Final Decision, and must describe in detail the reasons why the third party conformity assessment body believes that no ground(s) for adverse action exist.

**§ 1112.53 Can the CPSC Immediately Withdraw its Acceptance of the Accreditation of a Third Party Conformity Assessment Body?**

(a) When it is in the public interest to protect health and safety, and notwithstanding any other provision of this part, the CPSC may withdraw immediately and temporarily its acceptance of a third party conformity assessment body's accreditation for any portion of its CPSC scope while the CPSC pursues an investigation and potential adverse action under § 1112.51.

(1) For purposes of this part, "in the public interest to protect health and safety" means that the CPSC has credible evidence that:

(i) The integrity of test(s) being conducted under a scope for which the CPSC has accepted the third party conformity assessment body's accreditation, have been affected by undue influence or otherwise interfered with or compromised; and

(ii) The scope for which the CPSC has accepted the third party conformity assessment body's accreditation involve a product(s) which, if noncompliant with CPSC rules, bans, standards, and/or regulations, constitutes an imminently hazardous consumer product under section 12 of the CPSA.

(2) When presented with an allegation that, if credible, would result in immediate and temporary withdrawal of CPSC acceptance of a third party conformity assessment body's accreditation, the investigation and adverse action procedures described in § 1112.51 apply,



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except that instead of the timeframes described in § 1112.51, the following timeframes will apply when the CPSC pursues immediate and temporary withdrawal:

(i) The Initial Notice will generally inform the third party conformity assessment body that it has 7 calendar days to respond.

(ii) An administrative appeal of a Final Notice of immediate and temporary withdrawal will be timely if filed within 7 calendar days of the date of the Final Notice.

(b) If the third party conformity assessment body is already the subject of an investigation or adverse action process under § 1112.51, the immediate and temporary withdrawal will remain in effect until: the agency communicates in writing that the immediate and temporary withdrawal has been lifted; the investigation concludes and the agency does not propose an adverse action; or the adverse action process concludes with denial, suspension, or withdrawal.

(c) If the third party conformity assessment body is not already the subject of an investigation or adverse action process under § 1112.51, an investigation under § 1112.51(a) will be launched based on the same information that justified the immediate and temporary withdrawal.

**§ 1112.55 Will the CPSC Publish Adverse Actions?**

Immediately following a final adverse action, the CPSC may publish the fact of a final adverse action, the text of a final adverse action, or a summary of the substance of a final adverse action. After issuance of a final adverse action, the CPSC will amend its website listing of CPSC-accepted third party conformity assessment bodies to reflect the nature and scope of such adverse action.



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**PART 1118 – INVESTIGATIONS, INSPECTIONS, AND INQUIRIES UNDER THE CONSUMER PRODUCT SAFETY ACT**

7. The authority citation for part 1118 is revised to read as follows:

Authority: 15 U.S.C. 2063; 15 U.S.C. 2065; 15 U.S.C. 2068; 15 U.S.C. 2076; sec. 3, Pub. L. 110-314, 122 Stat. 3016.

8. Amend § 1118.2 by revising paragraph (a) to read as follows:

(a) After an inspection is initiated as set forth in § 1118.1, an officer or employee duly designated by the Commission shall issue the notice of inspection (hereinafter referred to as "notice"). Upon presenting the notice, along with appropriate credentials, to the person or agent in charge of the firm to be inspected, the Commission officer or employee is authorized for the purposes set forth in § 1118.1(a):

(1) To enter, at reasonable times, any factory, warehouse, third party conformity assessment body, or establishment in which products are manufactured, tested, or held, in connection with distribution in commerce, or any conveyance being used to transport products in connection with distribution in commerce; and

(2) To inspect, at reasonable times and in a reasonable manner, any conveyance or those areas of the factory, warehouse, third party conformity assessment body, or establishment where products are manufactured, tested, held, or transported and that may relate to the safety of those products; and



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(3) To have access to and to copy all relevant records, books, documents, papers, packaging, or labeling which:

(i) Is required by the Commission to be established, made or maintained, or

(ii) Show or relate to the production, inventory, testing, distribution, sale, transportation, importation, or receipt of any product, or that are otherwise relevant to determining whether any person or firm has acted or is acting in compliance with the Act and regulations, rules, and orders promulgated under the Act, and

(4) To obtain:

(i) Information, both oral and written, concerning the production, inventory, testing, distribution, sale, transportation, importation, or receipt of any product, and the organization, business, conduct, practices, and management of any person or firm being inspected and its relation to any other person or firm;

(ii) Samples of items, materials, substances, products, containers, packages and packaging, and labels and labeling, or any component at manufacturer's, distributor's, third party conformity assessment body's, or retailer's cost, unless voluntarily provided; and

(iii) Information, both oral and written, concerning any matter referred to in the Act and these rules.

Dated: _____.

_____

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission



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# Staff Briefing Package

## Requirements Pertaining to Third Party Conformity Assessment Bodies

March 14, 2012



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# Briefing Memo: Requirements Pertaining to Third Party Conformity Assessment Bodies



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

This document has been electronically approved and signed.

**Memorandum**

Date: March 14, 2012

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director
Robert J. Howell, Deputy Executive Director for Safety Operations

FROM: DeWane Ray
Assistant Executive Director
Office of Hazard Identification and Reduction

Randy Butturini
Office of Hazard Identification and Reduction

SUBJECT : Requirements Pertaining to Third Party Conformity Assessment Bodies

## 1. Introduction

On August 14, 2008, the Consumer Product Safety Improvement Act (CPSIA) was signed into law [Public Law 110-314]. Parts of the CPSIA amended the Consumer Product Safety Act (CPSA). Section 14 of the amended CPSA has requirements for accrediting conformity assessment bodies (laboratories) and establishing and publishing notices of requirements. The notices of requirements detail the conditions laboratories must meet in order for their tests to serve as a basis for a manufacturer, private labeler, or importer to issue a Children's Product Certificate. The U.S. Consumer Product Safety Commission (CPSC) has issued notices of requirements for various rules, standards, bans, or regulations enforced by the CPSC since August 14, 2008. Conformity assessment bodies apply for CPSC acceptance of accreditation to test to the requirements of the notice of requirements. After CPSC acceptance of a laboratory's application, certifiers may use test data from that laboratory (for the rules or test methods accepted by the CPSC) in support of the issuance of a Children's Product Certificate.

This memorandum summarizes CPSC staff's interpretations of sections 14(a)(3)(A), (C), and (E) of the CPSA for conformity acceptance body accreditation; section 14(e) of the CPSA for withdrawal and suspension of CPSC's acceptance of accreditation; and section 14(f)(2)(A), (B), and (D) of the CPSA for third party, governmental, and firewalled conformity assessment bodies' application for CPSC acceptance of accreditation. In addition, a proposed change to the



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audit final rule (pursuant to section 14(i)(1) of the CPSA) is described, and the definition of which establishments may be inspected pursuant to 16 CFR part 1118 is expanded to include laboratories.

## 2. Third Party Conformity Assessment Bodies

### 2.1. Types of Conformity Assessment Bodies

Third party conformity assessment bodies (laboratories) are designated as "independent," "governmental," or "firewalled," per section 14(f) of the CPSA. Our use of the term "independent" is to distinguish a conformity assessment body that is not otherwise "firewalled" or "governmental."

The definition of a "third party conformity assessment body" is located in section 14(f)(2)(A) of the CPSA:

> (A) IN GENERAL.--The term "third party conformity assessment body" means a conformity assessment body that, except as provided in subparagraph (D), is not owned, managed, or controlled by the manufacturer or private labeler of a product assessed by such conformity assessment body.

By this definition, a "third party conformity assessment body" is independent, being separate in ownership, management, and control from outside entities.

The CPSA defines a "governmental laboratory" in section 14(f)(2)(B) of the CPSA as:

> an entity that is owned or controlled in whole or in part by a government.

The government entity can be a domestic or a foreign national, regional, territorial, state, tribal, or local government body; it can also be a unit of an association or a union of sovereign states. The draft proposed rule would interpret a laboratory as being owned or controlled, in whole or in part, by a government, if any one of six characteristics apply. The six characteristics, with a brief explanation of the staff's reason for including each characteristic as a criterion, are:

- A government entity owns a 1 percent or greater ownership interest, whether direct or indirect, in the laboratory. This value was chosen as the smallest practical administrative unit to consider. The CPSC staff is aware that, in the notices of requirements, the Commission has considered a laboratory to be firewalled if the manufacturer or private labeler owns a minimum of a 10 percent share of the laboratory. The staff considers a lower ownership threshold amount to be appropriate in the governmental laboratory context because, with regard to governmental laboratories, the statute specifically describes relevant ownership or controlling interests to be "in whole *or in part"* (italics added).
- Direct financial investment or funding is supplied by a government entity, other than fee-for-service. Financial support could permit an outside entity to exert some influence on the behavior, practices, or polices of a laboratory because there are strong economic incentives for a laboratory to maintain its sources of funding.



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- A governmental entity has the ability to appoint a majority of the laboratory's senior internal governing body, the ability to appoint the presiding official of the laboratory's senior internal governing body, and/or the ability to hire, dismiss, or set the compensation level of laboratory personnel. Controlling the governing body of an entity is a method of controlling the entity itself; personnel and compensation decisions are key areas of management that indicate control over an enterprise.
- The laboratory's management or technical personnel include any government employees. There is a presumption that a government employee performs a function essential to the laboratory's operation. If the position is controlled by the government, then the government has control over some aspect of the laboratory's operation.
- The laboratory is subordinate to a governmental entity, other than an entity exercising only a regulatory function over the laboratory. (An administratively subordinate entity is under the control of a superior entity.)
- A governmental entity, acting in other than its role as a regulator, can determine:
    - The laboratory's testing outcomes (the ability to determine testing outcomes is an exercise of control);
    - Laboratory budget or financial decisions (the determination or allocation of budget and financial resources amounts to control over the aspects of a laboratory's operations that are dependent upon a revenue stream);
    - Whether the laboratory may accept particular offers of work (to determine what work is accepted is to control what work gets done); or
    - The laboratory's organizational structure or continuance (determination of the organizational structure amounts to control over key management functions because they can be influenced by where, or if, such functions exist in an enterprise—and determination of the laboratory's continued existence is the ultimate method of control).

The CPSA defines a "firewalled laboratory" in section 14(f)(2)(D) of the CPSA as a laboratory:

> that is owned, managed, or controlled by a manufacturer or private labeler . . ..

The draft proposed rule would add to the definition that the manufacturer or private labeler produces or imports a children's product that is subject to a CPSC rule for which the laboratory intends to test for certification or periodic testing purposes. For purposes of determining whether a laboratory is "firewalled," the term "manufacturer" includes trade associations.

In the draft proposed rule, a laboratory would be considered owned by a manufacturer or private labeler if the manufacturer or private labeler holds a 10 percent or more direct or indirect ownership interest in the laboratory. The CPSC has used a 10 percent direct ownership threshold to identify firewalled laboratories since it began implementing the CPSIA's third party testing requirements. Staff proposes to maintain the 10 percent ownership interest threshold because it is our estimation that a manufacturer or private labeler who possesses less than 10 percent ownership interest in a laboratory, and who otherwise does not exercise management or control



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of the laboratory, presents a low risk of exercising undue influence on the laboratory and its testing results. In addition, our experience over the past 3 years using this threshold indicates that it is readily understood by applicants, and it has been feasible in its application. We note that the Federal Communications Commission (FCC) also uses a 10 percent ownership threshold in its ownership disclosure requirements for applications (s*ee* 47 CFR § 1.2112).[1]

Staff proposes that laboratories that are owned indirectly (10 percent or more) by a manufacturer or private labeler who intends to use the laboratory for certification testing of its children's product(s) should be considered firewalled. The purpose of including indirect owners would be to ensure that laboratories partially owned by a manufacturer or private labeler through a subsidiary are included in the definition of "firewalled laboratories," even though there are one or more corporate levels separating the manufacturer/private labeler from the laboratory. By influencing the decisions of the subsidiary, a manufacturer or private labeler owner is capable of exercising undue influence on the laboratory. The draft proposed rule would calculate indirect ownership by multiplying the percentage of ownership levels between the laboratory and the manufacturer. As an example, if Children's Product Manufacturer X owned 50 percent of Company Y, and Company Y owned 30 percent of Laboratory Z, then Children's Product Manufacturer X's indirect ownership in Laboratory Z would be 50 percent x 30 percent, or 15 percent, and that would qualify Laboratory Z as a firewalled laboratory of Children's Product Manufacturer X.

To date, the CPSC has relied solely on ownership criteria to identify firewalled laboratories. However, CPSC staff now proposes to broaden the definition of a firewalled laboratory to address more directly a laboratory managed or controlled by a manufacturer or private labeler. Accordingly, the draft proposed rule would propose that a laboratory also be categorized as firewalled if any of the following apply (a brief explanation of staff's reasoning follows each factor):

- The third party conformity assessment body and a manufacturer or private labeler of the children's product are owned by a common "parent" entity. This is based on a suggestion from comments received on notices of requirements. Staff agrees with the commenters that a parent of a manufacturer or private labeler sufficiently possesses the interests of the manufacturer or private labeler that a laboratory also owned by the parent should be considered at comparable risk of undue influence.
- The manufacturer/private labeler has the ability to appoint a majority of the members or the chair of the laboratory's governing body, and/or to hire, fire, or set the compensation level of laboratory personnel. Staff proposes that these abilities amount to a form of management and/or control over the laboratory.
- The laboratory is a party to a contract with a manufacturer or private labeler of a product that the laboratory tests, and the contract explicitly limits the services that the laboratory can perform for other customers or can direct which entities or the number of other entities that also can be customers. Such a provision would indicate that the manufacturer or private labeler possessed a method of controlling and/or managing the laboratory's ability to collect fees from other customers.

[1] The FCC issues licenses for telecommunications services, authorizing radio equipment, assignment of broadcast licenses, and transfers of control of a licensee from one entity to another.



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This form of economic control is considered by staff to constitute a form of management or control.

## 2.2. Conformity Assessment Body Application for CPSC Acceptance

The draft proposed rule would require that to be considered for CPSC acceptance, laboratories must be accredited by an International Laboratory Accreditation Cooperation–Mutual Recognition Arrangement (ILAC-MRA) signatory accreditation body to have its test results for one or more CPSC rules and/or test methods used as a basis for a Children's Product Certificate or for periodic testing purposes. The ILAC-MRA signatory accredits the laboratory to the international standard ISO/IEC 17025:2005.[2] Applicant laboratories apply for CPSC acceptance of their accreditation by submitting a *CPSC Form 223 – Lab Accreditation*[3] (Form 223) and accompanying documents for one or more CPSC rules or test methods. This form contains fields for the laboratory name, contact information, and the name of the accreditation body that accredited the laboratory to ISO/IEC 17025:2005. The scope of the CPSC rules or test methods for which the laboratory is applying for acceptance must be specified on Form 223. The draft proposed rule would allow a laboratory to apply for acceptance for one or more rules or test methods on the same application.

After CPSC acceptance of a laboratory's accreditation, the laboratory may apply at any time to expand the number of rules or test methods for which its accreditation is accepted. At any time, a laboratory voluntarily may discontinue its participation as a CPSC-accepted laboratory. The laboratory would notify the CPSC in writing (including by electronic mail), indicating the name of the person responsible for submitting the request, describing the scope of the discontinuance, and specifying the beginning date for the discontinuance. The notification must include a statement indicating that the laboratory understands that it must reapply for acceptance of the accreditation scope for which it is requesting discontinuance; and it must also provide verification that the person requesting the discontinuance has the authority to make such a request on behalf of the laboratory.

The draft proposed rule would require an applicant laboratory to submit the following information in addition to Form 223:

- All applicants would be required to submit a copy of their accreditation body's certificate of accreditation to ISO/IEC 17025:2005 and a statement of scope document that indicates to which CPSC safety rule(s) and/or test method(s) the laboratory is accredited.

- Firewalled laboratory applicants would have additional submission requirements:
  - Copies of policies, procedures, and training documents (including program content) on how the laboratory will protect its test results from undue influence by the manufacturer, private labeler, or other interested party;

[2] International Standards Organization/International Electrotechnical Commission standard 17025:2005, *General requirements for the competence of testing and calibration laboratories*.

[3] The form can be found on the CPSC website at: http://www.cpsc.gov/cgibin/labregentry.



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- Copies of policies, procedures, and training documents (including program content) on how the CPSC will be notified immediately of any attempt by the manufacturer or private labeler to hide or exert undue influence over the laboratory's test results;
- Copies of policies, procedures, and training documents (including program content), indicating that allegations of undue influence may be reported confidentially to the CPSC;
- Copies of training records listing staff members who receive the training listed above, including training dates, locations, and the name and title of the trainer;
- Organizational charts of the laboratory that include the names of all of its personnel and their reporting relationships within the laboratory;
- Organizational charts of the broader organization, identifying the reporting relationship of the laboratory within the broader organization (including both position titles and staff names); and
- A list of all laboratory personnel with reporting relationships outside of the laboratory.

For firewalled laboratory applicants, a committee of senior CPSC staff reviews the application and related documentation, including the elements of the applicant's training program and records of training attendance; policies related to undue influence; organizational charts; and the certificate and scope documents associated with ISO 17025:2005 accreditation. If the review is favorable, the committee recommends to the Commission that the laboratory's accreditation as a firewalled laboratory be approved. Based on the Commission vote, the laboratory's application is approved or declined. Laboratories whose applications for acceptance of accreditation are approved are listed on the CPSC's website.[4]

- Governmental laboratory applicants have additional submission requirements:
  - A description of the laboratory's relationships with other entities, such as government agencies and joint venture partners;
  - Responses to questionnaires provided by the CPSC to the laboratory and to the affiliated government entity;
  - A copy of an executed memorandum addressing undue influence, which states: the laboratory's policy of rejecting undue influence over its testing results by any outside person or entity; the requirement that employees are to report immediately to their supervisor or other designated official any attempts to gain undue influence; and that the laboratory will not tolerate violations of the undue influence policy;
  - An attestation by a senior officer of the laboratory (with the authority to make binding policy statements) of the following:
    - The laboratory is seeking acceptance as a governmental laboratory;
    - This attestation is in support of all applications made by this laboratory to the CPSC for acceptance of its accreditation, including future applications;
    - The information provided continues to be accurate until the CPSC is notified otherwise by an authorized laboratory officer;

[4] The list of laboratories can be found at: http://www.cpsc.gov/cgi-bin/labsearch.



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- The word "government" refers to any central, provincial, municipal government in the laboratory's country and includes state-owned entities, even if those entities do not carry out governmental functions;
- The laboratory does not receive and will not accept favorable treatment relative to other CPSC-accepted laboratories in the same country regarding consumer products to be distributed in commerce in the United States requiring third party testing;
- The laboratory's testing results are not accorded greater weight than other CPSC-accepted laboratory test results for consumer products sold in the United States requiring third party testing;
- The laboratory has an expressed policy that forbids attempts at undue influence over any government authorities on matters affecting its operations;
- The senior officer attests to the accuracy of the statements made in the attestation;
- The laboratory will not conduct tests for certification or periodic testing purposes on products produced by an entity that the government owns or controls.

For governmental laboratory applicants, CPSC staff reviews the information provided. The CPSC staff requests a document (which may be a diagram) describing the laboratory's relevant legal relationships. A questionnaire is sent to the laboratory applicant for their completion. Once all of the documents have been returned and evaluated, a decision to approve or decline the application is made by CPSC staff; executive-level staff reviews any recommendation to approve a governmental laboratory.

It is possible that a laboratory's application could be ambiguous. For example, an applicant laboratory may state on Form 223 that it is 30 percent owned by another entity, but it is not clear whether the owning entity produces the product that the laboratory is applying to test. In such a case, this ownership might affect the determination of whether the applicant is a firewalled laboratory. As a second example, laboratories in foreign countries operate under a variety of legal systems, and the relationship between a governmental laboratory and its related government entity may be unclear. A governmental laboratory may have presented information on the questionnaire that needs clarification. In cases such as these, the CPSC would need additional information to complete its evaluation of the application for acceptance of accreditation. Therefore, in the draft proposed rule, the CPSC would be able to request additional information from an applicant laboratory to determine whether the laboratory meets the relevant criteria.

Applications for CPSC acceptance of accreditation are required for a laboratory's test results to be used for children's product certification purposes. However, once an application is submitted, the applicant laboratory may decide not to pursue this line of business. Because there is no requirement to complete the evaluation of an application once the applicant has decided not to pursue children's product certification, an applicant laboratory can withdraw its application at any time by notifying the CPSC.



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## 2.3. Laboratory Subcontracting

Under the proposed rule, laboratory subcontracting of tests conducted for certification of children's products would be prohibited, unless the subcontract is to another CPSC-accepted third party conformity assessment body whose scope includes the test being subcontracted. CPSC acceptance is necessary to ensure the technical competence of the testing and to ensure that policies protecting against undue influence are in place. Subcontracting to a non CPSC-accepted laboratory could lead to using a laboratory without the technical competence necessary for testing or using a non-firewalled first party laboratory for testing. Neither of these circumstances is acceptable. As an example of subcontracting, in order for Laboratory A to subcontract the test for lead-containing paint to Laboratory B, Laboratory B would need to have had its accreditation to 16 CFR part 1303 (lead-containing paint) accepted by the CPSC. Violations could be grounds for withdrawal of the CPSC's acceptance of the accreditation of the prime or subcontracting laboratory. The provisions of part 1112 apply to all CPSC-accepted laboratories, whether they are a prime contractor or a subcontractor.

## 2.4. Laboratory Recordkeeping Requirements

A CPSC-accepted conformity assessment body must keep records of test reports and technical records related to any and all tests that the laboratory conducts for children's product certification or periodic testing purposes. The records must be maintained for at least five years from the test date. The 5-year record retention requirement was selected in order to comply with the statute of limitations prescribed in 28 U.S.C. 2462. Additionally, all other records associated with CPSC requirements must be maintained for at least five years. The records should be readily retrievable and (if necessary) translated by the laboratory into English, upon request.

The CPSC likely will request to view these records only during an investigation. One type of investigation might pertain to how noncompliant products are associated with a Children's Product Certificate supported by test results indicating compliance with the applicable product safety rules. Another type of investigation might be in response to an allegation of undue influence. Requests for records regarding the product's testing and compliance are normal parts of such investigations. These records would be important to determining whether or how the product testing and certification system failed to operate as intended.

## 2.5. On-Site Laboratory Inspection

A CPSC-accepted laboratory would be required to agree to allow an officer or employee, duly designated by the Commission, to enter its facility and conduct an inspection. Such inspections would be limited to a CPSC-related investigation of whether grounds exist for adverse action against a laboratory. A CPSC-accepted laboratory inspection cannot be undertaken as a means of verifying accreditation requirements. The CPSC intends to use the audit procedures to evaluate its continuing acceptance of accreditation of a laboratory. Laboratory inspections used to verify accreditation requirements would be redundant with the accreditation body reassessment portion of an audit. Examples of when it would be desirable to enter a laboratory include: investigating an allegation of undue influence, or confirming the presence of a noncompliant children's product in the market that is supported by a certificate issued on the basis of a passing third party test result. In those cases, the CPSC's investigation may need to include inspecting the laboratory to obtain facts relevant to the case at hand.



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## 3. Audit Requirements

Section 14(i)(1) of the CPSA requires a periodic audit of laboratories as a condition of the CPSC's continuing acceptance of their accreditation. A notice of proposed rulemaking (NPR) implementing that provision of the statute was published in the *Federal Register* on August 13, 2009 (74 FR 40784). The audit final rule, which is subpart C of part 1112, is the subject of a separate package being submitted to the Commission as a companion to this package so that, if approved by the Commission, both rules could publish in the *Federal Register* on the same day. The draft proposed rule would make two changes to the audit rule. These changes are not in response to a comment received on the audit NPR; thus, they are best implemented through a draft proposed rule.

The first proposed modification of the audit rule would revise the definition of "audit" to add "and required documentation" to the requirement that a laboratory submit a CPSC Form 223 for audit purposes. Therefore, all laboratories would be required to submit the accreditation certificate and scope documents, in addition to a completed Form 223, for the examination portion of an audit. For firewalled and governmental laboratories, other required documentation would be submitted. These documents, in addition to Form 223, are necessary for the CPSC to conduct its examination portion of the audit. If the laboratory's status has changed (*e.g.*, an independent laboratory now meets the definition of a firewalled laboratory), the accompanying documentation would have to meet all of the requirements of the laboratory's present status.

The second proposed modification of the audit rule is in the timing of the audit. In the draft final rule, in the absence of any changes that would necessitate the submission of a new CPSC Form 223 (*e.g.*, scope, address, ownership), the laboratory would reregister at the CPSC every two years using CPSC Form 223. The proposal would require each laboratory to submit a new CPSC Form 223, and applicable accompanying documentation, no later than two years after the last CPSC Form 223 was submitted for audit purposes (or since the initial application). This proposal is to clarify the timing and to avoid a circumstance where continuous submissions of Form 223s—for purposes other than audit—could cause confusion in fulfilling this requirement. If multiple Form 223 submissions are made for reasons other than the examination portion of an audit, it is possible that more than two years could elapse without any Form 223 submission having included all of the documentation required for the examination portion of the audit. The proposal would clarify that, independent of other submissions, a Form 223, for audit purposes, must be submitted at least once every two years.

Initially, the CPSC will establish the date by which each laboratory must submit its audit documentation. The initial date will be based on factors such as the last date the laboratory submitted a Form 223 for audit purposes (or the date the CPSC accepted the accreditation of a laboratory for newly accepted laboratories), and the expiration date of the laboratory's ISO/IEC 17025:2005 accreditation. The 2-year timing for the reassessment portion of an audit was adopted because this period is commonly used for a reassessment or surveillance cycle of accreditation.

## 4. Notices of Requirements



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### 4.1. Existing Notices of Requirements

A notice of requirements is a list of the requirements that conformity assessment bodies must satisfy to qualify for CPSC acceptance of accreditation for testing to a particular CPSC standard or test method. Once a notice of requirements is issued pursuant to promulgation of a children's product safety rule, then the domestic manufacturer, importer, or private labeler is required to have testing performed by a CPSC-accepted third party conformity assessment body in order to issue the Children's Product Certificate. Future notices of requirements will be amendments to this proposed rule, if adopted.

Table 1 lists the standards and test methods for which notices of requirements have been published.

**Table 1: Notices of Requirements**

| Reference | Product or Material |
|---|---|
| 16 CFR part 1203 | Bicycle Helmets |
| 16 CFR part 1215 | Infant Bath Seats |
| 16 CFR part 1216 | Infant Walkers |
| 16 CFR Part 1217 | Toddler Beds |
| 16 CFR part 1219 | Full-Size Baby Cribs |
| 16 CFR part 1220 | Non-Full-Size Baby Cribs |
| 16 CFR part 1303 | Lead-containing Paint |
| 16 CFR part 1420[5] | All-Terrain Vehicles (ATVs) |
| 16 CFR section 1500.86(a)(5) | Clacker Balls |
| 16 CFR section 1500.86(a)(7) and (8) | Dive Sticks and Similar Articles |
| 16 CFR part 1501 | Toys and Other Articles Intended for use by Children Under Three Years of Age Which Present Choking, Aspiration, or Ingestion Hazards Because of Small Parts |
| 16 CFR part 1505 | Electrically Operated Toys or Other Electrically Operated Articles Intended for use by Children |
| 16 CFR part 1508[6] | Full-Size Baby Cribs |
| 16 CFR part 1509[7] | Non-Full-Size Baby Cribs |
| 16 CFR part 1510 | Rattles |
| 16 CFR part 1511 | Pacifiers |
| 16 CFR part 1512 | Bicycles |
| 16 CFR part 1513 | Bunk Beds |
| 16 CFR part 1610 | Flammability of Clothing Textiles |
| 16 CFR part 1611 | Flammability of Vinyl Plastic Film |
| 16 CFR part 1615 | Flammability of Children's Sleepwear, Sizes 0 through 6X |

[5] We note that recently we published a final rule in the *Federal Register,* revising 16 CFR part 1420. The final rule makes American National Standard, ANSI/SVIA–1–2010, the new mandatory standard for ATVs. Consequently, proposed § 1112.15(b)(9) would refer to the ANSI/SVIA–1–2010 safety standard for all-terrain vehicles for purposes of our acceptance of laboratory accreditation.

[6] This rule was revoked on December 28, 2010, because of the adoption of 16 CFR part 1219.

[7] This rule was revoked on December 28, 2010, because of the adoption of 16 CFR part 1220.



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| | |
|---|---|
| 16 CFR part 1616 | Flammability of Children's Sleepwear, Sizes 7 through 14 |
| 16 CFR part 1630 | Surface Flammability of Carpets and Rugs |
| 16 CFR part 1631 | Surface Flammability of Small Carpets and Rugs |
| 16 CFR part 1632 | Standard for the Flammability of Mattresses and Mattress Pads (FF 4-72, amended) |
| 16 CFR part 1633 | Standard for the Flammability (Open Flame) of Mattress Sets |
| CPSC Test Method CPSC-CH-E1001-08 | Children's Metal Jewelry, Determining Total Lead and/or the "Screening Test for Total Pb Analysis" Section of the 2005 CPSC Laboratory Standard Operating Procedure for Determining Lead |
| CPSC Test Method CPSC-CH-E1001-08 | Lead in Children's Metal Products |
| CPSC Test Method CPSC-CH-E1002-08 | Lead in Non-Metal Children's Products |
| CPSC–CH–C1001–09.3 | Standard Operating Procedure for Determination of Phthalates |
| ASTM F963-08, and section 4.27 of ASTM F963-07 for toy chests (CPSIA Section 106) | Third Party Testing for Certain Children's Products; Toys: Requirements for Accreditation of Third Party Conformity Assessment Bodies |

Comments were received in response to many notices of requirements. The topics mentioned included:

- The use of the international standard ISO/IEC 17025:2005 and the ILAC-MRA;
- Provisions to protect governmental and firewalled laboratories against undue influence;
- The use of alternative accreditation bodies;
- Evaluating requirements in standards that are not tests;
- Liability for governmental and firewalled laboratories;
- Third party certification as a substitute for third party testing; and
- Comments relating to specific standards.

A memorandum responding to the comments is located in Tab A.

## 4.2. New and Revised Notices of Requirements

### 4.2.1. Use of X-Ray Fluorescence

The draft proposed rule would change the test methods CPSC-CH-E1001-08.1, *Standard Operating Procedure for Determining Total Lead (Pb) in Metal Children's Products (including Children's Metal Jewelry)* and CPSC-CH-E1002-08.1, *Standard Operating Procedure for Determining Total Lead (Pb) in Non-Metal Children's Products.* The proposal would allow the use of X-ray fluorescence (XRF) spectrometry to determine the



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lead content in glass materials, crystals, and certain metals in support of children's product certification. The technical report detailing the analysis, findings, and limitations of the use of XRF for children's product certification can be found in Tab C.

### 4.2.2. Use of ASTM F963-11 Screening Method to Determine Lead Content

CPSC staff identified a potential opportunity to reduce the testing burdens for certification of conformity related to the new requirements in ASTM F963-11. Among the changes in ASTM F963-11, are changes in the requirements and test methods for eight elements of interest: antimony, arsenic, barium, cadmium, chromium, lead, mercury, and selenium. ASTM F963-11 extends the requirements from prior versions (that had limits for these elements in surface coatings) to consider, in addition, these elements in substrates. For both substrates and surface coatings, ASTM F963-11 limits soluble migration of each of these elements when tested in dilute acid. Additionally, a new optional screening test is established in section 8.3.1 of ASTM F963-11, which is based on the total concentration of those elements, determined by digesting the samples completely in hot, concentrated, strong acids, using methods based on CPSC test methods for lead content.

ASTM F963-11 allows the screening test from section 8.3.1 to be performed on a toy to establish that the total concentration of each of the eight elements of interest is lower than each of the soluble limits for those elements. For example, a toy that has only 10 ppm of each of those elements could not possibly leach more than the soluble limits for any of the elements (which are all greater than 10 ppm), and thus, the solubility test could be skipped. In another example, a toy that contained 2,000 ppm barium would not pass the screening test for barium and would require solubility testing according to section 8.3 to determine how much barium would leach out (compared to the limit of 1,000 ppm soluble barium).

CPSC staff recognized that firms potentially could reduce testing costs if a single test would meet the screening test of F963-11, section 8.3.1, and the CPSIA lead content requirements for paint, metals, or nonmetals. The methods provided in section 8.3.1 refer to CPSC test methods, but with a prescribed modification. The CPSC test methods for lead in paint,[8] lead in nonmetals,[9] and lead in metals[10] each allow for modifications based on sound chemical judgment and knowledge. CPSC staff tested a variety of well-characterized paint, metal, and nonmetal materials, and based upon the results and our professional judgment and experience, we found that the modifications detailed in section 8.3.1.2 represent sound chemical judgment to improve the recovery of antimony in certain samples and are acceptable for use for lead in paint, lead in metals, and lead in nonmetals. We also found them to be within the existing scope of allowable changes to the CPSC methods. (See Tab G). With these modifications considered acceptable, a CPSC-accepted testing laboratory accredited to the CPSC method for lead in paint, CPSC-CH-E1003-09, for example, could test the paint from a toy, according to CPSC-CH-E1003-09, with the modifications provided in section 8.3.1.2, and still fulfill the requirements of CPSC-CH-E1003-09 to certify lead content and use the same testing to determine the screening levels for the other elements of interest. Because samples that fail the screening may pass section 4.3.5 solubility limits, a

[8] http://www.cpsc.gov/about/cpsia/CPSC-CH-E1003-09_1.pdf
[9] http://www.cpsc.gov/about/cpsia/CPSC-CH-E1002-08_1.pdf
[10] http://www.cpsc.gov/about/cpsia/CPSC-CH-E1001-08_1.pdf



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testing laboratory must be accredited to ASTM F963-11, Section 8.3 to have its test results used to demonstrate compliance with the limits given in section 4.3.5. In the example above, the testing for lead in paint, with the modifications, could be used to determine if the elements of interest pass the screening test and the toy can be certified to section 4.3.5, without additional testing; paints exceeding screening limits for any of the elements of interest would have to be tested according to section 8.3 for heavy element solubility.

### 4.2.3. Safety Standard for Portable Bedrails

Additionally, the draft proposed rule would include a notice of requirements for 16 CFR part 1224, *Safety Standard for Portable Bedrails*. The notice of requirements can be found in Tab D. For the tests in 16 CFR part 1224, testing before the effective date of 16 CFR part 1112 is allowed if the following conditions are met:

1. The product was tested by a testing laboratory accredited to ISO/IEC 17025:2005 by a signatory to the ILAC-MRA at the time of the test. The scope of the testing laboratory's accreditation must include testing in accordance with 16 CFR part 1224. For firewalled testing laboratories, the testing laboratory must be one that the Commission has accredited by order on or before the time the product was tested, even if the order did not include the tests in 16 CFR part 1224. For governmental testing laboratories, the testing laboratory must be one whose accreditation was accepted by the Commission, even if the scope of accreditation did not include the tests in 16 CFR part 1224.
2. The testing laboratory's application for acceptance of its accreditation is accepted on or after the date the proposed 16 CFR part 1112 is published in the *Federal Register*, and before the effective date of 16 CFR part 1112.
3. The test results show compliance with 16 CFR part 1224.
4. The children's product was tested on or after the publication date of the 16 CFR part 1224 Final Rule, and before the effective date of 16 CFR part 1112.
5. The testing laboratory's accreditation remains in effect through the effective date of 16 CFR part 1112.

These provisions are patterned after those in 16 CFR parts 1217, 1219, and 1220, regarding retrospective testing.

### 4.2.4. Four Wheel All-Terrain Vehicles

A comparison of *American National Standard for Four Wheel All-Terrain Vehicles* ANSI/SVIA 1 - 2007 and 2010 revisions with respect to testing youth all-terrain vehicles concludes that, for purposes of third party testing of youth ATVs, the 2007 revision is functionally equivalent to the 2010 revision. Previously-tested youth ATVs do not require retesting to the 2010 revision. Testing laboratories whose accreditation to test youth ATVs for children's product certification purposes do not need to become reaccredited to the 2010 revision. However, new testing laboratory applicants must be accredited to the 2010 revision when applying for CPSC acceptance of their accreditation to test youth ATVs. Testing laboratories whose accreditation to test youth ATVs has previously been accepted by the CPSC must be accredited to the 2010 revision when reassessed by their accrediting body and apply for CPSC acceptance if the lab wishes to maintain CPSC listing for ATV testing. The



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memorandum describing the comparison of the 2007 and 2010 revisions of ANSI/SVIA 1 can be found in Tab E.

### 4.2.5. ASTM F 963-11 Toy Standard

The draft proposed rule would include a notice of requirements for ASTM F963-11, *Standard Consumer Safety Specification for Toy Safety*. The notice of requirements can be found in Tab F. Testing to requirements of ASTM F963-08 that are performed by a CPSC-accepted testing laboratory to support children's product certifications to ASTM F963-11 requirements would be accepted for a period, and only for those sections of ASTM F963-08 that are considered equivalent or functionally equivalent to ASTM F963-11. For those tests in ASTM F963-11 that have no equivalent or functionally equivalent test in ASTM F963-08, testing before the effective date of 16 CFR part 1112 is allowed, if the following conditions are met:

1. The children's product was tested by a testing laboratory accredited to ISO/IEC 17025:2005 by a signatory to the ILAC-MRA at the time of the test. The scope of the testing laboratory's accreditation must include the tests conducted. For firewalled testing laboratories, the testing laboratory must be one that the Commission has accredited by order on or before the time the product was tested, even if the order did not include the nonequivalent test methods. For governmental testing laboratories, the testing laboratory must be one whose accreditation was accepted by the Commission, even if the scope of the accreditation did not include the nonequivalent test methods.
2. The testing laboratory's application for acceptance of its accreditation is accepted by the CPSC by the effective date of 16 CFR part 1112.
3. The test results show compliance with ASTM F963-11.
4. The children's product was tested on or after the *Federal Register* notice for CPSC acceptance of ASTM F963-11, and before the effective date of 16 CFR part 1112.
5. The testing laboratory's accreditation remains in effect through the effective date of 16 CFR part 1112.

As noted above, these provisions are patterned after those in 16 CFR parts 1217, 1219, and 1220, regarding retrospective testing.

### 4.2.6. Safety Standard for Play Yards

In the Federal Register of September 20, 2011, the Commission published a proposed rule to establish a safety standard for play yards. The standard would be codified at 16 CFR part 1221. We are working on a final rule to establish a safety standard for play yards and hope to issue it in the near future. Consequently, proposed § 1112.15(b)(7) would include 16 CFR part 1221 among the list of CPSC rules and/or test methods for accreditation for third party conformity assessment bodies. If, however, the Commission does not issue a final rule to establish a safety standard for play yards, we will revise § 1112.15(b) accordingly, as part of this rulemaking process.



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## 5. Adverse Action Against a Conformity Assessment Body

Adverse action against a laboratory means that test data from that laboratory cannot (or can no longer) be used as a basis for issuing a Children's Product Certificate. The draft proposed rule would describe the following types of adverse actions:

- Denial of acceptance of accreditation;
- Suspension of acceptance of accreditation;
- Withdrawal of acceptance of accreditation on a temporary or permanent basis; and
- Immediate temporary withdrawal of acceptance of accreditation.

Denial or withdrawal of a laboratory's acceptance of accreditation may be done for administrative reasons, such as submitting incomplete information on an application for acceptance of accreditation or the loss of ISO/IEC 17025:2005 accreditation. The CPSC may suspend its acceptance of a laboratory's accreditation if the laboratory fails to cooperate with an investigation regarding undue influence or fails to comply with an applicable protocol.

Laboratory test results are used as the basis for issuing a Children's Product Certificate. If the accuracy or integrity of those test results is suspect, the testing and certification system outlined in the CPSIA is undermined. To help maintain the effectiveness of children's product certification, this draft proposed rule would establish the procedures for denying, withdrawing, or suspending the CPSC's acceptance of a laboratory's accreditation. Actions taken or not taken by the laboratory that undermine its technical competence and data integrity would be addressed by the CPSC through denial, suspension, or withdrawal of the CPSC's acceptance of the laboratory's accreditation.

Denial, suspension, or withdrawal of a laboratory's acceptance of accreditation may be done in response to actions taken by the laboratory, such as submitting false or misleading information on an application; failing to possess or maintain the technical capability to perform CPSC-regulated tests; allowing the exertion of undue influence on the laboratory; failing to comply with part of a protocol, standard, or requirement relating to a laboratory's audit; subcontracting testing to a non CPSC-accepted laboratory; failing to cooperate with an investigation; or failing to comply with any audit provisions. These actions are examples of events that can call into question the integrity of the data used to support children's product certification. If a laboratory engages in an action listed above, the chances increase of a noncompliant product entering commerce. The CPSC has an interest in the operation of the testing and certification system used to increase assurance of compliance of children's products with applicable children's product safety rules. If the operation of that system results in noncompliant products entering into commerce, the CPSC maintains an interest in determining how and where in the system the process failed and in being able to address those circumstances. Thus, the draft proposed rule would establish these procedures so that certifiers, distributors, retailers, and ultimately, consumers, can rely on test data from CPSC-accepted laboratories for certification purposes.

A proceeding to determine that CPSC acceptance of accreditation should be withdrawn or suspended would include the following steps:



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1. The CPSC will conduct an investigation.
2. Based on the investigation's findings, the CPSC will issue an initial notice of findings and proposed actions.
3. The laboratory will be provided an opportunity to respond to the initial notice.
4. Based on the response from the laboratory, the following actions may be taken:
   a. If the investigation finds, and the laboratory response does not change the finding, that acceptance of accreditation should be suspended or withdrawn, then a final notification of suspension or withdrawal shall be issued by the CPSC.
   b. If the investigation finds, and the laboratory response results in a new finding, that acceptance of accreditation should not be suspended or withdrawn, then an acceptance of the laboratory's response and termination of investigation will be issued by the CPSC.
5. If the acceptance of accreditation is withdrawn or suspended, the laboratory will be provided an opportunity for an administrative appeal.

The draft proposed rule would state that, following a final adverse action, the CPSC may publish the fact or text of the adverse action. In the event of a final adverse action, the CPSC would amend its website listing of laboratories to reflect the adverse action. If a laboratory's acceptance of accreditation is withdrawn, the draft proposed rule would state that the CPSC would inform the laboratory of whether it may submit a new application, and may establish requirements for the reacceptance of the laboratory's accreditation.

Because the accreditation of firewalled laboratories is accepted by Commission order, the draft proposed rule would require that suspension or withdrawal of a firewalled laboratory's acceptance of accreditation also will occur by order of the Commission.

Note that when it is in the interest of protecting public health or safety, the CPSC also may immediately, temporarily withdraw its acceptance of accreditation of a laboratory for any portion of its scope of tests. This is expected to be used only in circumstances where the integrity of the test(s) being conducted by the laboratory has been interfered with or compromised, and the laboratory's testing scope involves a product(s) which, if noncompliant with CPSC rules, bans, standards, and/or regulations, may constitute an imminently hazardous consumer product.

Activities that could result in adverse actions may be uncovered by the CPSC through an investigation prompted by the discovery of noncompliant products distributed in commerce. In addition, the CPSC could be alerted to such activities by receiving a report from someone. Because the CPSC desires to maintain the effectiveness of the testing and certification system, the draft proposed rule would include a section detailing how any person may submit information to the CPSC alleging one or more of the grounds for adverse action. The draft proposed rule would specify that requests for confidentiality of the submitter's identity must be clearly indicated in the submission. The draft proposed rule would outline that such reports to the CPSC should include submitter contact information, identification of the persons or entities (*e.g.*, conformity assessment body, manufacturer), a description of the acts or omissions that could form the basis of an adverse action, and a description of the impact of those acts or omissions. The draft proposed rule would state that the CPSC will review the information and determine whether an investigation is warranted.



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## 6. Small Business Impacts

CPSC staff prepared an initial regulatory flexibility analysis (IRFA) of the draft proposed rule, as required by the Regulatory Flexibility Act. The IRFA considers the potential impact of the draft proposed rule on small businesses that would be covered by it (*i.e.*, the laboratories or conformity assessment bodies). The IRFA, which is in Tab B, concludes that the draft proposed rule would not have a significant impact on a substantial number of small entities. The requirements in the draft proposed rule would apply only to laboratories that intend to provide the third party testing services required by the Consumer Product Safety Improvement Act of 2008. The only laboratories that are expected to provide such services are those expecting to receive sufficient revenue from furnishing the mandated testing to justify accepting the requirements of the draft proposed rule. Conformity assessment bodies that do not expect to receive sufficient revenue from providing these services to justify accepting these requirements would not be expected to pursue CPSC acceptance of their accreditation.

Although manufacturers, private labelers, and importers of children's products would not be regulated directly by the draft proposed rule, the IRFA states that the notices of requirements contained in the draft proposed rule could have an indirect impact on them. The notices of requirements that apply to lead-content testing specify the required test methods, which currently allow XRF analysis for testing for total lead content in substrate materials for homogenous polymer (or plastic) components and paint.[11] The Commission has received numerous requests to allow more extensive use of XRF analysis for purposes of third party testing because it is significantly less costly than other methods of testing for lead content, and therefore, could reduce significantly the cost of third party testing. CPSC staff is proposing that the use of XRF for third party testing purposes be allowed for determining the lead content of glass materials, crystals, and certain metals. If approved by the Commission, the use of this technology could reduce the laboratories' testing costs.

## 7. Conclusion

This memorandum presents for Commission consideration, a draft proposed rule that defines the term "conformity assessment body" and describes the types of conformity assessment bodies that are accepted by the CPSC to test children's products under section 14(a)(2) of the CPSA. It describes the requirements and procedures for becoming a CPSC-accepted third party conformity assessment body, how a third party conformity assessment body may voluntarily discontinue participation as a CPSC-accepted third party conformity assessment body, the grounds and procedures for withdrawal or suspension of CPSC acceptance of accreditation of a third party conformity assessment body, and how an individual may submit information alleging grounds for adverse action.

[11] For paints, Energy Dispersive X-ray Spectrometry Using Multiple Monochromatic Excitation Beams, according to ASTM F2853, is the only XRF technology acceptable for use in product certification. For polymeric materials, the optional use of Energy Dispersive XRF, according to ASTM F 2617-08, is included in http://www.cpsc.gov/about/cpsia/CPSC-CH-E1002-08_1.pdf.



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## 8. Recommended Effective Date

Staff recommends that the final rule for requirements pertaining to third party conformity assessment become effective 60 days after publication in the *Federal Register*.

## 9. Commission Options

The following options are available for Commission consideration:

1. Publish the draft proposed rule, as drafted by the Office of the General Counsel.
2. Publish the draft proposed rule, with changes, as directed by the Commission.
3. Consider other options, as directed by the Commission.

## 10. Staff Recommendation

CPSC staff recommends that the Commission publish the draft proposed rule, *Part 1112 - Requirements Pertaining to Third Party Conformity Assessment,* as drafted by the Office of the General Counsel.



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**TAB A: Responses to Comments on Notices of Requirements for Third Party Conformity Assessment Body Testing of Consumer Products**

**TAB A**



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**UNITED STATES**
**CONSUMER PRODUCT SAFETY COMMISSION**
**BETHESDA, MD 20814**

**Memorandum**

Date: May 9, 2011

TO: DeWane Ray
Assistant Executive Director
Office of Hazard Identification and Reduction

FROM : Randy Butturini
Office of Hazard Identification and Reduction

SUBJECT: Response to Comments on Notices of Requirements for Third Party Conformity Assessment Body Testing of Consumer Products

## 1. 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 CPSIA establishes requirements for third party testing of children's products that are subject to a safety rule. The Commission has established requirements for accreditation of third party conformity assessment bodies ("laboratories") for certain children's product safety rules, in accordance with section 102(a)(2) of the CPSIA, which created a new section 14(a)(3)(A) of the Consumer Product Safety Act to state that:[12]

> GENERAL APPLICATION. – Except as provided under subparagraph (F), the requirements of paragraph (2) shall apply to any children's product manufactured more than 90 days after the Commission has established and published notice of the requirements for accreditation of third party conformity assessment bodies to assess conformity with a children's product safety rule to which such children's product is subject."

Section 14(a)(3)(D) of the CPSA requires the Commission to review and revise periodically the accreditation requirements for third party conformity assessment bodies.

[12] http://edocket.access.gpo.gov/2008/E8-22167.htm.



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As of May 1, 2011, 17 notices of requirements have been published in the *Federal Register*; Table 1 lists the notices of requirements. Several commenters expressed their support of provisions in the notices of requirements. This memorandum summarizes the substantive comments received in response to the notices, and it presents CPSC staff's responses. Each comment and response is numbered for identification purposes.

**Table 1: Notices of Requirements Issued with Comments Received**

| **Regulation or Product(s)** | ***Federal Register* citation** | **Regulations.gov Docket Number** |
|---|---|---|
| Part 1303/Lead Paint | 73 FR 54564, (September 22, 2008) (Revision notice at 76 FR 18645 (April 5, 2011)) | CPSC-2008-0033 |
| Parts 1508, 1509, 1511/Full-size cribs, non-full-size cribs, and pacifiers | 73 FR 62965, (October 22, 2008) | CPSC-2008-0038 |
| Part 1501/Small parts | 73 FR 67838, (November 17, 2008) | CPSC-2008-0050 |
| Lead content in children's metal jewelry | 73 FR 78331 (December 22, 2008)[13] | CPSC-2008-0049 |
| Parts 1203,1510, 1512, 1513, sec. 1500.86(a)(7), and (a)(8)/Bicycle helmets, dive sticks, rattles, bicycles, and bunk beds | 74 FR 45428, (September 2, 2009) | CPSC-2009-0067 |
| Total lead in children's (metal and non-metal) products | 74 FR 55820, (October 29, 2009) | CPSC-2009-0090 |
| Part 1505, sec. 1500.86(a)(5)/ Electrically operated toys/articles and clacker balls | 75 FR 22746, (April 30, 2009) | CPSC-2010-0035 |
| Part 1215/Infant bath seats | 75 FR 31688, (June 4, 1020), (Correction notice at 75 FR 33683 (June 15, 2010)) | CPSC-2010-0064 |
| Part 1216/Infant walkers | 75 FR 35282, (June 21, 2010) | CPSC-2010-0066 |
| Part 1611/Vinyl plastic film | 75 FR 42311 (July 21, 2010) | CPSC-2010-0079 |
| Parts 1630 and 1631/ Carpets and rugs | 75 FR 42315 (July 21, 2010) | CPSC-2010-0078 |
| Part 1610/Clothing Textiles | 75 FR 51016 (August 18, 2010) (Revision notice at 76 FR 22608 (April 22, 2011) | CPSC-2010-0086 |

[13] The Commission has stayed the enforcement of the testing and certification requirements for total lead content in children's products (except for metal components of children's metal jewelry), and certain related products, until Dec. 31, 2011. See 76 FR 6765 (Feb. 8, 2011).



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| | | |
|---|---|---|
| Parts 1632 & 1633/ Mattresses, Mattress Pads, and Mattress Sets | 75 FR 51020 (August 18, 2010) Revision notice at 75 FR 72944 (November 29, 2010) | |
| Part 1420/ATVs | 75 FR 52616 (August 27, 2010) (Extension notice at 75 FR 76708 (December 9, 2010)[14] | CPSC-2010-0090 |
| Parts 1615 and 1616/Children's Sleepwear | 75 FR 70911 (November 19, 2010) | None |
| Parts 1219 and 1220/Full-Size Baby Cribs and Non-Full-Size Baby Cribs | 75 FR 81789 (December 28, 2010) | CPSC-2009-0064 |
| Part 1217/Toddler Beds | 76 FR 22030 (April 20, 2011) | CPSC-2009-0064 |

## 2. Comments on Baseline Accreditation Requirements

**Comment 1:** Some commenters supported the use of International Standards Organization/International Electrotechnical Commission (ISO/IEC) 17025:2005 standard on testing and calibration laboratories and the International Laboratory Accreditation Cooperation – Mutual Recognition Arrangement (ILAC-MRA) because this helps establish an internationally recognized consortium for organizations qualified to provide accreditation services. A commenter recommended that the CPSC conduct periodic reviews and revise the accreditation requirements to ensure that the highest standards for laboratory accreditation are being followed. The commenter suggested that if ISO/IEC 17025:2005 is superseded by a more stringent standard, then the CPSC should adopt the more stringent standard.

**Response 1:** Section 14(a)(3)(D) of the CPSA states: "[t]he Commission shall periodically review and revise the accreditation requirements established under subparagraph (B) to ensure that the requirements assure the highest conformity assessment body quality that is feasible." If a new version of ISO/IEC 17025:2005 is adopted by the ISO, the CPSC will review the new requirements and determine whether the new version would improve the CPSC's laboratory program. Any change to the requirements for CPSC-accepted third party conformity assessment bodies will be pursued as an amendment to 16 CFR part 1112.

**Comment 2:** Multiple commenters suggested that the Commission consider accepting laboratory accreditation from the National Environmental Laboratory Accreditation Conference (NELAC). A commenter noted that NELAC follows the ISO/IEC 17025:2005 standard and is similar to the American Association of Laboratory Accreditation (A2LA), an ILAC-MRA signatory accreditation body. The National Environmental Laboratory Accreditation Program (NELAP) implements the NELAC standards.

[14] The Commission has conditionally stayed the enforcement of the testing and certification requirements for youth model ATVs until November 27, 2011. See 76 FR 5566 (Feb. 1, 2011).



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Another commenter recommended that the CPSC accept the accreditation of laboratories accredited by the American Industrial Hygiene Association (AIHA), which is accredited to ISO/IEC 17011:2004, but was not an ILAC-MRA signatory (at the time the comment was submitted). The AIHA accredits laboratories to ISO/IEC 17025:2005 for the National Lead Laboratory Accreditation Program (NLLAP), administered by the U.S. Environmental Protection Agency (EPA). One commenter stated that, by not including AIHA-accredited laboratories, there are not a sufficient number of laboratories in the United States to handle the volume of testing required by the CPSIA.

Multiple commenters recommended that accreditation bodies that are part of the National Cooperation for Laboratory Accreditation (NACLA) be recognized by the CPSC, and thus, enable the laboratories accredited by NACLA members to provide test results for lead in paint that can be used as a basis for issuing a Children's Product Certificate. The NACLA does not rely on mutual recognition among accreditation bodies but has a Recognition Council to recognize accreditation bodies. NACLA members follow the provisions of ISO/IEC 17011:2004 and accredit laboratories to ISO/IEC 17025:2005.

**Response 2:** In September 2010, AIHA became an ILAC-MRA signatory. Laboratories accredited by AIHA after becoming an ILAC-MRA signatory may apply for CPSC acceptance of their accreditation. Therefore, the comment that the Commission should make AIHA a CPSC-designated accreditation body is moot. NACLA and NELAC currently are not signatories to the ILAC-MRA. NACLA and NELAC are domestic organizations that do not have recognition arrangements with foreign countries.

The Consumer Product Safety Act (CPSA or the Act), as amended by the Consumer Product Safety Improvement Act of 2008 (CPSIA), directs the CPSC to establish and publish notices of requirements for accreditation of third party conformity assessment bodies to assess conformity with a children's product safety rule to which such children's product is subject. The Act provides that accreditation of third party laboratories may be conducted by the Commission or by an independent accreditation organization designated by the Commission.

In consideration of the timelines established by the Act and the fact that children's consumer products are manufactured for the U.S. market in nations throughout the world, CPSC staff identified several objectives for a laboratory accreditation program that could accomplish the implementation of the CPSA. These objectives were:

1) Designate the core elements of a CPSC accreditation program to an entity that is established and has acceptance on a multinational level. The entity should follow internationally recognized standards for assessing the competence of laboratories and for the processes and standards used by accreditation bodies that evaluate such laboratories;

2) Designate one entity that could bring immediately on board, on a multinational level, the largest number of accreditation bodies that could begin the process of accrediting laboratories in accordance with the CPSC specific requirements for a children's product safety rule; and



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3) Avoid designation to accreditation programs or entities that are recognized only in a specific region, nation, or locality. The reasons for this objective are to: (a) keep the program as simple as possible for use by manufacturers, private labelers, importers, laboratories, and other interested parties; (b) avoid any perceived notions of barriers to fair trade practices; (c) establish a program that is manageable within agency resources; and (d) maintain a degree of consistency in the procedures used by the designated accreditation bodies.

CPSC staff recommended that the Commission continue to designate accreditation bodies that are signatories to the ILAC-MRA. CPSC staff believes that the laboratory accreditation requirements approved by the Commission are consistent with the direction of the CPSA and meet the objectives outlined above.

CPSC staff recognizes that there are other laboratory accreditation organizations or accreditation bodies. Some of these organizations may adhere to similar procedures and standards (but with some distinctions) as those established in the ILAC-MRA signatory program. However, expanding CPSC designations to such organizations would not meet all of the objectives outlined above.

Regarding laboratory testing capacity for lead in paint, CPSC staff is not aware of any evidence indicating that insufficient CPSC-accepted laboratory testing capacity for lead in paint exists. If lead in paint testing capacity becomes an issue in the future, the CPSC will address the situation.

**Comment 3:** A commenter recommended that laboratories: "be specifically CPSC accepted based on accreditation which the [ILAC-MRA] system, on its own, may not ensure." The commenter stated that this would secure the impartiality of certification better. The commenter opposed limiting accreditation bodies to ILAC-MRA signatories because there is no reciprocity with ILAC-MRA countries to accept accreditations from the Occupational Safety and Health Administration (OSHA), the American National Standards Institute, or the Standards Council of Canada.

**Response 3:** With regard to the commenter's suggestion that there are standards or norms that the ILAC-MRA system "on its own, may not ensure," the commenter did not specify what the ILAC-MRA system fails to ensure. Accordingly, we are unable to respond meaningfully to that portion of the comment. As for the impartiality of certification, we note that the CPSA does not require conformity assessment bodies to issue certificates. Instead, section 14(a)(2) of the CPSA assigns responsibility for certifying to "every manufacturer of [a children's product subject to a children's product safety rule] (and the private labeler of such children's product if such children's product bears a private label)."

The topic of reciprocity is addressed under Comment 7 below.

**Comment 4:** A commenter responding to the notice of requirements for accreditation of laboratories to assess conformity with 16 CFR part 1505 (electrically operated toys or other electrically operated articles intended for use by children) stated that many requirements of the regulation would not be evaluated by laboratory testing but rather evaluated via inspection,



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auditing, and construction review. For example, the fulfillment of requirements in §§ 1505.3, pertaining to labeling, 1505.4 pertaining to manufacturing requirements, and 1505.5, related to electrical design and performance, would generally not be evaluated by what is commonly understood as laboratory testing. The commenter suggested that ISO/IEC 17020:1998, *General criteria for the operation of various types of bodies performing inspection,* be used as the accreditation requirements for these activities. The commenter said that the CPSC could supplement ISO/IEC 17020:1998 criteria with additional specific requirements for individuals performing these activities to assure that individuals possess engineering education, training, and experience to evaluate compliance effectively.

**Response 4:** Section 14(a)(2) of the CPSA requires manufacturers of any children's product subject to a children's product safety rule to submit the product for third party testing. As structured by the CPSA, certification of compliance with children's product safety rules is based on product testing (not manufacturing facility inspection) at a third party conformity assessment body (laboratory). A third party conformity assessment body conducts all of the performance tests in the standard. The portions of the standard, rule, ban, or regulation that do not use testing are attested to by the manufacturer when it issues a Children's' Product Certificate for the product.

Inspection, as intended by ISO/IEC 17020:1998, is generally used for individual items or very small production volumes. Conformity assessment is used for assuring compliance to established standards and is applicable to larger production volumes. At this time, we decline to recommend adopting the suggestion of using ISO/IEC 17020:1998.

**Comment 5:** One commenter urged the Commission to consider third party certification of products (as opposed to third party testing) by certification bodies accredited to ISO/IEC 17065, *General Requirements for Bodies Operating Product Certification Systems*. The commenter stated that third party certification includes actions taken by the certifying body to ensure continuing conformance. The commenter suggested that requiring third party certification and marking would be less costly and more effective. The commenter urged the CPSC to consider the principles of product certification outlined in the American National Standards Institute (ANSI) document, *National Conformity Assessment Principles for the United States*.

Another commenter asked that the CPSC consider alternative criteria for accreditation to include organizations that are accredited to Standard ISO/IEC 17065.

**Response 5:** With regard to the suggestion that the Commission consider third party certification of products, section 14(a)(2) of the CPSA specifically states that samples of the children's product are submitted to a third party conformity assessment body for testing (not for certification), and that the manufacturer or private labeler of the children's product issues the certificate that certifies that the product complies with the applicable children's product safety rules. That responsibility cannot be delegated to another party. Thus, certification of a children's product by a third party certification body does not meet the requirements of the CPSA.



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With regard to the commenter's suggestion that the CPSC consider including alternative criteria for accreditation, to allow CPSC acceptance of accreditations to ISO/IEC 17065, ISO/IEC 17065 has not (as of the date of this memorandum) been finalized. This draft standard is still in development as a revision to ISO Guide 65:1996, *General Requirements for Bodies Operating Product Certification Systems*. Because ISO/IEC 17065 has not been finalized, we cannot evaluate whether this standard would meet the requirements of the CPSA. If we assume that the provisions of ISO Guide 65:1996 are maintained in ISO/IEC 17065, § 1.2 of ISO Guide 65:1996 states that the certification system used by the certification body may include one of more of a list of evaluation techniques. Included in that list are methods that do not involve testing for compliance to the applicable children's product safety rules. Section 14(a)(2)(B) of the CPSA requires Children's Product Certificates to be based on testing. Because ISO Guide 65:1996 allows for product certification without testing, certification by organizations that are accredited to ISO Guide 65:1996 may not include the required testing and cannot be used for children's product certification purposes.

With regard to the ANSI document, *National Conformity Assessment Principles for the United States*, this document mirrors many widely accepted concepts and processes used by conformity assessment bodies and certification bodies. For example, provisions in the ANSI document regarding testing competency and protection of a customer's data are mirrored in ISO/IEC 17025:2005 and ISO Guide 65:1996. However, the principles in the ANSI document are more closely related to product certification, and thus, are not appropriate for laboratories involved in support of children's product certification by the manufacturer. For example, conformity assessment principle number 12 in the ANSI document states:

> "As appropriate, conformity assessment bodies undertake reasonable surveillance procedures to ensure continued product conformity and protection of their mark."

Surveillance procedures and certification marks are activities typically undertaken by certification bodies, not laboratories conducting tests. Thus, we decline to recommend adopting the suggestion of using the ANSI document because it relates to certification activities not undertaken by testing.

Staff recommends no changes to the baseline CPSC criteria for acceptance of accreditation of third party conformity assessment bodies.

**Comment 6:** Some commenters supported the use of ISO/IEC 17025:2005 as an accreditation tool but emphasized the importance of ensuring that the scope of accreditation applies only to the testing for which the conformity assessment body has demonstrated competence.

**Response 6:** CPSC staff agrees with the commenters. Every conformity assessment body applying for CPSC acceptance of their accreditation must submit a statement of scope that lists explicitly the CPSC regulation(s) and/or test method(s) for which they are applying.

**Comment 7:** Multiple commenters suggested adopting reciprocity provisions as a part of laboratory accreditation requirements. Reciprocity in this context means that if the CPSC



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accepts the accreditation of foreign laboratories to test consumer products for compliance to the requirements of section 14 of the CPSA, the host country of the foreign laboratory must provide similar treatment to U.S.-based laboratories. Possible reciprocity provisions could include a statement that, in reviewing a laboratory's application, the CPSC will take into consideration whether the host country of the applicant provides similar accreditation for U.S.-based laboratories in their markets. Another possible reciprocity policy would require that the countries of non-U.S.-based laboratories that wish for their accreditation to be accepted by the CPSC, offer recognition to U.S-based laboratories for that country's certification programs.

One commenter stated that a reciprocity provision would benefit U.S. manufacturers because reciprocity would allow for streamlined testing requirements and protocols across international markets and would also keep manufacturers from sending testing samples to multiple testing facilities around the world in order to "shop" for passing testing results. Another commenter stated that without reciprocity provisions, U.S.-based laboratories are damaged by not having access to other countries' conformity assessment systems. The commenter recommended that the CPSC amend its proposed accreditation requirements to include reciprocity provisions identical to those used by OSHA under its Nationally Recognized Testing Laboratory (NRTL) program.

One commenter stated that without reciprocity provisions, the product safety scheme will lack the necessary shared interest in quality oversight to make it a functioning program.

**Response 7:** CPSC staff declines to recommend adopting reciprocity as a criterion in the CPSC third party conformity assessment body program, although we are aware that the other federal laboratory recognition programs contain such a provision. At this time, we have not determined that reciprocity promotes consumer safety. The mission of this agency is to protect the public against unreasonable risks of injury from consumer products. One way we accomplish that mission is by implementing the CPSIA's requirement that products subject to children's product safety rules be third party tested. Thus, our interest, in this instance, is to establish an effective and efficient laboratory program through which we recognize laboratories that are competent to conduct these third party tests.

As for the comment regarding shared interest in quality oversight, to the extent that the commenter is suggesting that reciprocity provisions are necessary for the CPSC's laboratory program to function, the commenter did not describe how or why having reciprocal testing-body recognition is necessary to implementing section 14 of the CPSA. We use accreditation by an ILAC-MRA signatory accreditation body to an international standard, ISO/IEC 17025:2005, and additional information to determine whether to accept the accreditation of an applicant laboratory. Sections 1.4 and 1.6 of ISO/IEC 17025:2005 specifically refer to the quality management system of the laboratory. Laboratories accredited to ISO/IEC 17025:2005 must implement a quality management system, appoint a staff member as quality manager, and continually improve the effectiveness of its management system through the use of quality policy, quality objectives, audit results, and other factors. None of these quality oversight items requires reciprocity between nations.



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For these reasons, CPSC staff recommends no change to the laboratory accreditation requirements based on this comment.

## 3. Comments on Firewalled/Governmental Laboratories and Undue Influence

**Comment 8:** One commenter stated the belief that validation of a laboratory's independence is critical to the success of all CPSC safety initiatives, including program development for third party testing of children's products. The commenter pointed to the OSHA's NRTL program and ISO Guide 65:1996 as a means to underscore the critical role of independence. ISO Guide 65:1996 details the requirements of operating without a conflict of interest and includes several requirements concerning organizational structure to protect impartiality and to prevent conflict of interest. The commenter suggested that the Commission should consider the requirements of Clause 4.2 of ISO Guide 65:1996 and look to OSHA's NRTL program as an example of the level of inquiry that should be required, the type of requirements that should be implemented, and to ensure impartiality and prevent conflict of interest.

The commenter noted that these issues deserve special emphasis for proprietary (firewalled) and governmental laboratories. Under the CPSC's laboratory accreditation requirements that were published in the notices of requirements and that are provided in additional detail in this proposed rulemaking, firewalled and governmental laboratories are required to demonstrate particular undue influence safeguards, as specified in the CPSA, in addition to the requirements of the ISO/IEC 17025:2005 standard.

**Response 8:** The OSHA program and ISO Guide 65:1996 are tailored to certification bodies/programs and not to laboratories that conduct tests. Under the structure of third party testing required by the CPSA (as amended by the CPSIA), product certification elements (certifying compliance with a CPSC rule) are the responsibility of the manufacturer or private labeler. The certifying manufacturer or private labeler must support its certificate of compliance with testing by a CPSC-accepted laboratory (referred to in the CPSA as third party conformity assessment body). There are international standards written specifically for different areas related to conformity assessment (*e.g.*, inspection activities, certification programs, laboratories). Because the CPSA requires the CPSC to establish requirements for the entities that conduct product testing, the CPSC programs require the ISO/IEC standard that is specifically applicable to testing laboratories (ISO/IEC 17025:2005). ISO/IEC 17025:2005 has provisions that require the laboratory to have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity. A third party laboratory must demonstrate that it is impartial and that its personnel are free from any undue commercial, financial, and other pressures that might influence their technical judgment. ILAC-MRA signatory accreditation bodies assess laboratories to these criteria during laboratory assessments.

In addition, the CPSA requires that firewalled and governmental laboratories satisfy certain criteria, which include protections against undue influence. The CPSC implements those criteria such that firewalled and governmental laboratory applicants must submit additional materials



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that address undue influence safeguards. For a full description of the additional application materials, see the preamble discussion of proposed § 1112.13(b) and (c).

Staff recommends that the criteria for safeguards against undue influence be addressed by the proposed CPSC requirements and that there should not be additional criteria based on programs or standards that are not specific for laboratories that conduct tests.

**Comment 9:** One commenter urged the CPSC to "differentiate between what are authentic, third party conformity assessment bodies from manufacturer-owned, firewalled labs." The commenter stated that such differentiation would be consistent with widely used terminology in the manufacturing communities and would reflect the structure of the laboratories better.

**Response 9:** The CPSC interprets the commenter as addressing our use of the term "third party conformity assessment body" to refer to any of the three types of laboratories accepted by the CPSC (independent, firewalled, and governmental). To many in the consumer product industry, a "third party conformity assessment body" corresponds only to an independent laboratory.

Section 14(f) of the CPSA defines and discusses the term "third party conformity assessment body" to include all three types of laboratories. Accordingly, the notices of requirements, and this proposed rule, describe all laboratories whose accreditation has been accepted by the Commission as "third party conformity assessment bodies" whether they are independent, governmental, or firewalled.

**Comment 10:** The notices of the requirements for accreditation of third party conformity assessment bodies require firewalled laboratory applicants to submit copies of training documents showing how employees are trained to notify the CPSC 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. Some commenters suggested that the Commission develop standards for these training documents. A commenter noted that standards for impartiality are addressed in ISO Guide 65:1996, which, as a starting place, could be used for this purpose. A commenter also suggested that the CPSC, in developing standards for training documents, consider other standards or best practices that are protective of laboratory and test result integrity.

**Response 10:** The CPSA includes a provision that requires all CPSC-accepted firewalled laboratories to establish procedures to ensure that employees may report immediately and confidentially allegations of undue influence to the CPSC, 15 U.S.C. § 2063(f)(2)(D). The notices of requirements have required firewalled laboratory applicants to submit copies of their training documents, in English, showing how employees are trained on those procedures. The proposed rule for 16 CFR part 1112 would continue that requirement.

A team of CPSC staff reviews applications from firewalled laboratories, including the submitted training documents. If the team concludes that the application materials satisfy the statutory requirements for acceptance as a firewalled conformity assessment body, the team recommends the applicant for Commission acceptance. Thus far, the training documents



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submitted by firewalled laboratory applicants have indicated clearly whether section 14(f)(2)(D) of the CPSA has been satisfied. However, the CPSC will take this suggestion under advisement as we consider future applications from firewalled laboratories. Should we determine that establishing standards for training documents would be helpful, we will consider the standards for impartiality in relevant standards and best practices.

We note that the accreditation bodies play a role in ensuring impartiality of firewalled laboratories as well. Section 4.1.5(b) of ISO/IEC 17025:2005 requires that the laboratory shall "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." Note 2 under § 4 of ISO/IEC 17025:2005, *Management Requirements,* states:

> If the laboratory wishes to be recognized as a third party laboratory, it should be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgment. The third party testing or calibration laboratory should not engage in any activities that may endanger the trust in its independence of judgment and integrity in relation to its testing or calibration activities.

The accreditation body evaluates the laboratory regarding this provision during the initial assessment and during each reassessment. Thus, the firewalled laboratory's accreditation body also evaluates the policies and procedures by which the laboratory avoids activities that would diminish confidence in its impartiality.

To the extent that these commenters also intended to suggest that the CPSC apply standards to the training documents submitted by government laboratory applicants, we note that, to date, the CPSC has not requested that governmental laboratory applicants submit training documents. Nor are we proposing in this rule that governmental laboratory applicants submit training documents to the CPSC. Section 102 of the CPSIA specifically requires that applicants for firewalled status have established procedures to ensure that, inter alia, the CPSC is notified immediately of any attempt at undue influence and that allegations of undue influence may be reported to the CPSC confidentially. In order to implement those provisions, we require firewalled applicants to submit training documents so that we can ensure that these safeguards have been communicated to employees. The statute does not require governmental laboratories to have established policies that involve employees notifying the CPSC immediately and confidentially of an attempt at undue influence. Thus, CPSC staff is not recommending requiring training documents from governmental laboratory applicants in support of such requirements. Instead, the CPSIA established five criteria that each governmental applicant must satisfy to have its accreditation accepted by the CPSC. To implement those criteria, the proposed rule would require a governmental laboratory applicant to submit responses to a questionnaire, a description of its relationship with other entities, an attestation, and the laboratory's undue influence policy. For more information on those requirements, see the preamble discussion of proposed § 1112.13(c).



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**Comment 11:** Some commenters recommended that the Commission establish safeguards to ensure that employees engaged in conformity assessment activities are not rewarded for positive outcomes of testing.

**Response 11:** The CPSC agrees that a third party conformity assessment body should not reward an employee for a "passing" test result. The notices of requirements have mandated, and this proposed rule would continue mandating that CPSC-accepted laboratories be accredited to the provisions in ISO/IEC 17025:2005 by a signatory to the ILAC-MRA. Section 4.1.5(b) of ISO/IEC 17025:2005 states that the laboratory shall "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." The laboratory's accreditation body checks for conformance to this section of ISO/IEC 17025:2005 during initial accreditation and each reassessment. Therefore, the CPSC considers the commenters' suggestion to be addressed already in the ISO/IEC 17025:2005 requirements, and additional CPSC requirements are not warranted.

**Comment 12:** One commenter who responded to several notices of requirements suggested that we require applicants, including the firewalled and governmental laboratories, as a means of assuring impartiality and avoiding undue influence, to submit the evidence used to validate the fulfillment of § 4.1.5(b) of ISO/IEC 17025:2005 as part of their application to the CPSC. The commenter argued that this information is particularly necessary because the requirements for firewalled laboratories to submit documents related to staff training on undue influence "are not sufficient on their own to pro-actively assure the Commission about the impartiality of a firewalled (or government) laboratory." The commenter contended that requiring evidence of the fulfillment of § 4.1.5(b) of ISO/IEC 17025:2005 would drive accreditation bodies and laboratories to pay more specific attention to ISO/IEC 17025:2005 § 4.1.5(b); promote consistency; and provide the CPSC with a means of monitoring compliance.

**Response 12:** Staff believes that requiring applicants to submit records used to validate the fulfillment of § 4.1.5(b) of ISO/IEC 17025:2005 to the CPSC is unnecessary. It is the role of the laboratory's accreditation body to evaluate whether a laboratory satisfies the requirements of ISO/IEC 17025:2005; it would be duplicative for the CPSC to perform the same evaluation. Accreditation bodies have the expertise to evaluate laboratories to all provisions of ISO/IEC 17025, including § 4.1.5(b).

With regard to the suggestion that if the CPSC required submission of the evidence of compliance with § 4.1.5(b) of ISO/IEC 17025:2005, accreditation bodies and laboratories would pay more specific attention to that requirement, we believe that accreditation bodies garner significant attention from laboratories. If a laboratory failed to meet the requirements of ISO/IEC 17025:2005 to the satisfaction of its accreditation body, the laboratory could lose its accreditation and a potentially significant portion of its business.

With regard to the suggestion that the submission of the records used to validate fulfillment of ISO/IEC 17025:2005 § 4.1.5(b) would promote consistency among laboratories, we respond that currently, we do not perceive any need to do so. The Commission has decided to designate laboratory accreditation to ILAC-MRA signatories, per section 14(a)(3)(C) of the CPSA. At this



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time, the CPSC is not aware that this designation has resulted in problems regarding undue influence. Requiring the submission of the records used to validate the fulfillment of ISO/IEC § 4.1.5(b) would impose a burden on the CPSC and laboratories, without corresponding benefit. Finally, we note that the fulfillment of the requirements of ISO/IEC 17025:2005 § 4.1.5(b) may be achieved in a number of ways. Decreasing variability in how laboratories fulfill that requirement would not necessarily increase protection against undue influence.

With regard to the suggestion that the submission of records used to validate fulfillment of ISO/IEC 17025:2005 § 4.1.5(b) would promote consistency among accreditation bodies, the ILAC-MRA evaluation process of an accreditation body involves a team of peer-review members drawn from multiple accreditation bodies located around the world. This multimember team arrangement tends to harmonize how the requirements of § 4.1.5(b) of ISO/IEC 17025:2005 are fulfilled around a common set of principles shared by the globally-distributed team members.

With regard to the suggestion that requiring the submission of evidence of the fulfillment of ISO/IEC 17025:2005 § 4.1.5(b) to the CPSC would provide us with a means of monitoring compliance, again, we do not agree. Records related to accreditation assessments and reassessments are maintained by the accreditation bodies and the laboratories. The draft final rule on the audit requirements (implementing § 14(i)(1) of the CPSA) requires a third party conformity assessment body to retain records relating to the last three reassessments conducted by the accreditation body and make such records available to the CPSC upon request. Records of nonconformities related to safeguards against undue influence (or any ISO/IEC 17025:2005 requirement) and the corrective actions must be made available to the CPSC upon request. Accordingly, we already have a means of monitoring compliance with this and every other provision in ISO/IEC 17025:2005.

With regard to the commenter's particular concern with firewalled and governmental laboratories, CPSC acceptance of these types of laboratories requires the submission and evaluation of additional information specifically dealing with avoiding undue influence. Proposed §§ 1112.13(b) and (c) provide details of the additional documentation we would require for CPSC acceptance of the accreditation of firewalled and governmental laboratories.

The CPSC is proposing to require these additional application materials from firewalled and government laboratories because we expect that they will provide us with helpful information concerning the structure and independence of these applicants.

**Comment 13:** Another commenter similarly pointed out that independent laboratories can "easily" satisfy ISO/IEC 17025:2005 § 4.1.5(b) but stated that the application of this requirement to firewalled and governmental laboratories "poses issues of commercial, financial, and political pressures." The commenter suggested that the CPSC impose "additional audit requirements and accreditation decisions" on firewalled and government laboratories, and that the CPSC require from such applicants "additional application information . . . which should include, but not be limited to, extensive public disclosure of both manufacturer and/or government laboratory personnel involved in the testing of the relevant product(s)."



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**Response 13:** The commenter did not specify what additional audit requirements or accreditation decisions it thought the CPSC should impose. However, with regard to this commenter's recommendation that the CPSC require additional application materials from firewalled and governmental applicants, as explained in the response to Comment 10 above, the proposed rule would require such materials.

We decline the suggestion to require extensive public disclosure of manufacturer and/or government laboratory personnel. We consider that mandating such disclosure would constitute an invasion of personal privacy that would be unwarranted when balanced against the public interest in the information. See Horowitz v. Peace Corps, 428 F.3d 271 (D.C. Cir. 2005) ("we must balance the private interest involved [namely, 'the individual's right of privacy'] against the public interest").

**Comment 14:** Some commenters suggested that the sampling frequency of firewalled laboratories should be double that of independent conformity assessment bodies. Although it was not clear from the submissions, these commenters may have been suggesting that the government laboratories also test twice as many samples as independent laboratories.

**Response 14:** Section 14(a)(2) of the CPSA requires that a manufacturer of a children's product subject to a children's product safety rule submit "sufficient samples of the children's product, or samples that are identical in all material respects to the product," to a third party conformity assessment body for testing. Under the terms of the statute, then, it is the manufacturer, as opposed to the laboratory, that determines what sample is provided to the laboratory for testing, and the agency has no authority to transfer responsibility for determining sample size to the laboratories. The CPSC has addressed the sufficiency of the number of samples required under section 14(a)(2) of the CPSA in the final rule *Testing and Labeling Pertaining to Product Certification*. 76 FR 69482 (November 8, 2011).

**Comment 15:** Some commenters also suggested that firewalled laboratories be required to meet additional requirements such as:

- Public disclosure that the manufacturer has a financial interest or ownership stake in the laboratory;
- Submission of materials that identify whether employee compensation or annual bonuses (including stock options) are tied to the financial performance of the controlling manufacturer;
- Submission of detailed protocols by which the engineering staff of the firewalled laboratory do not either transfer from or transfer to the manufacturer's staff, or otherwise look to the manufacturer for career advancement; and
- Evidence that employees are required to participate, and regularly pass, third party ethics and compliance audits and programs intended to detect and protect against undue influence. The International Federation of Inspection Agencies (IFIA) Compliance Code was mentioned as a possible standard. Employees should also be required to submit to any programs established by the manufacturer/firewalled laboratory, including training, reporting, monitoring, investigating, and enforcement, intended to protect against and detect undue influence.



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**Response 15:** With regard to the suggestion that the CPSC require firewalled laboratories to publicly disclose that the manufacturer has a financial interest or ownership stake in the laboratory, section 14(f)(2)(D) of the CPSA provides that a firewalled laboratory may be accepted by the Commission only if the Commission, by order, makes certain findings concerning the firewalled laboratory. The orders of the Commission accepting the accreditation of firewalled laboratories are public and are posted on the CPSC website. Accordingly, there is public disclosure of each firewalled laboratory applicant at the time the Commission votes on whether to accept the firewalled laboratory's accreditation. (See, *e.g.*, http://www.cpsc.gov/library/foia/foia10/brief/firewalled.pdf).

With regard to the suggestion that firewalled laboratories be required to identify whether employee compensation or annual bonuses (including stock options) are tied to the financial performance of the controlling manufacturer, and that the CPSC require submission of detailed protocols by which the engineering staff of the firewalled laboratory do not either transfer from or transfer to the manufacturer's staff or otherwise look to the manufacturer for career advancement, CPSC staff are not convinced that such information would be dispositive. The core concern is whether the testing process will be tainted. That concern drives the provisions that were in the notices of requirements, as well as the provisions proposed in this rule, which seek to ensure that the testing process is protected against undue influence. As explained in the response to Comment 16 below, in the NPR for 16 CFR part 1112, we are proposing to expand the definition of "firewalled laboratory," and we are requiring more information from those entities about safeguards against undue influence.

As we have noted in the responses to Comments 10 and 11 above, § 4.1.5(b) of ISO/IEC 17025:2005 requires that the laboratory have arrangements to ensure that it is free from undue influence. The accreditation body evaluates the laboratory's fulfillment of this provision at the initial accreditation and at each reassessment. Further, section 14(f)(2)(D)(ii) of the CPSA requires the Commission, by order, to find that the conformity assessment body has established procedures to ensure that its test results are protected from undue influence by the manufacturer, private labeler, or other interested party. Because multiple entities are evaluating the means by which the firewalled laboratory avoids undue influence by the manufacturer, additional application requirements for firewalled applicants are not seen as necessary at this time. At a future date, the CPSC may consider additional requirements for firewalled laboratories in response to evidence that the prevailing requirements are not effective.

Finally, as for the suggestion that the CPSC require evidence that employees are required to participate, and regularly pass, third party ethics and compliance audits and to submit to any programs established by the manufacturer/firewalled laboratory intended to detect and protect against undue influence, CPSC staff declines to adopt this suggestion. Under the proposed rule, a firewalled laboratory applicant would be required to submit, *inter alia*, copies of training documents, including a description of the training program content), showing how employees are trained to notify the CPSC 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; and training records (including training dates, location, and the name and title of the individual providing the training), listing the staff members who received the required training. At this time, it is the view of CPSC staff that



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requiring these training records sufficiently addresses the agency's interest in ensuring that firewalled laboratory personnel are adequately trained in detecting and protecting against undue influence. Again, however, CPSC staff will continue to consider this suggestion, and should we become aware that additional requirements concerning undue influence-related training of laboratory personnel would be helpful, we may recommend adopting additional training requirements in the future.

**Comment 16:** Other commenters expressed concern about the situation in which a laboratory and a manufacturer are owned by the same parent company. The commenter urged the Commission to expand the definition of "firewalled laboratories" to cover common parentage of laboratories.

The commenter further suggested that the definition of "firewalled laboratories" be extended to include laboratories that conduct 50 percent or more of their business with a single manufacturer or private labeler of children's products.

**Response 16:** The CPSC agrees that if a laboratory and a manufacturer share a common corporate parent, and the laboratory intends to test the manufacturer's children's products for certification purposes, the laboratory should be considered a firewalled laboratory. The proposed rule would address the situation of common parentage in the definition of a "firewalled laboratory." The CPSC proposes to have an applicant attest to whether it satisfies any aspect of the definition of a "firewalled laboratory." One attestation concerns common parentage; the applicant would need to attest to whether it is affiliated with a manufacturer or private labeler of the children's product. "Affiliated with" would mean that the conformity assessment body is in the same ownership network as a manufacturer or private labeler of the children's product, with the exception that "affiliated with" does not include a manufacturer or private labeler of the children's product that is owned, managed, or controlled by the conformity assessment body.

The CPSC considered the potential controlling effect of manufacturers with a significant part of a laboratory's business, and we concluded that evaluating such a factor would be challenging administratively and difficult to verify. Variables such as the time period and types of products to consider could have a significant impact on any calculation of a percentage of a laboratory's business.

However, the CPSC is proposing to address management and/or control of a laboratory by a manufacturer or private labeler by including, in the definition of "firewalled laboratory," laboratories over which a manufacturer or private labeler has the ability to appoint a majority of the laboratory's senior internal governing body, the ability to appoint the presiding official of the laboratory's senior internal governing body, or the ability to hire, dismiss, or set the compensation level of laboratory personnel. Another proposed aspect of this definition would deem a "firewalled" laboratory to be a laboratory that is under contract to a manufacturer or private labeler, such that the contract limits explicitly the services that the laboratory may perform for other customers, or limits explicitly, which or how many other entities, may be customers of the laboratory.



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**Comment 17:** A commenter suggested that as a requirement for accreditation, the CPSC might consider accrediting only manufacturer-controlled laboratories that agree that their entire organization, including the firewalled laboratories, will be held strictly liable for defective products. Further, for foreign governmental laboratories, the commenter suggested that the CPSC require, as a condition of accreditation, that any foreign governmental lab that seeks to test and certify products be required to agree to submit to the jurisdiction of U.S. regulatory agencies and U.S. courts without asserting claims of sovereign immunity or other claims seeking to limit their liability.

**Response 17:** The Commission declines to adopt the suggestion that we require firewalled laboratories to agree that their entire organizations will be held strictly liable for a defective product. The statutes enforced by the Commission are structured to assign liability to culpable persons or entities. To the extent that by "entire organization," the commenter means that the manufacturer owns, manages, or controls the firewalled laboratory, potential liability already exists under the statutes enforced by the Commission. It would be redundant to require the laboratory to agree to such liability as a condition of becoming accepted by the CPSC. To the extent that the commenter intends to suggest that the firewalled laboratory itself be held liable, the Commission does not have the authority to assign liability to an entity that is not already culpable under the law.

With regard to the suggestion that the CPSC require foreign governmental laboratories to agree to submit to the jurisdiction of U.S. regulatory agencies and courts without asserting claims of sovereign immunity, or asserting other bases for limiting their liability, such actions are beyond the scope of our laboratory accreditation authority.

**Comment 18:** One commenter who responded to more than one notice of requirements, advised the Commission to "consider the liability implications that may arise from accrediting a firewalled or foreign governmental laboratory in the event that one of those laboratories permits an unsafe product [to] enter the U.S. marketplace, as well as the legal remedies thereto."

**Response 18:** We interpret the commenter as expressing concern that there may be obstacles to the CPSC holding CPSC-accepted firewalled and foreign governmental laboratories legally accountable for the tests they conduct. Section 14 of the CPSA establishes that firewalled and governmental laboratories may be accredited by the Commission to conduct third party tests of children's products. We wish to assure this commenter that we pursue available legal remedies against entities that permit unsafe products to enter the U.S. marketplace. We also note that, under the proposed rule, the Commission would be able to withdraw its acceptance of a laboratory on such grounds as the laboratory failed to comply with the requirements of subpart B of the proposed rule, and/or the laboratory succumbed to undue influence.

**Comment 19:** One commenter suggested that the CPSC require assessments of a laboratory's independence and freedom from undue influence annually, or at least require that they coincide with other reassessment and surveillance visits.

**Response 19:** We agree that a laboratory's independence should be reassessed on a regular basis. The final rule on audit requires that the reassessment portion of an audit, which is



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conducted by the accreditation body, include an examination of the laboratory's management system to ensure that the laboratory is free from any undue influence.

In addition to a laboratory's reassessment visits, surveillance visits can be conducted by accreditation bodies during the period between reassessments. Surveillance visits are assessments that are conducted for a particular purpose, such as to follow-up on a previously observed problem or to ensure that a newly accredited laboratory has implemented necessary procedures. Surveillance visits may or may not be conducted for purposes of reviewing the impartiality of a laboratory, and thus, may or may not involve a reassessment of a laboratory's impartiality.

**Comment 20:** A commenter suggested that there is no objective basis for assessing the additional application materials submitted by governmental conformity assessment bodies.

**Response 20:** We interpret the commenter's suggestion as urging the Commission to issue objective standards for assessing these applications.

Section 14(f)(2) of the CPSA, as amended by section 102 of the CPSIA, establishes five criteria which, in addition to the baseline requirements, a third party conformity assessment body owned or controlled, in whole, or in part, by a government must satisfy. The criteria are:

> (i) 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;
>
> (ii) the entity's testing results are not subject to undue influence by any other person, including another governmental entity;
>
> (iii) the entity is not accorded more favorable treatment than other third party conformity assessment bodies in the same nation who have been accredited under this section;
>
> (iv) the entity's testing results are accorded no greater weight by other governmental authorities than those of other third party conformity assessment bodies accredited under this section; and
>
> (v) 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.

15 U.S.C. § 2063(f)(2)(B).

In order for the CPSC to evaluate whether a governmental laboratory applicant satisfies the statutory criteria, we have developed a standard questionnaire and request for documentation that each governmental laboratory applicant is asked to complete. The questionnaire accompanies the proposed rule as part of the CPSC's Paperwork Reduction Act package, and the required documents are described in proposed § 1112.13(c)(2). In addition, CPSC staff reviews governmental laboratory applications, using a standardized review document that provides grounds and reasoning for a finding relative to each of the five statutory criteria. These standardizations provide increased objectivity to the application review process, and the questionnaire and documentation requirements are being published via this proposed rule.



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**Comment 21:** Some commenters that are foreign governments contended that rather than assess additional application materials before acting on a governmental laboratory application, the CPSC should default to accepting each governmental laboratory applicant, unless there is evidence that the applicant fails to satisfy the statutory criteria. The commenters argued that the approach taken by the CPSC is not fair and is inconsistent with the principal of impartiality expressed in the statutory criterion, which requires that the applicant laboratory "is not accorded more favorable treatment than other third party conformity assessment bodies in the same nation who have been accredited."

The commenters also argued that the CPSC's approach violates the "mutual recognition principle of conformity assessment procedures" under the international treaty "Agreement on Technical Barriers to Trade" (TBT Agreement). The commenters also invoked article 6.3 of the TBT Agreement, which encourages members to negotiate agreements for the mutual recognition of conformity assessments, and the commenters suggested further consultations on these issues.

One commenter raised several issues under the World Trade Organization's TBT Agreement. The commenter stated that Article 2.4 of the TBT Agreement requires members to use relevant international standards (if they exist) as a basis for their technical regulations and said that ISO 9239-1, *Reaction to fire tests for floorings – Part 1: Determination of the burning behavior using a radiant heat source,* ISO 9239-2, *Reaction to fire tests for floorings – Part 2: Determination of flame spread at a heat flux level of 25 kW/m2*, and ISO 6925, *Textile floor coverings – Burning behavior – Tablet test at ambient temperature*, "contain fire test specifications for floorings." The commenter said that these international standards "would be an effective and appropriate means for the fulfillment of the objective pursued by CPSC."

Finally, another commenter referred to Article 5.1.2 of the TBT Agreement to state that "conformity assessment procedures shall not be more strict than necessary to give the Importing Member adequate confidence that products conform with the applicable technical regulations or standards." The commenter also cited Articles 2.4, 2.5, 2.9.3, 5.4, and 5.6.3 of the TBT Agreement and asked us to "identify parts, if any, of the new regulation which in substance deviate from relevant international standards and to explain why such deviation has become necessary."

**Response 21:** To the extent that these commenters are suggesting that the CPSC's approach has been partial to nongovernmental laboratory applicants, we acknowledge that there are criteria imposed by the CPSIA that apply only to governmental laboratory applicants. We have chosen to determine whether the criteria are satisfied before acting on each application. Similarly, we have not accepted any firewalled laboratory applicant without determining first that they satisfy the statutory criteria relevant to that type of laboratory (See 15 U.S.C. § 2063(f)(2)(D)). We have chosen to defer action on governmental and firewalled laboratory applications until we determine that the statutory criteria are satisfied because we want to ensure that CPSC-accepted third party conformity assessment bodies have the structures and practices required by the statute to avoid undue influence, or any other interference with, or compromise of, the integrity of the testing process. This is consistent with the goal of the CPSIA that children's products entering the U.S. marketplace have been tested by a competent and unbiased laboratory.



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We do not agree that this approach is unfair. Because neither governmental nor firewalled laboratories are independent entities, both are potentially subject to undue influence from the organizations to which they are connected, which have interests beyond product testing. The CPSIA imposes additional requirements on firewalled and government laboratories so that only laboratories that are structured to avoid undue influence sufficient to satisfy the statutory criteria may be accepted. The CPSC remains committed to implementing fairly the conformity assessment program established by the CPSIA, with the primary goal of product safety in mind.

The notices of requirements have not contradicted the TBT Agreement. The CPSC is willing to accept laboratories recognized by foreign governments if the laboratories satisfy the statutory requirements, including the five statutory criteria listed above (as long as the laboratory satisfies the baseline criteria) in the case of laboratories owned or controlled, in whole or in part, by a government. In fact, the CPSC has accepted the accreditation of several governmental laboratories, and it has applied the same statutory criteria to governmental laboratories, regardless of whether the governmental laboratory was located in a foreign country or in the United States. (Indeed, we note that the definition of "government participation" in section 14(f)(2)(B) of the CPSA (for purposes of a "third party conformity assessment body") is not limited to foreign governments.) The CPSC consults extensively with laboratories seeking to become accepted to test products under section 14 of the CPSA. We remain open to consulting more on these issues with any interested laboratory applicant.

With respect to specific articles in the TBT Agreement, the commenter addressing Article 2.4 of the TBT agreement may have misinterpreted the notice of requirements. The notice of requirements simply establishes the conditions under which the CPSC will accept the accreditation of a third party conformity assessment body to test a children's product for compliance with a particular children's product safety rule. The notice of requirements does not affect the regulations pertaining to the children's product itself.

Similarly, the commenter addressing Article 5.1.2 of the TBT agreement may have misinterpreted the notice of requirements. This commenter was responding to the notice of requirements pertaining to 16 CFR part 1630, *Standard for the Surface Flammability of Carpets and Rugs (FF 1-70)* and/or part 1631, *Standard for the Surface Flammability of Small Carpets and Rugs (FF 2-70)* (See 75 FR 42315 (July 21, 1010)). The notice of requirements for 16 CFR parts 1630 and/or 1631, however, did not affect or alter the standards established or test methods required in 16 CFR parts 1630 and/or 1631. It simply informed laboratories of the process and requirements by which they could apply to test children's products according to the test method detailed in parts 1630 and/or 1631. A laboratory that has been ISO/IEC 17025:2005-accredited by an ILAC-MRA signatory to conduct flammability tests for floor coverings pursuant to a standard other than 16 CFR parts 1630 and/or 1631 that has similar test methods would likely not find it difficult to expand its accreditation scope with its accreditation body to include 16 CFR parts 1630 and/or 1631 and subsequently apply to the CPSC to test children's products subject to these regulations.

Moreover, consistent with Article 5.1.2 of the TBT Agreement, the notices of requirements have not established procedures and requirements for laboratories that are more strict than



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necessary to give the CPSC adequate confidence that children's products tested by CPSC-accepted laboratories conform to applicable CPSC standards, regulations, rules, or bans. We are unclear as to which relevant international standards the commenter would like us to compare the notices of requirements, and explain why differences between the two are necessary. To the extent that the commenter is asking for differences between various substantive safety standards, we again note that the notices of requirements do not affect the underlying consumer product safety standard or children's product safety rule.

## 4. Comments on the Suspension and/or Withdrawal of CPSC's Acceptance of Conformity Assessment Bodies

**Comment 22:** Some commenters suggested that if a third party conformity assessment body tested a product later found to be noncompliant with the applicable rules, that conformity assessment body should lose its accreditation temporarily. (We interpret "lose accreditation" to mean a loss of the CPSC's acceptance of their accreditation.) The commenters suggested varying loss schedules depending on the type of laboratory, with increasing periods of suspension for repeat offenses. For firewalled and government laboratories, the commenters suggested that acceptance of their accreditation should be lost for 3 months after the first offense, 6 months after the second offense, 1 year after the third offense, and permanent loss for four offenses over a 2-year period. For independent laboratories, the commenters suggested a written warning after the first offense, a 1-month loss after the second offense, a 3-month loss after the third offense, and upon the fourth offense, the CPSC would re-evaluate the laboratory's practices, and the accreditation body would conduct a reassessment.

**Response 22:** We decline to adopt the suggestion that laboratories lose CPSC acceptance of their accreditation (either for a specified time or permanently) after noncompliant products associated with the laboratories' test reports are found in the marketplace because factors independent of the laboratory may have led to the presence of noncompliant products. For example, poor process control at the manufacturer after certification could lead to some noncompliant products being produced after the laboratory had tested compliant samples. As another example, a manufacturer may have made a material change to the product that affected compliance, without sending samples for testing to a laboratory. Setting a withdrawal schedule based solely on the presence of noncompliant products would risk holding laboratories responsible for factors beyond their control and of which they had no knowledge.

In addition, CPSC staff does not recommend adopting a graduated system of penalties because we consider it preferable to deal with laboratory infractions on a case-by-case basis.

**Comment 23:** Some commenters suggested that the CPSC establish a defined system for "de-listing" a third party conformity assessment body "for just cause." (We interpret "de-listing" to mean that the CPSC withdraws its acceptance of the laboratory's accreditation and removes the laboratory from the listing of accepted laboratories on the CPSC website http://www.cpsc.gov/cgi-bin/labsearch). The commenter provided examples of what would constitute "just cause":



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- Evidence of conflict of interest or where there is undue influence by a manufacturer, a common parent company, or other party, which could have affected test results;
- A laboratory has been found to be incompetent to conduct required testing due to personnel or laboratory equipment changes; or
- A laboratory has a record of repeatedly certifying products that are later identified as non-compliant.

**Response 23:** The CPSC agrees with the commenter that there should be greater clarity of what conduct or circumstances are sufficient for the agency to withdraw its acceptance of the accreditation of a third party conformity assessment body. Subpart D of the proposed rule would address adverse actions that the CPSC may take against a laboratory. These adverse actions would include: withdrawing CPSC acceptance of a laboratory's accreditation and removing the laboratory from the CPSC website listing of accepted laboratories. Proposed § 1112.47 would establish three basic grounds for withdrawal, which would include a manufacturer, private labeler, or governmental entity exerting undue influence on the laboratory or otherwise interfering with or compromising the integrity of the testing process. Proposed § 1112.41 would establish the procedures for withdrawal.

## 5. Comments Specific to a Notice of Requirements

**Lead Content in Children's Metal Jewelry**
**CPSC-2008-0049, *Federal Register* Notice 73 FR 78331 (December 22, 2008)**

**Comment 24:** Another commenter requested an exclusion in the CPSC test method for determining total lead in children's metal products (including children's metal jewelry). The suggested exclusion was that samples of electroplated jewelry—for which the electroplating is a metal excluded from testing for lead (such as gold or silver)—not be required to contain the electroplating when tested. The commenter suggested the following change to procedures A.2 and B.2:

> Component parts of children's products including metal jewelry items generally weigh several grams or more, and an aliquot (with no paint or similar surface coating, but including any electroplated or other coating which is considered to be part of the substrate, excluding precious or other metals exempt from testing) will have to be obtained.

**Response 24:** We decline to adopt the suggested change to the CPSC test method, CPSC-CH-E1001-08, because test methods are an inappropriate place to list testing exclusions. The test method is limited to describing how to conduct a test, not whether a material should be tested.

The commenter is correct that an excluded material, such as gold of at least 10 karats, does not require testing for lead. On August 26, 2009, the Commission published in the *Federal Register* a list of materials determined not to contain lead and that are excluded from testing (74 FR, 43031). This created a new section, § 1500.91 of the *Hazardous Substances and Articles: Administration and Enforcement Regulations*.



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If the commenter submits samples for testing without the electroplating, those test results, combined with the exclusion for a plating material (such as gold greater than 10 karats), could be used as the basis for issuing a Children's Product Certificate for a finished product consisting of units from the same lot or batch as the samples, plus the electroplating. However, once the electroplating occurs, the combination of the base material and the electroplating are considered one component part. If finished product samples are submitted for testing, the electroplating must be part of the tested specimen.

**Comment 25**: A commenter urged the CPSC to consider X-ray fluorescence (XRF) spectrometry as a valid testing option to screen for products with very low lead levels; more precise testing would be required if the uncertainty range of the instrument included the lead concentration limit.

Another commenter urged the CPSC to consider the use of a specific XRF technology, energy dispersive X-ray fluorescence spectrometry (EDXRF), as a validated method for the testing of lead in substrates of consumer products. The commenter referred to inter-laboratory testing that compared EDXRF technology to "wet chemistry" techniques (Inductively Coupled Plasma and Atomic Absorption Spectrometry) to measure lead in multiple substrates. The commenter opined that the economic and other benefits of using EDXRF over "wet chemistry" may be even more pronounced with application to the nondestructive measurement of lead in the substrate of product samples.

**Response 25:** The CPSC has accepted the use of certain types of XRF testing but only for certain polymeric materials and for paints.[15] CPSC staff also has proposed allowing the use of XRF to determine the lead content of glass materials, crystals, and certain metals. CPSC staff continues to evaluate improvements to technology and methods on an ongoing basis.

**Total Lead in Children's (Metal and Non-Metal) Products**
**CPSC-2009-0090, *Federal Register* Notice 74 FR 55820, (October 29, 2009)**

**Comment 26:** A commenter suggested that the CPSC expand the use of XRF beyond polymeric materials to test paints and thin film coatings for the purposes of a manufacturer, importer, or retailer's providing certification. Another commenter expressed a desire for the CPSC to allow the XRF method described in ASTM F2853-10 to be used to measure lead content in multiple substrates, in addition to homogeneous polymeric materials.

[15] The CPSC test method CPSC-CH-E1002-08 (and its revision, CPSC-CH-E1002-8.1), *Standard Operating Procedure for Determining Total Lead (Pb) in Non-Metal Children's Products*, includes an option for the use of XRF for the analysis of lead in certain polymeric materials. See 74 FR 55820 (Oct. 29, 2009) (notice of requirements for total lead in children's products); see also 76 FR 6765 (Feb. 8, 2011) (notice extending the stay of enforcement pertaining to total lead content in children's products [except for metal components of children's metal jewelry] until December 31, 2011). ASTM International, formerly the American Society for Testing and Materials (ASTM) test method F2853-10, *Standard Test Method for Determination of Lead in paint Layers and Similar Coatings or in Substrates and Homogeneous Materials by Energy Dispersive X-Ray Fluorescence Spectrometry Using Multiple Monochromatic Excitation Beams*, can be used for the analysis of lead content in paints (16 CFR part 1303). See 76 FR 18645 (Apr. 5, 2011) (revision to notice of requirements for lead paint).



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**Response 26:** On April 5, 2011, the CPSC published a notice revising the requirements for accreditation of laboratories to test for lead in paint. In that notice, the Commission approved the use of ASTM International (formerly the American Society for Testing Materials, ASTM) test method F2853-10, *Standard Test Method for Determination of Lead in Paint Layers and Similar Coatings or in Substrates and Homogeneous Materials by Energy Dispersive X-Ray Fluorescence Spectrometry Using Multiple Monochromatic Excitation Beams*, for the analysis of lead content in paint. Additionally, in the draft proposed rule, CPSC staff proposed allowing the use of XRF to determine the lead content of glass materials, crystals, and certain metals. CPSC staff continues to evaluate improvements to technology and methods on an ongoing basis.

**Comment 27:** Another commenter suggested that, in addition to using a cryogenic mill for sample preparation, the CPSC should allow the test specimen to be cut into small representative pieces, with a maximum length in any dimension of 2.0 millimeters. The commenter also suggested a procedural change in the test method for determining lead in metals (CPSC-CH-E1001-08). The suggested change calls for the tester to observe when no particles are visible in one step and omits a heating period in another step.

**Response 27:** New revisions, dated June 21, 2010, of CPSC test methods: CPSC-CH-E1001-08.1 and CPSC-CH-E1002-08.1 have been posted on the CPSC website. In test method CPSC-CH-E1002-08.1, the commenter's suggestion has been implemented. The sample preparation method instructs the tester to:

> Cut the test specimen into small pieces. Hard-to-digest plastics may need to be cryomilled to get finer powder. The minimum size is left to the discretion and flexibility of the tester for the material being evaluated.

With regard to the suggested change in test method CPSC-CH-E1001-08, CPSC staff does not have sufficient proof that the method of not heating the acid to 60 degrees C (in step 6 of the Hot Block method), or using a longer time period, would result in consistent measurements. In addition to the Hot Block Method, the CPSC allows another testing method, based on the EPA method 3051A2, which uses microwave digestion. Both methods are allowed in the revised test method, CPSC-CH-E1001-08.1.

**16 CFR part 1303 – Lead in Paint**
**CPSC-2008-0033, *Federal Register* Notice 73 FR 54564, (September 22, 2008); Revised April 5, 2011 (76 FR 18645)**

**Comment 28:** Two commenters noted that the absence of a specified testing method in 16 CFR part 1303, *Ban of Lead-Containing Paint and Certain Consumer Products Bearing Lead-Containing Paint*, leads to uncertainty and confusion among accreditation bodies and laboratories about which testing methods are adequate for meeting the requirements of the standard.



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**Response 28:** The Commission addressed these comments in a notice published in the *Federal Register* on April 5, 2011, in which it amended the notice of requirements for testing for lead paint (see 76 FR 18645). The notice of April 5, 2011, listed the test methods that are approved for compliance determination: CPSC-CH-E1003-09, CPSC-CH-E1003-09.1, and/or ASTM F2853-10 (which uses a specific type of XRF technology).

**Comment 29:** A commenter encouraged the CPSC to continue to work to ensure that the current ASTM F40 Committee (Declarable Substances in Materials) review process of a proposed standard method for lead in paint using traditional XRF technologies undergoes the same rigorous scientific and statistical requirements as we used during the ASTM F2853-10 standard method development process.

**Response 29:** CPSC staff continues to evaluate improvements to technology and methods on an ongoing basis. The Commission has not determined that other XRF technologies are as effective, precise, or reliable as the methods described in the notice of requirements for determination of the lead content in paint.

**16 CFR parts 1630 and 1631 - Carpets and Rugs**
**CPSC-2010-0078, *Federal Register* Notice 75 FR 42315 (July 21, 2010)**

**Comment 30:** A commenter requested that the Commission continue the stay with respect to handmade "Oriental" carpets. The regulation at 16 CFR §1630.2(b) states that "[o]ne of a kind, carpet or rug, such as an antique, an Oriental, or a hide, may be excluded from testing under this Standard pursuant to conditions established by the Consumer Product Safety Commission." There is a corresponding regulation applying to small carpets and rugs at 16 CFR § 1631.2(b). The commenter noted that the CPSC has not established such conditions, and encouraged the Commission to do so. Pending the establishment of the conditions, the commenter sought a continuation of the stay.

**Response 30:** CPSC staff recommends that the Commission decline the request to continue (or reinstitute) the stay for handmade "Oriental" carpets. With regard to children's products, publication of the notice of requirements (on July 21, 2010) had the effect of lifting the stay. With regard to non-children's products, the Commission announced the lifting of this stay, effective January 26, 2011 (75 *Federal Register*, 81236, December 27, 2010). The CPSIA was enacted in August 2008; the carpets and rugs industry had ample opportunity to prepare for the law's testing and certification requirements.

In the years since the flammability regulations at 16 CFR parts 1630 and 1631 were promulgated, the CPSC has handled on an individual basis requests for exclusion of one-of-a-kind carpets or rugs. The commenter is correct that the Commission has not formally established the conditions under which a carpet or rug would be excluded under 16 CFR §§ 1630.2(b) and/or 1631.2(b), but such matters are outside the scope of this rulemaking.

**Comment 31**: Some commenters recommended that the CPSC support and approve the testing of flammability of carpets and rugs by laboratories accredited by the National Voluntary



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Laboratory Accreditation Program (NVLAP). One commenter added that this should also include "internal" laboratories. The commenters expressed the opinion that that the existing procedures (testing methods, protocols, and recordkeeping requirements) in FF 1-70 (16 CFR part 1630) and FF 2-70 (16 CFR part 1631) are effective in protecting consumers and children and that no additional safety benefit is gained by "different testing protocols." One commenter expressed the belief that the requirement for accreditation of third party conformity assessment bodies to assess conformity with 16 CFR parts 1630 and/or 1631 will only add costs, with no additional safety benefits, for children's carpet and rug products.

**Response 31:** It is common for U.S. laboratories that test carpets and rugs in accordance with 16 CFR part 1630 and/or 1631 to be ISO/IEC 17025:2005-accredited by NVLAP. NVLAP falls under the jurisdiction of the National Institute of Standards and Technology (NIST). Because NVLAP is a signatory to the ILAC-MRA, it is a Commission-designated accreditation body, as prescribed in the notices of requirements. Several NVLAP-accredited laboratories have been accepted and posted on the CPSC website for testing to 16 CFR parts 1630 and 1631. Worldwide, there are more than 25 CPSC-accepted laboratories for 16 CFR part 1630 and/or 16 CFR part 1631 (with several different ILAC-MRA accreditation bodies represented). NVLAP accreditation is not a hindrance to CPSC acceptance of third party conformity assessment bodies (laboratories) for testing to 16 CFR parts 1630 and/or 1631.

In response to the commenter who asked that the CPSC allow internal laboratories that are accredited by NVLAP, CPSC staff assumes that this refers to laboratories that are owned by carpet or rug manufacturers. In these cases, the notice of requirements approved by the Commission allows NVLAP accreditation to serve as a "baseline" requirement for CPSC acceptance. However, in accordance with the CPSA (as amended by the CPSIA), laboratories that are owned by a manufacturer of a product that is subject to the regulation for which it conducts tests must meet additional criteria for Commission acceptance as a firewalled third party conformity assessment body.

As for the commenters suggesting that the implementation of different testing protocols will provide no safety benefit, the notice of requirements makes no changes to the flammability test methods that appear in 16 CFR parts 1630 and 1631. The commenters may be referring to the language in the CPSA (as amended by the CPSIA) that the manufacturer "must submit sufficient samples of the children's product, or samples that are identical in all material respects to the product," for testing by a CPSC-accepted third party conformity assessment body, and/or the CPSA language related to Commission rulemaking for a continued testing program (including periodic and random sample testing, and compliance labeling). These "testing protocols" are required for children's carpets and rugs by the CPSIA and the recently issued final rule, *Testing and Labeling Pertaining to Product Certification* (76 FR 69482 (November 8, 2011) (to be codified at 16 CFR part 1107)).

**Comment 32:** One commenter asked whether conformity assessment bodies in its country that were accredited by a signatory to the ILAC-MRA and accredited to ISO 9239-1, 9239-2, and 6925 "fulfill the requirements listed in 16 CFR parts 1630 and 1631" or whether there are additional requirements that a conformity assessment body must meet to have CPSC accept its accreditation.



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**Response 32:** The purpose of the CPSC's laboratory program is to authorize laboratories to conduct CPSC tests capable of supporting a Children's Product Certificate. Although there may be other product standards and test methods in existence, the purpose of this program is limited to conducting third party tests of children's products under section 14 of the CPSA. A laboratory must be accredited by an ILAC-MRA signatory to ISO/IEC 17025:2005 and must have the relevant CPSC regulation or test method in its scope of accreditation to apply successfully for CPSC acceptance of its accreditation. ISO 9239-1, 9239-2, and 6925 all specify methods for assessing the burning behavior of floorings and/or floor coverings. The CPSC regulations at 16 CFR parts 1630 and 1631 assess the surface flammability of carpets and rugs. To the extent that a laboratory was accredited to ISO/IEC 17025:2005, but it did not have 16 CFR part 1630 and/or 1631 in its scope of accreditation, it would not be eligible for acceptance by the CPSC to test children's products under 16 CFR part 1630 and/or 1631. The CPSC standards contain specific test methods for assessing compliance with CPSC requirements. Because other test methods do not assess for compliance with CPSC requirements, accreditation to such other test methods is not sufficient for CPSC acceptance of accreditation.

**Comment 33:** One commenter, a government agency, said that the notice of requirements raised serious concerns for the textile industry in its country and "may imply new additional costly requirements."

**Response 33:** We believe that the commenter may have misinterpreted the notice of requirements. The regulations pertaining to carpets and rugs have been in place for several decades, and the notice of requirements did not alter those regulations. To the extent that the commenter is expressing concern over the cost of third party testing for children's products, such a comment is beyond the scope of the proposed rulemaking because the draft proposed rule would establish requirements for laboratories, and it would not address testing costs associated with manufacturers.

**Requirements for Electrically Operated Toys or Other Electrically Operated Articles Intended for Use by Children, CPSC-2010-0035, *Federal Register* Notice 75 FR 22746 (April 30, 2010)**

**Comment 34:** A commenter suggested that the CPSC should accept evaluation results from certification bodies recognized by the U.S. Occupational Safety & Health Administration (OSHA) as a Nationally Recognized Testing Laboratory (NRTL) with UL 696 in their scope of recognition. According to the commenter, the requirements in UL 696 are "nearly identical" to those in 16 CFR part 1505.

**Response 34:** As explained more fully above in the response to Comment 2, in order to ensure a consistent, global approach toward CPSC acceptance of accredited laboratories, the CPSC has decided only to consider acceptance of laboratories accredited by ILAC-MRA signatory accreditation bodies.



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In addition, and as explained in the response to a comment concerning carpets and rugs (Comment 31), a laboratory that wishes to conduct tests upon which a manufacturer of a children's product subject to a particular rule may base a certificate of compliance, must have that particular rule listed in its scope of accreditation. This requirement ensures that the laboratory understands the CPSC regulation and test methods associated with the regulation and has been evaluated as competent to conduct that testing. Although UL 696 has been revised to be consistent with 16 CFR part 1505, an NRTL laboratory with UL 696 in its scope of recognition must be accredited to ISO/IEC 17025:2005 by an ILAC-MRA signatory accreditation body to 16 CFR part 1505 before the laboratory may apply to the CPSC for acceptance of that accreditation.

**16 CFR parts 1632 and 1633 – Mattresses, Mattress Pads, and Mattress Sets**
**CPSC-2010- 0085, *Federal Register* Notice 75 FR 51020**

Comment 35: One commenter urged us to adopt a longer implementation period for third party testing under 16 CFR part 1632 and to broaden this notice of requirements' retrospective testing provisions.

Response 35: The Commission already responded to this comment in a notice published in the *Federal Register* on November, 29, 2010 (75 FR 72944), in which we revised the retrospective testing provision applicable to third party testing under 16 CFR parts 1632 and 1633.

**16 CFR part 1420 - Youth All-Terrain Vehicles (ATVs)**
**CPSC-2010-0090, *Federal Register* Notice 75 FR 52616 (August 27, 2010)**

**Comment 36:** One commenter supported the Commission's publication of the notice of requirements for ATVs, and they specifically offered support for the "CPSC's analysis to determine whether an ATV is intended for a child and not just rely[ing] on what the ATV industry/manufacture[r] states that it is." Some commenters expressed safety concerns with ATVs. Two commenters suggested that the CPSC include Y–12+ model ATVs in the "youth ATV" category, along with the Y–6+ and the Y–10+ models. One commenter claimed that the CPSC is excluding the Y–12+ model from the category "youth ATV." The commenter stated that because the models are intended to be used by 12 year olds, they should fall under the scope of the CPSIA's definition of a "children's product." Both commenters noted that because the T model ATV is intended for children 14 years old and older, the Y–12+ model will be used primarily by children 12 and 13 years old.

**Response 36:** Section 232 of the CPSIA mandated that the CPSC establish the American National Standard for Four Wheel All-Terrain Vehicles Equipment Configuration, and Performance Requirements developed by the Specialty Vehicle Institute of America (American National Standard ANSI/SVIA–1–2007) as a mandatory standard for four-wheel all-terrain vehicles.



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This standard includes "Category Y" classifications, which are for off-road use by operators under age 16. These categories are: Y–6+, intended for use by children age 6 or older; Y–10+, intended for use by children age 10 or older; Y–12+, intended for use by children age 12 or older, and T, intended for use by both children age 14 or older *with adult supervision,* and by persons age 16 or older. While CPSC staff appreciates the comment that a significant percentage of the riders of the Y–12+ model will be children 12 years old, and *not* the children who are older than 12, no data were provided to support that statement.

CPSC staff does not have data to indicate which portion of the "12 or older" category represents the rider of Y–12+ ATV models most. The CPSIA defines a "children's product" in § 3(a)(2) of the CPSA as:

> (2) CHILDREN'S PRODUCT.--The term "children's product" means a consumer product designed or intended primarily for children 12 years of age or younger. In determining whether a consumer product is primarily intended for a child 12 years of age or younger, the following factors shall be considered:
>
> (A) A statement by a manufacturer about the intended use of such product, including a label on such product if such statement is reasonable.
>
> (B) Whether the product is represented in its packaging, display, promotion, or advertising as appropriate for use by children 12 years of age or younger.
>
> (C) Whether the product is commonly recognized by consumers as being intended for use by a child 12 years of age or younger.
>
> (D) The Age Determination Guidelines issued by the Commission staff in September 2002, and any successor to such guidelines.

The CPSC cannot categorically include Y–12+ model ATVs as "youth ATVs" because the age range for that model includes children over the age of 12; however, the definition of a "children's product" is limited to products designed or intended primarily for children 12 years of age or younger. When it is unclear whether a product should be considered a children's product, the agency will apply the four factors. Different manufacturers may mark, package, and market their ATVs as primarily intended for children older than 12, or as primarily intended for 12 year olds. The CPSC will determine on a per-model basis, using the four factors listed above, whether a particular model Y–12+ ATV is primarily intended for use by children 12 years of age or younger (and is therefore considered a children's product in need of third party testing to support a certification). Indeed, some commenters commended the Commission for applying the four statutory factors, rather than relying solely on the manufacturer's statements regarding whether an ATV is intended for a child.

The commenter is incorrect that the CPSC has excluded Y–12+ model ATVs from third party testing. In the August 27, 2010, *Federal Register* notice that described the third party testing requirements, the Commission stated: "for the purposes of this notice of requirements, the term 'youth' ATVs *at a minimum* refers to categories Y–6+ and Y–10+ in ANSI/SVIA 1 -2007." (*See* 75 FR at 52616; emphasis added). Thus, the Commission has indicated that the Y–12+ model may be considered for inclusion as a product that must meet third party testing requirements. Again, it will depend upon application of the four factors to a particular model.



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On August 12, 2011, the President signed into law Public Law 112-28 (PL 112-28), which amended the CPSIA in several respects. One provision in PL 112-28 created an exception from the lead limits for off-highway vehicles. Consequently, all-terrain vehicles, recreational off-highway vehicles, and snowmobiles are no longer subject to the lead limits in section 101 of the CPSIA.

**Comment 37:** One commenter requested that the Commission extend the date on which ATV manufacturers must begin third party testing and certification. The commenter further requested that the Commission consider additional forms of relief in the event there continues to be an insufficient number of CPSC-accepted laboratories.

**Response 37:** The Commission responded to this comment in notices published in the *Federal Register* on December 9, 2010 (75 FR 76709) and February 1, 2011 (76 FR 5565), in which we first extended, and then conditionally stayed, third party testing for youth ATVs.

As noted above, in the response to Comment 36, all-terrain vehicles, recreational off-highway vehicles, and snowmobiles are no longer subject to the lead limits in section 101 of the CPSIA.

**Third Party Testing for Certain Children's Products; Toys: Requirements for Accreditation of Third Party Conformity Assessment Bodies, CPSC-2011-0050, *Federal Register* Notice 76 FR 45698 (August 3, 2011)**

**Comment 38:** Two entities submitted letters before we published the notice of requirements pertaining to ASTM F-963-08 (76 FR 46598 (August 3, 2011)), and these letters were placed in the administrative record as comments. For convenience, we will refer to the entities as commenters. (We did receive a third submission, but it appeared to be from a laboratory seeking to be listed as a third party conformity assessment body rather than a comment on the notice of requirements.)

One commenter urged us to refrain from issuing a notice of requirements to ASTM F-963 because they said that requiring third party testing would "dramatically and permanently harm small batch toymakers." The commenter sought an indefinite stay of enforcement of the third party testing requirements for ASTM F-963 or delayed publication of the notice of requirements. The commenter cited testing costs, the impact of a third party testing requirement relative to the production of toys for the holiday season, the complexity of ASTM F-963, and congressional consideration of changes to the CPSIA.

Another commenter expressed concern about "potential confusion in the marketplace that may result from a lack of coordination between timing of the effective date" of a third party testing requirement and revisions to the ASTM F-963 toy standard. It recommended that we set the effective date of third party testing requirements to coincide with an expected revision of the toy standard and the date on which the revision would become a mandatory standard (as provided by section 106 of the CPSIA). It also urged us to clarify that, in cases where requirements overlap between versions of the standard, manufacturers do not need to test to demonstrate compliance with both standards. The commenter also sought flexibility on the



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acceptance of retrospective testing because, they explained, delays in our acceptance of third party conformity assessment body accreditation could force "redundant testing" on manufacturers who seek to test to new or revised standards before their effective date.

**Response 38:** With respect to the request to refrain from issuing the notice of requirements or to issue an indefinite stay of enforcement, we note that the notice of requirements with regard to ASTM F-963 was published in the *Federal Register* on August 3, 2011 (76 FR 46598). Thus, the request to refrain from issuing the notice of requirements is moot. We also decline to issue an indefinite stay of enforcement. We note, however, that the notice of requirements, as well as changes resulting from Public Law 112-28, have addressed some of the commenter's concerns. For example, in the notice of requirements, the Commission stated that it would "stay enforcement of the testing and certification requirements of section 14 of the CPSA with respect to toys subject to ASTM F 963 until December 31, 2011" (76 FR at 46601). Public Law 112-28 also provided some relief, specifically to small batch manufacturers, through the creation of a new section 14(i)(4) of the CPSA, which establishes "special rules" for small batch manufacturers that would result in alternative testing requirements or exemptions from third party testing.

As for the second commenter's concern about effective dates, revisions to the toy standard, and potentially "redundant" testing, we are sensitive to potential disruptions and confusion that may result when standards are revised. The notice of requirements acknowledged that we anticipated another revision to ASTM F-963 and invited comment on "how to make the transition in testing requirements as clear and efficient as possible should the standard change" (76 FR at 46599). The enactment of Public Law 112-28 has magnified the need to develop policies with respect to transitions in testing requirements when standards change because Public Law 112-28 revised section 104 of the CPSIA to establish a process for subsequent revisions to voluntary standards for durable infant and toddler products. The resulting process is similar to that under section 106 of the CPSIA (which pertains to toys and ASTM F-963). The issuance of future notices of requirements, relative to revised or changing standards, is complicated further by the fact that, after August 14, 2011, all notices of requirements are subject to the rulemaking requirements in 5 U.S.C. 553 and 601 through 612 of the Administrative Procedures Act.

Nevertheless, we agree that "redundant" testing should not be necessary when the relevant provision in the toy standard has not changed, or not changed materially, between revisions. For example, assume that the 2008 version of the standard imposed a particular test on a toy. If a revised standard, in 2012, imposes the same test on the toy, then we believe it would be unnecessary to require manufacturers to take toys that had been tested to the 2008 standard and retest them to the 2012 standard. Similarly, we believe it would be unnecessary, and contrary to public policy, to expect third party conformity assessment bodies that have been accredited to conduct that particular test under the 2008 standard to cease testing until they are re-accredited to the 2012 standard. These issues, however, are complex and may necessitate greater cooperation or coordination between the CPSC and voluntary standards organizations, manufacturers, third party conformity assessment bodies, and accreditation bodies, and so we will consider such issues further.

**Notice of Requirements for Accreditation of Third Party Conformity Assessment**



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**Bodies to Assess Conformity with the Limits on Phthalates in Children's Toys and Child Care Articles, CPSC-2011-0052, *Federal Register* Notice 76 FR 49286 (August 10, 2011)**

**Comment 39:** One commenter said they appreciated our inclusion of two test methods for phthalates (a revised CPSC test method and a Chinese test method) in the notice of requirements, but they asked us to allow for other "proven internal test methods." The commenter explained that testing laboratories may modify existing test methods or develop their own methods for testing for phthalates so that restricting the notice of requirements to two test methods could result in manufacturers retesting products and testing backlogs at test laboratories. The commenter said that we should allow other methods "as long as it can be shown that these are equivalent to the CSPC methods." The commenter said that equivalency could be shown through side-by-side comparisons with the CPSC method, method validation data, participation in inter-laboratory studies, or other requirements established by the CPSC.

Another commenter supported our inclusion of the revised CPSC test method and Chinese test method, but asked that we consider Health Canada's test method for total phthalate content in PVC products. The commenter said that recognizing the Canadian test method would reduce redundant testing by enabling firms to certify compliance with U.S. and Canadian phthalate requirements using one test.

**Response 39:** We are receptive to considering other test methods and to adding those methods to a notice of requirements. Parties who believe that our accreditation criteria should be expanded to include a specific test method should contact us, or alternatively, use the petition process at 16 CFR part 1051 to ask us to amend this rule (assuming that the draft proposed rule is published and later finalized). The commenter did not indicate a specific test method that we should allow to be used to determine phthalate concentrations. Thus, we cannot determine equivalency to our existing test methods.

With respect to the Canadian test method, we assume that the commenter is referring to *Determination of Phthalates in Polyvinyl Chloride Consumer Products*, Health Canada test method C-34. We share the desire to reduce the testing burden, when possible, through harmonization, and we developed CSPC test method CPSC-CH-C1001-09.3 (and its predecessors) specifically including test method C-34, for determining phthalates, as well as many other methods that were deemed acceptable as optional means of extraction and analysis of the phthalates in samples. Thus, tests by a CPSC-accepted testing laboratory using the C-34 test method are allowed for children's product certification purposes.

**Comment 40:** Two commenters sought clarification about what materials need to be tested for phthalates. One commenter referred to our *Statement of Policy: Testing of Component Parts with Respect to Section 108 of the CPSIA* (dated August 7, 2009) ("Statement of Policy"), noting that the Statement of Policy gave examples of materials that do not normally contain phthalates and would not require testing or certification. The commenter then said that the notice of requirements caused confusion because a joint statement by a majority of the Commissioners indicated that the notice of requirements did not expand the universe of materials or products to be tested or certified and that the Statement of Policy remained in effect, yet the notice of requirements itself did not reflect the Statement of Policy. Thus, the commenter asked us to



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revise the notice of requirements to "specifically list all plastic materials that are known not to contain phthalates, including, but not limited to, those identified in the (Statement of Policy) . . .." The commenter also provided a list of more than 30 plastic materials which it said are known not to contain phthalates.

The second commenter also referred to the Statement of Policy, but they asked that we revise the Statement of Policy to "make it clear . . . that the excluded material list compiled, is not exhaustive and similar, related or other such materials may not require testing and may be added in the future." The commenter said, however, that "it is likely impossible to create an exhaustive list of *all* materials that may not include phthalates and therefore may not require testing" (emphasis in original).

**Response 40:** While we recognize the commenters' desire for greater clarification with respect to materials that may or may not contain phthalates, the principal purpose of a notice of requirements is to establish the criteria under which we will accept the accreditation of a third party conformity assessment body. In this instance, the notice of requirements identified the two test methods to which third party conformity assessment bodies should be accredited, and any information describing the materials that normally do not contain phthalates was intended to provide helpful guidance, rather than establish accreditation criteria. We acknowledge that the Statement of Policy discussed materials or products that are not known to contain phthalates and that the notice of requirements referred to the Statement of Policy and other previous CPSC documents; however, that portion of the notice of requirements was intended to inform interested parties about the prior CPSC documents and to indicate that they remain in effect.

With respect to expanding the list of materials that may or may not contain phthalates and the question of whether such a list should be part of a notice of requirements, we will consider whether additional guidance on materials containing or not containing phthalates should be developed. However, we decline to include such a list in a notice of requirements or the draft proposed rule. Our experience indicates that when a regulation or document attempts to provide a list of examples, the list often is construed as being exhaustive or definitive, resulting in multiple requests to amend the rule or revise the document to add or delete items from the list. Given our scarce resources, and for the reasons mentioned in this paragraph, we do not believe that it would be prudent to include either a list of materials containing phthalates or a list of materials known not to contain phthalates as part of this rulemaking.

**Comment 41:** One commenter discussed Public Law 112-28 and the exception it created for inaccessible component parts containing phthalates. In brief, section 5 of Public Law 112-28 amended section 108 of the CPSIA to create an exclusion for "inaccessible component parts." The commenter sought clear direction from us about "how the phthalate standard will apply to inaccessible components," and they asked that we "immediately amend the Statement of Policy to clarify that inaccessible components are exempt from the phthalate standard and therefore exempt from third party testing."

**Response 41:** We published the Statement of Policy and the notice of requirements before Public Law 112-28 was enacted. Thus, issues concerning implementation of the phthalates provision in Public Law 112-28 and revisions to the Statement of Policy are outside the scope of



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the notice of requirements and the draft proposed rule. Further, the notice of requirements establishes the criteria and process for CPSC acceptance of accreditation of laboratories for testing children's products under section 14 of the CPSA. Determination of which component parts require testing is outside the scope of a notice of requirements.

**Comment 42:** One commenter said that because phthalates are added intentionally to some plastics, paints, and other materials and are not ubiquitous environmental contaminants, manufacturers of products "produced exclusively from materials on the phthalate exclusion list (or other materials not likely to contain phthalates)" are "generally able to be certain that they are not intentionally adding phthalates and that phthalate-containing materials are not present in their factories." The commenter asked that we "explicitly recognize such knowledge as a reasonable basis for certifying compliance" with the phthalates limits and "allow self-certification by such entities."

**Response 42:** We decline to revise the notice of requirements or to draft the rule to incorporate the commenter's suggestion. Section 14(a)(2) of the CPSA is clear that, with respect to children's products, a manufacturer must certify the product based upon testing by a third party conformity assessment body accredited under section 14(a)(3) of the CPSA. Self-certification based upon a manufacturer's knowledge would not be consistent with section 14(a)(2) of the CPSA.

## 6. Miscellaneous Comments

**Comment 43:** One commenter agreed with the proposed notice of requirements for 16 CFR part 1505, *Requirements for Electrically Operated Toys or other Electrically Operated Articles Intended for use by Children*, and 16 CFR § 1500.86(a)(5) (Clacker Balls) and suggested that officials be sent to manufacturer sites (domestic and foreign) to conduct audits to see that the tests are performed properly and to ensure that the manufacturers perform all steps of the tests submitted by them to the accredited agencies.

**Response 43:** The commenter may have misunderstood the notice of requirements. The tests to assess compliance are performed at laboratories, not at manufacturing sites (unless a manufacturing site has a firewalled laboratory). If the commenter is referring to firewalled laboratories or third party laboratories, in general, the CPSC has designated accreditation bodies that are signatories to the ILAC-MRA to conduct accreditation of third party conformity assessment bodies to be accepted by the Commission. ILAC-MRA signatories visit independent and firewalled laboratories during initial assessments and regular reassessments to assess the laboratory's continued compliance with the requirements of ISO/IEC 17025:2005. In every assessment and reassessment, the accreditation body must demonstrate that it has adequately assessed all of the laboratory's technical competencies and management systems competencies (as prescribed in ISO/IEC 17025:2005) associated with its scope of testing.

**Comment 44:** Most notices of requirements included provisions allowing certificates of compliance to be based on testing performed by an accredited third party conformity assessment body prior to the Commission's acceptance of its accreditation. This practice is sometimes



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referred to as allowing "retrospective" testing. In the notices of requirements, the Commission prescribed particular circumstances under which retrospective testing could support a Children's Product Certificate. For example, the Commission stated that the product should be tested by a third party conformity assessment body that was, at the time of product testing, ISO/IEC 17025:2005 accredited by an ILAC-MRA signatory accreditation body; the accreditation scope in effect at the time of testing had to include testing to the regulation or test method identified in the notice; and the Commission placed constraints on how far back in time the retrospective testing could occur. Initially, the Commission did not allow any retrospective testing by firewalled laboratories. Later, the Commission allowed retrospective testing by firewalled laboratories if the firewalled laboratory had already been accepted by an order of the Commission for testing to a test method or regulation specified in an earlier notice of requirements.

A commenter, in response to one of the initial notice of requirements, supported the position of not allowing any retrospective testing by firewalled laboratories. This commenter viewed not allowing any retrospective testing by firewalled laboratories as a way to reduce any possible conflicts of interest and ensure that no undue influence occurred in the certification process.

**Response 44:** We consider that if the Commission has already accepted a laboratory as firewalled, the laboratory has previously shown that it has policies and procedures in place consistent with laboratory independence and impartiality. We will monitor this policy and, if necessary, revise it in future notices of requirements. We note that because retrospective testing issues arise only in the context of the initiation of the third party testing requirement, this NPR does not address retrospective testing.

**Comment 45:** Some commenters argued that the CPSA as amended by the CPSIA does not require third party testing of those children's products that are subject to a regulation of general applicability (e.g., 16 CFR § 1610, *Standard For the Flammability of Clothing Textiles*). In the view of these commenters, the only children's products for which third party testing is required are those children's products subject to a regulation whose reach is limited to children's products (e.g., 16 CFR §§ 1615, 1616, *Standard for the Flammability of Children's Sleepwear*). One commenter stated that the safety of children's products subject to rules of general applicability can be assured via the General Conformity Certificates that are required for non-children's products under section 14(a)(1) of the amended CPSA.

Some of the commenters who disagreed that the amended CPSA requires third party testing of children's products subject to rules of general applicability asserted that, even if the Commission views the text of the statute as requiring third party testing for such products, we should nevertheless use our implementing authority under section 3 of the CPSIA to limit the third party testing requirement to rules of limited applicability – that is, rules applicable solely to children's products. Similarly, one commenter urged the Commission to use authority granted in section 14(b) of the CPSA to "assess the necessity of third party testing on a case-by-case basis."

One commenter argued that we have been inconsistent in describing what is a children's product safety rule. It noted that in the proposed rule on "Testing and Labeling Pertaining to Product Certification," we stated that, "[c]urrently, the rule on children's bicycle helmets is the



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only children's product safety rule that contains requirements for a reasonable testing program." 75 Fed. Reg. 28336, 28348 (May 20, 2010). Because the FFA regulations such as 16 CFR part 1610, *Standard for the Flammability of Clothing Textiles*, contain reasonable testing programs, the commenter asserted that we must not consider FFA regulations to be children's product safety rules. The commenter argued that we should offer the reasonable testing program requirements in 16 CFR part 1610 the same treatment we have afforded to all children's product safety rules with existing reasonable testing programs (i.e., bicycle helmets).

**Response 45:** Section 14(a)(2) of the CPSA requires manufacturers and private labelers of a children's product subject to a children's product safety rule to certify that their children's product complies with the relevant children's product safety rule. Section 14(f)(1) of the CPSA defines "children's product safety rule" as "a consumer product safety rule under this Act 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." 15 U.S.C. § 2063(f)(1).

Thus, the statute defines a children's product safety rule to mean a consumer product safety rule. The Commission has taken the position that the statute requires third party testing to support a certification of a children's product if that children's product is subject to a consumer product safety rule. A "consumer product safety rule" becomes a "children's product safety rule" not when the product subject to the rule is limited to children's products, but rather when the product subject to the rule includes children's products.

With regard to the comment that a General Conformity Certificate would adequately assure the safety of children's products, we again refer to the statute. Section 14(a)(2) of the CPSA requires that a certification based on third party testing is required for "any children's product that is subject to a children's product safety rule." General Conformity Certificates are required for non-children's products and are not required to be based on third party testing. However, Public Law 112-28 does allow small batch manufacturers to use alternative testing requirements once the Commission has identified such testing requirements or they are allowed an exemption if the Commission determines that no alternative testing requirement is available or economically practicable.

As for the comment regarding section 3 of the CPSIA, the statute gives us some latitude in implementing the CPSIA, but it does not authorize us to avoid implementing the statute altogether. Courts have held that an agency's authority to implement a new statute does not encompass avoiding the statutory obligation itself. *See U.S. v. Markgraf*, 736 F.2d 1179, 1183 (7th Cir. 1984) ("An administrative agency cannot abdicate its responsibility to implement statutory standards under the guise of determining that inaction is the best method of implementation."). *See also Friends of the Earth, Inc. v. EPA*, 446 F.3d 140, 145 (D.C. Cir. 2006) (An administrative agency may not avoid the plain language of a statute by asserting that its preferred approach would be better policy, nor can a court "set aside a statute's plain language simply because the agency thinks it leads to undesirable consequences in some applications.")

Finally, the comment regarding inconsistency in determining what a children's product safety rule was submitted in response to the notice of requirements for clothing textiles, which was



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published on August 18, 2010 – several months after the publication of the proposed rule on "Testing and Labeling Pertaining to Product Certification." The publication of the clothing textiles notice of requirements clearly indicates that the Commission decided the clothing textiles standard is a children's product safety rule. In fact, the Commission reaffirmed its position when it revised the clothing textiles notice of requirements on April 22, 2011. *See* 76 FR 22608. The Commission also issued other FFA-related notices of requirements subsequent to the publication of the proposed rule on "Testing and Labeling Pertaining to Product Certification." *See, e.g.*, 75 FR 42311 (July 21, 2011). Accordingly, we consider the quoted sentence in the preamble to the proposed rule on "Testing and Labeling Pertaining to Product Certification" to be in error because, as shown by subsequent CPSC actions, FFA regulations may be children's product safety rules and the subject of a notice of requirements.

**Comment 46:** Some commenters expressed concern over the cost of third party testing. One commenter noted that, in particular for regulations under the Flammable Fabrics Act (FFA), 15 U.S.C. 1191-1204, the tests involve hazards, which could result in "required testing of additional samples, longer lead times for testing, and added expenses." Some commenters urged a thorough cost-benefit analysis of the CPSC's rules related to testing and certification, component parts, and/or the notices of requirements. Some of these commenters argued that the additional cost of third party testing carries no benefit because third party testing does not enhance product safety.

Another commenter stated that "[r]equiring third party testing further triggers compliance" with requirements under the two recent notices of proposes rulemaking (NPRs), *Testing and Labeling Pertaining to Product Certification* (to be codified at 16 CFR § 1107) (75 Fed. Reg. 28336 (May 20, 2010) and *Conditions and Requirements for Testing Component Parts of Consumer Products* (to be codified at 16 CFR § 1109) (75 Fed. Reg. 28208 (May 20, 2010)). The commenter opined that "these regulatory burdens dilute the focus from … ensuring that the product is safe and compliant with regulatory standards."

**Response 46**: We are sensitive to testing cost concerns and note that Public Law 112-28 expressly required us to seek public comment on opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation and listed seven issues for public comment. In the *Federal Register* of November 8, 2011 (76 FR 65956), we invited comment on the seven issues and on opportunities to reduce the cost of third party testing requirements. The comment period for the notice ended on January 23, 2012, and we will address the comments in a separate proceeding.

However, with respect to conducting cost-benefit analyses for the rules identified in the comment, the CPSIA did not require us to conduct such analyses. We also note that we issued final rules on "Testing and Labeling Pertaining to Product Certification" (76 FR 69482 (November 8, 2011)) and "Conditions and Requirements for Relying on Component Part Testing or Certification, or Another Party's Finished Product Testing or Certification, to Meet Testing and Certification Requirements," (76 FR 69546 (November 8, 2011)). The preamble to the final rule on "Testing and Labeling Pertaining to Product Certification" summarized and responded to a similar comment on cost-benefit analyses (see 76 FR at 69484 (comment 2 and response)).



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Yet, with respect to the comment that a notice of requirements somehow "triggers compliance" with these two rules, we disagree. A notice of requirements establishes the criteria under which we will accept the accreditation of a third party conformity assessment body to test children's products for compliance to a children's product safety rule. Section 14(a)(3)(A) of the CPSA states that the third party testing requirement applies to any children's product manufactured more than 90 days after we have established and published the notice of requirements. Section 14(i)(2) of the CPSA creates the obligation for continuing testing. In any event, the final rule on "Testing and Labeling Pertaining to Product Certification" does not become effective until February 8, 2013. The final rule on "Conditions and Requirements for Relying on Component Part Testing or Certification, or Another Party's Finished Product Testing or Certification, to Meet Testing and Certification Requirements," while effective on December 8, 2011, pertained to the conditions and requirements under which passing component part test reports, certification of component parts of consumer products, or finished product testing or certification procured or issued by another party, can be used to meet, in whole or in part, the testing and certification requirements of sections 14(a) and 14(i) of the CPSA. As such, component part testing as described by that final rule is voluntary, rather than mandatory.

**Comment 47:** One commenter asserted that requiring manufacturers of children's clothing textiles subject to the FFA regulations at 16 CFR part 1610, *Standard for the Flammability of Clothing Textiles*, to issue certifications based on third party testing "bypasses the entire FFA rulemaking process." The commenter argued that section 4(b) of the FFA requires that regulations or amendments to regulations be based on certain findings which the CPSC has not made, and argued that we have effectively amended part 1610 to require third party testing of children's clothing textiles. The commenter stated that when the test methods in part 1610 were promulgated, and "[i]n accordance with Section 4(b) of the FFA," the CPSC hosted several meetings attended by industry and testing representatives who worked cooperatively to develop test methods that the representatives and CPSC agreed were appropriate to assess compliance with the flammability standards. The commenter stated that the third party testing requirements, along with the requirements proposed in the testing and labeling and component parts NPRs, "entirely undermines this cooperative effort."

This commenter also asserted that the testing requirements in part 1610 are sufficient for children's products subject to those regulations, and that requiring third party testing does not provide additional assurance of the product's ability to pass the applicable product safety standard. The commenter asked the Commission to hold a public meeting if we do not agree that the testing regime under part 1610 is sufficient for the industry to demonstrate compliance with the standard.

**Response 47:** The purpose of the *Standard for the Flammability of Clothing Textiles* is to keep dangerously flammable textiles and garments made of these textiles out of commerce. The standard provides methods of testing the flammability of clothing and textiles intended to be used for clothing by classifying fabrics into 3 classes of flammability based on their speed of burning. The CPSC has not amended 16 CFR part 1610 by implementing the third party testing requirements of section 14 of the CPSA.



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Section 4 of the FFA prescribes the process for promulgating a regulation under that statute. Section 4(b) of the FFA requires, in relevant part, that each FFA "standard, regulation, or amendment thereto… be based on findings that such standard, regulation, or amendment thereto is needed to adequately protect the public against unreasonable risk of the occurrence of fire leading to death, injury, or significant property damage, is reasonable, technologically practicable, and appropriate." 15 U.S.C. 1193(b). Section 4(b) of the FFA does not mandate consultation with industry. It requires findings in support of an FFA regulation. The fact that industry representatives cooperated with the CPSC when part 1610 was promulgated does not mean that the CPSC, in implementing section 14(a)(3)(B)(vi) of the CPSA, must host meetings before issuing a notice of requirements. We therefore decline the commenter's suggestion to hold a public meeting on this matter.

With regard to the commenter's assertion that tests conducted under part 1610 sufficiently assure compliance with the standard and thus third party testing is not necessary, we note that, absent the CPSIA, a manufacturer of a clothing textile was not required to conduct the test prescribed by part 1610 at all. If the manufacturer wished to issue an FFA guaranty that the product complied with part 1610, then the manufacturer had to conduct the tests prescribed by part 1610, but that testing was purely optional.

**Comment 48**: One commenter stated that the Commission should have allowed 60 days for the comments to be submitted in response to the notices of requirements, noting that the TBT Committee has recommended 60 day comment periods. This commenter also observed that the notice of requirements was effective on publication, thus there was no opportunity to comment prior to the notice taking effect.

**Response 48:** The notices of requirements that invited public comments have all contained a 30-day comment period and have all been effective upon publication. Nevertheless, this proposed rule provides a 75-day comment period. The public may comment on all aspects of the proposal, even those parts that were previously contained in the notices of requirements.

## 7. Comments Considered Out of Scope

Several commenters raised issues that were not present in the notices of requirements and are not directly relevant to this proposed rule; such issues, therefore, are outside the scope of this rulemaking.

**Comment 49:** One commenter recommended that the Commission address the procedures for filing certificates of compliance, including who "owns" the certificate and what is the required retention period for certificates.

**Response 49:** This issue is outside the scope of this rulemaking because neither the notices of requirements, nor this proposed rule, concern the requirements or processes for certificates of compliance. We note that the recently issued final rule, *Testing and Labeling Pertaining to Product Certification* (76 FR 69482 (November 8, 2011) (to be codified at 16 CFR part 1107)),



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addresses the length of time manufacturers are required to keep records of certificates of compliance.

**Comment 50:** One commenter suggested that the CPSC specify what will be considered "sufficient samples" of a children's product to submit for third party testing. The commenter was concerned that different laboratories would require different sampling schedules, and they suggested that manufacturers might choose to use laboratories that require the least onerous sampling schedule. The commenter recommended that the CPSC prescribe a specific testing schedule based on a statistical scheme for sample product runs of the children's products. The commenter also suggested that the number of samples selected for testing should be based on the size and duration of the production run of the children's product.

**Response 50:** The proposed rule is limited to establishing the requirements for conformity assessment bodies in order for their test results to be used for children's product certification purposes. The certifier, not the laboratory, determines what constitutes a sufficient number of samples to test for certification. The recently issued final rule on *Testing and Labeling Pertaining to Product Certification* (76 FR 69482 (November 8, 2011) (to be codified at 16 CFR part 1107)), addresses sample size issues to a certain extent, and we also issued a proposed rule pertaining to "representative samples" (76 FR 69586 (November 8, 2011)) pursuant to Public Law 112-28.

**Comment 51:** One commenter stated: "component or raw material testing is another major concern," and they urged that "allowing for reasonable component testing is a critical need to avoid a crushing financial burden on small businesses."

**Response 51:** The scope of this rulemaking is limited to the requirements related to the accreditation of third party conformity assessment bodies. Whether, and under what circumstances, component parts of children's products may be third party tested separately in support a certificate of compliance is not related to the criteria and process for CPSC acceptance of the accreditation of third party conformity assessment bodies. On November 8, 2011, the Commission published in the *Federal Register* a final rule, *Conditions and Requirements for Relying on Component Part Testing or Certification, or Another Party's Finished Product Testing or Certification, to Meet Testing and Certification Requirements* (76 FR 69546 (November 8, 2011), codified at 16 CFR part 1109), which should address the commenter's concerns.

**Comment 52:** Some commenters described their opinions concerning whether third party testing of children's products for lead content should be required. Overall, the commenters supported third party testing in this context.

**Response 52:** Section 101 of the CPSIA established the lead content limits for children's products. Section 14(a)(2)(A) of the CPSA requires manufacturers of children's products to submit samples of a children's product to a third party conformity assessment body for testing as a basis for certifying the children's product. These comments refer to the statutory requirements and are beyond the scope of this proposed rulemaking.



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**Comment 53:** In response to the notice of requirements for accreditation of third party conformity assessment bodies to assess conformity of youth products under the CPSC regulation on all-terrain vehicles (ATVs) (16 CFR part 1420), one commenter urged that children younger than the age at which one can legally drive traditional motor vehicles should not be allowed to operate ATVs. In the view of this commenter, ATVs have become a serious public health concern for children. The commenter described study findings and statistics in support of his view.

**Response 53:** The notice of requirements related to ATVs provided the criteria and processes for CPSC acceptance of the accreditation of laboratories that will be able to conduct the third party tests of youth ATVs that may support manufacturers' certificates of compliance with 16 CFR part 1420. Therefore, the question of whether children should be allowed to operate ATVs is beyond the scope of the ATV notice of requirements and the draft proposed rule.

**Comment 54:** Several commenters remarked on the cost of complying with the lead content requirements in the context of small businesses selling handcrafted items. One commenter remarked that handcrafted, one-of-a-kind items cannot each be destructively tested. The commenter suggested that the CPSC regulations mirror California's Lead-Containing Jewelry Law, AB 2901. Another commenter asked if the regulations had exceptions to the testing requirements. Another commenter stated that the testing costs will tend to decrease consumer options because small manufacturers will not be able to stay in business. This commenter's main concern was that all "units" of children's items must be tested for lead content and phthalates, and that relying on testing by suppliers is not sufficient. The commenter offered the following suggestions:

1. Waive the testing requirements for small-volume manufacturers, such as those with less than $1 million in revenue.
2. If a waiver is not possible, provide free testing to small businesses that produce children's products.
3. Allow third party certification of components from manufacturers to be used as a basis for a finished product certificate.

**Response 54:** This scope of the draft proposed rule is limited to the requirements related to the accreditation of third party conformity assessment bodies. This rulemaking does not address the requirements related to the testing and certification of consumer products. Therefore, these comments are out of scope for this proposed rule.

Additionally, one provision in PL 112-28 directs the CPSC to seek public comment on seven specific issues, including:

- the extent to which modification of the certification requirements may have the effect of reducing redundant third party testing by, or on behalf of, two or more importers of a product that is substantially similar or identical in all material respects;

- the extent to which products with a substantial number of different components subject to third party testing may be evaluated to show compliance with an applicable rule, ban,



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standard, or regulation by third party testing of a subset of such components selected by a third party conformity assessment body;

- the extent to which manufacturers with a substantial number of substantially similar products subject to third party testing may reasonably make use of sampling procedures that reduce the overall test burden without compromising the benefits of third party testing; and

- other techniques for lowering the cost of third party testing, consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

The Commission has published a *Federal Register* notice seeking public comment on issues regarding reducing the testing burden for children's product certifiers. *See Application of Third Party Testing Requirements; Reducing Third Party Testing Burdens*, (76 FR 69596 (November 8, 2011)). PL 112-28 also requires us to review the public comments, and it states that we may prescribe new or revised third party testing regulations if we determine that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.

**Comment 55:** One commenter raised concerns that the third party testing requirements would create a competitive advantage for the larger firms and drive many small businesses out of the market. The commenter recommended that the law (presumably the CPSIA) be amended to focus on manufacturers directly linked to the production of unsafe products for children and penalize them as opposed to the small business community.

**Response 55:** The commenter may have misunderstood the purpose of a notice of requirements. A notice of requirements establishes the accreditation requirements for laboratories to test for compliance to specific rules, bans, standards, or regulations, and it does not establish requirements for manufacturers, other than establishing a date by which children's products must be certified based on third party testing results. Therefore, regarding statutory amendments, the effects of third party testing on small businesses, and penalties for manufacturers, this comment is out of the scope of this proposed rule.

As discussed in the response to Comment 45, the Commission has published a *Federal Register* notice seeking public comment on issues regarding reducing the testing burden for children's product certifiers. Further, PL 112-28 created a new section 14(i)(4) of the CPSA to provide for special rules for small batch manufacturers. The provision contemplates the possible development of alternative testing requirements for "covered products" made by "small batch manufacturers," and it defines "covered product" and "small batch manufacturer." The provision also provides for possible exemptions of small batch manufacturers from the third party testing requirements, and it imposes certain limits on third party testing requirements.



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**TAB B: Initial Regulatory Flexibility Analysis for a Proposed Rule Establishing Requirements for Third Party Conformity Assessment Bodies**

**TAB B**



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

**Memorandum**

Date: January 5, 2011

TO: Randy Butturini
Office of Hazard Identification and Reduction

THROUGH: Gregory B. Rodgers, Ph.D.
Associate Executive Director
Directorate for Economic Analysis

Deborah V. Aiken, Ph.D.
Senior Staff Coordinator
Directorate for Economic Analysis

FROM: Robert Franklin
Economist
Directorate for Economic Analysis

SUBJECT: Initial Regulatory Flexibility Analysis for a Draft Proposed Rule Establishing Requirements for Third Party Conformity Assessment Bodies

This memorandum provides an initial regulatory flexibility analysis of a draft proposed rule that would establish requirements for third party conformity assessment bodies (laboratories). The Regulatory Flexibility Act (RFA) requires that draft proposed rules be reviewed for their potential economic impact on small entities, including small businesses. Section 603 of the RFA requires that Commission staff prepare an initial regulatory flexibility analysis and make it available to the public for comment when the notice of proposed rulemaking (NPR) is published. The initial regulatory flexibility analysis must describe the impact of the draft proposed rule on small entities and identify any alternatives that may reduce the impact. Specifically, the initial regulatory flexibility analysis must contain:

1. a description of the reasons why action by the agency is being considered;
2. a succinct statement of the objectives of, and legal basis for, the draft proposed rule;
3. a description of, and where feasible, an estimate of the number of small entities to which the draft proposed rule will apply;
4. a description of the projected reporting, recordkeeping, and other compliance requirements of the draft proposed rule, including an estimate of the classes of small entities subject to the requirements and the type of professional skills necessary for the preparation of reports or records; and
5. an identification, to the extent possible, of all relevant federal rules that may duplicate, overlap, or conflict with the draft proposed rule.



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Additionally, the initial regulatory flexibility analysis must contain a description of any significant alternatives to the draft proposed rule that accomplish the stated objectives of the draft proposed rule while reducing the economic impact on small entities.

## Reasons the Commission Is Considering the Draft Proposed Rule

Section 14(a)(2) of the Consumer Product Safety Act (CPSA), as amended by the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires that any children's product that is subject to a children's product safety rule be tested by an accredited third party conformity assessment body. The draft proposed rule would codify the requirements for the accreditation of the third party laboratories that assess conformity with children's product safety rules, the process for a laboratory to discontinue voluntarily providing the CPSIA-required third party testing, and the procedures by which the Commission may suspend or withdraw its acceptance of the accreditation of a laboratory.

(In a separate but related rulemaking, on August 13, 2009, the Commission proposed a rule that would establish requirements for the periodic audit of laboratories. An initial regulatory flexibility analysis of that proposal is included in the *Federal Register* notice (74 FR 40784)).

## Objectives of and Legal Basis for the Draft Proposed Rule

The primary objective of the draft proposed rule is to codify the requirements pertaining to laboratories, including the requirements and processes related to obtaining U.S. Consumer Product Safety Commission (CPSC) acceptance of their accreditation. This will make it easier for interested parties to locate the application requirements because, from October 2008 to the present, the Commission has issued various notices of requirements pertaining to specific regulations or test methods. This rule would result in a compilation of the requirements in a single location.

The draft proposed rule would also establish the grounds for, and procedures by which, the Commission could suspend or withdraw its acceptance of the accreditation of a laboratory. Additionally, where the required test method or methods are not specified in a children's product safety rule, provisions in the draft proposed rule would establish the test method(s) that laboratories must use to assess conformity with the particular rule.

The legal bases of the rule are found in section 14 of the CPSA, as amended by section 102 of the CPSIA, and section 3 of the CPSIA. Section 3 of the CPSIA grants the CPSC the authority to issue regulations to implement the CPSIA and the amendments made by the CPSIA. Section 14(a)(3) of the CPSA provides the authority for the CPSC to establish the accreditation requirements for third party conformity assessment bodies. Section 14(e) of the CPSA provides the authority for the CPSC to suspend and/or withdraw the acceptance of the accreditation of a third party conformity assessment body.



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## Description and Estimate of the Number of Small Entities to Which the Draft Proposed Rule Would Apply

The draft proposed rule would apply to laboratories that intend to offer their testing services to manufacturers and private labelers of children's products for purposes of supporting a certification that the products conform to applicable children's product safety rules. The draft proposed rule would not impose any requirements on laboratories that do not intend to provide these services.

Although there are 5,041 firms in the United States[16] classified as "testing laboratories" (NAICS code 54138), only a small subset of these laboratories are expected to provide third party conformity assessments of children's products for purposes of section 14 of the CPSA. As of August 29, 2011, the CPSC has accepted the accreditation of 87 laboratories located in the United States.[17] This number could increase, somewhat, over the next year or so, as the remaining notices of requirements for accreditation are issued and the stays of enforcement of the requirements for third party testing that the Commission issued pending clarification of the regulations and testing requirements are lifted.

According to criteria established by the U.S. Small Business Administration (SBA), a testing laboratory is considered small if its revenue is less than $12 million a year. Of the laboratories located in the United States with CPSC-accepted accreditations, 22 are owned by large U.S.-based companies, and 12 are owned by large, foreign-based companies. Fifty-three laboratories (61 percent of the laboratories with U.S. locations) could be small businesses, according to the criteria established by the SBA.

## Projected Reporting, Recordkeeping, and Other Compliance Accreditation Requirements

The draft proposed rule would establish the requirements for CPSC acceptance of the accreditation of a laboratory. Therefore, the rule applies only to laboratories that intend to provide third party testing of children's products in support of the certifications required by section 14(a)(2) of the CPSA. The draft proposed rule would not impose any requirements on laboratories that do not intend to provide these services.

The draft proposed rule would require that, as a condition of CPSC acceptance of their accreditation, the laboratory must be accredited to the International Organization for Standardization/International Electrotechnical Commission Standard ISO/IEC 17025:2005–

[16] Based on 2007 data from the U.S. Census Bureau compiled by the U.S. Small Business Administration (available at: http://www.sba.gov/advo/research/us_rec07.txt).

[17] The CPSC has recognized the accreditation of at least 346 testing laboratories worldwide. However, most of the laboratories are located in other countries. Only domestic firms are relevant for purposes of the RFA.



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*General requirements for the competence of testing and calibration laboratories*. The accreditation must be made by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation–Mutual Recognition Arrangement (ILAC-MRA). The scope of the accreditation must list the specific regulations or test methods contained in the product safety rules or in the notices of accreditation requirements that are required as the basis for certifying that children's products conform to the applicable product safety rules. This aspect of the draft proposed rule simply would codify the existing conditions for CPSC acceptance of accreditation that have been stated in every notice of requirements published previously by the Commission.

The draft proposed rule would require that laboratories provide the Commission with their accreditation and scope documents. These records normally are generated during the accreditation process and can be provided to the CPSC electronically. The application for CPSC acceptance of accreditation would be accomplished using CPSC Form 223. This is an electronic application form, and all of the information that is required to be supplied on the form should be readily available to the laboratory. The professional skills required on Form 223, and the related documents, pertain to skills that a competent, accredited laboratory would be expected to possess.

The draft proposed rule would also require laboratories that are managed, owned, or controlled by a manufacturer or private labeler (or "firewalled" laboratories) to submit additional materials. The purpose of the additional documents is to provide evidence that, despite the fact that the laboratory is managed, owned, or controlled by a manufacturer or private labeler, the testing process is independent of that relationship. The acceptance of a firewalled laboratory's accreditation would occur by Commission order only, after the Commission has reviewed the documents and made certain findings. The additional documents that "firewalled "laboratories musts provide include:

1. The third party conformity assessment body's established policies and procedures that explain:
    a. how test results are protected from undue influence by the manufacturer, private labeler, or other interested party;
    b. that the CPSC will be notified immediately 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; and
    c. that allegations of undue influence may be reported confidentially to the CPSC;
2. Training documents, including a description of the training program content, showing how employees are trained annually on the policies and procedures described in subparagraph (1) above;
3. Training records listing the staff members who received the required training identified in subparagraph (2) above. The records must include training dates, location, and the name and title of the individual providing the training;
4. An organizational chart(s) of the third party conformity assessment body that includes the names of all third party conformity assessment body personnel, both temporary



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and permanent, and their reporting relationship within the third party conformity assessment body;
5. An organizational chart(s) of the broader organization, which identifies the reporting relationships of the third party conformity assessment body within the broader organization (using both position titles and staff names); and
6. A list of all third party conformity assessment body personnel with reporting relationships outside of the third party conformity assessment body. The list must identify the name and title of the relevant conformity assessment body employee(s) and the names, titles, and employer(s) of all individuals outside of the third party conformity assessment body to whom they report.

The draft proposed rule would also establish additional requirements for Commission acceptance of the accreditation of laboratories that are owned or controlled, in whole or in part, by a government. Laboratories that are owned or controlled by foreign governments do not meet the definition of a small entity under the Regulatory Flexibility Act. As of August 1, 2011, the CPSC has approved one application from a domestic governmental laboratory.

In addition to the baseline requirements (accreditation to ISO/IEC 17025:2005 by a signatory to the ILAC-MRA and submission of the submission of CPSC Form 223, and related documents to the CPSC), laboratories that are owned or controlled by a government entity must provide additional information and materials to the CPSC so that the CPSC can determine whether the laboratory satisfies the criteria for the acceptance of the accreditation of a governmental laboratory. The additional information and materials are:

1. A description illustrating the relationships with other entities, such as government agencies and joint venture partners. The description may be in the form of a diagram;
2. Responses to questionnaires provided by the CPSC to a governmental third party conformity assessment body applicant, along with a separate questionnaire for the affiliated government entity to complete;
3. A copy of an executed memorandum addressing undue influence.
    a. The memorandum must be:
        i. addressed to all staff of the third party conformity assessment body;
        ii. drafted on company letterhead;
        iii. issued by senior management;
        iv. written in the primary language used for business communications in the area where the third party conformity assessment body is located; and if it is not English, then the laboratory must provide an English translation;
        v. displayed prominently for staff to reference for as long as the accreditation of the third party conformity assessment body is accepted by the CPSC; and
    b. The memorandum must state:
        i. that the policy of the laboratory is to reject undue influence over its testing results by any outside person or entity, regardless of that person or entity's affiliation with any organization;



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ii. that employees are required to report immediately to the supervisor or any other official designated by the third party conformity assessment body about any attempts to gain undue influence; and
iii. that the third party conformity assessment body will not tolerate violations of the undue influence policy.

4. Attestation. A senior officer of the governmental third party conformity assessment body who has the authority to make binding statements of policy on behalf of the third party conformity assessment body, must attest to the following:
   a) that the third party conformity assessment body seeks acceptance as a governmental third party conformity assessment body under the CPSC's program of requirements for the testing of children's products;
   b) that the official intends that this attestation is to be considered in support of any and all applications made by this third party conformity assessment body for acceptance of its accreditation by the CPSC, including future applications related to additional CPSC rules and/or test methods;
   c) the attestation, and any other document submitted in support of the application, is accurate in its representation of current conditions or policies at the third party conformity assessment body, to the best of the official's knowledge, information, and/or belief. The official affirms that the information in the attestation, and any other document submitted in support of the application, will be understood by the CPSC as continuing in its accuracy in every respect, until and unless notice of its revocation by an authorized officer of the third party conformity assessment body is received by the CPSC. The official understands further that acceptance by the CPSC carries with it the obligation to comply with 16 CFR part 1112, in order to remain on the CPSC's list of accepted third party conformity assessment bodies. The attestation is submitted as a condition of acceptance of this laboratory by CPSC as a governmental third party conformity assessment body.
   d) The word "government" in the attestation refers to any government (*i.e.*, central, provincial, or municipal) in this third party conformity assessment body's country or administrative area and includes state-owned entities, even if those entities do not carry out governmental functions.
   e) With regard to consumer products to be distributed in commerce in the United States and subject to CPSC third party testing requirements, this third party conformity assessment body does not receive and will not accept from any governmental entity, treatment that is more favorable than that received by other third party conformity assessment bodies in the same country or administrative area, which have been accepted as accredited for third party testing by CPSC. More favorable treatment includes, but is not limited to, authorization to perform essential export-related functions, while competing CPSC-accepted laboratories in the same country or administrative area are not permitted to perform those same functions.
   f) With regard to consumer products to be sold in the United States and subject to CPSC third party testing requirements, this third party conformity assessment body's testing results are not accorded greater weight by any government entity that may be evaluating such results for export control purposes, compared to other



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third party conformity assessment bodies in the same country or administrative area, which have been accepted as accredited for third party testing by CPSC.

g) The third party conformity assessment body has an expressed policy, known to its employees, that forbids attempts at undue influence over any governmental authorities on matters affecting its operations.
h) When a governmental third party conformity assessment body is owned or controlled by a governmental entity that also has any ownership or control over consumer product production, the senior officer of the applicant third party conformity assessment body must attest that the third party conformity assessment body will not conduct CPSC tests in support of a Children's Product Certificate for products for export to the United States that have been produced by an entity in which that governmental entity holds such ownership or control, until it has applied for, and been accepted by, the Commission as a dual-governmental, firewalled third party conformity assessment body.

There are no fees payable to the CPSC associated with applying for CPSC acceptance of accreditation. The amount of time required to complete Form 223 and submit the related documents to the CPSC is less than 1 hour for most laboratories. The amount of time could be somewhat higher for firewalled and governmental laboratories, which are required to submit additional materials.

The costs of obtaining ISO/IEC 17025:2005 accreditation by an ILAC-MRA accreditation body typically include: a one-time application fee, an annual fee for each field in which the laboratory is accredited, and an assessment fee. These charges will vary somewhat among accreditation bodies; but representative charges, based on the published fee schedule of one accreditation body are: $800 for the initial application fee, $1,300 per field for the annual fee, and $135 per hour per assessor. A representative of an accreditation body stated that assessments can take from 1 to 5 days, with 2.5 days being about average. The laboratory will also probably be charged for the travel, lodging, and meals of the assessor(s) conducting the assessment.

Based on the above discussion, a laboratory seeking accreditation in one field of testing can expect to pay around $4,800 in fees, plus the travel, lodging, and meal expenses. The cost could be higher if the assessment takes more than 2.5 days. If the laboratory is seeking accreditation in more than one field, such as chemical and mechanical testing, the cost will be higher because there will be additional fees for each field, and the assessment will likely take more time. There will be some cost to the laboratory in terms of laboratory personnel, who must prepare documents for the assessment and also work with the assessors during the assessment.

If a laboratory is already accredited to ISO/IEC 17025:2005 by an accreditation body that is a signatory to the ILAC-MRA, and the laboratory is seeking simply to expand its scope of accreditation to include specific CPSC tests, then the cost to the laboratory will be substantially less. In some cases, if the scope already includes closely related tests, the accreditation body might be willing to add the CPSC tests to the scope without additional charges. In other cases, there could be some administrative or assessment charges, but these would be less than would be required for a full initial assessment.



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For most product safety rules, the required test methods were specified in the regulation that established the safety rule. However, in the case of the requirements limiting the lead content of children's products, the test methods are specified in the notices of requirements for accreditation, which are one of the subjects of the draft proposed rule. The draft proposed rule would expand the list of acceptable test methods for measuring lead content to include the use of X-ray fluorescence (XRF) spectrometry for measuring the lead content of glass materials, crystals, and certain metals. Because XRF can be significantly less expensive than other approved test methods, such as inductively coupled plasma or atomic absorption spectrometry, this provision could lower laboratories testing costs. Some or all of the cost reductions could be passed onto the consumer product manufacturers in the form of lower testing prices.

ISO/IEC 17025:2005 has requirements for the periodic reassessment of accredited laboratories. The Commission is addressing these requirements in the separate, but related, rulemaking on periodic audits.

### Recordkeeping Requirements

The draft proposed rule would require that third party conformity assessment bodies maintain certain records associated with the testing conducted for purposes of section 14 of the CPSA for at least 5 years. The retention requirement would apply to all test reports and technical records, records related to subcontracted tests, and customer reports, if different from the test record, if they are related to tests conducted for purposes of section 14 of the CPSA. Additionally, all internal documents describing testing protocols and procedures (such as instructions, standards, manuals, guides, and reference data) that have applied to a test conducted for purposes of section 14 of the CPSA must be retained for a period of at least 5 years from the date such test was conducted. The cost of storing the record for 5 years could be less than $200, if the records are stored in electronic format; but the costs could be several thousand dollars, or more, if stored on paper in commercial warehouse space.

Upon request by the CPSC, the third party conformity assessment body must make any and all of the records required by this section available for inspection, either in hard copy or electronic form, within 48 hours. If the records are not in the English language, the third party conformity assessment body must make copies of the original (non-English language) records available to the CPSC within 48 hours, and they must make an English translation of the records available to the CPSC within 30 calendar days of the date the CPSC requested an English translation.

### Grounds and Procedures for Adverse Actions Against Laboratories

The draft proposed rule would also establish the grounds and procedures that the CPSC would use to take adverse actions against a laboratory. Adverse actions include: denying the acceptance of the laboratory's accreditation, suspending the acceptance of the laboratory's accreditation for a period of time, or withdrawing the acceptance of the laboratory's accreditation on a temporary or permanent basis. Grounds for adverse actions include: failing to comply with



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CPSC requirements, failing to cooperate with the CPSC during an investigation, and allowing a manufacturer or other party to exert undue influence on the testing process. Among other things, the rule would establish the requirements for the notices that the CPSC must provide to laboratories before taking adverse actions, the time limits for responses by the laboratories to the notices, and the appeal rights of the laboratories regarding proposals of adverse action.

During an investigation of an allegation, some costs would be incurred by the laboratory for actions such as making employees available for interviews with CPSC investigators and providing the CPSC with documents or records requested by the investigators, and allowing CPSC investigators access to its facilities. The costs incurred would depend upon the scope of the investigation. If the CPSC proposed an adverse action against the laboratory, the laboratory could incur some cost in preparing a reply to the notice, if the laboratory chooses to reply. The number of investigations of laboratories that the CPSC will open is not known.

### Summary

Laboratories that intend to provide the third party testing services required by the CPSIA will incur some costs to obtain CPSC acceptance of their accreditation. The costs would be low for laboratories that are already accredited to ISO/IEC 17025:2005 by a body that is an ILAC-MRA signatory. If the laboratory is not already accredited to ISO/IEC 17025:2005 by an ILAC-MRA signatory, it can expect to incur fees of around $4,800. The fees could be higher if the laboratory sought accreditation in more than one field of testing or the assessment took more than 2.5 days. There will also be some cost to the laboratory to prepare documents for the assessment and to work with the assessors. If the CPSC opened an investigation of the laboratory, the laboratory would likely incur some costs in connection with the investigation. The proposed rule would require that laboratories maintain certain records for 5 years, which could also add to a laboratory's cost, depending upon how it maintains the records.

As noted, the requirements would apply only to those laboratories that intend to provide the third party testing services for purposes of section 14 of the CPSA. The only laboratories that are expected to provide such services are those that anticipate receiving sufficient revenue from providing the mandated testing to justify accepting the requirements as a business decision. Laboratories that do not expect to receive sufficient revenue from these services to justify accepting these requirements would not be expected to pursue accreditation for this purpose. Therefore, one would not expect the requirements to have a significant adverse impact on a substantial number of laboratories.

## Federal Rules that Duplicate, Overlap, or Conflict with the Draft Proposed Rule

Commission staff has not identified any federal rules that duplicate, overlap, or conflict with the proposed rule.



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## Significant Alternatives Considered

The Regulatory Flexibility Act (RFA) directs agencies to describe significant alternatives to the draft proposed rule that would reduce the significant economic impacts on small entities and at the same time accomplish the agency's objectives. CPSC staff considered two alternatives to provisions in the draft proposed rule. One alternative was for the CPSC to accept the accreditation of laboratories that had been accredited by bodies other than just those that are signatories to the ILAC-MRA. The second alternative involved accepting X-ray fluorescence (XRF) spectrometry test methods for determining lead content.

## Accepting Accreditations by Bodies that Are Not ILAC-MRA Signatories

Comments were received in response to several notices of requirements that the CPSC should also accept the accreditation of laboratories that had been accredited by organizations or accreditation bodies that are not signatories to the ILAC-MRA. Some of the accreditation bodies not affiliated with the ILAC-MRA include: the American Industrial Hygiene Association (AIHA), the National Lead Laboratory Accreditation Program (NLLAP), the National Environmental Laboratory Accreditation Conference (NELAC), and accreditation bodies that are members of the National Cooperation for Laboratory Accreditation (NACLA).

If the CPSC accepted the accreditation of laboratories that were accredited by these other organizations, it would reduce the cost of laboratories accredited by bodies that are not ILAC-MRA signatories in obtaining CPSC acceptance. Under the draft proposed rule, to gain CPSC acceptance of their accreditation, these laboratories would have to seek additional accreditation by a body that is a signatory to the ILAC-MRA. It is not known how many laboratories that are accredited by non-signatories to the ILAC-MRA intend to offer conformity assessment testing services to manufacturers or private labelers of children's products.

CPSC staff recognizes there are other laboratory accreditation organizations or accreditation body cooperatives and that some of these organizations may adhere to similar rules and standards as those established in the ILAC-MRA signatory program. However, CPSC designations to such organizations would not meet all of the objectives that the CPSC had in mind when it established accreditation by a body that was a signatory to the ILAC-MRA as a baseline accreditation requirement. The CPSC sought to designate a program that operated and was accepted on a broad multinational level and that could bring on board immediately a large number of accreditation bodies and avoid designating accreditation programs or entities that were recognized only in specific regions, nations, or localities. In the absence of establishing conditions for accreditation bodies, any person or entity can claim to be able to accredit laboratories to ISO/IEC 17025:2005 regardless of their qualifications to do so. It should also be noted that the AIHA, one of the suggested alternative accreditation bodies, is now signatory to the ILAC-MRA.



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## Alternative Test Methods for Lead

The CPSC has received a number of requests to allow more extensive use of XRF analysis in meeting the third party test requirements because XRF analysis is significantly less expensive than the other test methods for lead content testing. Based on its continuing research of testing methods, the Commission has approved the use of certain XRF methods for determining the lead content of homogenous polymer components and paints, and the draft proposed rule would further allow the use of certain XRF methods for determining the lead content of glass materials, crystals and certain metals. However, for other materials, the CPSC staff has not determined that XRF is as effective, precise, and reliable as the approved methods and, therefore, the draft proposed rule does not expand the approved use of XRF to cover all materials or substances.

## Other Potential Alternatives

The RFA directs agencies to consider some specific alternatives to a draft proposed rule including:

1) the establishment of different compliance or reporting requirements for small entities or timetables that take into account the resources available to small entities;
2) clarification, consolidation, or simplification of compliance and reporting requirements for small entities;
3) use of performance rather than design standards; and
4) exemption from coverage of the rule, in whole or part, for certain or all small entities.

Other than the alternatives specifically discussed above (regarding accreditation by bodies that are not signatories to the ILAC-MRA and alternative testing methods for lead content), the Commission did not identify any significant alternatives that would also meet the agency's objectives and fulfill its obligations under the CPSA, as amended by the CPSIA. However, CPSC staff welcomes comments on suggesting other alternatives that could reduce the burden on small entities and still fulfill the agency's objectives.



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## TAB C: Study on the Applicability of X-ray Fluorescence Spectrometry for Measuring Lead in Metal and Glass Substrate

**TAB C**



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# Study on the Applicability of X-ray Fluorescence Spectrometry for Measuring Lead in Metal and Glass Substrate

Jan 2012

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# 1. SUMMARY

The U.S Consumer Product Safety Commission (CPSC) requires manufacturers and importers of children's products to certify that their products do not exceed 100 parts per million (ppm) lead in accessible component parts, as required by the Consumer Product Safety Improvement Act (CPSIA) of 2008. A bill containing certain amendments to CPSIA, H.R. 2715, was enacted by Congress on August 12, 2011 (http://www.gpo.gov/fdsys/pkg/PLAW-112publ28/pdf/PLAW-112publ28.pdf). Under section 2, part 3(A), the CPSC is directed to determine the extent to which technology—other than that already approved by the Commission—exists for third party laboratories to test or to screen consumer products with the goal of reducing third party testing costs. This report describes how X-ray fluorescence spectrometry (XRF or XRF spectrometry) potentially could be used to test homogeneous metal and glass materials found in children's products. The current CPSC test method[18] allows the use of XRF for determining lead content in homogeneous polymeric or plastic materials. This report examines extending the use of XRF beyond the already-approved method for polymeric materials, to include glass and metal substrates.

XRF spectrometry has the potential, with certain limitations, to measure reliably lead content in homogeneous metal and glass materials at the concentrations necessary to certify compliance with the 100 part per million (ppm) limit now required under the CPSIA for children's products. With the appropriate test methods and reference materials, XRF spectrometry is suitable in many cases for the determination of lead in homogeneous materials.

A standard test method for determining lead in homogeneous materials by energy dispersive XRF using multiple monochromatic beams, ASTM F2853-10e1,[19] was developed by ASTM International Committee F40 on Declarable Substances. The standard and the interlaboratory research report[20] have been published and are available on the ASTM website at: http://www.astm.org/Standards/F2853.htm. Currently, ASTM Committee F40 is also developing a second proposed new standard, WK2333, Analysis of Heavy Metals in Glass by Field Portable X-ray Fluorescence (portable instruments capable of performing ASTM F2853-10e1 are not available currently). This ASTM draft standard is intended to apply to handheld XRFs. Another standard test method[21] using XRF, designed to screen for lead in uniform materials that occur in electrotechnical products, is available. The IEC 62321 method describes procedures for using XRF to screen for lead, based on a regulatory limit of 1000 mg/kg set in Restriction of Hazardous Substances Directive (RoHS), adopted by the European Union. CPSC staff conducted testing of samples and reference materials using XRF instrumentation meeting the requirements of ASTM F2853-10e1 and using a portable XRF analyzer, the results of which are detailed in this report and compared to other analytical techniques.

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[18] U.S. CPSC. Test Method CPSC-CH-E1002-08.1 *Standard Operating Procedure for Determining Total Lead (Pb) in Non-Metal Children's Products, Revised June 21, 2010.* http://www.cpsc.gov/about/cpsia/CPSC-CH-E1002-08_1.pdf .

[19] ASTM F2853-10e1, Standard Test Method for Determination of Lead in Paint Layers and Similar Coatings or in Substrates and Homogeneous Materials by Energy Dispersive X-Ray Fluorescence Spectrometry Using Multiple Monochromatic Excitation Beams.

[20] ASTM Research Report F40-1001 Interlaboratory Study to Establish Precision Statements for ASTM F2853-10, July 1, 2010.

[21] International Electrotechnical Commission (IEC) Method 62321 ED 1.0 B:2008.



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Although CPSC staff found that available XRF methods and instruments were not as reliable at determining lead content in certain metal and glass materials as current CPSC wet chemistry techniques,[1,22] staff developed a pragmatic approach to allow the use of XRF in appropriate instances. The recommended approach to using XRF for determination of lead in homogeneous metals, glass, and other siliceous materials is to allow the use of appropriate XRF instruments and methods by limiting their applicability to materials with lead content significantly above or below the CPSIA limits, while requiring full wet chemical testing according to CPSC methods for borderline materials. In this manner, laboratories could opt to perform this potentially cost-saving technique as a preliminary test, requiring only a subset of samples to be subjected to a full chemical test.

## 2. SCOPE AND APPLICABILITY

CPSC staff set out in this study to illustrate the performance of various types of XRF when testing for lead in a variety of mixed metal alloys, as well as glass and other siliceous materials. A variety of well-characterized materials, including aluminum, zinc, iron, tin, and glass—with a wide range of lead concentrations—were tested by XRF. The XRF results were compared to certificates of analysis and/or test results by wet chemical methods. This testing was designed to illustrate when XRF might be an acceptable method and when it might not. The materials tested were selected not only to include the range of typical metals found in children's products, but also to include many materials that possess known interferences and that provide substantial challenges to the software "solvers" built into XRF instruments. Because of the choice of materials, it was anticipated that the measurement uncertainty for many samples would be due largely to complexities of the sample and matrix, rather than simply the limits of detection for the instrument.

### 2.1 Current Test Method

The current CPSC staff test methods for determining total lead in metal and glass materials involve digesting (dissolving) a homogenous, representative portion of the component part in a combination of hot concentrated acids, such as nitric, hydrochloric, and hydrofluoric acids, and analyzing the diluted acid solution by spectroscopic means, such as inductively coupled plasma optical emission spectrometry (ICP), inductively coupled plasma mass spectrometry (ICP-MS), flame atomic absorption spectrometry (FLAA), or graphite furnace atomic absorption spectrometry (GFAA). These analytical techniques have been determined by CPSC staff to be sufficient to assess lead content results for certification of compliance to the CPSIA lead content limit of 100 ppm (100 mg/kg). These methods are time-consuming, typically requiring several hours to prepare and analyze samples; they are destructive of the component part; and they require expensive, calibrated equipment. Also, these methods use corrosive and poisonous acids that result in hazardous wastes.

### 2.2 Potential Advantages of Using XRF for Homogeneous Substrate Analysis:

The main advantages of using XRF over the current digestion/ICP method would be:

[22] U.S. CPSC. Test Method CPSC-CH-E1001-08.1 *Standard Operating Procedure for Determining Total Lead (Pb) in Metal Children's Products (including Children's Metal Jewelry), Revised June 21, 2010. http://www.cpsc.gov/about/cpsia/CPSC-CH-E1001-08_1.pdf.*



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- XRF analysis can be nondestructive for homogeneous materials, depending upon geometry.
- Little to no sample preparation is required, which greatly reduces the analysis time and cost. Sample measurement times for XRF analysis are typically less than 5 minutes per measurement, versus several hours to grind, digest, and analyze metals and glass using the current test method. The faster analysis times obtained using XRF would be expected to result in lower test costs.
- XRF does not involve use of hazardous acids, so the costs of hazardous material disposal that are associated with current wet chemical methods are eliminated.
- Some XRF analyzers are portable, allowing for field-screening of products.

### 2.3 Limitations of XRF Analysis:

Analysis of component part substrate materials for lead that may be found in children's products by XRF has the following limitations:

The actual penetration depth of x-rays into sample specimen is generally small, typically a few microns. If the lead concentration on the surface of a material differs from the bulk, direct analysis of the material by XRF will not produce quantitative results. Heterogeneous materials, such as electroplated metals or glazed ceramics, would require some type of sample preparation to produce a homogeneous specimen for quantitative XRF analysis.

XRF instruments generate x-ray radiation. With the specialized training and safety precautions required for the use of XRF, radiation safety is achieved easily.

XRF is matrix sensitive,[23] and different models of XRF instruments with different "solver" routines for interpreting the spectra can have limitations with certain metal alloys and other matrices, which present difficulties in analysis due to how they absorb, reflect, or emit x-rays of relevant energies, as described below.

Spectral and matrix interferences must be taken into account during analysis. Spectral interferences result from spectral overlaps among the X-ray lines that are unresolved due to limited resolution of the detector. Some well-known overlaps include: Arsenic (As) Kα peak directly overlapping lead (Pb) Lα peak, the sum peak of iron (Fe) Kα overlapping Pb Lβ peak, selenium (Se) Kβ peak overlapping Pb Lβ peak. The XRF manufacturers' software may provide tools or de-convolution algorithms to compensate for these spectral interferences, but the precision of the lead analysis may be affected. Other spectral interferences noted in this study include bismuth (Bi) Lα peak overlapping Pb Lα peak when the concentration of Bi is much greater than lead in the material tested, and the tail of tungsten (W) Lβ peak overlapping Pb Lα peak for materials that had very high W concentrations (>10%). Figure 1 shows some examples of spectral overlaps observed.

[23] The matrix is the local environment of chemical components in a sample, other than the analyte.



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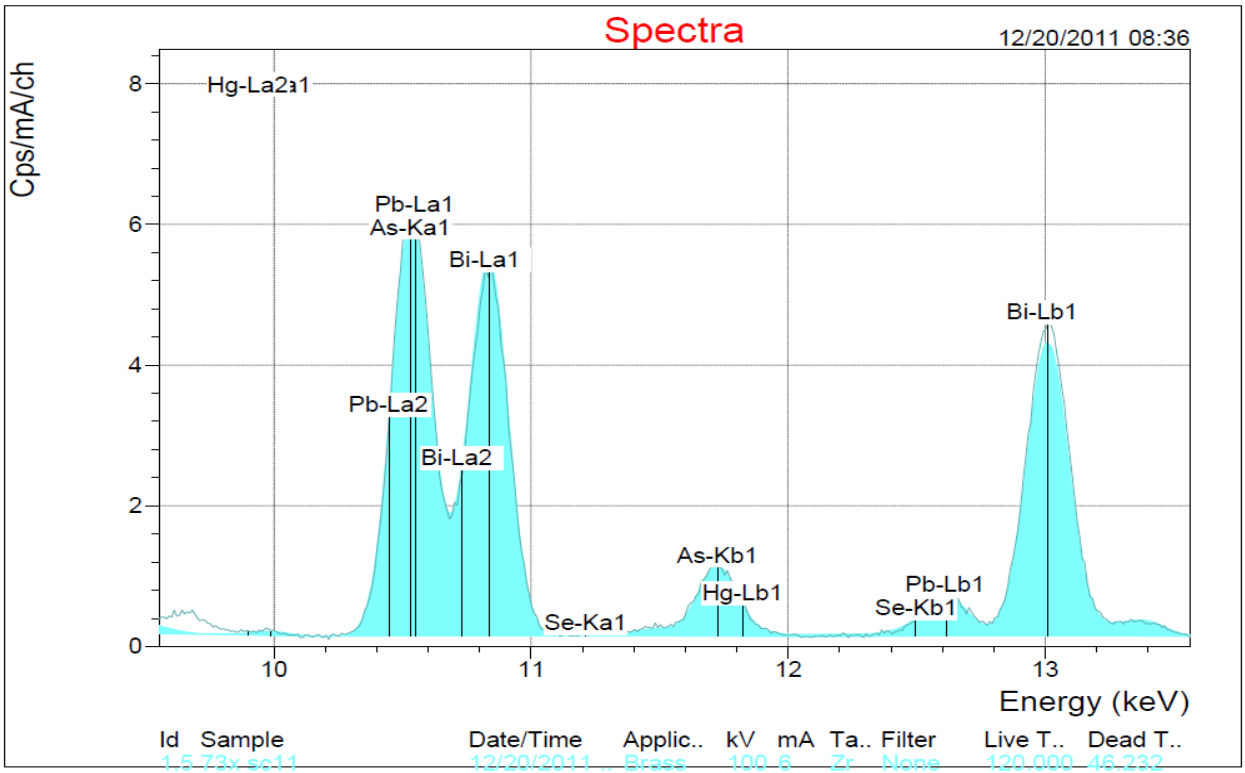


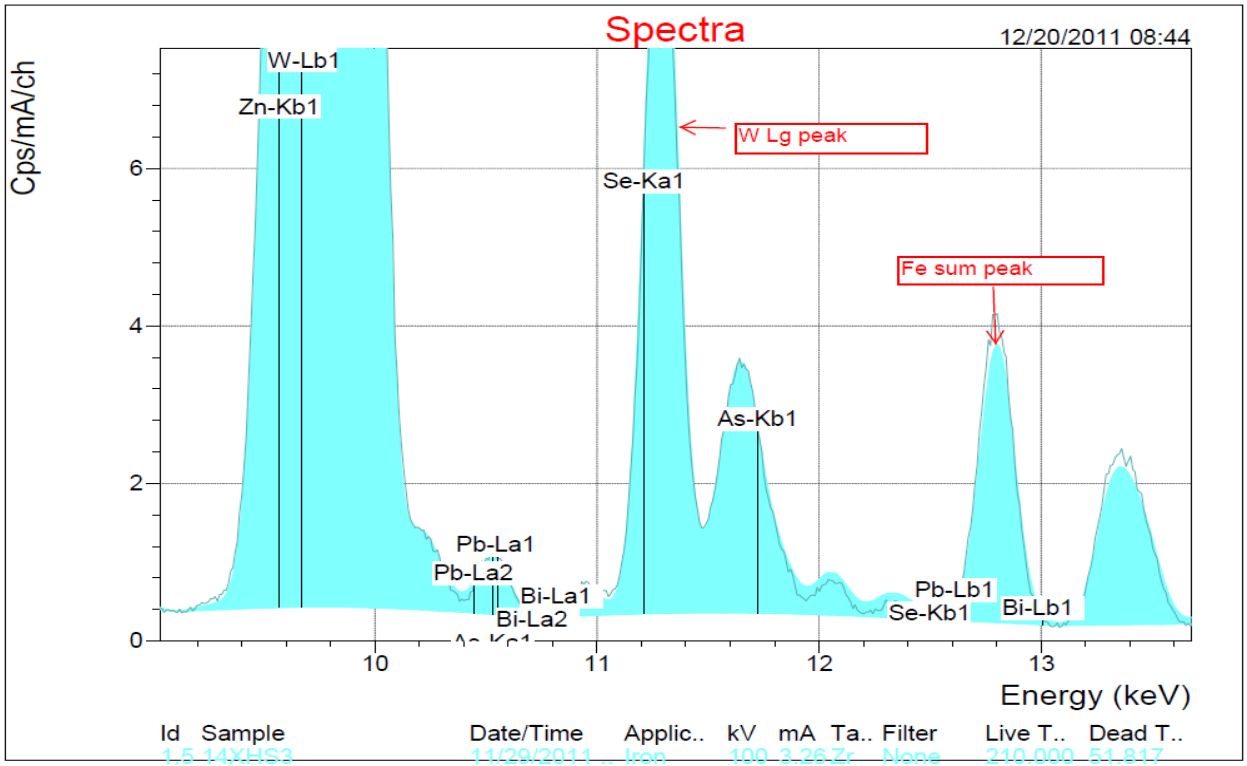


Figure 1. XRF Spectra for Reference Materials 73X SC11 and 14X HS3



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# 3. SUMMARY OF METHODS

## 3.1 XRF Instruments

The XRF instruments used in this study are property that the CPSC currently owns. There are many types of XRF analyzers from different manufacturers, and the CPSC does not endorse the instruments used in this study or any other. The purpose of this study was not to evaluate every XRF analyzer on the market, but to determine if it is feasible to use XRF to measure lead in homogeneous metal or glass materials in order to certify compliance to the CPSIA limit for lead content. A description of the XRF instruments used is as follows:

HD Prime, manufactured by X-ray Optical Systems Inc. Bench top energy dispersive XRF that uses multiple monochromatic excitation beams. The analyzer meets the requirements of ASTM F2853-10e1. The software allows the user to select the type of material analyzed, but measurement times and calibration are set by the manufacturer. The manufacturer provides reference materials to allow the user to verify calibration, but the user cannot make any changes to calibration parameters.

Thermo NITON XL3t 970 and XL3t 700, manufactured by Thermo Fisher Scientific. Portable or handheld energy dispersive XRF with a silicon drift detector. The software allows the user to select a few operating parameters, such as type of material analyzed, filter settings, and measurement time. There is also a system check option in the software that allows the user to perform a calibration of the detectors energy (keV) scale. The manufacturer provides reference materials to allow the user to verify calibration, but the user cannot make changes to parameters in the empirical calibration provided by the manufacturer. The operating parameters selected for this study were:

Measurement time–120 seconds

Filter–All time on main filter. This is the optimum filter setting for lead analysis per manufacturer guidance.

Sample type–*Metals, Electronic Alloys* on model XL3t 970 was selected for metal materials. *Mining Mode Cu/Zn* on model XL3t 700 was selected for glass materials.

Epsilon 5, manufactured by PANalytical. Fully integrated floor model energy dispersive XRF featuring a 3-dimensional, polarizing optical geometry, a 600-watt X-ray tube and a high-resolution germanium (Ge) x-ray detector. Measurements performed in vacuum. The Epsilon 5 software gives the user full control of the instrument calibration and data handling. Quantitative analysis requires the use of standards, such as certified reference materials, and the standards must be of the same matrix as samples to be analyzed.

## 3.2 Materials Tested

Reference materials analyzed included glass, as well as aluminum, zinc, brass, and iron alloys. The reference materials selected had lead concentrations ranging from low parts per million (ppm) levels to percentages (%),[24] but each material type tested included some standards containing lead near the 100 ppm range. In addition to the reference materials, 12 homogeneous

[24] Note that 1 percent is equivalent to 10,000 ppm.



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metal component parts and 9 crystal/glass component parts from consumer products were analyzed using XRF instrumentation, as well as current test methods using ICP. A description of the metal and glass component parts is provided in Appendix B. These metal and glass component parts will be referred to as samples in the report.

### 3.3 ICP Calibration and Analysis

ICP Calibration standards were prepared at lead concentrations of 0.00, 0.10, 0.25, 0.50, 1.00, 5.00, and 10.0 µg/ml lead by dilution of a 1000 µg/ml lead standard (SPEX CertiPrep, Metuchen NJ; Cat# PLPB2-2Y). A quality control standard at 0.50 µg/ml was prepared by the dilution of a 100 µg/ml multi-element standard (SPEX CertiPrep, Metuchen NJ; Cat# QC-21). An internal standard of 2 µg/ml yttrium in 2% nitric acid was prepared using a 1000 µg/ml standard (SPEX CertiPrep, Metuchen NJ; Cat# PLY-2Y). Standards, blanks, and samples were analyzed on a plasma flow: 15.0L/min; nebulizer flow: 0.75 L/min; pump speed: 20 rpm; auxiliary flow: 1.5 L/min; lead wavelength: 220.353; yttrium wavelength: 324.228; power 1.30kW; and replicates: 4). The 0–10 µg/ml calibration curves had correlation coefficients greater than 0.999 with less than 5 percent error for the quality control standard.

## 4. RESULTS AND DISCUSSION

### 4.1 Energy Dispersive XRF Using Multiple Monochromatic Beams (HDXRF)

Table 1 provides a summary of the results for lead concentration obtained using HDXRF on reference materials with the certified or expected values noted on certificates. The full data set is presented in Appendix A, Tables 1–6. Five measurements were obtained on different locations on the reference materials. The certified concentration interval is generally contained in the estimated interval that illustrates accuracy. The estimated standard deviation for HDXRF measurements are not proportional to concentration.

Figures 2A-E show the correlation between certificates of analysis and the mean lead concentration measurements obtained by HDXRF. A linear regression with a forced intercept of 0 is indicated for each set of data in Figures 2A–E. Calculating the predicted concentration from these regression equations for the case of certified concentration (x) equals 100 ppm yields a range of 89.9 to 100.8 ppm for various materials.

Appendix A, Table 7 compares results for lead concentration obtained using HDXRF on the samples with ICP measurements obtained on the same samples. Multiple measurements were made on most samples, except for small samples, such as crystal rhinestones.

The HDXRF lead results generally compare favorably with the certified lead values listed for the reference materials and the ICP lead results obtained for the samples, with certain exceptions, particularly for iron and steel alloys and for tin alloys.

The HDXRF instrument reports lead concentration together with a reported uncertainty at 95 percent confidence that the instrument calculates based on proprietary analysis of the temporal



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data collected over the course of a measurement. The HDXRF results with the given uncertainty (at 95 percent confidence) overlap with the reported certified values and given uncertainty of the reference materials in all cases except the following:

- 11X C4, iron;
- 11X 0331.1, corrosion-resistant iron with 14% nickel (Ni), 2 % chromium (Cr);
- 14X HS3, steel with 18%W, 11% cobalt (Co), and 5% Cr;
- 73X SC11, tin with 12% antimony (Sb), 11% copper (Cu). This material also contains 0.56% Bi and 0.29% As, which may produce some spectral overlaps with lead peaks;
- NIST 1412 and BCR 126a, glass. These reference materials contained lead exceeding 4% (40,000 ppm), which is beyond the intended calibration range the instrument's software solver was optimized to measure; and
- BCR 664, glass. The certificate lists lead at 53.1±2.6 mg/kg with the 95% confidence interval included. The mean HDXRF result with the 95% confidence interval included is 64 ± 2 mg/kg.

The HDXRF measurement results obtained on the samples and non-certified materials are usually within ±20% of ICP-OES results, with the following exceptions:

- 164X ALSUS 7A, aluminum material with reported lead of 0.11% or 1100mg/kg. The intended use of this material is not as a calibration standard but for routine calibration checks. The certificate for this material states that the values are not certified as accurate. Aliquots of this material were obtained by grinding with a rotary tool and were analyzed by ICP. The mean ICP result from measurement of 3 aliquots was 1073mg/kg, about 30 percent greater than the results obtained by HDXRF.

- All the tin-based samples containing >1% Bi as noted from HDXRF analysis had HDXRF measurements for lead 30–70 percent lower than what was obtained using ICP.

- The crystal samples containing lead >1%. These materials contained lead exceeding the calibration range that the instrument's software solver was optimized to measure. Results on the summary page of the HDXRF computer display did indicate properly results of >5000 ppm in all cases for which the crystals contained >1% lead, as determined by ICP analysis.

- For sample 10-304-4674-02pk, HDXRF analysis indicated this material contained >80% Al and about 4% Zn, and smaller amounts of other metals. The HDXRF measurement results for lead were about 30–40 percent higher than obtained by ICP. The degree of homogeneity of this material is questionable based on the standard deviation of the 4 HDXRF measurement results, which may explain partly the discrepancy between the HDXRF and ICP results.

Taking the limitations observed into account, along with experience from long-term use of this method and professional judgment, CPSC staff determined that incorrect determinations can



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be avoided by assigning an "inconclusive" result to any HDXRF measurement of lead concentration in homogeneous metals, glass, or other siliceous materials, where the interval of the reported result, plus or minus the reported uncertainty, includes the range within 30 percent of the CPSIA limit. An average of at least three measurements, none of which is in this "inconclusive" range, should be obtained in order to have a "conclusive" result. For "inconclusive" results, additional testing would be necessary such as by digestion and ICP analysis, according to CPSC test methods, in order to make a determination.



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*Table 1. HDXRF Analysis of Metal and Glass Reference Materials for Lead*

| Standard ID | Material | Certified or Expected Value for Pb mg/kg | Width of the 95% Confidence Interval on the Certified Value | HDXRF Pb mean (n=5) mg/kg | Width of 95% Confidence Interval about the HDXRF mean (n=5)[25] |
|---|---|---|---|---|---|
| AA242.2 | Aluminum | 470 | ±10 | **462** | **±94** |
| AA295.2 | Aluminum | 300 | ±10 | **283** | **±2** |
| A330.0Al-B012 | Aluminum | 1300 | ±50 | **1191** | **±36** |
| 164X ALSUS 8A | Aluminum | 10 | na | **26** | **±5** |
| 164X ALSUS 6 | Aluminum | 500 | na | **540** | **±26** |
| 164X ALSUS 7A | Aluminum | 1100 | na | **793** | **±29** |
| 41X ZSC1 | Zinc | 621 | ±18 | **619** | **±49** |
| 41X ZSC2 | Zinc | 1110 | ±20 | **1094** | **±29** |
| 41X ZSC3 | Zinc | 273 | ±12 | **269** | **±22** |
| 41X ZSC4 | Zinc | 1560 | ±30 | **1590** | **±33** |
| 41X ZSC6 | Zinc | 77 | ±5 | **69** | **±14** |
| 31X TB1 | Brass | 2010 | ±30 | **1986** | **±91** |
| 31X B19 | Brass | 25100 | ±300 | **22757** | **±785** |
| 31X B4 | Brass | 640 | ±40 | **683** | **±73** |
| 31X B6 | Brass | <5 | na | **20** | **±5** |
| 31X B5 | Brass | 210 | ±10 | **210** | **±26** |
| 11X C1 | Iron | 110 | ±20 | **135** | **±11** |
| 11X C4 | Iron | 155 | ±16 | **327** | **±73** |
| 11X C8 | Iron | 230 | ±20 | **363** | **±33** |
| 11X C9 | Iron | 44 | ±8 | **106** | **±53** |
| 11 X 0331.1 | Iron | 300 | ±20 | **525** | **±43** |
| IARM 182B | Iron | 1900 | ±100 | **1631** | **±115** |
| 73X SC 11 | Tin | 610 | ±20 | **436** | **±24** |
| 44X ZnCd30 | 70% Zn/ 30% Cd | 890 | na | **869** | **±56** |
| 95X 117 | 45%Bi/23 %Pb | 230000 | na | **183003** | **±4206** |
| 14X HS3[26] | Steel with 10%Co/18 %W | 100 | ±10 | <5 | na |
| NIST 612 | Glass | 38.6 | ±0.2 | **43** | **±2** |
| NIST 616 | Glass | 1.85 | ±0.04 | <5 | na |
| NIST 1412 | Glass | 40800 | ±1580 | **48307** | **±614** |
| ROHS1-3 | Glass | 0 | na | **15** | **±1** |
| ROHS2-3 | Glass | 1000 | na | **951** | **±92** |
| ROHS3-3 | Glass | 5000 | na | **5051** | **±147** |

[25] Width of 95% Confidence Interval about the mean (n=5) equals (2.776 x (standard deviation))/(√5).

[26] This iron-based alloy contained a high concentration of tungsten (W) in addition to 440 mg/kg arsenic (As). There appears to be some spectral overlaps of lead peaks due to high W levels that have impacted software calculations.



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| | | | | | |
|---|---|---|---|---|---|
| BCR 664 | Glass | 53.1 | ±2.6 | **64** | **±2** |
| BCR 126A | Glass | 222700 | ±600 | **487648** | **±8324** |

na = not available



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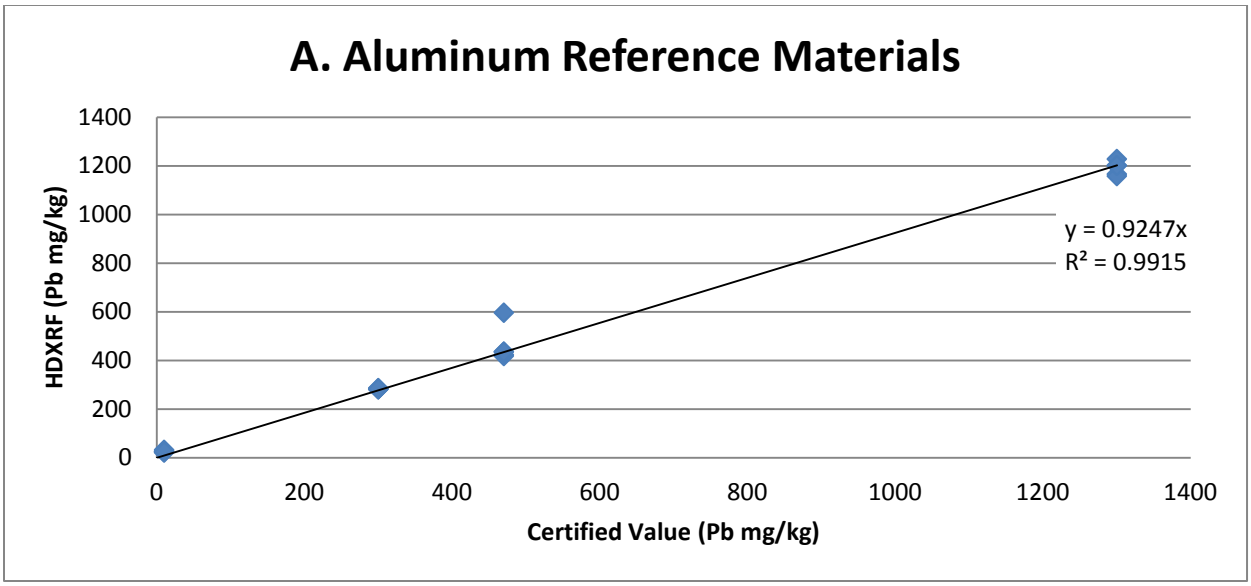


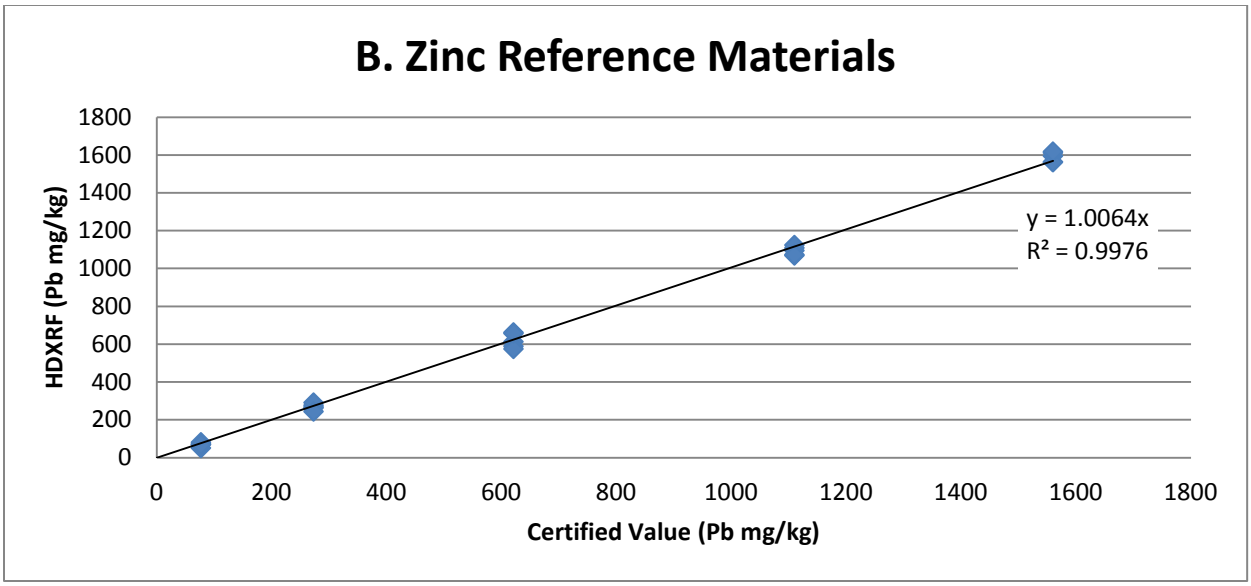


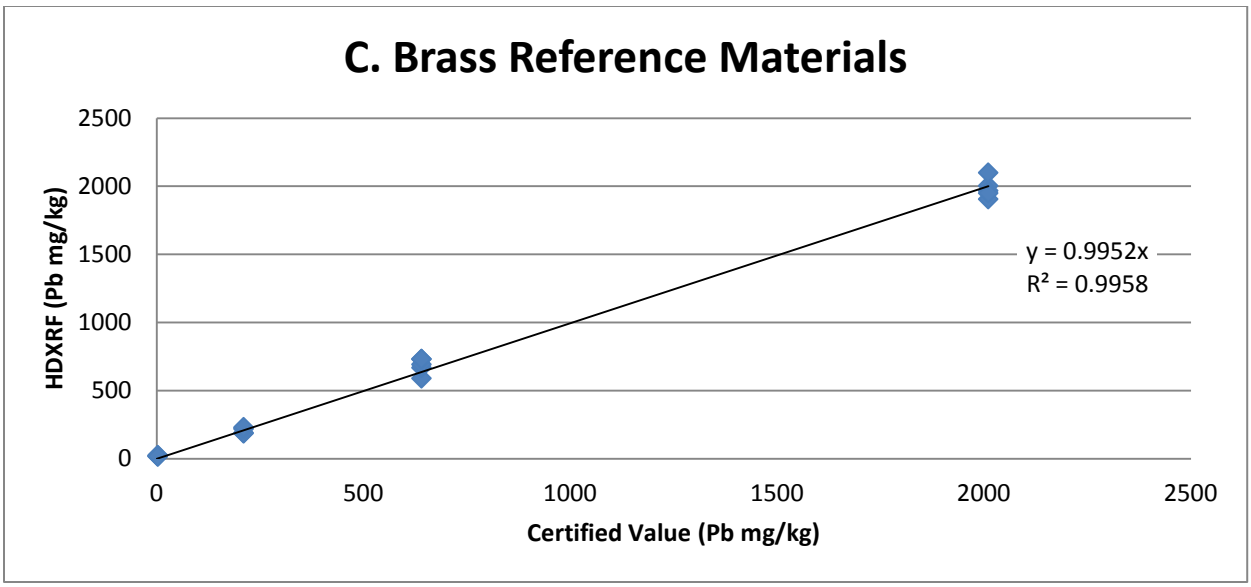


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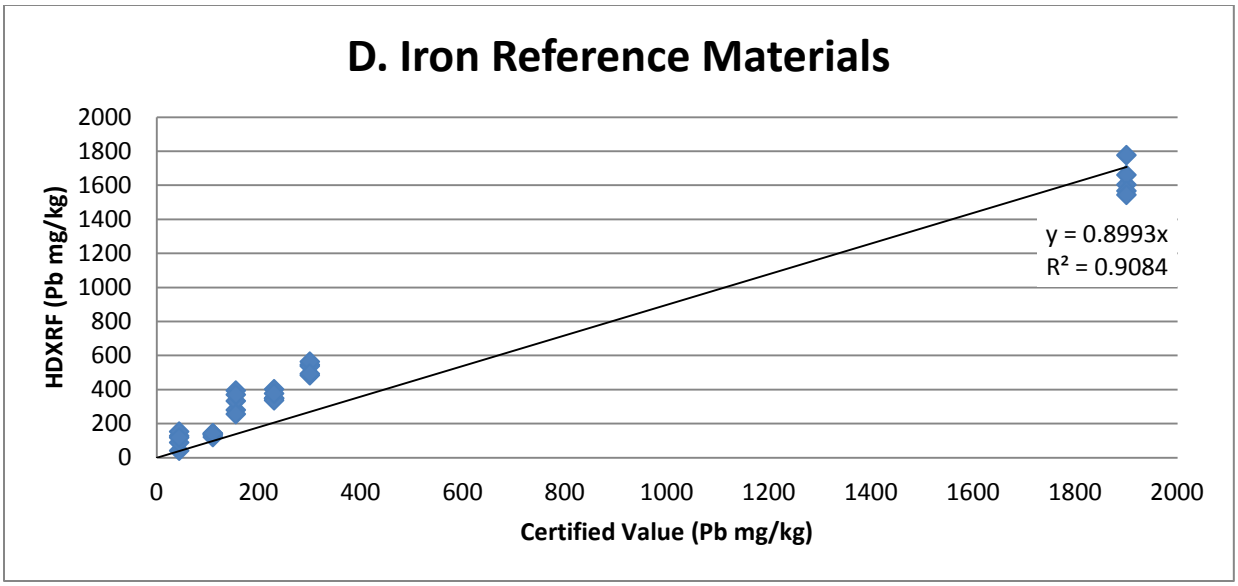


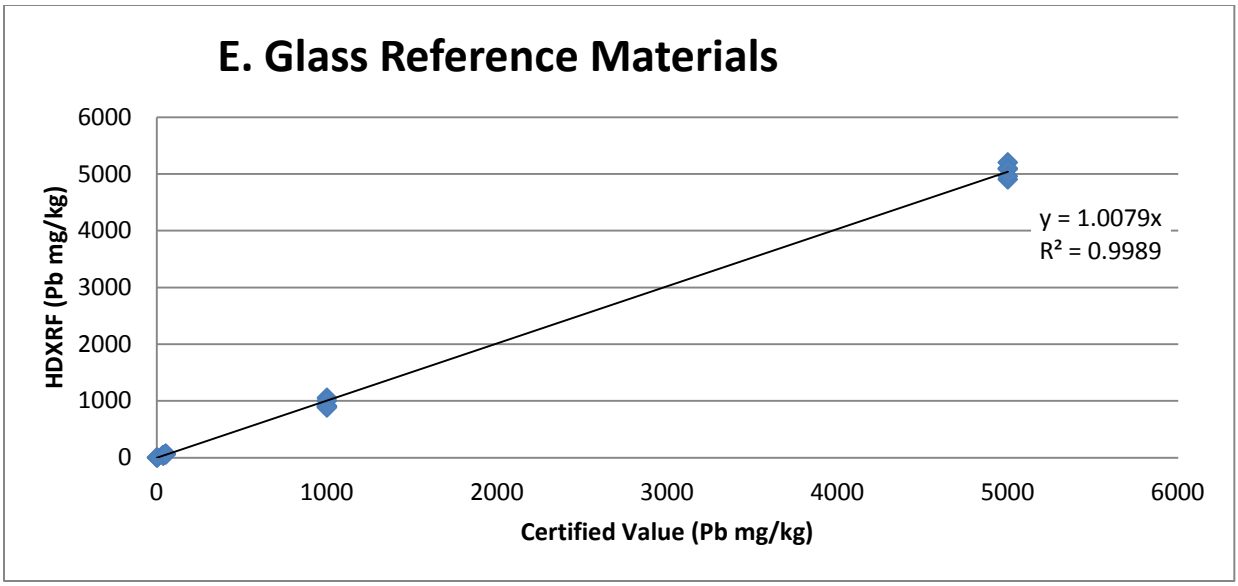


*Figures 2A–E.* Charts showing correlation of HDXRF results to Certificate of Analysis values. Data for 164X ALSUS 7a and 164X ALSUS 6 not included in chart for Aluminum reference materials. These are classified as XRF set-up samples, and certificate states the reported values are not certified as accurate. Data from reference materials containing >5000 mg/kg lead were not included in charts. The HDXRF is not specifically calibrated for lead in the % range. The calibration set by manufacturer was developed for testing lead content nearer the regulatory limits. The *summary* page of the HDXRF computer display indicates results of >0.5% as >5000 ppm. There is a *full result* display page that shows actual values >5000 ppm, but the lead results for reference materials containing lead in % range do not correlate as well to certified values as found for measurements on reference materials containing lead<5000 ppm.

## 4.2 Portable Handheld Energy Dispersive XRF

Table 2 provides a summary of the results for lead concentration obtained using handheld energy dispersive XRF (HHXRF) on reference materials with the certified or expected values



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noted on certificates. The full data set is presented in Appendix A, Tables 8–13. Five measurements were obtained on different locations on the reference materials. The certified concentration interval is generally contained in the estimated interval, which illustrates accuracy. The estimated standard deviation for HHXRF measurements is not proportional to concentration.

Figures 3A–E show the correlations between certificates of analysis and the mean lead concentration measurements obtained by HHXRF. A linear regression with a forced intercept of 0 is indicated for each set of data in Figures 3A–E. Calculating the predicted concentration from these regression equations for the case of certified concentration (x) equals 100 ppm yields a range of 96.4 to 118.8 ppm for various materials.

Appendix A, Table 14 compares lead results obtained using HHXRF on the samples, with ICP measurements obtained on the same samples. Multiple measurements were made on most samples, except for small samples, such as crystal rhinestones.

The HHXRF instrument reports lead concentration together with a reported uncertainty that the instrument calculates based on proprietary analysis of the temporal data collected over the course of a measurement. The HHXRF results for lead content in aluminum and glass reference materials with the given uncertainty (at 95 percent confidence) overlap with the reported certified values, except for BCR 126a, which is a glass material containing more than 20 percent lead, which may be beyond the optimum calibration range set by the manufacturer for this application.

Figures 3A–E show good correlations between HHXRF results and the certified lead values for the zinc and brass reference materials, but there is some apparent bias with HHXRF lead results being greater than certified lead values listed for these materials. The calibration parameters set by the manufacturer may not be optimized for measuring lead in the 100–1,000 ppm range. There is an optional sample analysis mode that is not available on the HHXRF used by the CPSC, which allows the user to input slope and intercept values generated from analyzing known standards.

There was less correlation between HHXRF results and the certified lead for the iron reference materials. The HHXRF was also unable to detect lead in 11X C1, which is iron containing 110mg/kg lead. HHXRF results and certified values listed for the following additional materials did not show apparent correlations:

- 14X HS3, steel with 18%W, 11% cobalt (Co), and 5% Cr.
- 73X SC11, tin with 12% antimony (Sb), 11% copper (Cu). This material also contains 0.56% Bi and 0.29% As, which may produce some spectral overlaps with lead peaks.

The HHXRF measurement results obtained on the samples are usually within ±20% of ICP-OES results with the following exceptions:

- All the tin-based samples containing >1% Bi as noted from HHXRF analysis had HHXRF measurements for lead 30–50 percent lower than what was obtained using ICP.
- For samples 10-304-4674-02pk and 10-304-4674-02pp, HDXRF analysis indicated this material contained >80% Al and about 4% Zn and smaller amounts of other



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metals. The HHXRF measurement results for lead were about 30 percent higher than obtained by ICP.

Taking the limitations observed into account, along with experience from long-term use of this method and professional judgment, CPSC staff determined that incorrect determinations can be avoided by assigning an "inconclusive" result to any HHXRF measurement of lead concentration in metals, glass, or other siliceous materials, where the interval of the reported result, plus or minus the reported uncertainty, includes the range within 30 percent of the CPSIA limit. An average of at least three measurements, none of which is in this "inconclusive" range, should be obtained in order to have a "conclusive" result. For "inconclusive" results, additional testing would be necessary in order to make a determination, such as by digestion and ICP analysis according to CPSC test methods.

Furthermore, applying certain quality control and instrument validation requirements for IEC 62321 to the use of HHXRF is a suitable way to ensure reliable results. Specifically, the limitations should include following sampling, testing, calibration, quality control guidelines described in section 6 of IEC 62321, as well as determining the limit of detection (LOD) for lead in each material or metal type, following guidelines in section 6 of IEC 62321. The lead LOD shall be equal to or less than 30 mg/kg for the specific material or metal type tested. Some types of XRF spectrometers may not have sensitivity to obtain sufficient LOD for testing certain metal types for certifying to lead requirements.



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Table 2. HHXRF Analysis of Aluminum Reference Materials for lead

| Standard ID | Material | Certified or Expected Value for Pb mg/kg | Width of the 95% Confidence Interval on the Certified Value | HDXRF Pb mean (n=5) mg/kg | Width of 95% Confidence Interval about the HDXRF mean (n=5)[27] |
|---|---|---|---|---|---|
| AA242.2 | Aluminum | 470 | ±10 | **446** | **±8** |
| AA295.2 | Aluminum | 300 | ±10 | **322** | **±6** |
| A330.0Al-B012 | Aluminum | 1300 | ±50 | **1441** | **±29** |
| 164X ALSUS 8 A | Aluminum | 10 | na | <LOD | na |
| 164X ALSUS 6 | Al 88%/Cu 12% | 500 | na | **780** | **±13** |
| 164X ALSUS 7 A | Aluminum | 1100 | na | **1035** | **±21** |
| 41X ZSC1 | Zinc | 621 | ±18 | **746** | **±12** |
| 41X ZSC2 | Zinc | 1110 | ±20 | **1282** | **±54** |
| 41X ZSC3 | Zinc | 273 | ±12 | **365** | **±27** |
| 41X ZSC4 | Zinc | 1560 | ±30 | **1866** | **±62** |
| 41X ZSC6 | Zinc | 77 | ±5 | **124** | **±6** |
| 31X TB1 | Brass | 2010 | ±30 | **2353** | **±32** |
| 31X B19 | Brass | 25100 | ±300 | **27140** | **±160** |
| 31X B4 | Brass | 640 | ±40 | **824** | **±13** |
| 31X B6 | Brass | <5 | na | **98** | **±12** |
| 31X B5 | Brass | 210 | ±10 | **301** | **±20** |
| 11X C1 | Iron | 110 | ±20 | <LOD | na |
| 11X C4 | Iron | 155 | ±16 | **202** | **±35** |
| 11X C8 | Iron | 230 | ±20 | **215** | **±24** |
| 11X C9 | Iron | 44 | ±8 | <LOD | na |
| 11 X 0331.1 | Iron | 300 | ±20 | **466** | **±16** |
| IARM 182B | Iron | 1900 | ±100 | **1806** | **±102** |
| 73X SC 11 | Tin | 610 | ±20 | **304** | **±38** |
| 44X ZnCd30 | 70% Zn/ 30% Cd | 890 | na | **866** | **±21** |
| 95X 117 | 45%Bi/23 %Pb | 230000 | na | **229280** | **±1101** |
| 14X HS3 | Steel with 10%Co/18%W | 100 | ±10 | <LOD | na |
| NIST 612 | Glass | 38.6 | ±0.2 | **40** | **±5** |
| NIST 616 | Glass | 1.85 | ±0.04 | <LOD | na |
| NIST 1412 | Glass | 40800 | ±1580 | **41980** | **±349** |
| ROHS1-3 | Glass | 0 | na | <LOD | na |
| ROHS2-3 | Glass | 1000 | na | **1110** | **±11** |
| ROHS3-3 | Glass | 5000 | na | **5507** | **±72** |
| BCR 664 | Glass | 53.1 | ±2.6 | **56** | **±3** |
| BCR 126A | Glass | 222700 | ±600 | **171780** | **±1759** |

na = not available

[27] Width of 95% Confidence Interval about the mean (n=5) equals (2.776 x (standard deviation))/(√5).



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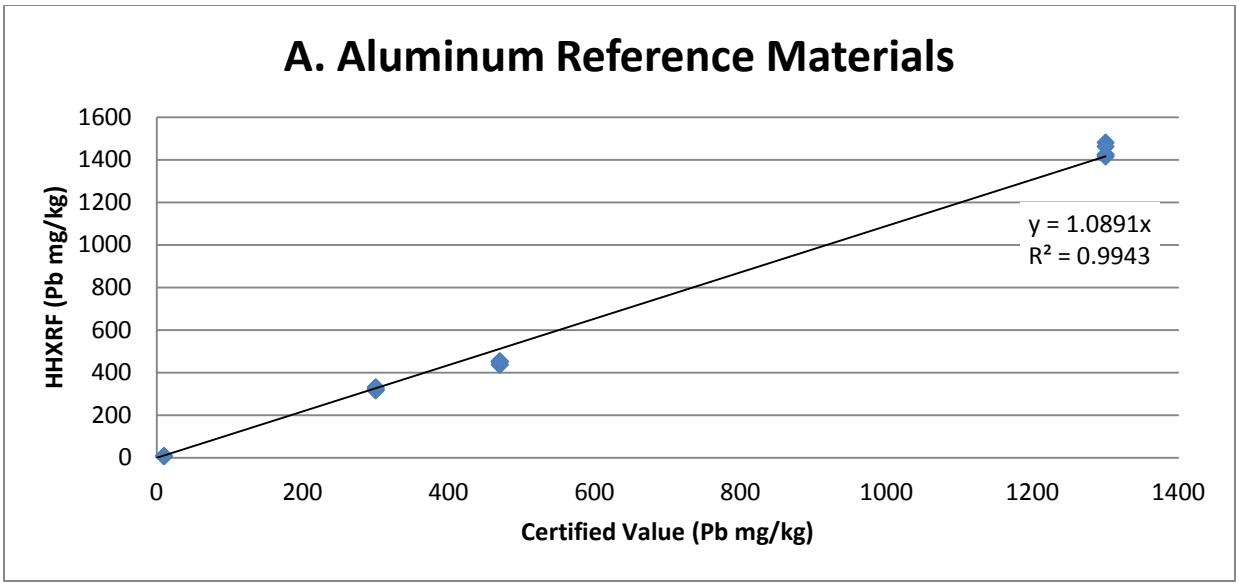


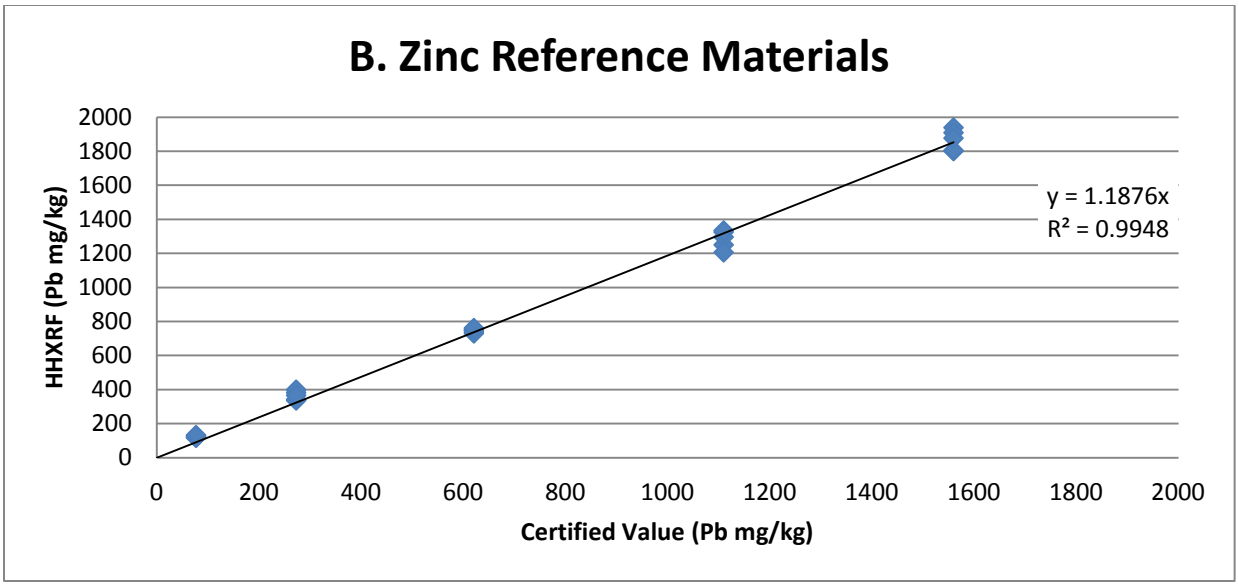


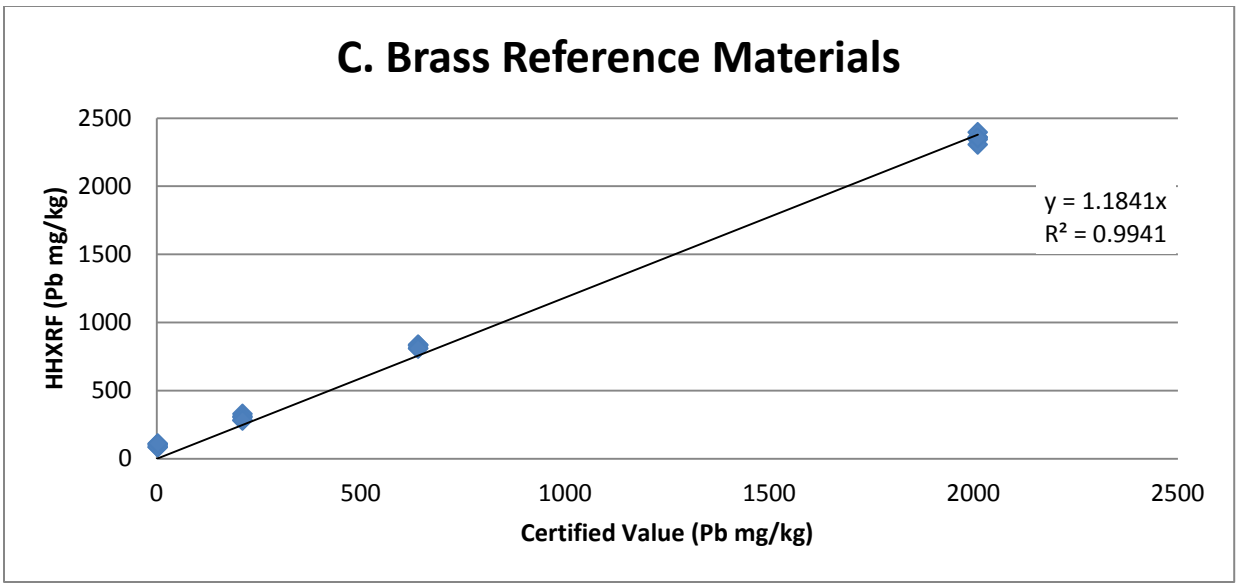




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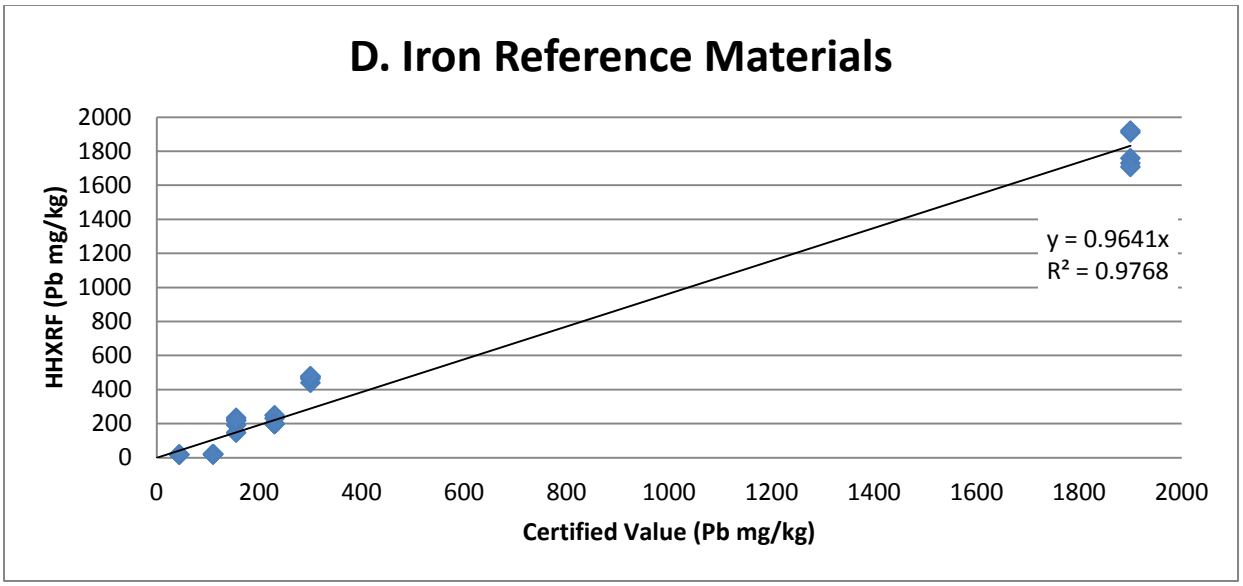


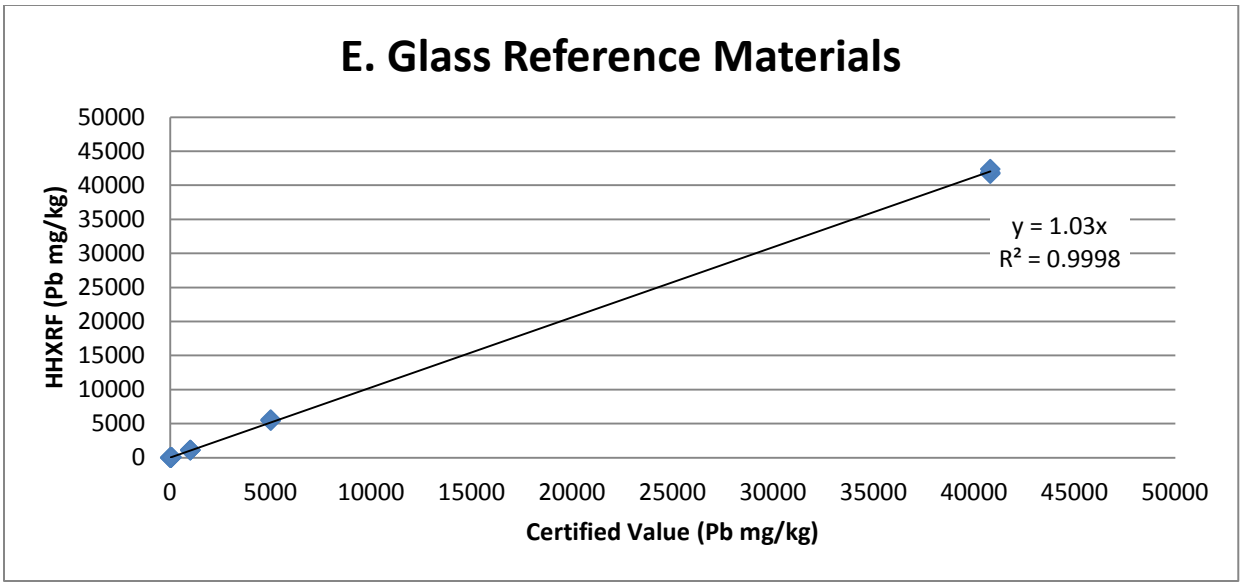


*Figures 3A–E.* Charts showing correlation of HHXRF results to Certificate of Analysis values. Data for 164X ALSUS 7a and 164X ALSUS 6 not included in chart for Aluminum reference materials. These are classified as XRF set-up samples, and certificate states the reported values are not certified as accurate. Data from reference materials containing >50,000 mg/kg lead were not included in charts.

## 4.3 Laboratory Energy Dispersive XRF

The author of this report developed applications using the certified reference materials for the following metal types: zinc, aluminum, brass, and iron, by measuring the certified reference materials with the PANalytical Epsilon 5 XRF spectrometer and setting up the regression lines used to convert measured count rates into concentrations using the instrument software. Matrix effects were accounted for using applications available on instrument computer software. The calibration plots are shown in figures 4A–D. The reference materials were reanalyzed as samples, and results are shown in Table 3. Samples that had similar metal type as the reference



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materials were also analyzed using the specific application for that metal type; results are included in Table 3.

The calibration plots shown in Figures 4A-D indicate good regression fits based on correlation coefficients near 1. Epsilon 5 XRF results for the reference materials reanalyzed as samples, generally agree with certified values, with the exception of a few iron materials. Epsilon 5 XRF results for the aluminum samples are within ±20% of ICP results obtained on the same sample. This is illustrative of the capacity of energy dispersive XRF to determine lead concentrations when specific calibrations for known, similar matrix materials are developed and used along with optimization of excitation energy, filters and other parameters specific to a particular matrix.



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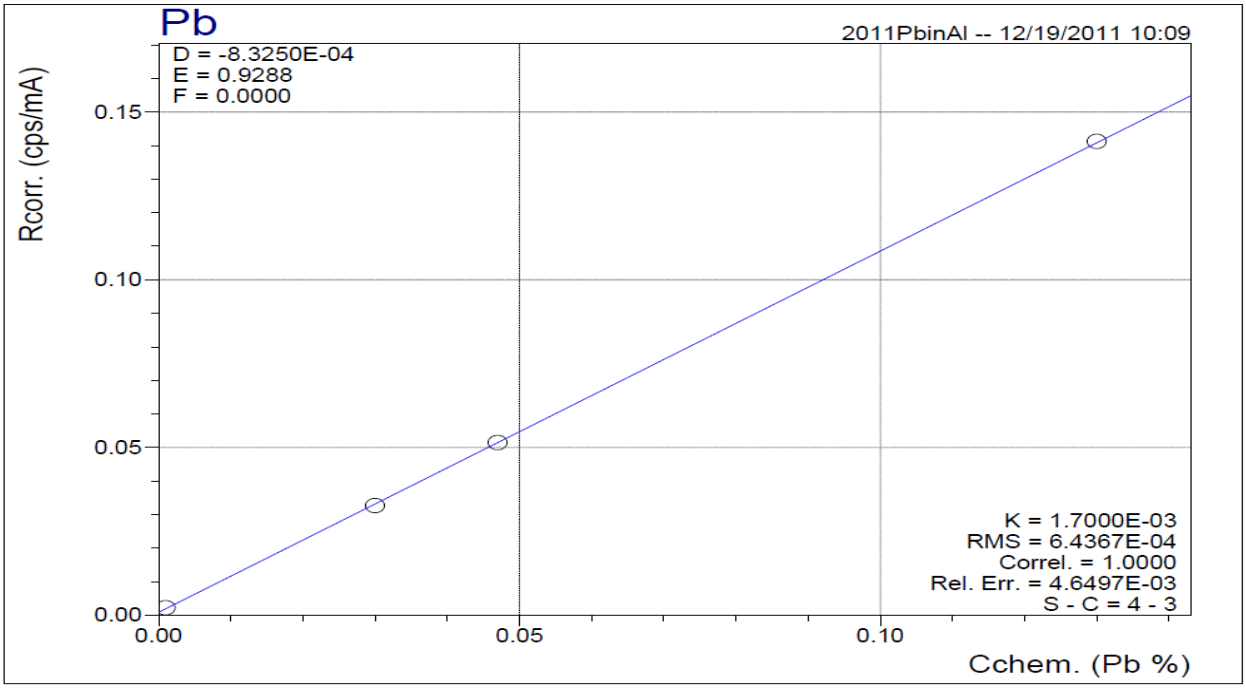
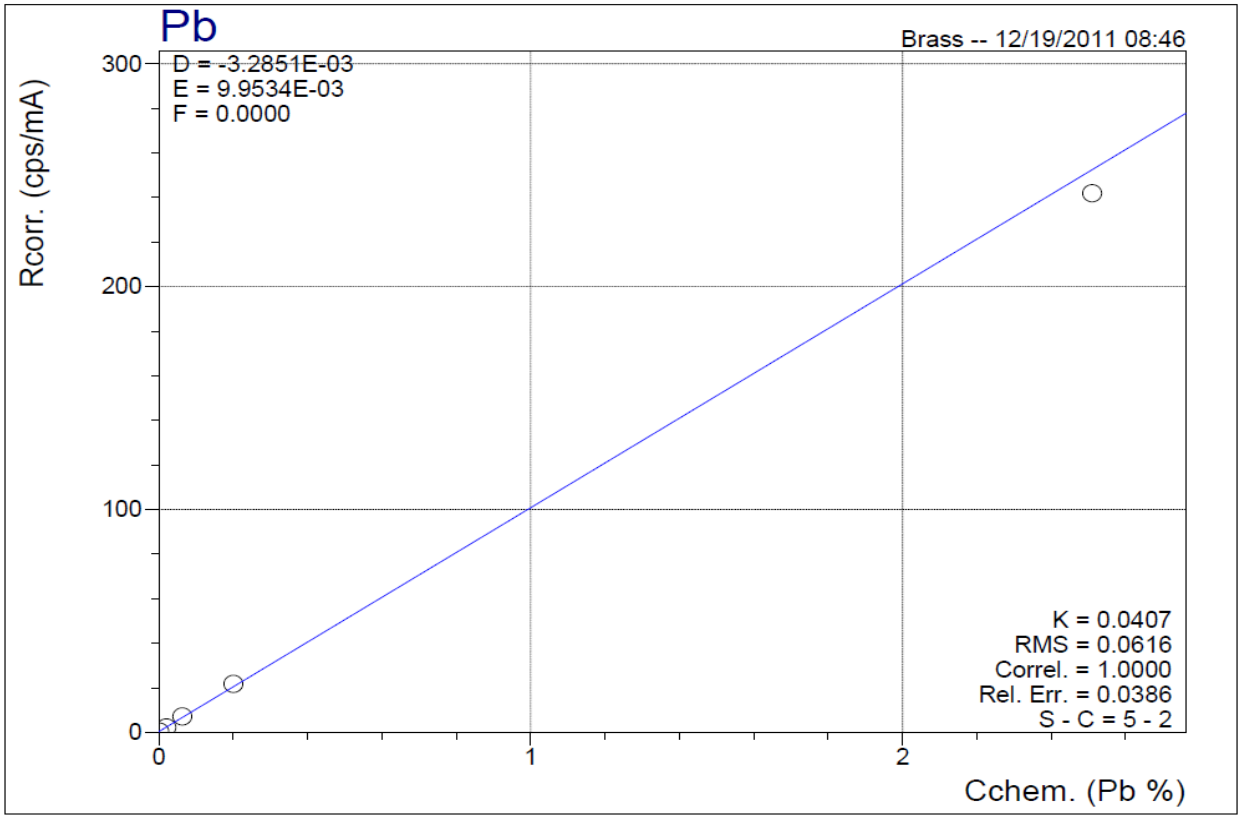
A. Epsilon 5 Calibration of Pb in Aluminum




B. Epsilon 5 Calibration of Pb in Brass



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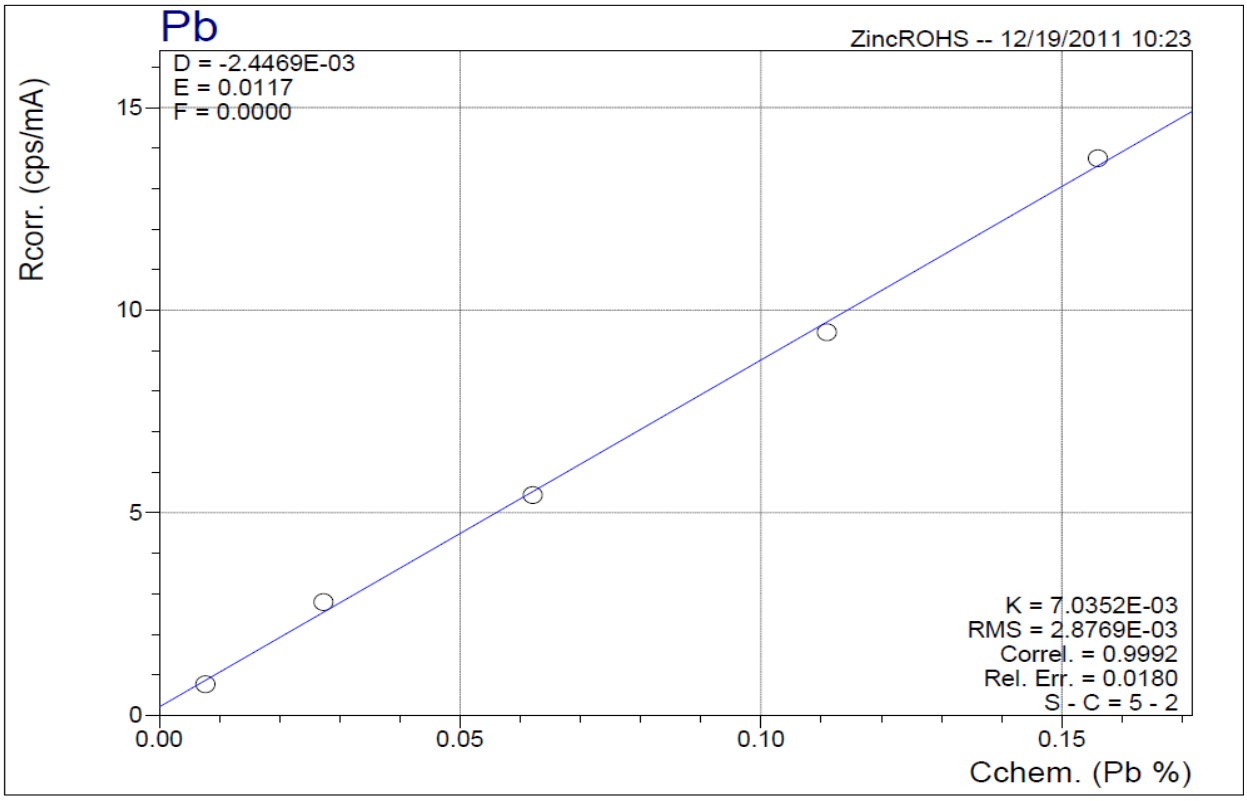
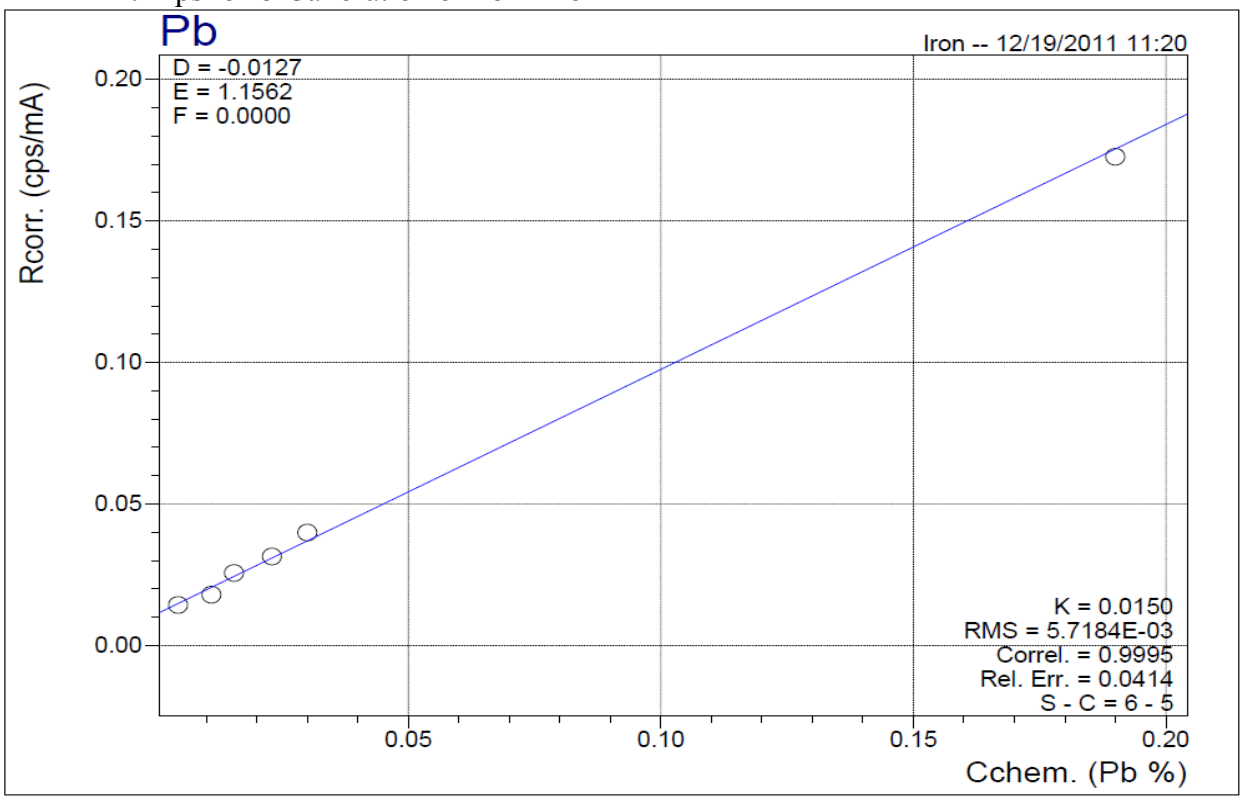
C. Epsilon 5 Calibration of Pb in Zinc




D. Epsilon 5 Calibration of Pb in Iron




Figures 4A-D. Calibration Plots obtained using Epsilon 5



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Table 3. Epsilon 5 XRF Results

| Standard/Sample ID | Material | Certified or Expected Value or ICP result for Pb mg/kg | Width of the 95% Confidence Interval on Certified Value | Epsilon 5 Pb mg/kg |
|---|---|---|---|---|
| AA242.2 | Aluminum | 470 | ±10 | 476 |
| AA295.2 | Aluminum | 300 | ±10 | 288 |
| A330.0Al-B012 | Aluminum | 1300 | ±50 | 1301 |
| 164X ALSUS8A | Aluminum | 10 | na | 13 |
| 164XALSUS6 | Aluminum | 500 (*845) | na | 716 |
| 164XALSUS7A | Aluminum | 1100 (*1073) | na | 905 |
| 10-304-3743 | Aluminum | 615 | na | 534 |
| 10-304-3744 | Aluminum | 598 | na | 478 |
| 10-304-4674-02pk | Aluminum | 1655 | na | 1801 |
| 10-304-4674-02pp | Aluminum | 1557 | na | 1707 |
| 41X ZSC1 | Zinc | 621 | ±18 | 566 |
| 41X ZSC2 | Zinc | 1110 | ±20 | 1166 |
| 41X ZSC3 | Zinc | 273 | ±12 | 298 |
| 41X ZSC4 | Zinc | 1560 | ±30 | 1480 |
| 41X ZSC6 | Zinc | 77 | ±5 | 81 |
| 31X TB1 | Brass | 2010 | ±30 | 2075 |
| 31X B19 | Brass | 25100 | ±300 | 23730 |
| 31X B4 | Brass | 640 | ±40 | 707 |
| 31X B6 | Brass | <5 | na | 12 |
| 31X B5 | Brass | 210 | ±10 | 203 |
| 11X C1 | Iron | 110 | ±20 | 213 |
| 11X C4 | Iron | 155 | ±16 | 162 |
| 11X C8 | Iron | 230 | ±20 | 232 |
| 11X C9 | Iron | 44 | ±8 | <LOD |
| 11X 0331.1 | Iron | 300 | ±20 | 339 |
| IARM 182B | Iron | 1900 | ±100 | 1642 |

*Results obtained by ICP analysis on set-up samples

na = not available



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# 5. CONCLUSIONS AND RECOMMENDATIONS

Although CPSC staff found that available XRF methods and instruments were not as reliable at determining lead content in certain metal and glass materials as current CPSC wet chemistry techniques, staff applied professional judgment based on this work and extensive experience with XRF techniques and instruments to develop a pragmatic approach to allow the use of XRF in appropriate instances.

## 5.1 HDXRF

HDXRF technology is suitable in many cases for the accurate determination of lead in glass and homogeneous metals. A standard test method, ASTM 2853-10e1, is available. The current CPSC test methods should be updated to recognize ASTM 2852-10e1 for determining lead in certain metals and siliceous materials (glass), with the following limitations:

1. Applicable only for analysis of homogeneous materials. It is not suitable for testing electroplated metal alloys or glazed ceramics.
2. Multiple measurements on different locations of the sample component part should be performed to ensure some degree of spatial homogeneity. If the relative standard deviation (the standard deviation divided by the mean) of 3 or more XRF measurements of a sample component part exceeds 30 percent,[28] analysis using wet chemical procedures should be done before certifying that the items meet CPSIA requirements for lead. Most visually homogeneous samples tested met this measure of homogeneity.
3. Any XRF measurement of lead concentration in metals, glass or other siliceous materials where the interval comprised of the reported result, plus or minus the reported uncertainty, includes the range within 30 percent above or below the CPSIA limit, shall be considered "inconclusive." An average of at least three measurements, none of which is in this "inconclusive" range, as defined in this paragraph, should be obtained in order to have a "conclusive" result.[29]
4. For "inconclusive" results, additional testing is necessary in order to make a determination, such as by digestion and ICP analysis according to CPSC test methods.
5. Iron metal types that contain elements that have some spectral overlaps with lead may not be suitable to test by XRF for certifying to lead requirements. The XRF lead result, plus the 95 percent uncertainty, will likely exceed 70 ppm for low lead iron materials that also contain arsenic, as noted in Appendix A, Table 4 for reference material 11X C9.

[28] CPSC staff arrived at this recommendation based on the finding that the relative standard deviation of the five measurements taken for each reference material was between 1 and 19 percent (with one exception). Given that reference materials are manufactured and/or selected specifically to be homogeneous, this was considered to be a normal variation for homogeneous samples and up to approximately 50 percent more variation than in the case of these reference materials was considered to be an acceptable test for homogeneity.

[29] For example, if the XRF instrument reports a result of 65 ppm lead with an uncertainty of 10 ppm lead for a material subject to the CPSIA limit of 100 ppm lead content, this measurement would be considered inconclusive because 65 ppm + 10 ppm = 75 ppm which is less than 30 percent below the applicable limit of 100 ppm. A reported result of 60 ppm with a reported uncertainty of 8 ppm would be a conclusive measurement of a material subject to the CPSIA lead content limit of 100 ppm, as 68 ppm is more than 30 percent below the applicable limit of 100 ppm.



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## 5.2 HHXRF

HHXRF analyzers may be suitable for the accurate determination of lead in glass and certain homogeneous metals. Standard test methods with scopes that cover CPSIA lead limit of 100 ppm in metal or glass are not currently available. A standard test method for determining lead in homogeneous plastic materials,[30] ASTM 2617-08, is recognized in the CPSC test method.[1]

The IEC 62321 method describes procedures for using XRF to screen for lead, based on a regulatory limit of 1000 mg/kg set in Restriction of Hazardous Substances Directive (RoHS), adopted by the European Union. Laboratories using this method can test an item with XRF, and if the item tested has a lead result in mg/kg of less than 700 - $3\sigma$,[31] the item is determined to be below the RoHS limit for lead. The RoHS limit for lead of 1000 mg/kg is much higher than the CPSIA lead limit of 100 mg/kg, but the sampling and calibration procedures described in the IEC 62321 method could be used to establish a method using XRF to screen for lead in children's products at the CPSIA lead limit of 100 mg/kg.

The current CPSC test methods should be updated to recognize applicable standard test methods using XRF that are developed. In the interim, CPSC test methods should be updated to allow laboratories to use HHXRF or other types of laboratory XRF analyzers for testing glass and metal items with the same limitations as noted in section 5.1 HDXRF and the following additional conditions:

1. Follow sampling, testing, calibration, quality control guidelines described in section 6 of IEC 62321.
2. A set of calibration standards, minimum 4, should be used to validate that the instrument is suitable for testing for each material or metal type to be tested. The calibration standards should cover the applicable range to certify that lead meets the CPSIA requirements (0–2000 mg/kg). At least one standard in each calibration set should have lead concentration less than 100 mg/kg.
3. Verify the instrument performance daily, by analyzing one or more reference materials of the same matrix or metal type as the materials on which analyses will be performed. The lead concentration of the reference material should be in the range of 50–300 mg/kg, and the determined concentration from the measurement must be in agreement with the known or certified value. The measured result with the given uncertainty (at 95 percent confidence) should overlap with the reported certified values and given uncertainty of the reference materials.
4. The limit of detection (LOD) for lead in each material or metal type should be determined following guidelines in section 6 of IEC 62321. The lead LOD shall be equal to or less than 30 mg/kg for the specific material or metal type tested. Some types of XRF spectrometers may not have sensitivity to obtain sufficient LOD for testing certain metal types for certifying to lead requirements.

[30] ASTM F2617-08 Standard Test Method for Identification and Quantification of Chromium, Bromine, Cadmium, Mercury, and Lead in Polymeric Material using Energy Dispersive X-ray Spectrometry.

[31] $3\sigma$ is the 99.7 percent confidence level.



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## Appendix A

Table 1. HDXRF Analysis of Aluminum Reference Materials for Pb

| Standard ID | Certified or Expected Value for Pb mg/kg | Width of the 95% Confidence Interval on the Certified Value | Replicate | HDXRF Pb mg/kg | HDXRF 95% Confidence Interval width on the Pb measurement (mg/kg) |
|---|---|---|---|---|---|
| AA242.2 | 470 | ±10 | 1 | 418 | ±5.3 |
| | | | 2 | 423 | ±5.3 |
| | | | 3 | 436 | ±5.5 |
| | | | 4 | 435 | ±5.4 |
| | | | 5 | 596 | ±7.7 |
| | | | **mean** | **462** | |
| | | | **stdev** | **76** | |
| AA295.2 | 300 | ±10 | 1 | 282 | ±4 |
| | | | 2 | 281 | ±4 |
| | | | 3 | 286 | ±4 |
| | | | 4 | 282 | ±4 |
| | | | 5 | 284 | ±4 |
| | | | **mean** | **283** | |
| | | | **stdev** | **2** | |
| A330.0Al-B012 | 1300 | ±50 | 1 | 1166 | ±10 |
| | | | 2 | 1158 | ±10 |
| | | | 3 | 1228 | ±11 |
| | | | 4 | 1202 | ±10 |
| | | | 5 | 1201 | ±10 |
| | | | **mean** | **1191** | |
| | | | **stdev** | **29** | |
| 164X ALSUS 8A | 10 | | 1 | 27 | ±1.4 |
| | | | 2 | 25 | ±1.2 |
| | | | 3 | 21 | ±1.2 |
| | | | 4 | 32 | ±1.5 |
| | | | 5 | 24 | ±1.3 |
| | | | **mean** | **26** | |
| | | | **stdev** | **4** | |
| 164X ALSUS 6 | 500 | | 1 | 512 | ±6.2 |
| | | | 2 | 564 | ±6.8 |
| | | | 3 | 544 | ±6.5 |
| | | | 4 | 554 | ±6.7 |
| | | | 5 | 525 | ±6.3 |
| | | | **mean** | **540** | |
| | | | **stdev** | **21** | |
| 164X ALSUS 7A | 1100 | | 1 | 756 | ±6.7 |
| | | | 2 | 806 | ±7.2 |
| | | | 3 | 814 | ±7.3 |
| | | | 4 | 785 | ±7 |
| | | | 5 | 803 | ±7.2 |
| | | | **mean** | **793** | |
| | | | **stdev** | **23** | |



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Table 2. HDXRF Analysis of Zinc Reference Materials for Pb

| Standard ID | Certified or Expected Value for Pb mg/kg | Width of the 95% Confidence Interval on the Certified Value | Replicate | HDXRF Pb mg/kg | HDXRF 95% Confidence Interval width on the Pb measurement (mg/kg) |
|---|---|---|---|---|---|
| 41X ZSC1 | 621 | ±18 | 1 | 662 | ±44 |
| | | | 2 | 613 | ±42 |
| | | | 3 | 589 | ±41 |
| | | | 4 | 575 | ±41 |
| | | | 5 | 657 | ±44 |
| | | | **mean** | **619** | |
| | | | **stdev** | **39** | |
| 41X ZSC2 | 1110 | ±20 | 1 | 1095 | ±55 |
| | | | 2 | 1109 | ±55 |
| | | | 3 | 1124 | ±55 |
| | | | 4 | 1069 | ±54 |
| | | | 5 | 1073 | ±54 |
| | | | **mean** | **1094** | |
| | | | **stdev** | **23** | |
| 41X ZSC3 | 273 | ±12 | 1 | 263 | ±29 |
| | | | 2 | 277 | ±30 |
| | | | 3 | 268 | ±30 |
| | | | 4 | 291 | ±31 |
| | | | 5 | 244 | ±29 |
| | | | **mean** | **269** | |
| | | | **stdev** | **17** | |
| 41X ZSC4 | 1560 | ±30 | 1 | 1595 | ±66 |
| | | | 2 | 1612 | ±66 |
| | | | 3 | 1563 | ±65 |
| | | | 4 | 1563 | ±65 |
| | | | 5 | 1618 | ±66 |
| | | | **mean** | **1590** | |
| | | | **stdev** | **26** | |
| 41X ZSC6 | 77 | ±5 | 1 | 70 | ±20 |
| | | | 2 | 81 | ±21 |
| | | | 3 | 51 | ±21 |
| | | | 4 | 73 | ±22 |
| | | | 5 | 69 | ±21 |
| | | | **mean** | **69** | |
| | | | **stdev** | **11** | |



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Table 3. HDXRF Analysis of Brass Reference Materials for Pb

| Standard ID | Certified or Expected Value for Pb mg/kg | Width of the 95% Confidence Interval on the Certified Value | Replicate | HDXRF Pb mg/kg | HDXRF 95% Confidence Interval width on the Pb measurement (mg/kg) |
|---|---|---|---|---|---|
| 31X TB1 | 2010 | ±30 | 1 | 2004 | ±93 |
| | | | 2 | 1906 | ±91 |
| | | | 3 | 2100 | ±94 |
| | | | 4 | 1968 | ±91 |
| | | | 5 | 1950 | ±93 |
| | | | **mean** | **1986** | |
| | | | **stdev** | **73** | |
| 31X B19 | 25100 | ±300 | 1 | 22818 | ±204 |
| | | | 2 | 22441 | ±201 |
| | | | 3 | 23833 | ±211 |
| | | | 4 | 22307 | ±200 |
| | | | 5 | 22388 | ±199 |
| | | | **mean** | **22757** | |
| | | | **stdev** | **632** | |
| 31X B4 | 640 | ±40 | 1 | 590 | ±52 |
| | | | 2 | 668 | ±54 |
| | | | 3 | 692 | ±53 |
| | | | 4 | 731 | ±56 |
| | | | 5 | 732 | ±54 |
| | | | **mean** | **683** | |
| | | | **stdev** | **58** | |
| 31X B6 | <5 | | 1 | 16 | ±12 |
| | | | 2 | 21 | ±13 |
| | | | 3 | 26 | ±11 |
| | | | 4 | 21 | ±12 |
| | | | 5 | 18 | ±11 |
| | | | **mean** | **20** | |
| | | | **stdev** | **4** | |
| 31X B5 | 210 | ±10 | 1 | 225 | ±25 |
| | | | 2 | 190 | ±24 |
| | | | 3 | 186 | ±25 |
| | | | 4 | 218 | ±24 |
| | | | 5 | 231 | ±26 |
| | | | **mean** | **210** | |
| | | | **stdev** | **21** | |



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Table 4. HDXRF Analysis of Iron Reference Materials for Pb

| Standard ID | Certified or Expected Value for Pb mg/kg | Width of the 95% Confidence Interval on the Certified Value | Replicate | HDXRF Pb mg/kg | HDXRF 95% Confidence Interval width on the Pb measurement (mg/kg) |
|---|---|---|---|---|---|
| 11X C1 | 110 | ±20 | 1 | 121 | ±73 |
| | | | 2 | 137 | ±73 |
| | | | 3 | 143 | ±72 |
| | | | 4 | 134 | ±74 |
| | | | 5 | 142 | ±74 |
| | | | **mean** | **135** | |
| | | | **stdev** | **9** | |
| 11X C4 | 155 | ±16 | 1 | 280 | ±86 |
| | | | 2 | 333 | ±86 |
| | | | 3 | 394 | ±86 |
| | | | 4 | 256 | ±93 |
| | | | 5 | 370 | ±86 |
| | | | **mean** | **327** | |
| | | | **stdev** | **58** | |
| 11X C8 | 230 | ±20 | 1 | 402 | ±96 |
| | | | 2 | 349 | ±97 |
| | | | 3 | 349 | ±98 |
| | | | 4 | 337 | ±97 |
| | | | 5 | 377 | ±97 |
| | | | **mean** | **363** | |
| | | | **stdev** | **26** | |
| 11X C9 | 44 | ±8 | 1 | 41 | ±93 |
| | | | 2 | 89 | ±99 |
| | | | 3 | 128 | ±92 |
| | | | 4 | 153 | ±92 |
| | | | 5 | 118 | ±92 |
| | | | **mean** | **106** | |
| | | | **stdev** | **43** | |
| 11 X 0331.1 | 300 | ±20 | 1 | 546 | ±81 |
| | | | 2 | 484 | ±86 |
| | | | 3 | 538 | ±86 |
| | | | 4 | 564 | ±86 |
| | | | 5 | 493 | ±86 |
| | | | **mean** | **525** | |
| | | | **stdev** | **35** | |
| IARM 182B | 1900 | ±100 | 1 | 1604 | ±72 |
| | | | 2 | 1661 | ±28 |
| | | | 3 | 1567 | ±72 |
| | | | 4 | 1544 | ±72 |
| | | | 5 | 1777 | ±29 |
| | | | **mean** | **1631** | |
| | | | **stdev** | **93** | |

Table 5. HDXRF Analysis of Other Metal Alloy Reference Materials for Pb



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| Standard ID | Material | Certified or Expected Value for Pb mg/kg | Width of the 95% Confidence Interval on the Certified Value | Replicate | HDXRF Pb mg/kg | HDXRF 95% Confidence Interval width on the Pb measurement (mg/kg) |
|---|---|---|---|---|---|---|
| 73X SC 11 | Tin | 610 | ±20 | 1 | 465 | ±60 |
| | | | | 2 | 430 | ±58 |
| | | | | 3 | 415 | ±60 |
| | | | | 4 | 426 | ±59 |
| | | | | 5 | 444 | ±59 |
| | | | | **mean** | **436** | |
| | | | | **stdev** | **19** | |
| 44X ZnCd30 | 70% Zn/ 30% Cd | 890 | | 1 | 879 | ±6.7 |
| | | | | 2 | 803 | ±7.2 |
| | | | | 3 | 929 | ±7.3 |
| | | | | 4 | 859 | ±7 |
| | | | | 5 | 877 | ±7.2 |
| | | | | **mean** | **869** | |
| | | | | **stdev** | **45** | |
| 95X 117 | 45%Bi/23%Pb | 230000 | | 1 | 185599 | ±1924 |
| | | | | 2 | 182119 | ±1898 |
| | | | | 3 | 186116 | ±1926 |
| | | | | 4 | 177669 | ±1660 |
| | | | | 5 | 183510 | ±1908 |
| | | | | **mean** | **183003** | |
| | | | | **stdev** | **3388** | |
| *14X HS3 | Steel with 10%Co/18%W | 100 | ±10 | 1 | <5 | |
| | | | | 2 | <5 | |
| | | | | 3 | <5 | |
| | | | | 4 | <5 | |
| | | | | 5 | <5 | |

*This iron-based alloy contained a high concentration of tungsten (W) in addition to 440 mg/kg arsenic (As). There appears to be some spectral overlaps of lead peaks due to high W levels that have impacted software calculations.



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Table 6. HDXRF Analysis of Glass Reference Materials for Pb

| Standard ID | Certified or Expected Value for Pb mg/kg | Width of the 95% Confidence Interval on the Certified Value | Replicate | HDXRF Pb mg/kg | HDXRF 95% Confidence Interval width on the Pb measurement (mg/kg) |
|---|---|---|---|---|---|
| NIST 612 | 38.6 | ±0.2 | 1 | 41 | ±3.2 |
| | | | 2 | 44 | ±3.5 |
| | | | 3 | 43 | ±3.3 |
| | | | 4 | 45 | ±3.3 |
| | | | 5 | 41 | ±3.2 |
| | | | **mean** | **43** | |
| | | | **stdev** | **2** | |
| NIST 616 | 1.85 | ±0.04 | 1 | <5 | |
| | | | 2 | <5 | |
| | | | 3 | <5 | |
| NIST 1412 | 40800 | ±1580 | 1 | 48225 | ±427 |
| | | | 2 | 47651 | ±422 |
| | | | 3 | 49001 | ±434 |
| | | | 4 | 48501 | ±429 |
| | | | 5 | 48156 | ±426 |
| | | | **mean** | **48307** | |
| | | | **stdev** | **495** | |
| ROHS1-3 | 0 | | 1 | 15 | ±1.5 |
| | | | 2 | 15 | ±1.5 |
| | | | 3 | 16 | ±1.5 |
| | | | 4 | 15 | ±1.6 |
| | | | 5 | 16 | ±1.5 |
| | | | **mean** | **15** | |
| | | | **stdev** | **1** | |
| ROHS2-3 | 1000 | | 1 | 910 | ±9.2 |
| | | | 2 | 1055 | ±10 |
| | | | 3 | 901 | ±9.3 |
| | | | 4 | 1004 | ±10 |
| | | | 5 | 885 | ±9.2 |
| | | | **mean** | **951** | |
| | | | **stdev** | **74** | |
| ROHS3-3 | 5000 | | 1 | 4905 | ±43 |
| | | | 2 | 5203 | ±46 |
| | | | 3 | 5099 | ±45 |
| | | | 4 | 5087 | ±44 |
| | | | 5 | 4960 | ±43 |
| | | | **mean** | **5051** | |
| | | | **stdev** | **119** | |
| BCR 664 | 53.1 | ±2.6 | 1 | 64 | ±2.5 |
| | | | 2 | 62 | ±2.5 |
| | | | 3 | 62 | ±2.5 |
| | | | 4 | 66 | ±2.6 |
| | | | 5 | 64 | ±2.5 |
| | | | **mean** | **64** | |
| | | | **stdev** | **2** | |
| BCR 126A | 222700 | ±600 | 1 | 475993 | ±4195 |
| | | | 2 | 494767 | ±4361 |
| | | | 3 | 495570 | ±4368 |
| | | | 4 | 482629 | ±4254 |
| | | | 5 | 489280 | ±4313 |
| | | | **mean** | **487648** | |
| | | | **stdev** | **8324** | |

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Table 7. HDXRF Analysis of Homogeneous Metal and Glass Samples for Pb

| Sample ID | Material | Replicate | HDXRF Pb mg/kg | HDXRF 95% Confidence Interval | ICP Pb mg/kg |
|---|---|---|---|---|---|
| 10-304-3243 | Aluminum | 1 | 563 | ±5.9 | 604 |
| | | 2 | 625 | ±6.1 | 634 |
| | | 3 | 615 | ±6 | 607 |
| | | 4 | 754 | ±6.8 | |
| | | 5 | 639 | ±6.2 | |
| | | **mean** | **639.2** | | **615.0** |
| | | **stdev** | **70.3** | | **16.5** |
| 10-304-3244 | Aluminum | 1 | 589 | ±5.8 | 602 |
| | | 2 | 482 | ±5.1 | 577 |
| | | 3 | 626 | ±6 | 614 |
| | | 4 | 624 | ±5.8 | |
| | | 5 | 592 | ±5.7 | |
| | | **mean** | **582.6** | | **597.7** |
| | | **stdev** | **58.8** | | **18.9** |
| 11-840-8965-03 | Tin (2% Bi) | 1 | 352 | ±17 | 1024 |
| | | 2 | 734 | ±21 | 1085 |
| | | 3 | 311 | ±16 | 900 |
| | | **mean** | **465.7** | | **1003.0** |
| | | **stdev** | **233.3** | | **94.3** |
| 11-840-8965-04 | Tin (2% Bi) | 1 | 337 | ±18 | 1004 |
| | | 2 | 334 | ±16 | 1015 |
| | | 3 | 265 | ±19 | 1001 |
| | | 4 | 314 | ±16 | |
| | | **mean** | **312.5** | | **1006.7** |
| | | **stdev** | **33.3** | | **7.4** |
| 11-840-8967-06 | Tin (2% Bi) | 1 | 678 | ±20 | 1000 |
| | | 2 | 726 | ±22 | 1010 |
| | | 3 | | | 1004 |
| | | **mean** | **702.0** | | **1005** |
| | | **stdev** | **33.9** | | **5.0** |
| 11-840-8967-07 | Tin (2% Bi) | 1 | 486 | ±19 | 932 |
| | | 2 | 419 | ±19 | 1017 |
| | | 3 | | | 965 |
| | | **mean** | **452.5** | | **971** |
| | | **stdev** | **47.4** | | **42.9** |
| 11-840-8968-03 | Tin (2% Bi) | 1 | 314 | ±16 | 986 |
| | | 2 | 590 | ±19 | 992 |
| | | 3 | 556 | ±19 | 1005 |
| | | 4 | 409 | ±18 | |
| | | **mean** | **467.3** | | **994.3** |
| | | **stdev** | **128.9** | | **9.7** |



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Table 7.
Continued

| Sample ID | Material | Replicate | HDXRF Pb mg/kg | HDXRF 95% Confidence Interval | ICP Pb mg/kg |
|---|---|---|---|---|---|
| 11-840-8968-07 | Tin (2% Bi) | 1 | 312 | ±15 | 987 |
| | | 2 | 270 | ±15 | 982 |
| | | 3 | 275 | ±15 | 987 |
| | | 4 | 250 | ±15 | |
| | | **mean** | **276.8** | | **985.3** |
| | | **stdev** | **25.9** | | **2.9** |
| 10-840-8728-06z | Zn | 1 | 26 | ±13 | 36 |
| | | 2 | 25 | ±14 | 37 |
| | | | | | 36 |
| | | **mean** | **25.5** | | **36** |
| | | **stdev** | **0.7** | | **0.6** |
| 10-840-8728-02z | Zn | 1 | 47 | ±11 | 80 |
| | | 2 | 77 | ±16 | 79 |
| | | 3 | | | 78 |
| | | **mean** | **62** | | **79** |
| | | **stdev** | **21.2** | | **1.0** |
| 10-304-4674-02pk | Al80%/Zn4% | 1 | 2300 | ±20 | 1670 |
| | | 2 | 2344 | ±20 | 1639 |
| | | 3 | 1930 | ±17 | 1655 |
| | | 4 | 2587 | ±22 | |
| | | **mean** | **2290** | | **1655** |
| | | **stdev** | **271** | | **15.5** |
| 10-304-4674-02pp | Al80%/Zn4% | 1 | 1793 | ±15 | 1565 |
| | | 2 | 1723 | ±15 | 1565 |
| | | 3 | 1815 | ±16 | 1540 |
| | | **mean** | **1777** | | **1557** |
| | | **stdev** | **48** | | **14.4** |
| 11-304-4324 p | Glass crystals | 1 | 696171 | ±6145 | 201972 |
| 11-304-4324 b | Glass crystals | 1 | 662874 | ±5851 | 258650 |
| 11-304-4211 p | Glass crystals | 1 | 31293 | ±276 | 182777 |
| 11-304-4211 c | Glass crystals | 1 | 49364 | ±437 | 304438 |
| 11-304-4209 c | Glass crystals | 1 | 135048 | ±1192 | 297061 |
| 11-304-4209 r | Glass crystals | 1 | 68 | ±4 | 40 |
| | | 2 | 40 | ±4 | |
| | | 3 | 36 | ±3 | |
| | | **mean** | **48** | | **40** |
| | | **stdev** | **17** | | |



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Table 7.
Continued

| Sample ID | Material | Replicate | HDXRF Pb mg/kg | HDXRF 95% Confidence Interval | ICP Pb mg/kg |
|---|---|---|---|---|---|
| 12-304-3904-01 o | glass bead | 1 | 113 | ±4 | 96.3 |
| | | 2 | 162 | ±4 | 93.1 |
| | | 3 | 140 | ±4 | 132.8 |
| | | 4 | 164 | ±4 | |
| | | **mean** | **145** | | **107.4** |
| | | **stdev** | **24** | | **20.1** |
| 12-304-3904-01 g | glass bead | 1 | 305 | ±15 | 258.8 |
| | | 2 | 320 | ±12 | 323.0 |
| | | 3 | 321 | ±12 | 256.8 |
| | | 4 | 312 | ±11 | |
| | | 5 | 326 | ±12 | |
| | | **mean** | **320** | | **279.5** |
| | | **stdev** | **6** | | **33.6** |
| 12-304-3904-01 p | glass bead | 1 | 624 | ±46 | 670.4 |
| | | 2 | 874 | ±92 | 658.6 |
| | | 3 | 724 | ±60 | 678.0 |
| | | 4 | 582 | ±50 | |
| | | 5 | 742 | ±60 | |
| | | **mean** | **731** | | **669.0** |
| | | **stdev** | **119** | | **9.7** |



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Table 8. HHXRF Analysis of Aluminum Reference Materials for Pb

| Standard ID | Material | Certified or Expected Value for Pb mg/kg | Width of the 95% Confidence Interval on the Certified Value | Replicate | HHXRF Pb mg/kg | HHXRF 95% Confidence Interval width on the Pb measurement (mg/kg) |
|---|---|---|---|---|---|---|
| AA242.2 | Aluminum | 470 | ±10 | 1 | 452 | ±17 |
| | | | | 2 | 437 | ±17 |
| | | | | 3 | 453 | ±17 |
| | | | | 4 | 437 | ±17 |
| | | | | 5 | 449 | ±17 |
| | | | | **mean** | **446** | |
| | | | | **stdev** | **8** | |
| AA295.2 | Aluminum | 300 | ±10 | 1 | 319 | ±14 |
| | | | | 2 | 322 | ±14 |
| | | | | 3 | 320 | ±14 |
| | | | | 4 | 316 | ±14 |
| | | | | 5 | 331 | ±14 |
| | | | | **mean** | **322** | |
| | | | | **stdev** | **6** | |
| A330.0Al-B012 | Aluminum | 1300 | ±50 | 1 | 1423 | ±34 |
| | | | | 2 | 1481 | ±35 |
| | | | | 3 | 1415 | ±34 |
| | | | | 4 | 1424 | ±33 |
| | | | | 5 | 1462 | ±34 |
| | | | | **mean** | **1441** | |
| | | | | **stdev** | **29** | |
| 164X ALSUS 8 A | Aluminum | 10 | | 1 | <LOD | ±14 |
| | | | | 2 | <LOD | ±13 |
| | | | | 3 | <LOD | ±13 |
| 164X ALSUS 6 | Al 88%/Cu 12% | 500 | | 1 | 777 | ±26 |
| | | | | 2 | 799 | ±27 |
| | | | | 3 | 764 | ±22 |
| | | | | 4 | 778 | ±26 |
| | | | | 5 | 781 | ±26 |
| | | | | **mean** | **780** | |
| | | | | **stdev** | **13** | |
| 164X ALSUS 7 A | Aluminum | 1100 | | 1 | 1055 | ±27 |
| | | | | 2 | 1042 | ±26 |
| | | | | 3 | 1053 | ±26 |
| | | | | 4 | 1018 | ±25 |
| | | | | 5 | 1007 | ±26 |
| | | | | **mean** | **1035** | |
| | | | | **stdev** | **21** | |



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Table 9. HHXRF Analysis of Zinc Reference Materials for Pb

| Standard ID | Material | Certified or Expected Value for Pb mg/kg | Width of the 95% Confidence Interval on the Certified Value | Replicate | HHXRF Pb mg/kg | HHXRF 95% Confidence Interval width on the Pb measurement (mg/kg) |
|---|---|---|---|---|---|---|
| 41X ZSC1 | Zinc | 621 | ±18 | 1 | 739 | ±55 |
| | | | | 2 | 730 | ±54 |
| | | | | 3 | 749 | ±55 |
| | | | | 4 | 751 | ±50 |
| | | | | 5 | 761 | ±45 |
| | | | | **mean** | **746** | |
| | | | | **stdev** | **12** | |
| 41X ZSC2 | Zinc | 1110 | ±20 | 1 | 1250 | ±68 |
| | | | | 2 | 1296 | ±70 |
| | | | | 3 | 1325 | ±70 |
| | | | | 4 | 1334 | ±69 |
| | | | | 5 | 1206 | ±66 |
| | | | | **mean** | **1282** | |
| | | | | **stdev** | **54** | |
| 41X ZSC3 | Zinc | 273 | ±12 | 1 | 336 | ±40 |
| | | | | 2 | 382 | ±42 |
| | | | | 3 | 399 | ±43 |
| | | | | 4 | 342 | ±36 |
| | | | | 5 | 366 | ±37 |
| | | | | **mean** | **365** | |
| | | | | **stdev** | **27** | |
| 41X ZSC4 | Zinc | 1560 | ±30 | 1 | 1801 | ±81 |
| | | | | 2 | 1805 | ±81 |
| | | | | 3 | 1939 | ±84 |
| | | | | 4 | 1909 | ±83 |
| | | | | 5 | 1877 | ±81 |
| | | | | **mean** | **1866** | |
| | | | | **stdev** | **62** | |
| 41X ZSC6 | Zinc | 77 | ±5 | 1 | 117 | ±31 |
| | | | | 2 | 128 | ±31 |
| | | | | 3 | 118 | ±31 |
| | | | | 4 | 123 | ±25 |
| | | | | 5 | 132 | ±25 |
| | | | | **mean** | **124** | |
| | | | | **stdev** | **6** | |



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Table 10. HHXRF Analysis of Brass Reference Materials for Pb

| Standard ID | Material | Certified or Expected Value for Pb mg/kg | Width of the 95% Confidence Interval on the Certified Value | Replicate | HHXRF Pb mg/kg | HHXRF 95% Confidence Interval width on the Pb measurement (mg/kg) |
|---|---|---|---|---|---|---|
| 31X TB1 | Brass | 2010 | ±30 | 1 | 2362 | ±88 |
| | | | | 2 | 2344 | ±88 |
| | | | | 3 | 2397 | ±84 |
| | | | | 4 | 2307 | ±71 |
| | | | | 5 | 2356 | ±86 |
| | | | | **mean** | **2353** | |
| | | | | **stdev** | **32** | |
| 31X B19 | Brass | 25100 | ±300 | 1 | 27062 | ±271 |
| | | | | 2 | 27232 | ±272 |
| | | | | 3 | 27205 | ±272 |
| | | | | 4 | 27300 | ±300 |
| | | | | 5 | 26900 | ±300 |
| | | | | **mean** | **27140** | |
| | | | | **stdev** | **160** | |
| 31X B4 | Brass | 640 | ±40 | 1 | 831 | ±54 |
| | | | | 2 | 837 | ±54 |
| | | | | 3 | 834 | ±54 |
| | | | | 4 | 811 | ±44 |
| | | | | 5 | 809 | ±44 |
| | | | | **mean** | **824** | |
| | | | | **stdev** | **13** | |
| 31X B6 | Brass | <5 | | 1 | 100 | ±25 |
| | | | | 2 | 86 | ±24 |
| | | | | 3 | 108 | ±26 |
| | | | | 4 | 84 | ±21 |
| | | | | 5 | 111 | ±27 |
| | | | | **mean** | **98** | |
| | | | | **stdev** | **12** | |
| 31X B5 | Brass | 210 | ±10 | 1 | 311 | ±36 |
| | | | | 2 | 282 | ±35 |
| | | | | 3 | 329 | ±37 |
| | | | | 4 | 304 | ±29 |
| | | | | 5 | 281 | ±29 |
| | | | | **mean** | **301** | |
| | | | | **stdev** | **20** | |



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Table 11. HHXRF Analysis of Iron Reference Materials for Pb

| Standard ID | Material | Certified or Expected Value for Pb mg/kg | Width of the 95% Confidence Interval on the Certified Value | Replicate | HHXRF Pb mg/kg | HHXRF 95% Confidence Interval width on the Pb measurement (mg/kg) |
|---|---|---|---|---|---|---|
| 11X C1 | Iron | 110 | ±20 | 1 | <LOD | ±48 |
| | | | | 2 | <LOD | ±47 |
| | | | | 3 | <LOD | ±23 |
| | | | | 4 | <LOD | ±41 |
| | | | | 5 | <LOD | ±43 |
| 11X C4 | Iron | 155 | ±16 | 1 | 192 | ±29 |
| | | | | 2 | 234 | ±30 |
| | | | | 3 | 147 | ±27 |
| | | | | 4 | 219 | ±29 |
| | | | | 5 | 220 | ±29 |
| | | | | **mean** | **202** | |
| | | | | **stdev** | **35** | |
| 11X C8 | Iron | 230 | ±20 | 1 | 197 | ±40 |
| | | | | 2 | 231 | ±40 |
| | | | | 3 | 199 | ±36 |
| | | | | 4 | 249 | ±40 |
| | | | | 5 | 200 | ±40 |
| | | | | **mean** | **215** | |
| | | | | **stdev** | **24** | |
| 11X C9 | Iron | 44 | ±8 | 1 | <LOD | ±38 |
| | | | | 2 | <LOD | ±39 |
| | | | | 3 | <LOD | ±33 |
| 11 X 0331.1 | Iron | 300 | ±20 | 1 | 440 | ±34 |
| | | | | 2 | 463 | ±35 |
| | | | | 3 | 470 | ±33 |
| | | | | 4 | 477 | ±34 |
| | | | | 5 | 478 | ±33 |
| | | | | **mean** | **466** | |
| | | | | **stdev** | **16** | |
| IARM 182B | Iron | 1900 | ±100 | 1 | 1759 | ±57 |
| | | | | 2 | 1911 | ±59 |
| | | | | 3 | 1730 | ±60 |
| | | | | 4 | 1921 | ±58 |
| | | | | 5 | 1708 | ±60 |
| | | | | **mean** | **1806** | |
| | | | | **stdev** | **102** | |



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Table 12. HHXRF Analysis of Other Metal Alloy Reference Materials for Pb

| Standard ID | Material | Certified or Expected Value for Pb mg/kg | Width of the 95% Confidence Interval on the Certified Value | Replicate | HHXRF Pb mg/kg | HHXRF 95% Confidence Interval width on the Pb measurement (mg/kg) |
|---|---|---|---|---|---|---|
| 73X SC 11 | Tin | 610 | ±20 | 1 | 299 | ±61 |
| | | | | 2 | 360 | ±62 |
| | | | | 3 | 313 | ±61 |
| | | | | 4 | 254 | ±60 |
| | | | | 5 | 292 | ±60 |
| | | | | **mean** | **304** | |
| | | | | **stdev** | **38** | |
| 44X ZnCd30 | 70% Zn/ 30% Cd | 890 | | 1 | 862 | ±66 |
| | | | | 2 | 834 | ±65 |
| | | | | 3 | 871 | ±66 |
| | | | | 4 | 892 | ±65 |
| | | | | 5 | 872 | ±65 |
| | | | | **mean** | **866** | |
| | | | | **stdev** | **21** | |
| 95X 117 | 45%Bi/23%Pb | | | 1 | 230687 | ±790 |
| | | | | 2 | 229001 | ±796 |
| | | | | 3 | 230112 | ±796 |
| | | | | 4 | 228600 | ±800 |
| | | | | 5 | 228000 | ±800 |
| | | | | **mean** | **229280** | |
| | | | | **stdev** | **1101** | |
| 14X HS3 | Steel with 10%Co/18%W | 100 | ±10 | 1 | <LOD | ±66 |
| | | | | 2 | <LOD | ±68 |



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Table 13. HHXRF Analysis of Glass Reference Materials for Pb

| Standard ID | Material | Certified or Expected Value for Pb mg/kg | Width of the 95% Confidence Interval on the Certified Value | Replicate | HHXRF Pb mg/kg | HHXRF 95% Confidence Interval width on the Pb measurement (mg/kg) |
|---|---|---|---|---|---|---|
| NIST 612 | Glass | 38.6 | ±0.2 | 1 | 44 | ±6.4 |
| | | | | 2 | 35 | ±6.1 |
| | | | | 3 | 41 | ±6.3 |
| | | | | **mean** | **40** | |
| | | | | **stdev** | **5** | |
| NIST 616 | Glass | 1.85 | ±0.04 | 1 | <LOD | ±4.3 |
| | | | | 2 | <LOD | ±5.8 |
| NIST 1412 | Glass | 40800 | ±1580 | 1 | 41858 | ±471 |
| | | | | 2 | 41709 | ±453 |
| | | | | 3 | 42374 | ±477 |
| | | | | **Avg** | **41980** | |
| | | | | **stdev** | **349** | |
| ROHS1-3 | Glass | 0 | | 1 | <LOD | ±9.5 |
| | | | | 2 | <LOD | ±7.9 |
| | | | | **Avg** | **<LOD** | |
| | | | | **stdev** | | |
| ROHS2-3 | Glass | 1000 | | 1 | 1108 | ±45 |
| | | | | 2 | 1121 | ±46 |
| | | | | 3 | 1100 | ±45 |
| | | | | **Avg** | **1110** | |
| | | | | **stdev** | **11** | |
| ROHS3-3 | Glass | 5000 | | 1 | 5486 | ±55 |
| | | | | 2 | 5587 | ±56 |
| | | | | 3 | 5448 | ±55 |
| | | | | **Avg** | **5507** | |
| | | | | **stdev** | **72** | |
| BCR 664 | Glass | 53.1 | ±2.6 | 1 | 59 | ±6 |
| | | | | 2 | 56 | ±6 |
| | | | | 3 | 52 | ±5.9 |
| | | | | **Avg** | **56** | |
| | | | | **stdev** | **3** | |
| BCR 126A | Glass | 222700 | ±600 | 1 | 173778 | ±2513 |
| | | | | 2 | 171099 | ±2442 |
| | | | | 3 | 170463 | ±2264 |
| | | | | **Avg** | **171780** | |
| | | | | **stdev** | **1759** | |



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Table 14. HHXRF Analysis of Homogeneous Metal and Glass Samples for Pb

| Sample/Material ID | Material | Replicate | HHXRF Pb mg/kg | HHXRF 95% Confidence Interval | ICP Pb mg/kg |
|---|---|---|---|---|---|
| 10-304-3243 | Aluminum | 1 | 531 | ±16 | 604 |
| | | 2 | 524 | ±16 | 634 |
| | | 3 | 621 | ±18 | 607 |
| | | 4 | 513 | ±16 | |
| | | 5 | 589 | ±17 | |
| | | **Mean** | **555.6** | | **615.0** |
| | | **Stdev** | **46.9** | | **16.5** |
| 10-304-3244 | Aluminum | 1 | 504 | ±16 | 602 |
| | | 2 | 515 | ±16 | 577 |
| | | 3 | 466 | ±15 | 614 |
| | | 4 | 548 | ±16 | |
| | | 5 | 565 | ±17 | |
| | | **Mean** | **519.6** | | **597.7** |
| | | **Stdev** | **38.7** | | **18.9** |
| 11-840-8965-03 | Tin (2% Bi) | 1 | 619 | ±117 | 1024 |
| | | 2 | 479 | ±118 | 1085 |
| | | 3 | 468 | ±115 | 900 |
| | | **Mean** | **522.0** | | **1003.0** |
| | | **Stdev** | **84.2** | | **94.3** |
| 11-840-8965-04 | Tin (2% Bi) | 1 | 679 | ±86 | 1004 |
| | | 2 | 667 | ±87 | 1015 |
| | | 3 | 638 | ±86 | 1001 |
| | | **Mean** | **661.3** | | **1006.7** |
| | | **Stdev** | **21.1** | | **7.4** |
| 11-840-8967-06 | Tin (2% Bi) | 1 | 566 | ±127 | 1000 |
| | | 2 | 541 | ±126 | 1010 |
| | | 3 | 650 | ±127 | 1004 |
| | | **Mean** | **586** | | **1005** |
| | | **Stdev** | **57.1** | | **5.0** |
| 11-840-8967-07 | Tin (2% Bi) | 1 | 828 | ±109 | 932 |
| | | 2 | 708 | ±107 | 1017 |
| | | 3 | 639 | ±107 | 965 |
| | | **Mean** | **725** | | **971** |
| | | **Stdev** | **95.6** | | **42.9** |
| 11-840-8968-03 | Tin (2% Bi) | 1 | 768 | ±98 | 986 |
| | | 2 | 761 | ±99 | 992 |
| | | 3 | 787 | ±99 | 1005 |
| | | **Mean** | **772.0** | | **994.3** |
| | | **Stdev** | **13.5** | | **9.7** |



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Table 14.
Continued

| Sample/Material ID | Material | Replicate | HHXRF Pb mg/kg | HHXRF 95% Confidence Interval | ICP Pb mg/kg |
|---|---|---|---|---|---|
| 11-840-8968-07 | Tin (2% Bi) | 1 | 625 | ±115 | 987 |
| | | 2 | 578 | ±118 | 982 |
| | | 3 | 640 | ±117 | 987 |
| | | **Mean** | **614.3** | | **985.3** |
| | | **Stdev** | **32.3** | | **2.9** |
| 10-840-8728-02z | | 1 | <LOD | ±52 | 80 |
| | | 2 | | | 79 |
| | | 3 | | | 78 |
| | | **Mean** | | | **79** |
| | | **Stdev** | | | **1.0** |
| 10-304-4674-02pk | Al80%/Zn4% | 1 | 2157 | ±43 | 1670 |
| | | 2 | 2288 | ±43 | 1639 |
| | | 3 | 2188 | ±45 | 1655 |
| | | **Mean** | **2211** | | **1655** |
| | | **Stdev** | **68.5** | | **15.5** |
| 10-304-4674-02pp | Al80%/Zn4% | 1 | 2109 | ±44 | 1565 |
| | | 2 | 2108 | ±43 | 1565 |
| | | 3 | 2093 | ±43 | 1540 |
| | | **Mean** | **2103** | | **1557** |
| | | **Stdev** | **9.0** | | **14.4** |
| 11-304-4324 p | Glass crystals | 1 | 278214 | ±19763 | 201972 |
| 11-304-4324 b | Glass crystals | 1 | 331197 | ±32555 | 258650 |
| 11-304-4211 p | Glass crystals | 1 | 199707 | ±12490 | 182777 |
| 11-304-4211 c | Glass crystals | 1 | 357393 | ±25424 | 304438 |
| 11-304-4209 c | Glass crystals | 1 | 345041 | ±40291 | 297061 |
| 12-304-3904-01 o | glass bead | 1 | 94 | ±9 | 96.3 |
| | | 2 | | | 93.1 |
| | | 3 | | | 132.8 |
| | | **Mean** | | | **107.4** |
| | | **Stdev** | | | **20.1** |
| 12-304-3904-01 g | glass bead | 1 | 302 | ±24 | 258.8 |
| | | 2 | | | 323.0 |
| | | 3 | | | 256.8 |
| | | **Avg** | | | **279.5** |
| | | **Stdev** | | | **33.6** |
| 12-304-3904-01 p | glass bead | 1 | 704 | ±37 | 670.4 |
| | | 2 | | | 658.6 |
| | | 3 | | | 678.0 |
| | | **Avg** | | | **669.0** |
| | | **Stdev** | | | **9.7** |



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## Appendix B

## Sample Identifications and Reference Material Certificates of Analysis

| Sample Identification | Product/Part |
|---|---|
| 11-840-8968-07 | Jewelry pendant |
| 10-840-8728-02Z | Zipper slide |
| 10-304-4674-02pk | Children's badminton racket metal frame |
| 10-304-4674-02pp | Children's badminton racket metal frame |
| 11-304-4324 p | Pink rhinestone |
| 11-304-4324 b | Black rhinestone |
| 11-304-4211 p | Pink rhinestone |
| 11-304-4211 c | Clear rhinestone |
| 11-304-4209 c | Clear rhinestone |
| 12-304-3904-01 o | Orange glass cylindrical bead from bead set |
| 12-304-3904-01 g | Green glass cylindrical bead from bead set |
| 12-304-3904-01 p | Purple glass cylindrical bead from bead set |
| 10-304-3243 | Scooter, handle bar clamp |
| 10-304-3244 | Scooter, handle bar clamp |
| 11-840-8965-03 | Jewelry pendant |
| 11-840-8965-04 | Jewelry pendant |
| 11-840-8967-06 | Jewelry pendant |
| 11-840-8967-07 | Jewelry pendant |
| 11-840-8968-03 | Jewelry pendant |



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**TAB D: Notice of Requirements for 16 CFR part 1224, *Safety Standard for Portable Bedrails***

**T**
**A**
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**UNITED STATES**
**CONSUMER PRODUCT SAFETY COMMISSION**
**4330 EAST WEST HIGHWAY**
**BETHESDA, MARYLAND 20814**

**Memorandum**

Date: February 8, 2012

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director
Robert J. Howell, Assistant Executive Director for Safety Operations

FROM: DeWane J. Ray, Assistant Executive Director
Office of Hazard Identification and Reduction

Rohit Khanna, Project Manager
Office of Hazard Identification and Reduction

SUBJECT: Accreditation Requirements for Third Party Conformity Assessment Bodies to Test Portable Bed Rails for Compliance to 16 CFR Part 1224, *Safety Standard for Portable Bed Rails*

# I. Introduction

On August 14, 2008, the Consumer Product Safety Improvement Act (hereafter referred to as the "Act" or "CPSIA") was signed into law [Public Law 110-314]. Section 102 of the Act mandates that third party testing be conducted for certain children's products. Before importing for consumption or warehousing or distributing in commerce any children's product that is subject to a U.S. Consumer Product Safety Commission (CPSC) children's product safety rule, every manufacturer of such children's product (and the private labeler of such children's product if such product bears a private label) shall: (A) submit sufficient samples of the children's product, or samples that are identical in all material respects, to a third party conformity assessment body (hereafter referred to as a third party testing laboratory) accredited under requirements to be established by the Commission to be tested for compliance with such children's product safety rule; and (B) based on the assessment by the third party testing laboratory, issue a certificate which certifies that such children's product complies with the children's product safety rule.[32]

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

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

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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.

This memorandum presents CPSC staff's recommendation for establishing accreditation requirements for laboratories wanting to test products for compliance to the regulation for portable bed rails. The test methods for portable bed rails are described in 16 CFR part 1224, *Safety Standard for Portable Bed Rails.*

## II. Safety Standard for Portable Bed Rails

On February 22, 2012, the Commission voted to issue a final rule to establish a safety standard for portable bed rails. The Commission issued the final rule pursuant to section 104 of the CPSIA, and section 104(b)(1)(B) of the CPSIA states that such rules are consumer product safety standards.

Section 14(a)(2) of the Consumer Product Safety Act ("CPSA") requires manufacturers of children's products that are subject to a "children's product safety rule" to submit sufficient samples of the children's product, or samples that are identical in all material respects to the product, to an accredited third party conformity assessment body to be tested for compliance with such children's product safety rule. Section 14(f)(1) of the CPSA defines "children's product safety rule" as "a consumer product safety rule under this Act 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." Thus, because the final rule establishing a safety standard for bed rails is a consumer product safety standard, it is a "children's product safety rule" for which third party testing is required.

Consequently, to enable third party testing to be done, there is a need to establish the criteria for the acceptance of the accreditation of third party conformity assessment bodies to test products for compliance to the safety standard for bed rails. We recommend, therefore, that the Commission apply the same "baseline" accreditation requirements that apply to all third party conformity assessment bodies. We further recommend that, consistent with previous notices of requirements for rules issued under section 104 of the CPSIA, that the scope of accreditation include testing in accordance with 16 CFR part 1224.

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

Staff's recommended accreditation approach uses and builds upon existing systems of conformity assessment based upon ISO/IEC standards and internationally recognized accrediting bodies. In the field of children's products, some manufacturers, importers, and/or retailers have instituted their own processes for third party testing to demonstrate conformity with certain mandatory and voluntary safety standards. Some of these systems already may dictate testing by third party laboratories that are accredited by an ILAC-MRA signatory accreditation body in accordance with ISO/IEC 17025:2005. It is possible that some products in the marketplace will undergo testing earlier than the mandatory effective date, as established by the Commission, in a way that would support certification with the safety standard for portable bed rails.



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

1. The product[33] was tested by a third party conformity assessment body accredited to ISO/IEC 17025:2005 by an ILAC-MRA signatory at the time of the test. The scope of the testing laboratory's accreditation must include the test methods specified in this notice. For firewalled conformity assessment bodies, the firewalled conformity assessment body must be one that the Commission has accredited by order at or before the time the product was tested, even if the order did not include the test methods specified in this notice. For governmental testing laboratories, the testing laboratory must be one whose accreditation was accepted by the Commission, even if the scope of accreditation did not include the test methods specified in this notice.;
2. The testing laboratory's application for acceptance of its accreditation is accepted by the CPSC by the effective date of 16 CFR part 1112.
3. The test results show compliance with 16 CFR part 1224.
4. The children's product was tested on or after the publication date of the 16 CFR part 1224 Final Rule, and before the effective date of 16 CFR part 1112.
5. The testing laboratory's accreditation remains in effect through the effective date of 16 CFR part 1112.

These provisions are patterned after those in 16 CFR parts 1217, 1219, and 1220, regarding retrospective testing.

This policy would allow for certification of products on the basis of testing performed relatively recently by an accredited third party laboratory, thereby providing a substantial degree of assurance of compliance with the standard.

Under this approach, firms that elect voluntarily to have their portable bed rails tested by competent laboratories before the safety standard's effective date will not be required to have those same products retested to verify initial product compliance once 16 CFR part 1112 becomes effective to certify compliance to the 16 CFR part 1224. 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.[34] Manufacturers and private labelers that do not elect voluntarily to have their portable bed rails tested by competent laboratories prior to the effective date of the safety standard must have third party testing conducted by a CPSC-accepted laboratory to certify products manufactured on or after the effective date.

Staff recommends that governmental laboratories be treated like other third party laboratories with respect to certifications based on testing prior to the effective date. Nonetheless,

[33] 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.

[34] 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.



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manufacturers and private labelers must consider carefully that governmental laboratories also will need to meet the conditions for governmental entities as required by the Act.

Staff recommends that laboratories owned, managed, or controlled by a manufacturer or private labeler be treated like other third party laboratories with respect to certifications based on testing prior to the effective date. Nonetheless, manufacturers and private labelers (or other parties who seek product certification) must consider carefully that such laboratories also must meet the conditions for firewalled conformity assessment bodies, as required by the Act.

## IV. Environmental Considerations

Generally, CPSC mandatory requirements are considered to "have little or no potential for affecting the human environment," and environmental assessments are not usually prepared for such actions (see 16 CFR § 1021.5(c)(1)). Nothing in these recommended accreditation requirements alters that expectation. Therefore, staff does not expect such requirements to have any negative environmental impact.

## V. Staff Recommendation for Accreditation Requirements for Third Party Laboratories to Test Portable Bed Rails

Staff recommends that the Commission approve staff's proposed approach for accepting accreditation of laboratories to test for compliance with the regulation for portable bed rails at 16 CFR part 1224. Staff recommends that the Commission approve publishing the accreditation acceptance requirements in a Federal Register (FR) notice as drafted by the Office of the General Counsel. The FR notice would establish the requirements for laboratories to become accredited to test for compliance with the regulation for portable bed rails.



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**TAB E: Comparison of *American National Standard for Four Wheel All-Terrain Vehicles* ANSI/SVIA 1 - 2007 and 2010 Revisions with Respect to Testing Youth All-Terrain Vehicles**

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

**Memorandum**

Date: February 7, 2012

TO : Elizabeth Leland, Project Manager - ATVs

THROUGH: George A. Borlase, Ph. D., P.E.
Associate Executive Director, Directorate for Engineering Sciences

Mark Kumagai
Director, Division of Mechanical Engineering

FROM : Caroleene Paul, Division of Mechanical Engineering

SUBJECT : Comparison of *American National Standard for Four Wheel All-Terrain Vehicles* ANSI/SVIA 1 - 2007 and 2010 revisions with respect to testing youth all terrain vehicles

## I. Introduction

The *American National Standard for Four Wheel All-Terrain Vehicles*, ANSI/SVIA 1, is developed and published by the Specialty Vehicle Institute of America (SVIA). The voluntary standard addresses design, configuration and performance aspects of ATVs and includes specific test requirements for youth ATVs. Work on the original standard was undertaken in 1985 by the SVIA and completed in 1990 with the publication of ANSI/SVIA 1-1990. The standard was revised and published in 2001, 2007, and 2010.

This memorandum compares the requirements for youth ATVs in the 2007 and 2010 editions of the standard and determines whether the changes would affect how a third party assessment body would test youth ATVs. The memo concludes that the 2010 provisions concerning youth ATVs are functionally equivalent to the 2007 version. By "functionally equivalent" we mean that the provisions have been modified, but the changes do not constitute a substantial change in the requirement that would affect the associated conformance testing.



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## II. Youth ATV requirements

Section 4.7.2 PTO (power take-off)

The 2007 and 2010 editions of the voluntary standard specify throttle control operation on ATVs with PTOs. PTOs are mechanisms that allow the ATV's engine to provide rotational power to accessory equipment (e.g. augers) and are not commonly found on ATVs.

The 2010 edition of the standard adds a provision that states that youth ATVs shall not have PTOs. PTOs are not found on youth ATVs because PTOs require significant horsepower to operate and are more commonly used by adults in farm applications. The change in the 2010 edition of the standard does not affect testing of youth ATVs because the determination is made by observation so no testing is involved to determine whether an ATV has a PTO.

Section 4.16.1.5 Foot Environment with Non-Fixed Structure

The 2007 and 2010 editions of the voluntary standard specify requirements for protection of the operator's foot by physically preventing contact between the foot and the vehicle's tires or the ground. If the physical barrier can be removed or retracted, additional requirements are specified to reduce or prevent operation of the vehicle in an unsafe condition.

The 2010 edition of the standard adds a provision that states that youth ATVs shall not have non-fixed structures (physical barrier that can be removed or retracted) in the foot area of the ATV. The change in the 2010 edition of the standard does not affect testing of youth ATVs because the type of structure (i.e. fixed or non-fixed) in the foot environment can be verified through observation without testing the ATV.

Section 7.2 Service Brake Performance – Brake Test Speed

The 2007 edition of the standard specifies that the brake test speed for all ATVs (including all youth ATV categories) is the speed that is the multiple of 5 mph which is 4 mph to 8 mph less than the maximum speed of the ATV. For example, if the maximum speed of an ATV is 20 mph, the brake test speed is 15 mph because it is the multiple of 5mph that is between 12 mph and 16 mph.

The maximum unrestricted speeds for youth ATVs are:

| Youth ATV Category | Age Range | Maximum Unrestricted Speed | Maximum Limited Speed |
|---|---|---|---|
| Y6+ | 6 years and older | 15 mph | 10 mph |
| Y10+ | 10 years and older | 30 mph | 15 mph |
| Y12+ | 12 years and older | 30 mph | 15 mph |



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The 2010 edition of the standard specifies brake test speed requirements for ATVs that are identical to the requirements in the 2007 edition with one exception for Y6+ ATVs (see above table). The brake test speed for Y-6+ ATVs with a maximum speed of 10 mph or greater shall be 10 mph, and the brake test speed for Y6+ ATVs with a maximum speed less than 10 mph shall be the maximum speed of the vehicle.

This change in brake test speed for Y6+ ATVs is a reflection of the limitations of the formula for calculating brake test speeds when the maximum speed of the vehicle is less than 15 mph because the formula could result in a brake test speed of 5 mph. A brake test speed of 5 mph is too slow to measure the braking capabilities of a vehicle; therefore, the 2010 edition of the standard specifies brake test speeds that allow measurement of the braking capabilities of Y6+ ATVs.

The change in the 2010 edition of the standard does not affect testing of youth ATVs because the change specifically makes it possible to test the brake performance of Y6+ ATVs and does not change the performance brake requirement or the conformance testing of ATVs.

## III. Conclusion

With respect to testing youth ATVs, the 2010 edition of ANSI/SVIA 1 *American National Standard for Four Wheel All-Terrain Vehicles* is functionally equivalent to the 2007 edition of the standard because the changes specified in the 2010 edition do not substantially change the requirements and do not affect the associated conformance testing.

The exemption of youth ATVs from having PTOs and non-fixed structures in the foot environment has no bearing on the testing of youth ATVs. In addition, correcting a limitation in the formula for calculating brake test speeds to make it possible to perform brake tests on vehicles that have maximum speeds of 15 mph does not change the performance brake requirement or the conformance testing of these vehicles.


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**TAB F: Third Party Testing for Certain Children's Products; Toys: Requirements for Accreditation of Third Party Conformity Assessment Bodies for ASTM F963-11**

**T A B F**



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

**Memorandum**

Date:

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director
Robert J. Howell, Assistant Executive Director for Safety Operations

FROM: DeWane Ray
Assistant Executive Director
Office of Hazard Identification and Reduction

Richard McCallion
Mechanical, Recreational, and Sports Program Area Team Lead
Office of Hazard Identification and Reduction

SUBJECT: Third Party Testing for Certain Children's Products; Toys: Requirements for Accreditation of Third Party Conformity Assessment Bodies for ASTM F 963-11

## I. Introduction

On February 10, 2009, the Consumer Product Safety Improvement Act (CPSIA) made the provisions of ASTM F 963-07e1 (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) a mandatory consumer product safety standard. The provisions of ASTM F 963-08 (except for section 4.27 (regarding toy chests) of ASTM F 963-07e1, which remains in effect) currently are considered a mandatory consumer product safety standard. On December 15, 2011, ASTM proposed that ASTM F 963-11 replace ASTM F 963-08 and become the mandatory standard upon Commission acceptance.

This memorandum presents U.S. Consumer Product Safety Commission (CPSC) staff's recommendations for establishing the criteria for the mandatory requirement of third party testing of toys pursuant to the requirements of ASTM F 963-11, which may be used as a guideline for adopting future ASTM revisions upon acceptance by the Commission.



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Staff recommends that certain provisions of ASTM F 963-11 not be subject to third party testing as the Commission previously accepted in F 963-08. First, staff recommends that the Commission except from third party testing those sections of ASTM F 963 that address products outside the Commission's jurisdiction (*e.g.*, cosmetics). Staff also recommends excepting from third party testing, the sections of ASTM F 963-11 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 4.3.6.1in F 963-11). We also recommend that requirements 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 was the subject of a separate notice of requirements [FR notice August 10, 2011, CPSC Docket No. CPSC-2011-0052].

## II. F 963-11 Accreditation Requirements

In general, F 963-11 contains refinements, corrections, and new requirements over F 963-08 that increase safety and enhance the clarity and utility of the standard. Some of the substantive changes include adding requirements regarding the amount of heavy metals in substrates of toys and updating the test methods for determining those levels to the most current requirements and procedures; aligning the levels of lead allowed in surface coatings with the newest federal requirements; and the altering of test procedures related to certain requirements. ASTM also made editorial updates that do not affect the testing requirements. Additionally, the new version has three new annexes, which, although not binding, contain important information for toy manufacturers.

Staff recommends that the Commission require third party testing for the following 35 sections of ASTM F 963-11:

- Section 4.3.5.1(2), Surface Coating Materials – Soluble Test for Metals
- Section 4.3.5.2, Toy Substrate Materials
- 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 (except bath toy 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, Plastic 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


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- 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 Nearly 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

## III. F 963-11 Equivalency

Twenty-three of the 35 sections included in the staff recommendation for third party testing are equivalent to sections in F 963-08. These new sections are identical without any modifications to those sections in F 963-08. The equivalent sections are as follows:

- 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 4.6, 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 (except bath toy projections)[35]
- Section 4.9, Accessible Points (except labeling and/or instructional literature requirements)
- Section 4.10, Wires or Rods
- Section 4.11, Nails and Fasteners

[35] This Section is not identical to F 963-08. The F 963-11 version has added a provision for bath toy projections. However, staff is recommending not to require third party testing for bath toy projections because the F 963-11 standard states there are no objective means for judging compliance to this new provision.



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- Section 4.13, Folding Mechanisms and Hinges
- 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 4.23.1, Rattles with nearly spherical, hemispherical, or circular flared ends
- 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 4.35, Pompoms
- Section 4.38, Magnets (except labeling and/or instructional literature requirements)

Staff considers an additional seven of the 35 sections in F 963-11 to be functionally equivalent to sections of F 963-08. Functionally equivalent means that these seven sections have been modified, but the modifications do not constitute a substantial change in the requirement that would affect the associated conformance testing. This includes sections with a revised list of product exclusions or exemptions, changes in dimensional requirements, a requirement change that does not affect compliance with the standard, or editorial changes. These functionally equivalent sections are:

- Section 4.5, Sound Producing Toys
- Section 4.12, Plastic Film
- Section 4.14, Cords, Straps, and Elastics
- Section 4.22, Teethers and Teething Toys
- Section 4.24, Squeeze Toys
- Section 4.32, Certain Toys with Nearly Spherical Ends
- Section 4.36, Hemispheric-Shaped Objects

The remaining five sections in F 963-11 are considered to be nonequivalent to sections of F 963-08. These new sections have undergone substantial revisions, and therefore, are considered not to be equivalent to the existing sections of ASTM F 963-08. This includes modifications to existing test methods, requirements for additional testing, and new requirements. The five sections considered by staff to be nonequivalent are as follows:

- Section 4.3.5.1(2), Surface Coating Materials – Soluble Test for Metals
- Section 4.3.5.2, Toy Substrate Materials
- Section 4.15, Stability and Overload Requirements
- Section 4.37, Yo-Yo Elastic Tether Toys
- Section 4.39, Jaw Entrapment in Handles and Steering Wheels


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## IV. Recommendations

Staff recommends that the Commission approve an approach for mandatory third party conformance testing, acceptance of certifications, and acceptance of laboratory accreditation based on the individual requirements of ASTM F 963-11, that takes into account testing laboratories that are recognized by CPSC for testing to ASTM F 963-08 in addition to laboratories that are not currently recognized by CPSC for any F 963 testing. Additionally, staff recommends the Commission adopt this approach for mandatory third party testing of future updates to ASTM F 963.

Testing to requirements of F 963-08 that is performed by a CPSC-recognized third party testing laboratory to support compliance certifications to F 963-11 requirements will be accepted only for those sections of F 963-11 that are considered equivalent or functionally equivalent to F 963-08. Laboratories that are CPSC recognized for F 963-08 that wish to have CPSC acceptance to conduct testing for nonequivalent sections of F 963-11 must register with the Commission for those nonequivalent sections of F 963-11 for which the laboratory seeks CPSC acceptance. Testing laboratories (both those previously accepted for F 963-08 and those not previously accepted) may apply for CPSC acceptance for any of the 35 sections of F 963-11 identified by staff. Those laboratories that are already recognized for sections of F 963-08 may wish to focus first on the identified non-equivalent sections.

Certification based on testing to non-equivalent sections of F 963-11before the effective date of 16 CFR part 1112 is allowed if the following conditions are met:

1. The children's product was tested by a testing laboratory accredited to ISO/IEC 17025:2005 by a signatory to the ILAC-MRA at the time of the test. The scope of the testing laboratory's accreditation must include a reference to the year of the standard (ASTM F 963-11) and the specific section number. For firewalled testing laboratories, the testing laboratory must be one that the Commission has accredited by order on or before the time the product was tested, even if the order did not include the nonequivalent test methods. For governmental testing laboratories, the testing laboratory must be one whose accreditation was accepted by the Commission, even if the scope of accreditation did not include the nonequivalent test methods.
2. The testing laboratory's application for acceptance of its accreditation is accepted on or after publication of the proposed rule for 16 CFR part 1112 in the *Federal Register*, and before the effective date of 16 CFR part 1112.
3. The test results show compliance with the nonequivalent sections of ASTM F 963-11.
4. The children's product was tested after February 22, 2012, and before the effective date of 16 CFR part 1112.
5. The testing laboratory's accreditation remains in effect through the effective date of 16 CFR part 1112.

These provisions are patterned after those in 16 CFR parts 1217, 1219, and 1220, regarding retrospective testing.

The effective date for required third party testing to F 963-11 shall be 60 days after the publication of the final rule for 16 CFR part 1112, and shall apply to all products manufactured on or after that date.


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CPSC Acceptance of ASTM F 963 Requirements

It is the staff's recommendation that testing to those requirements of F 963-08 that are equivalent and functionally equivalent to the requirements of F 963-11 be accepted by laboratories that have been accredited to the 08 version of the standard until laboratories have been accredited to the 11 version of the standard. . This may result in CPSC accepting third party testing certifications for the same requirements from laboratories accredited to different versions of F 963. However, this will not affect compliance to the standard and will facilitate continuous third party testing for equivalent and functionally equivalent sections of F 963 during the regulatory update.

Staff recommends that the Commission publish a proposed Notice of Requirements for establishing the criteria for third party laboratories to test compliance with the requirements of the mandatory standard, F 963-11 in proposed 16 CFR part 1112.



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**TAB G: Comparison of CPSC Methods and Modifications from ASTM F963-11, Section 8.3.1 for Determination of Lead Content**

**TAB G**



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# Comparison of CPSC Methods and Modifications from ASTM F963-11, Section 8.3.1 for Determination of Lead Content

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*This report was prepared by the CPSC staff, has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.*



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# 1.0 SUMMARY

The U.S. Consumer Product Safety Commission (CPSC) requires manufacturers and importers of children's products to certify that their products do not exceed 100 parts per million (ppm) lead (Pb) in accessible component parts, as required in the Consumer Product Safety Improvement Act (CPSIA) of 2008. Currently, the CPSC has test methods for determining total lead content of paint,[36] metals,[37] and nonmetals[38]. A toy safety standard, ASTM F963-11,[39] was developed by ASTM International. CPSC staff tested samples and reference materials using the CPSC methods and by a new test from ASTM F963-11, section 8.3.1, which is based on the CPSC methods, with modifications. Based on the results of this study and CPSC staff expert chemical judgment, staff found that the modifications to CPSC methods detailed in ASTM F963-11, section 8.3.1 are acceptable to use to determine lead content of paint, metal, or non-metal materials. Allowing the modifications in section 8.3.1 to be considered to be within the scope of already-allowed variations to CPSC lead methods[40] provides a potential cost-reduction opportunity by allowing this single test to be used in some cases to support certification to CPSIA lead requirements and to the ASTM standard for heavy elements.

# 2.0 SCOPE AND APPLICABILITY

## 2.1 Test Methods

ASTM F963-11, section 8.3.1 and the CPSC's lead test methods are very similar. In fact, F963-11, section 8.3.1.1 states: "Toy material under test is to be digested per the appropriate CPSC Method." The difference is stated in 8.3.1.2: "With the following modification . . .." Section 8.3.1.2 goes on to provide the details of the modification, which are discussed below:

## 2.2 Modifications for Surface Coating Materials and for Metals

Concentrated nitric acid is to be replaced with aqua regia (a ratio of three parts hydrochloric acid to one part nitric acid). This affects the CPSC methods for metals and for paints and similar surface coatings. The CPSC method for metals states that the digestion process uses 8 milliliters (mL) of nitric acid, which is replaced with 8 mL of aqua regia for ASTM F963-11, section 8.3.1. The CPSC method for paint uses 4 mL of nitric acid in the digestion, which is replaced with 4 mL of aqua regia.

## 2.3 Modifications for Glass, Ceramic, and Other Siliceous Materials

Section 8.3.1 specifies that glass and ceramic components, which should also include other siliceous materials, shall be digested with a 3:1 ratio of hydrofluoric acid to nitric acid. The

[36] Test Method: *CPSC-CH-E1003-09, Standard Operating Procedure for Determining Lead (Pb) in Paint and Other Similar Surface Coatings April 26, 2009.*

[37] Test Method: *CPSC-CH-E1001-8.1, Standard Operating Procedure for Determining Total Lead (Pb) in Metal Children's Products (including Children's Metal Jewelry), Revision June 21, 2010.*

[38] Test Method *CPSC-CH-E1002-08.1, Standard Operating Procedure for Determining Total Lead (Pb) in Non-Metal Children's Products, Revised June 21, 2010.*

[39] ASTM F963-11, Standard Consumer Safety Specification for Toy Safety.

[40] The three previously mentioned CPSC test methods all specifically allow modifications based on sound chemical knowledge to digest the lead from various materials completely.



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normal CPSC method uses 4 mL of nitric acid and 1 mL of hydrofluoric acid, which was replaced in section 8.3.1 with 3.75 mL of hydrofluoric acid and 1.25 mL of nitric acid.

### 2.4 Modifications for Plastics

Plastic materials vary greatly in composition and physical properties. The normal CPSC method for the digestion of plastics uses 5 mL of nitric acid and microwave-assisted digestion. ASTM F963-11, section 8.3.1 does not require changes to the CPSC method, it but states that certain polymeric materials, such as polyvinyl chloride (PVC) and chlorinated PVC (CPVC), *may* require a 3:1 ratio of nitric acid to 30 percent hydrogen peroxide for complete digestion. In this study, plastic compounds tested to ASTM F963-11 were tested using 3.75 mL of nitric acid and 1.25 mL of 30 percent hydrogen peroxide.

## 3.0 COMPARISON TESTING

### 3.1 Outline of Testing

Several standard reference materials or samples were analyzed following the CPSC procedures and the ASTM F963-11, section 8.3.1 modified CPSC procedures. In all cases, sample masses, final dilution volumes, reaction times, and analysis conditions were unchanged, such that the only design variable was the digestion acid.

### 3.2 Paints Results

Lead analysis of paints via CPSC and ASTM F963-11 methods produce analytical results that effectively can determine if a material contains in excess of 90 ppm lead, as shown in Table 1. The percent recoveries by both methods were within the quality control limit of ±15 percent of the certificate of analysis value.

**Table 1: Lead in Paint Comparison**

| Sample Name | Certificate of Analysis (ppm Pb) | Total Lead Content (CPSC) (ppm Pb) | | Total Lead Content (ASTM F963-11) (ppm Pb) | |
|---|---|---|---|---|---|
| | | Average (3 tests) | Standard Deviation | Average (3 tests) | Standard Deviation |
| NIST 2580[41] | 43,000 | 41,050 | 592 | 41,749 | 102 |
| NIST 2581[42] | 4,500 | 4,259 | 76 | 4,295 | 61 |

[41] National Institute of Standards and Technology Standard Reference Material 2580 (https://www-s.nist.gov/srmors/certificates/view_certGIF.cfm?certificate=2580).

[42] National Institute of Standards and Technology Standard Reference Material 2581 (https://www-s.nist.gov/srmors/certificates/view_certGIF.cfm?certificate=2581).



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| | | | | | |
|---|---|---|---|---|---|
| NIST 2582[43] | 200 | 188 | 1.3 | 187 | 1.4 |

## 3.3 Metals Results

Lead analysis of metals via CPSC and ASTM F963-11 methods produce analytical results that effectively can determine if a material contains in excess of 100 ppm lead, as shown in Table 2. The percent recoveries by both methods were within the quality control limit of ±15 percent of the certificate of analysis value, except for the case of NIST 53e, which had incomplete recovery by both methods. NIST 53e contains 84 percent lead. Residue remaining in the digestion vessel indicates that not all material was dissolved in the acids by either method; however, because the results were thousands of times above the limits for lead in metals, no attempt was made to adjust the methods as commonly would be done with incomplete digestion (such as redigesting with a greater ratio of acid to sample). This is a known limitation of the CPSC method for some extremely high-lead alloys.

**Table 2: Metals Comparison**

| Sample Name | Certificate of Analysis (ppm Pb) | Total Lead Content (CPSC) (ppm Pb) | | Total Lead Content (ASTM F963-11) (ppm Pb) | |
|---|---|---|---|---|---|
| | | Average (3 tests) | Standard Deviation | Average (3 tests) | Standard Deviation |
| NIST 53e[44] | (840,000)[45] | 641,000 | 28,600 | 418,400 | 26,100 |
| NIST 54d[46] | 6,200 | 5,900 | 10 | 5,900 | 59 |
| NIST SRM 1728[47] | 544 | 476 | 5.1 | 492 | 4.1 |
| Sample welding solder | Not Applicable | 1,200 | 19 | 1,400 | 21 |

## 3.4 Glass, Ceramic, and Other Siliceous Materials Results

Lead analysis of glass via CPSC and ASTM F963-11 methods produce analytical results that effectively can determine if a material contains in excess of 100 ppm lead, as shown in Table 3.

[43] National Institute of Standards and Technology Standard Reference Material 2582 (https://www-s.nist.gov/srmors/certificates/view_certGIF.cfm?certificate=2582).
[44] National Institute of Standards and Technology Standard Reference Material 53e (https://www-s.nist.gov/srmors/certificates/view_certGIF.cfm?certificate=53E).
[45] Expected value, not certified for lead content.
[46] National Institute of Standards and Technology Standard Reference Material 54d (https://www-s.nist.gov/srmors/certificates/view_certGIF.cfm?certificate=54D).
[47] National Institute of Standards and Technology Standard Reference Material 1728 (https://www-s.nist.gov/srmors/certificates/view_certGIF.cfm?certificate=1728).


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The percent recoveries were within the quality control limit of ±15 percent of the certificate of analysis value.

**Table 3: Glass Comparison**

| Sample Name | Certificate of Analysis (ppm Pb) | Total Lead Content (CPSC) (ppm Pb) | | Total Lead Content (ASTM F963-11) (ppm Pb) | |
|---|---|---|---|---|---|
| | | Average (3 tests) | Standard Deviation | Average (3 tests) | Standard Deviation |
| NIST 89[48] | 162,500 | 141,900 | 3,700 | 147,000 | 3,400 |
| NIST 1412[49] | 40,900 | 37,400 | 450 | 37,400 | 390 |

## 3.5 Plastic Materials Results

Lead analysis of plastics via CPSC and ASTM F963-11 methods produce analytical results that effectively can determine if a material contains in excess of 100 ppm lead. The percent recoveries were within the quality control limit of ±15 percent of the certificate of analysis value.

**Table 4: Plastic Comparison**

| Sample Name | Certificate of Analysis (ppm Pb) | Total Lead Content (CPSC) (ppm Pb) | | Total Lead Content (ASTM F963-11) (ppm Pb) | |
|---|---|---|---|---|---|
| | | Average (3 tests) | Standard Deviation | Average (3 tests) | Standard Deviation |
| ERM EC681K[50] | 98 | 106 | 11 | 101 | 0.9 |
| PVC2[51] | 500 | 517 | 11 | 525 | 14 |
| PVC3[52] | 1000 | 1007 | 19 | 1023 | 3.3 |

[48] National Institute of Standards and Technology Standard Reference Material 89 (https://www-s.nist.gov/srmors/certificates/view_certGIF.cfm?certificate=89).

[49] National Institute of Standards and Technology Standard Reference Material 1412 (https://www-s.nist.gov/srmors/certificates/view_certGIF.cfm?certificate=1412).

[50] European Reference Material EC681k (http://www.erm-crm.org/ERM_products/search/certificates/EC681k.pdf).

[51] Analytical Services Inc. Plastic Powder Standards (PVC), Code No. PL(PVC)3-5E(P), Lot No. 012110, Sample No. 2.

[52] Analytical Services Inc. Plastic Powder Standards (PVC), Code No. PL(PVC)3-5E(P), Lot No. 012110, Sample No. 3.



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## 4.0 CONCLUSION

Both CPSC and ASTM F963-11 analytical methods for lead content are similar or equivalent; CPSC staff's professional chemical judgment finds that both methods are acceptable for use in the determination of lead content. The modifications from CPSC methods described in ASTM F963-11, section 8.3.1 do not materially impact the analytical results and are considered to be within the scope of already-allowed variations to CPSC lead methods.



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