The contents of this document will be discussed at the Commission Meeting (Briefing) scheduled for January 23, 2013.

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

This document has been electronically approved and signed.

THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.

A DECISION MEETING ON THIS MATTER IS SCHEDULED ON: February 6, 2013

DATE: January 16, 2013

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Kenneth R. Hinson, Executive Director
Stephanie Tsacoumis, General Counsel

FROM: David M. DiMatteo, Attorney, OGC

SUBJECT: Draft Final Rule: Requirements Pertaining to Third Party Conformity Assessment Bodies

The Office of the General Counsel is providing for Commission consideration the attached draft *Federal Register* notice for a final rule. The final rule 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 draft final 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 draft final 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 attached document in the *Federal Register*, as drafted.

_____ _____
(Signature) (Date)

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

_____

_____

_____

_____ _____
(Signature) (Date)

III. Do not approve publication of the attached document in the *Federal Register*.

_____ _____
(Signature) (Date)

IV. Take other action. (Please specify.)

_____

_____

_____

_____ _____
(Signature) (Date)

Attachment: Draft *Federal Register* notice for final rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies*

Billing Code CPSC-6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1118

[CPSC Docket No. CPSC-2012-0026]

Requirements Pertaining to Third Party Conformity Assessment Bodies

AGENCY: Consumer Product Safety Commission.

ACTION: Final Rule.

SUMMARY: The Consumer Product Safety Commission (CPSC, Commission, or we) is issuing a final rule establishing requirements pertaining to the third party conformity assessment bodies (laboratories) whose accreditations are accepted to test children's products in support of the certification required by the Consumer Product Safety Act (CPSA), as amended by the Consumer Product Safety Improvement Act of 2008 (CPSIA). The final rule establishes 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 addresses adverse actions that may be imposed against CPSC-accepted third party conformity assessment bodies. The final rule also amends the audit requirements for third party conformity assessment bodies and amends the Commission's regulation on inspections.

DATES: The rule is effective [INSERT DATE 90 DAYS AFTER PUBLICATION IN FEDERAL REGISTER] and applies to products manufactured on or after that date. The incorporation by reference of the publications listed in this rule is approved by the Director of the Federal Register as of [INSERT DATE 90 DAYS AFTER PUBLICATION IN FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Scott Heh, Office of Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; 301-504-7646; e-mail: sheh@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

On May 24, 2012, the Commission published a notice of proposed rulemaking to establish requirements for third party conformity assessment bodies whose accreditations are accepted to test children's products in support of the certification that the CPSA requires. As explained in the following section, the CPSA requires that certain children's products must be tested by a third party conformity assessment body (also sometimes called a laboratory), and the manufacturer or private labeler of that product must issue a certificate, based on the third party testing, stating that the product meets all applicable CPSC requirements. This rule finalizes the proposal published on May 24, 2012.

B. 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 (this term includes the importer) 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).

As noted above, 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 (this term includes the importer) 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 it requires the Commission to publish "a notice of the requirements for accreditation of third party conformity 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.

Section 14(a)(3)(C) of the CPSA provides that the Commission may either accredit laboratories itself, or it 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. 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 accredited 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.

The final rule establishes the requirements for CPSC acceptance of the accreditation of a laboratory to test children's products under section 14 of the CPSA. As discussed in detail in the preamble to the proposed rule, the requirements of the final rule are largely the same as the requirements used by the CPSC since passage of the CPSIA in August 2008. 77 FR at 31087-

89. In addition, the rule delineates how a laboratory may discontinue voluntarily its participation with the CPSC, and it establishes the procedures for the suspension and/or withdrawal of CPSC acceptance of the accreditation of a laboratory. The final rule also amends the recent final rule titled, "Audit Requirements for Third Party Conformity Assessment Bodies" (audit final rule), which implements section 14(i)(1) of the CPSA. Finally, the final rule makes particular conforming amendments to 16 CFR 1118.2(a).

II. Comments on the Proposed Rule and the Commission's Responses

In this section, we describe and respond to the comments received on the proposed rule. A summary of each of the commenter's topics is presented, and each topic is followed by our response. We received six comments on seven topics. Several commenters make general statements supporting the overall purpose of the proposed rule. All of the comments can be viewed at: www.regulations.gov, by searching under the docket number of the rulemaking, CPSC-2012-0026.

A. Sample Homogeneity and X-Ray Fluorescence Spectrometry

(*Comment 1*) With regard to the proposed test methods for determining lead content on component parts, a commenter notes the proposed requirement that three or more measurements must be made when using the x-ray fluorescence spectrometry (XRF or EDXRF) method described in ASTM F2853-10, also known as Energy Dispersive XRF Spectrometry Using Multiple Monochromatic Excitation Beams (currently allowed for lead in paint testing). As described in the proposed test method, the three measurements are intended to ensure some degree of spatial homogeneity or assurance that the material tested does not indicate falsely compliance with the lead content limit of 100 parts per million (ppm) because a "local" area, unrepresentative of the component part, was tested. The commenter recommends removal of the

requirement to sample three or more areas using the lead content testing method described in ASTM F2853-10.

The commenter states that any empirical evidence of nonhomogenieties resulting in a false determination of compliance is "questionable at best." The commenter raises several objections to the "wet chemistry" method (Inductively Coupled Plasma, or ICP, using various spectrometric techniques), including a procedural step where 30 to 100 milligrams (mg) of a sample are collected and subjected to testing. The commenter points out that the ICP method does not require samples from three areas of the component part to be tested, and the commenter questions why the XRF method should be subject to that requirement. The commenter opines that this is a policy issue to be determined by the Commission and not a technical issue to be determined by CPSC staff. The commenter states that if a component part "appears not to have visual anomalies, it can reasonably be presumed to in fact be homogeneous with respect to its lead content." The commenter adds that very small component parts may pose practical difficulties in providing locations for three measurements and that the proposed testing method has no allowance for very small component part testing. The commenter concludes that the test method, ASTM F2853-10, requires only one measurement when used to determine the lead content of a paint sample.

Another commenter expresses concern that the small spot size (on the order of 1 mm^2) increases the sensitivity of the test method ASTM F2853-10 to nonhomogenieties in the lead content of the component part under test.

Another commenter expresses concern that the testing for homogeneity requires the use of XRF in the test methods for lead content determination (the requirement that at least three spatially separated measurements be made). The commenter points out that the ICP method

requires only 30 to 100 mg of material, which the commenter considers "incongruous" with respect to homogeneity.

Another commenter remarks that the CPSC test method CPSC-CH-E1001-08.2 (total lead (Pb) in nonmetal children's products), states that a homogenized aliquot[1] should be prepared after grinding a sufficient sample of a component part for ICP testing. The commenter states that there is no clear guidance on how to determine what is "sufficient." The commenter also notes that if a sample is not homogeneous, ICP testing is required (instead of XRF). However, the commenter asserts that if the component part is nonhomogeneous, the ICP testing results can vary, depending on where the sample is taken. The commenter opines that ICP testing of nonhomogeneous component parts may not adequately reflect the component part's lead content, and XRF testing, using multiple locations, is better for determining the component part's lead content.

(*Response 1*) We decline to revise the test method for determining lead content that requires multiple sample areas to be tested when using forms of XRF. We believe that XRF has the potential, with certain limitations, to measure reliably lead content in some homogeneous metal and glass materials at the concentrations necessary to certify compliance with the 100 parts per million (ppm) limit now required under the CPSIA for children's products. With the appropriate test methods and reference materials, CPSC staff considers homogeneous substrates to be necessary in order for the XRF methods included in ASTM F2853-10, or in the proposed CPSC test methods, to be effective in determining the compliance of the sample being tested. Multiple measurements are required to determine that such homogeneity exists, which allows the use of the XRF measurements for children's product certification purposes. We agree that it is

[1] An aliquot in chemistry is a portion of a sample.

important to obtain a sufficient sample for wet chemistry testing. The CPSC wet chemistry test methods for determining lead in a substrate include instructions for the user to make every effort to homogenize the sample prior to taking 30 to 100 mg for testing. Thus, a sufficient sample would be an amount that ensures that the portion selected for testing actually represents the total lead content of the component part under evaluation.

With respect to small parts and the need to determine homogeneity, there are no limitations on using XRF for testing small component parts. Small parts may be rotated so that different surface areas would be tested. If three completely distinct areas could not be tested, three separate tests could still be done on overlapping areas.

(*Comment 2*) A commenter asserts that all XRF techniques are being subjected to additional homogeneity requirements that are really intended only for the ASTM F2853-10 method. The commenter asserts that the relatively large spot size of other XRF methods mitigates the need for the repeated measurements in the proposed test method. The commenter recommends that in order to mitigate some of the heterogeneity effect:

> . . . an 8 mm diameter x-ray surface shot (HHXRF),[2] with a scatter that widens in three dimensions, should be as much of a heterogeneity correction as the 100 mg sample size for wet chemistry to be considered quantitative under EN 71-3 and others.

The commenter adds that even though other types of XRF spectrometers that do not meet the requirements of ASTM F2853-10 are far less vulnerable to nonhomogenieties in a test sample, a homogeneity test for XRF methods should be retained, rather than eliminated, "because the need to limit all EDXRF techniques to materials that are proven to be homogeneous is beyond question."

[2] HHXRF is an acronym for "handheld x-ray fluorescence spectrometry," and it is used to distinguish this type of handheld device from other forms of XRF spectrometry.

(*Response 2*) We decline to remove the requirement to test multiple areas of the component part for lead from the test method. We believe that for dense materials, like metals and glass, typical XRF instruments sample a very small mass of the sample because the penetration of the x-rays is limited. Thus, it is appropriate when testing dense materials, to measure multiple areas to ensure homogeneity when using these test methods as the basis for issuing a Children's Product Certificate.

(*Comment 3*) A commenter notes that in § 1112.15(b)(29) of the proposed rule, in order for a laboratory to have its accreditation accepted by the Commission to test for lead content in children's metal products, a third party conformity assessment body must have the CPSC test method CPSC–CH–E1001–08, CPSC–CH–E1001–08.1, or CPSC–CH–E1001–08.2 in its statement of scope. The commenter further notes that in § 1112.15(b)(28) of the proposed rule, in order for a laboratory to have its accreditation accepted by the Commission to test for lead content in children's metal jewelry, a third party conformity assessment body must have the CPSC test method CPSC–CH–E1001–08 or CPSC–CH–E1001–08.1 in its statement of scope. The commenter requests that the "-08.2" version of the test method be allowed to be used by a laboratory for the testing of lead in children's metal jewelry, adding that this method allows the use of XRF testing.

(*Response 3*) We agree with the commenter that CPSC test method CPSC–CH–E1001–08.2 should be allowed under § 1112.15(b)(28) of the final rule. In the proposed rule, test method CPSC–CH–E1001–08.2 inadvertently was not included in proposed § 1112.15(b)(28), although it was intended that the test method be allowed. Therefore, in the final rule, § 1112.15(b)(28) expressly allows use of test method CPSC–CH–E1001–08.2.

(*Comment 4*) A commenter requests that a procedure for plated metals and glazed ceramics be developed for XRF using the ASTM F2853-10 method. This procedure would involve grinding a plated metal or glazed ceramic sample, as is done in preparation for an ICP test, and then testing the blended sample using the ASTM F2853-10 method.

Another commenter requests that the CPSC make explicit that XRF can be used to test electroplated metals for lead content. The commenter notes that electroplating does not fall into the definition of a "paint or other similar surface-coating material" described in 16 CFR 1303.2(b)(1).

(*Response 4*) We disagree with the commenter's request to develop a procedure using the ASTM F2853-10 method for plated metals and ceramics because the method has not been validated for use on ground metals, which behave differently than solids when tested XRF, due to different scattering behavior and the presence of interstitial air gaps. Electroplated metals and glazed ceramics pose an especially difficult analysis challenge for XRF. Because such coatings become part of the substrate and are not subject to the lead paint ban, it is necessary to consider the single, nonhomogeneous material that results from the electroplating or ceramic glaze bonding with the substrate. The idea for a method suggested by the commenter could potentially be developed by some party in the future. We are particularly concerned that the small volume and mass of a sample probed by XRF would not adequately serve to indicate the homogeneity of the sample.

We decline the request to allow XRF to be used to test electroplated materials because currently it is not possible to determine the correct lead content in such materials by this method. The commenter is correct that electroplated coatings that become part of the substrate are not considered paint under 16 CFR part 1303. The combined electroplated metal (*i.e.*, the

electroplating and the substrate together) must meet the 100 ppm lead limit. The x-rays used in XRF penetrate only a very small distance through metals, and as such, tend to sample the outer surface to a much higher degree than the base metal (substrate). The limited depth of x-ray penetration means that electroplating can screen the base metal from being properly measured by XRF. Additionally, because the x-rays do penetrate somewhat into the base metal, such a measurement also is not suitable for determining the lead in the electroplated coating itself, although it is only the combination of the two that is required to meet the 100 ppm lead content limit.

(*Comment 5*) A commenter questions the difference between the XRF method described in ASTM F2853-10 and other methods of XRF in their ability to detect lead in paint. Currently, only ICP techniques, or the XRF method described in ASTM F2853-10, are allowed to be used to determine the lead content in paint for children's product certification purposes. The commenter asserts that improvements in detector technology have improved the performance of handheld XRF instruments. The commenter adds that work is under way to convert the traditional lead in paint measurement of "Mass Loading," or micrograms per cm^2, into a concentration measurement of ppm.

(*Response 5*) At present, no XRF method, other than ASTM F2853-10, is recognized by the CPSC to determine accurately the lead content of painted surfaces of consumer products. The lead paint ban in 16 CFR part 1303 is based on the definition of "lead paint" as paint containing in excess of 0.009 percent lead by weight. Measurements in micrograms per cm^2 cannot be used to make such a determination without knowing the density and thickness of the paint, neither of which is generally known at the time of testing.

(*Comment 6*) A commenter states that other forms of XRF are at least as accurate as the ASTM F2853-10 method, and they disagree with the use of the phrase "may be," rather than the same language used for the ASTM F2853-10 method of describing suitable instruments for the accurate determination of lead in glass materials and homogeneous metals.

(*Response 6*) The commenter is referring to Tab C in the Staff Briefing Package, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, for the proposed rule. Tab C, titled, *Study on the Applicability of X-ray Fluorescence Spectrometry for Measuring Lead in Metal and Glass Substrate*, describes how XRF potentially could be used to test homogeneous metal and glass materials found in children's products. The report examines extending the use of XRF beyond the already-approved method for polymeric materials to include glass and metal substrates.

At the time the report was prepared, the CPSC test methods for determining the lead content of metal and nonmetallic component parts did not include procedural steps or limitations on the use of XRF for homogeneous glass materials, crystals, and some metals. The report recommended updating the CPSC test methods to allow laboratories to use HHXRF or other types of laboratory XRF analyzers for testing glass and metal items, with limitations.

Since then, the CPSC test methods have been updated. The phrase "may be" is not used in the context of XRF in either the proposed rule or the proposed CPSC test methods, other than stating: "Destructive sample preparation techniques may be required for certain components to create a uniform sample for testing."

(*Comment 7*) A commenter states that the limitations applied to other forms of XRF listed in the test methods, CPSC-CH-E1001-08.2 and CPSC-CH-E1002-08.2, should apply to the form of XRF described in ASTM F2853-10. According to the commenter, the CPSC test methods apply

only four limitations to the form of XRF described in ASTM F2853-10. The commenter recommends the following additional limitations be applied to the form of XRF described in ASTM F2853-10:

- Verify the instrument performance daily, by analyzing one or more reference materials of the same matrix or metal type as the materials on which the analyses will be performed.
- For testing metals, if the form of XRF described in ASTM F2853-10, deviates from the method described in the ASTM test method, all of the limitations in test method CPSC-CH-E1001-08.2 applied to other forms of XRF should be applied to the form of XRF described in ASTM F2853-10.
- Because uncoated wood and fabrics were not evaluated in the interlaboratory study of the form of XRF described in ASTM F2853-10, all of the limitations in test method CPSC-CH-E1002-08.2 applied to other forms of XRF should be applied to the form of XRF described in ASTM F2853-10.

(*Response 7*) With regard to the first bullet point in the commenter's recommendations, we agree that it is important for reasonable quality assurance/quality control (QA/QC) requirements to be a part of all types of XRF testing. However, we found that section 13.3 of ASTM F2853-10 provides guidance on quality control samples that should be followed to verify system control. The absence of an applicable existing standard for other XRF methods, and the wide variety of XRF instrumentation used in the more general case, led us to make the specific QA/QC directions discussed. We included in the lead test methods quality control guidelines described in section 6 of International Electrotechnical Commission (IEC) Method 62321 ED 1.0 B; but because that method is designed for higher lead concentrations, we added the requirement

to verify XRF spectrometer performance daily by analyzing a reference material with 50 to 300 ppm lead content.

The second and third bullet points in the commenter's recommendations suggest that additional limitations should be placed on ASTM F2853-10 testing for metals other than zinc. We believe that the staff study presented in Tab C of the Staff Briefing Package for the NPR was sufficient and that CPSC-CH-E1001-08.2 adequately deals with other metals for XRF testing using the method described in ASTM F2853-10. The third bullet point suggests that for natural wood and for fabric, ASTM F2853-10 testing should have the same requirements as traditional XRF testing, and CPSC staff believes that is the case as the method is written.

(*Comment 8*) A commenter requests clarification on several technical issues related to XRF testing.

First, the commenter asks if the term "matrix" means "metal" or the specific alloy used as a reference material in the test method CPSC-CH-E1001-08.2.

Second, the commenter asks for guidance on how many glass or other substrate standards should be used daily to verify instrument performance in the test method CPSC-CH-E1002-08.2. Finally, the commenter questions the value of a relative standard deviation (RSD) of 30 percent for very low instrument readings using the XRF method described in ASTM F2853-10. In the commenter's opinion, this proposed requirement does not take instrument repeatability into account and makes more expensive ICP testing necessary, even though the readings are not close to the compliance limits. The commenter recommends that when the testing results are well below the concentration limit that would render a reading inconclusive, the XRF results should not be excluded from indicating compliance with the lead content limit.

(*Response 8*) With regard to the commenter's first and second questions, it is not possible to know the exact alloy that is to be tested or to have sample standards that exactly match its chemical composition. Thus, "matrix" is used as a generic term to include metals and alloys similar to the sample to be tested. Laboratories should develop QA/QC procedures, including having various relevant metals, glass, and plastic standards to verify instrument performance. Exactly how extensive such a collection must be should be left up to the individual laboratories, their accreditation bodies, and their customers.

We agree with the commenter's final comment. Notably, this comment illustrates that at very low lead concentrations, differences of just a few ppm in measurements can result in an RSD indicating nonhomogeneity where possibly the instrumental variability is dominating the calculation. We believe that it is appropriate to allow XRF use where at least three measurements were taken by XRF as described in this method, and the result of each of those measurements is below 50 percent of the limit (*i.e.*, below 50 ppm), subject to the remaining limitations given for all types of XRF. Staff has posted two new test methods, CPSC-CH-E1001-08.3 (http://www.cpsc.gov/about/cpsia/CPSC-CH-E1001-08_3.pdf) and CPSC-CH-E1002-08.3 (http://www.cpsc.gov/about/cpsia/CPSC-CH-E1002-08_3.pdf) on the CPSC website, which includes this change, and the final rule allows this as an option for laboratory accreditation.

(*Comment 9*) One commenter refers to the requirement in Public Law 112-28 for the CPSC to provide alternative testing requirements for small batch manufacturers for testing compliance with some product safety rules and to exempt small batch manufacturers from the third party testing requirements if no alternative testing requirement is available or economically practicable. The commenter proposes that the Commission allow handheld XRF spectrometry,

which the commenter notes, the Commission recognizes is less expensive than other approved test methods. The commenter suggests that the Commission allow it to be used for third party testing of other substrates, in addition to the homogenous polymer substrates for which it has already been approved. The commenter is willing "to work with the Commission "on the execution of a plan that will prevent the needless exemption of an entire subset of the market that we all agree is in need of this regulatory oversight."

(*Response 9*) The CPSC has proposed the use of XRF spectrometry to determine the lead content of glass materials, crystals, and some metals. At this time, we are not recommending that handheld XRF spectrometry be approved for the third party testing of other substrates. CPSC staff has not determined that handheld XRF spectrometry possesses enough accuracy, precision, and reliability required for the determination of the lead content of substrates other than in homogenous polymer products and the proposed materials.

Public Law 112-28 requires the Commission to provide alternative testing requirements for small batch manufacturers for certain children's product safety rules. If no alternative method is available, the Commission, with some exceptions, is to exempt small batch manufacturers from the third party testing requirements. However, developing alternative testing requirements for small batch manufacturers is not within the scope of the current rulemaking proceeding, which concerns the accreditation requirements for third party conformity assessment bodies.

(*Comment 10*) A commenter asks that the CPSC propose a technical, rather than a proprietary solution, for lead content testing. The commenter asserts that the CPSC must allow new and emerging technologies the same access to the proposed test methods.

(*Response 10*) The CPSC does not endorse one product or technique over another, equally effective product or technique. For lead content testing, multiple methods and technologies are

available for use by a laboratory. Each acceptable method has been proven to meet the technical requirements (*e.g.*, precision, accuracy, repeatability) needed to determine compliance to the lead content limit of 100 ppm. The CPSC supports the development of new technologies for achieving the goals of improved product safety and reduced costs to manufacturers. We decline to change the final rule based on this comment.

B. Laboratory Accreditation

(*Comment 11*) A commenter emphasizes the importance of the CPSC's evaluation of the integrity of each laboratory's independence and its compliance with the requirements of International Standards Organization/International Electrotechnical Commission (ISO/IEC) 17025(E). The commenter states:

> By making the accreditation and audit requirements more focused on the authentication of independence, the CPSC will be able to adopt requirements that will further its commitment to ensure that all approved laboratories are meeting the conditions for their continuing accreditation.

(*Response 11*) It is unnecessary to change the final rule based on this comment because the rule already addresses the commenter's concerns. We agree that a laboratory's independence should be reassessed on a regular basis. The final rule on the audit of third party conformity assessment bodies (16 CFR part 1107, subpart C) 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.

For the Commission to accept a laboratory as firewalled, the laboratory must have policies and procedures in place, consistent with laboratory independence and impartiality. To evaluate whether a laboratory satisfies these criteria on independence and impartiality, the final rule requires that a laboratory seeking CPSC-accepted firewalled status submit copies of various documents to the CPSC. The applicant 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 CPSC's purpose in reviewing such documents would be to assess whether the laboratory has established the necessary written procedures to maintain its independence from the manufacturer or private labeler. We also 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 and explaining that an allegation of undue influence may be reported confidentially to the CPSC. Our purpose in 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 to exert undue influence.

(*Comment 12*) A commenter recommends that reciprocity provisions be built into the accreditation and audit provisions for laboratories. The commenter asserts that in the absence of aligned standards and compliance protocols, accreditation for foreign laboratories from countries with reciprocity provisions is the optimum approach to third party testing and provides a "level playing field" for manufacturers and laboratories without compromising the accreditation program's integrity. The commenter adds that for trade purposes, U.S.-based laboratories should be allowed to provide their services in any market that contains foreign-based laboratories seeking CPSC acceptance of their accreditation.

The commenter adds that the Occupational Safety and Health Administration (OSHA) Nationally Recognized Laboratories (NTRL) program and the Federal Communications Commission (FCC) accreditation program for Telecommunications Certification Bodies include reciprocity provisions. The commenter states that such reciprocity provisions benefit U.S.

manufacturers, by streamlining compliance requirements across markets and allowing laboratories to bundle services.

(*Response 12*) We decline to adopt reciprocity as a criterion in the CPSC third party conformity assessment body. In implementing the CPSIA's requirement that products subject to CPSC children's product safety rules be third party tested, the CPSC's interest is to establish an effective and efficient program through which we recognize laboratories worldwide that are competent to conduct these third party tests. The use of International Laboratory Accreditation Cooperation – Mutual Recognition Arrangement (ILAC-MRA) signatory accreditation bodies creates a level playing field, by providing an internationally available, consistent, accreditation process for laboratories, regardless of where they are located. Any CPSC-accepted laboratory, whose scope includes the tests conducted, may test children's products for compliance to the applicable CPSC children's product safety rules. Reciprocity provisions regarding U.S.-based laboratory activities in other nations are not necessary to ensure the technical competence and objective assessment of compliance from a CPSC-accepted laboratory.

(*Comment 13*) Two commenters note that the proposed rule defines a "firewalled" laboratory, in part, as one that "is under a contract to a manufacturer or private labeler . . . that explicitly limits the services [it] may provide for other customers and/or limits which or how many other entities may also be customers of the [laboratory]." (Proposed § 1112.11(b)(1)(ii)(D)). The commenters assert that the definition constitutes an unnecessary and unwarranted intrusion into the private contractual rights of independent laboratories and their customers.

One commenter notes that absent any indication that such a contractual relationship, in fact, constitutes "ownership or control" by a manufacturer over a laboratory, the proposed rule/staff

justification offers no foundation for this provision, and in fact, appears to have no valid purpose (including any based on congressional intent in this regard) for such an overly broad definition of "firewalled lab." Another commenter recommends that this provision be modified to reflect that, absent any indication that such a contractual relationship, in fact, constitutes "ownership or control" by a manufacturer over a laboratory, the laboratory should not be considered to be a "firewalled lab."

(*Response 13*) The preamble to the proposed rule included a discussion noting that a contractual relationship between a manufacturer and a laboratory that explicitly limits which or how many other entities may also be customers of the laboratory would grant the manufacturer such a significant interest in the work of the laboratory that the Commission would consider the interest "controlling." Section 1112.11(b)(1)(ii)(D) of the proposed rule would designate a laboratory with such a contractual relationship with a manufacturer as "firewalled."

After reviewing the comments regarding this section of the proposed rule, we agree with the commenters that this type of contractual relationship would not necessarily result in a situation where the manufacturer controls the laboratory. Because the specific details of these types of contracts are highly variable, it would be impractical and complex to assess independently each contract on a case-by-case basis. Further, we consider that such an assessment would result in little benefit to consumer safety, above the other elements in the rule that define a firewalled laboratory, and above the criteria CPSC acceptance of a laboratory's accreditation. Therefore, we are removing the provision regarding contractual relationships as one of the criteria that define a "firewalled" laboratory in § 1112.11(b)(1)(ii)(D) of the final rule.

(*Comment 14*) One commenter recommends that the provision stating that a "one percent or greater ownership or control" for a governmental laboratory (proposed § 1112.11(c)(1)), should

instead be a higher percentage and/or a fact-based determination based on the "undue influence" definition whereby the governmental ownership or control causes the laboratory to "compromise the integrity of its testing processes or results."

(*Response 14*) We decline to select another percentage for governmental ownership or control based on this comment. Section 14(f)(2)(B) of the CPSA states that a governmental third party conformity assessment body is an entity that is owned or controlled in whole or in part by a government. "In part" can be interpreted to be any proportion of ownership or control, and therefore, it is not limited to a minimum value. As stated in the proposed rule: "Selecting one percent as an ownership threshold is a practical matter of selecting the smallest whole number as an expression of ownership." The commenter does not provide a recommended value greater than one percent to indicate governmental ownership or control. Nor does the commenter provide a rationale for using an ownership percentage other than one percent.

We decline to adopt the commenter's recommendation with regard to considering a fact-based determination. The definition of a "governmental third party conformity assessment body" in section 14(f)(2)(B)(ii) of the CPSA states that the laboratory's test results are not "subject to undue influence." We interpret "subject to undue influence" to mean being liable or vulnerable to undue influence, not to an after-the-fact determination that undue influence had actually been exerted to compromise the integrity of testing results. Thus, we consider being vulnerable to the exercise of undue influence, not whether the undue influence has occurred, as being "subject to undue influence."

(*Comment 15*) One commenter recommends eliminating the provision that a laboratory will be classified as "governmental" if any of that laboratory's "management or technical personnel include any government employees." (Proposed § 1112.11(c)(4)). The commenter asks whether

the phrase "technical personnel" should be deleted or clarified to indicate that such individuals cannot be employees of both the government and the laboratory, or whether another modification should be provided because some government employees might be assigned temporarily to a laboratory for specific training/oversight/similar legitimate function.

(*Response 15*) We decline the commenter's recommendation. We assume that a government management or technical employee is present in the laboratory to perform a function essential to the laboratory's testing operations. If the management or technical position is controlled by the government, then the government has control over some aspect of the laboratory's testing and test results. Therefore, additional safeguards against the exercise of undue influence are warranted.

(*Comment 16*) One commenter recommends that the Commission modify proposed § 1112.43 to clarify that only "material" omissions or "materially incorrect" information in an application for acceptance can be grounds for denial of the application and that the laboratory is to be afforded a reasonable opportunity to correct an omission or error in its application.

(*Response 16*) We decline the commenter's recommendation to change the proposed rule because all of the information described as grounds for denial of an application in § 1112.43 of the rule is considered material. If any of the information described in § 1112.43(a) is not provided, that would be considered to be a material omission. Any inaccurate information would be considered materially incorrect. Clarification in this section is not necessary because the plain language of § 1112.43(a) of the rule includes the omissions of information considered to be material.

We do not agree with the commenter that changes are needed to the proposed rule to provide an applicant a reasonable opportunity to correct an omission or error in its application because

the language in the proposed rule already provides such opportunity. Section 1112.17(a) of the final rule (unchanged from the proposal) allows CPSC staff to contact a laboratory with any questions regarding an application or to request the submission of missing information. Section 1112.43(b) in the final rule provides that "the CPSC's denial of an application will follow the process described in § 1112.51 of this subpart." Section 1112.51 of the final rule stipulates that the CPSC will provide an initial notice that advises the laboratory of the specific grounds for a denial of an application. Some common reasons for denial of an application include: a missing scope document or a missing or incorrect test method reference within a scope document.

In § 1143(a)(1) of the final rule, a laboratory has 30 calendar days to respond and correct the issue. Further, the procedures in the final rule allow for a laboratory to request an extension of time with an explanation and an estimate for how much additional time is needed. Even in cases in which an applicant cannot correct the issue within an allotted extension and an application is denied, the applicant may reapply for CPSC acceptance when all required elements are fulfilled.

(*Comment 17*) One commenter recommends that the Commission specify that only a "material" failure "to comply with an applicable [test method] protocol, standard or requirement . . ." (proposed § 1112.47(b)) or a "material" failure "to comply with any provision of Subpart B" (1112.47(c)) may provide grounds for CPSC withdrawal of a laboratory's accreditation, not just any minor/technical failure, which the commenter asserts the proposed rule now seems to allow.

(*Response 17*) We decline the commenter's recommendation to add the additional language in section 1112.47(b) or (c) of the final rule because the plain language of those sections, as proposed, already addresses the commenter's concerns. Any failure "to comply with an applicable protocol, standard, or requirement . . ." is grounds for withdrawal of CPSC acceptance

listed in § 1112.47(b) of the proposed rule (unchanged in the final rule), because the applicable protocol, standard, or requirement is considered to be "material" or it would not have been included in the rule. Similarly, any failure "to comply with any provision of Subpart B" in § 1112.47(c) of the final rule may be grounds for withdrawal of CPSC acceptance because those requirements would not be included in the rule unless they were considered "material."

(*Comment 18*) A commenter recommends that § 1112.53 of the proposed rule should specify in more detail the circumstances under which the CPSC may immediately suspend its acceptance of a laboratory's accreditation.

(*Response 18***)** We disagree that the changes suggested by the commenter are needed in this section of the proposed rule because the proposed rule at § 1112.53 already clearly describes, in detail, the circumstances under which the CPSC may withdraw immediately and temporarily its acceptance of a laboratory's accreditation. The CPSC may take such action when it is in the public interest to protect health and safety. The section defines "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 has 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 noncompliant with CPSC rules, bans, standards, and/or regulations, constitutes an imminently hazardous consumer product under section 12 of the CPSA.

We believe this language, which is unchanged from the proposal, clearly defines the threshold for CPSC to consider immediate withdrawal of its acceptance of accreditation.

(*Comment 19*) A commenter requests that the status of CPSC-accepted laboratories be disclosed publicly and that it should be readily ascertainable on the CPSC's website. The list of CPSC−accepted laboratories on the CPSC website at: www.cpsc.gov/labsearch, currently does not display whether a laboratory is categorized as independent, firewalled, or governmental. The commenter asserts that it is in the interest of commercial customers and consumers to display this information and that the proposed rule should be modified to require that in applying for acceptance by the CPSC, "a lab must accede to the public disclosure of its acceptance status" (independent, firewalled, governmental) on the website display of CPSC-accepted laboratories.

(*Response 19*) We decline to list the independent, firewalled, or governmental status of accepted laboratories on the CPSC website. Section 14 of the CPSA does not differentiate between "third party conformity assessment bodies" based on whether they are independent, governmental, or firewalled laboratories, provided the laboratory complies with the applicable criteria established in sections 14(f)(2)(A), (B), and (D). To list CPSC-accepted governmental and firewalled laboratories differently than independent laboratories might confuse manufacturers into thinking that the CPSC has assigned them a different status of acceptance of accreditation, which is not the case. Once its accreditation is accepted by the CPSC, a laboratory may conduct tests within its scope for children's product certification purposes, regardless of its status as an independent, governmental, or firewalled laboratory.

Many of the CPSC-accepted governmental laboratories have a small portion of government ownership and little-to-no government involvement in their operations. These laboratories operate essentially as independent laboratories, but by law, they must be categorized as "governmental" because they have partial government ownership, such as through a joint

venture. Other governmental laboratories are associated with state-funded institutions. Because forms of governmental involvement can vary, listing a laboratory as "governmental" would not necessarily convey any meaningful information to the public.

For firewalled laboratories, firewalled status applies only to a manufacturer or private labeler who owns, manages, or controls the laboratory. The laboratory is considered independent for any other manufacturer or private labeler who may wish to use the laboratory's services. Furthermore, notices of CPSC approval of firewalled laboratories are already published elsewhere on the CPSC website and are publicly available. *See* http://www.cpsc.gov/about/cpsia/labaccred.html.

C. Inspections and Investigations

(*Comment 20*) One commenter recommends modifying proposed § 1112.27 to clarify that laboratories must allow on-site inspections by CPSC personnel or their designated representative, without exception. The commenter notes that this should be enforced uniformly, to allow participation in the program.

(*Response 20***)** We do not believe that the requested modification is necessary. The language in proposed § 1112.27 states: "A third party conformity assessment body, *as a condition of its accreditation*, *must allow* an officer or employee duly designated by CPSC to enter and inspect the third party conformity assessment body for purposes of an investigation under this part." (emphasis added). The language in proposed § 1112.27 (unchanged in the final rule) is clear regarding the compulsory nature of allowing on-site inspections when asked by CPSC personnel for the purpose of an investigation as a condition of accepting the laboratory's accreditation.

(*Comment 21***)** Two commenters request that "failure to cooperate" should be defined to address specifically only the actions or inactions that are within the scope of an investigation,

and they should not be defined in regard to any other request from CPSC staff. The commenters opine that "a request to receive a subpoena for requested documents or the assertion of any other legal rights or procedures available to the lab in question should explicitly not be considered 'failure to cooperate.'"

(*Response 21***)** Because both the CPSA and the final rule specifically state that accreditation may be suspended for failing to cooperate with an investigation, we believe that the current text of the final rule already meets the commenters' request to limit the suspension to the scope of the investigation.

Section 14(e)(3) of the CPSA states:

> The Commission may suspend the accreditation of a conformity assessment body if it fails to cooperate with the Commission in an investigation under this section.

Section § 1112.45 of the final rule: *What Are the Grounds for Suspension of CPSC Acceptance?* implements section 14(e)(3) of the CPSA by stating:

> (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.

Finally, a laboratory that exercises any legal procedural right available under law would not be considered to have "failed to cooperate" under the final rule. Such a legal procedural right would include a laboratory request for the issuance of a subpoena before providing documents to the CPSC.

(*Comment 22***)** One commenter states that the suspension of acceptance of accreditation of a laboratory should be warranted only when a laboratory exhibits a pattern of evading legitimate CPSC requests or inquiries related to an inspection or investigation. This commenter states that a "failure to cooperate" should specifically exclude: "reasonable delays in providing requested information or documents, considering all the circumstances." The commenter asks that the

phrase "failure to respond to CPSC inquiries or requests" (section 1112.45(a) of the proposed rule) be defined more specifically to specify, for example, a 20-day period or other reasonable time, based on the circumstances.

(*Response 22***)** We decline to adopt the commenter's recommendations. We agree with the commenter that evasive responses to CPSC inquiries could be grounds for suspension of the CPSC's acceptance of the laboratory's accreditation. Section 1112.45 of the final rule states:

> 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.

Because the text of the proposed and final rule already includes responding evasively to investigations, we believe that the current text already meets the commenter's concerns. It is not necessary for a pattern of evasion to be established before suspension of acceptance of accreditation is considered. Requiring a pattern of evasion would allow laboratories to respond to inquiries in a manner that is evasive some of the time, until a pattern is established. Because inspections or investigations frequently pertain to the presence of noncompliant children's products in the marketplace, evasive responses are never acceptable.

With regard to the commenter's statement regarding "reasonable delays," what is considered "reasonable" varies, based on the nature of the request. Therefore, specifying a period is impractical. For example, a request for a corrected phone number, compared to a request for testing records covering a multiyear period, will have different "reasonable" expected response periods. Thus, 20 days may be excessive for a telephone number correction, while that period may be unreasonably short for the collection and transmission of voluminous records. Further, the phrase "other reasonable time based on the circumstances" does not add specificity to what is considered "reasonable."

(*Comment 23***)** Two commenters state that a request by the CPSC for a laboratory's "protocols and procedures" should relate only to the specific grounds for the investigation, not to testing in general.

(*Response 23***)** We decline the commenters' request because the rule, as proposed, already addresses the commenters' concerns. Section 1112.25(a)(4) of the proposed rule: *What are a third party conformity assessment body's recordkeeping responsibilities?* requires laboratories to maintain internal documents describing testing "protocols and procedures" that have applied to a test conducted for purposes of section 14 of the CPSA. Section 1112.51 of the rule, as proposed (unchanged in the final rule), limits investigations to applications for acceptance of accreditation, submissions alleging grounds for an adverse action, or other information received by the CPSC that relates to a third party conformity assessment body's ability to become or remain CPSC-accepted.

(*Comment 24***)** Two commenters recommend that the term "Investigation" be defined to mean more than a nonspecific request for information, with one commenter proposing a definition of "Investigation" as a "formal inquiry based on specific and sufficient facts that give rise to a reasonable belief by the CPSC that a material violation of this rule has occurred." This commenter then suggests that "Investigations" should be limited to the scope and the specific, material violation implicated by those facts. The commenter adds that "Investigations" "should only be allowed when something akin to "probable cause" arises about a specific violation of a lab and should not be allowed to be fishing expeditions by the agency."

(*Response 24***)** We decline to add a formal pleading requirement or the equivalent of a "probable cause" requirement because determining whether an investigation is warranted is a fact-based judgment best made on a case-by-case basis.

Section 1112.49(a) of the final rule (unchanged from the proposal) allows any person to submit information alleging grounds for adverse action, as set forth in part 1112. The submitter is required to allege that one or more of the grounds for adverse action set forth in part 1112 exist. Section 1112.49(a) of the final rule describes the kind of information necessary for CPSC to substantiate an allegation for an adverse action. Any investigation resulting from the information submitted under § 1112.49 would be investigated under the procedures described in § 1112.51. If a person submitting information does not provide sufficient information to investigate an allegation, it will be difficult for the agency to substantiate the allegation, as is indicated in § 1112.49(b), which states:

> Upon receiving the information, the CPSC will review the information to determine if it is sufficient to warrant an investigation. The CPSC may deem the information insufficient to warrant an investigation if the information fails to address the categories of information outlined in paragraph (a) of this section above.

The language of § 1112.49(a) sets the threshold regarding the types and sufficiency of the information necessary to warrant an investigation. Therefore, it is unnecessary to define the term "Investigation," as the commenters have requested.

D. Undue Influence

(*Comment 25*) One commenter recommends that the Commission specify that the exercise of "undue influence" over the laboratory sufficient to justify CPSC "withdrawal" of its acceptance of the laboratory (proposed § 1112.47(a)) must be "directly related and material to the scope of the testing for which the laboratory was accepted by the CPSC." The commenter notes that this is particularly important regarding the requirements for "firewalled" laboratories.

(*Response 25*) We decline to adopt the commenter's recommendation. The current language of §§ 1112.47(a) and 1112.51 of the final rule (unchanged from the proposal) permits the CPSC flexibility in assessing the nature of various undue influences acting upon conformity assessment

bodies, whereas the commenter's recommendation would narrow this flexibility. This could have unintentional and unforeseeable consequences affecting the CPSC's ability to address instances of undue influence for testing under the jurisdiction of the CPSC.

The commenter does not explain why the withdrawal of CPSC acceptance of a firewalled laboratory should be treated differently than other types of laboratories. The CPSC regards any exercise of undue influence on the integrity of a laboratory's test results as calling into question the integrity of all of the laboratory's test results, including those related to the testing of children's products.

If a laboratory disagrees with a CPSC final notice of adverse action, § 1112.51 of the final rule describes procedures for filing an administrative appeal. In addition, for firewalled laboratories, any suspension or withdrawal of CPSC acceptance of accreditation must be done by order of the Commission. These procedures allow a laboratory to present its case, if there is disagreement with the CPSC staff findings that support an adverse action.

E. Adverse Actions

(*Comment 26*) One commenter recommends that the Commission clarify in the rule that, except for situations that warrant an "immediate suspension" of a laboratory, a laboratory may be suspended or withdrawn from acceptance only after a formal "investigation" and an adequate opportunity for the laboratory to respond under the rule.

The commenter further recommends that the Commission should allow "immediate withdrawal" of a laboratory's acceptance of accreditation (proposed § 1112.53) only upon an affirmative vote of the Commission (not a mere staff determination that withdrawal is necessary "to protect the public health and safety"). The commenter notes that Commission action is necessary for the

analogous action by the CPSC to waive the 6(b) notification rights of a company to disclose immediately product-specific information to the public, and likewise, should be required here.

(*Response 26***)** We decline the commenter's recommendation for allowing for an "immediate suspension" because the final rule, which is unchanged from the proposed rule, already includes a section describing the procedures to be used during an investigation, and further clarification is not necessary.

Subpart D of the final rule (unchanged from the proposal), *Adverse Actions: Types, Grounds, Allegations, Procedural Requirements, and Publication*, includes § 1112.51, *What are the procedures relevant to adverse actions?* describes the procedures that will be used to conduct an investigation, and it also includes established procedures and opportunities for the laboratory to respond.

We decline to adopt the commenter's recommendation that an affirmative vote of the Commission be required for "immediate withdrawal" of a laboratory's acceptance of accreditation. Section 14(a)(3)(C) of the CPSA states that accreditation of third party conformity assessment bodies may be conducted by the Commission or an independent accreditation organization designated by the Commission. Currently, CPSC staff has been tasked with reviewing and accepting the accreditation of independent and governmental laboratories. While CPSC staff also reviews accreditation and application materials from firewalled applicants, section 14(f)(2)(D) of the CPSA provides that the Commission may accept a firewalled laboratory's accreditation by order of the Commission after determining that the firewalled applicant meets statutory requirements.

Section 14(e) of the CPSA authorizes the Commission to withdraw or suspend its accreditation or acceptance of accreditation of a laboratory under certain conditions. To parallel

the acceptance process to accredit firewalled laboratories, the withdrawal of acceptance of accreditation of firewalled laboratories occurs by Commission vote. In order to maintain the parallel structure of Commission acceptance of accreditation, the Commission does not require a vote to withdraw or suspend acceptance of accreditation of independent or governmental laboratories.

F. Recordkeeping

(*Comment 27***)** One commenter suggests modifying the document retention requirement of proposed § 1112.25(a) (1) to specify that only "test reports and technical records that are directly related and material to the scope of the laboratory's acceptance related to that testing" must be retained under the rule.

(*Response 27*) The proposed rule requires third party conformity assessment bodies to keep "test reports and technical records *related* to tests conducted for purposes of section 14 of the CPSA" (emphasis added). The commenter does not provide any information regarding the advantage of limiting the retention to those records that are "directly related and material" to the laboratory's testing for purposes of section 14 of the CPSA. Moreover, we are not sure that the suggested change would make a difference in the records that conformity assessment bodies would be required to keep. Therefore, we decline to make the commenter's recommended change.

(*Comment 28*) One commenter suggests modifying proposed § 1112.25(a) (2) to require only that the subcontractor laboratory's test report be "available with the prime contractor laboratory's test report" and not necessarily "appended to" it.

(*Response 28*) We agree with the commenter and will revise § 1112.25(a) (2) of the final rule to require making the subcontractor's laboratory test report available to the CPSC upon

request, but not necessarily appended to the prime contractor's test report. We note that appending a subcontractor's test report would satisfy the requirement to make the report available.

(*Comment 29***)** One commenter recommends modifying proposed § 1112.25(b) to require that documents required to be retained be provided to the CPSC, upon request, within "48 hours or within a reasonable time given the particular circumstances." The commenter also asserts that we should require only that English translations of documents be supplied to the CPSC "that are relevant and reasonably necessary with regard to the CPSC's specific inquiry or investigation."

(*Response 29*) We decline to make the commenter's recommended change to § 1112.25(b) regarding changing "48 hours" to "48 hours or within a reasonable time given the particular circumstances" when records are requested by the CPSC. However, we are revising § 1112.25(b) of the final rule to remove the "within 48 hours" language in the proposed rule and replace it with "such as through an Internet website." The revised language is consistent with the recordkeeping language in 16 CFR part 1107 (testing and labeling rule) and 16 CFR part 1109 (component part testing rule), which require submission of records upon request, but do not specify a time frame within which the records must be submitted and allow for submittal of electronic records "such as through an Internet website." Implicit in the requirement to submit records to the CPSC upon request is the commenter's concept of "within a reasonable time given the particular circumstances." The time frame necessary to respond to a document request by the CPSC, by its nature, must be determined on a case-by-case basis. Therefore, stating an explicit time frame, such as "48 hours," as the proposed rule specified, would not fit the many different circumstances that might occur when the CPSC requests records.

Regarding the commenter's suggestion that we should only require English translations of documents "that are relevant and reasonably necessary with regard to the CPSC's specific inquiry or investigation," the documents required in §§ 1112.25(a)(1)-(4) of the final rule are always considered to be "relevant and reasonably necessary with regard to the CPSC's specific inquiry or investigation." Hence, that is the reason for the requirement to maintain those records. Therefore, we decline to make the commenter's recommended change because the proposed and final rules inherently require maintaining records "that are relevant and reasonably necessary with regard to the CPSC's specific inquiry or investigation."

(*Comment 30***)** One commenter recommends that we modify the proposed rule to clarify generally that "except for the status of an accepted laboratory, confidential business information, copyrighted information and trademarks, trade secrets and other information and documents provided to the CPSC by a laboratory under this rule is strictly protected from any third party disclosure under the all applicable laws, including, without limitation, the Consumer Product Safety Act."

(*Response 30***)** We decline the commenter's recommendation because it is unnecessary to clarify the final rule by adding the language requested by the commenter. Confidential business information, copyrighted information and trademarks, trade secrets, and other information and documents provided to the CPSC by a laboratory are all subject to protections from third party disclosure or other protections under existing applicable laws, and the final rule does not change that.

G. Definitions

(*Comment 31***)** A commenter notes that the proposed rule defined a "quality manager" for an accredited laboratory as having "defined responsibility and authority for ensuring the

management system related to quality is implemented and followed at all times." The commenter states that a laboratory may institute an ISO 9000-compliant management system and "may not address the fulfillment of ISO/IEC 17025, which may NOT include competence requirements for testing." The commenter asserts that the definition appears to refer only to compliance with the management system and not to all sections of ISO/IEC 17025:2005(E).

(*Response 31***)** The definition of a "quality manager" provided in the Audit Final Rule (16 CFR §1112.3, *Definitions* is the same as the definition of a "quality manager" in section 4.1.5.i of ISO/IEC 17025:2005(E). We agree with the commenter that, regardless of the definition of a "quality manager," a laboratory must comply with all the requirements of ISO/IEC 17025:2005(E) in order for its accreditation to be accepted by the CPSC.

H. Retrospective Testing

(*Comment 32*) One commenter notes that most of the previous NORs have provided for "retrospective testing" by laboratories, *i.e.*, CPSC recognition of testing and certification using the new standard after the date of the method's initial publication by the agency and before the NOR formally goes into effect. The commenter also notes that the two new CPSC lead substrate test methods have already been posted on the CPSC website, including a reference in the laboratory accreditation application page of that site, which indicates that laboratories can now begin applying for private accreditation. Thereafter, CPSC acceptance, to these new methods, should be allowed, despite the fact that there has been no retrospective testing allowance provided for in the proposed rule. The commenter recommends that the final rule allow retrospective testing using the new methods, effective back to April 10, 2012, the date those new methods were first published by the CPSC.

(*Response 32*) We agree with the commenter regarding allowing retrospective testing for the new CPSC lead substrate test methods, CPSC-CH-E1001-08.2 and CPSC-CH-E1002-08.2, and we describe the circumstances where retrospective testing under those test methods and others will be accepted by the CPSC in section III.B.3.b of the preamble.

III. Description of the Final Rule

A. Subpart A – Purpose and Definitions

1. Purpose (§ 1112.1)

This section of the final rule, describing the major topics addressed in part 1112, is substantially the same as proposed. As in the proposal, this section notes 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. This section notes 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. The description of the purpose in § 1112.1 of the final rule is unchanged from the proposed rule, with the following exception. Proposed § 1112.1 used the phrase "that are accepted by" when referring to CPSC acceptance of a third party conformity assessment body's acceptance of accreditation by the CPSC. The final rule replaces the phrase "that are accepted by" used in proposed § 1112.1 with "whose accreditations are accepted by" in the final rule because the revised language describes more

accurately the CPSC acceptance of the accreditation process. This change is not a substantive change and has been made throughout the rule, where appropriate, for consistency.

2. Definitions (§ 1112.1)

(i) Definitions Amending the Audit Rule

Proposed § 1112.3 amended two definitions that appear in the audit final rule. One definition is the term "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. We did not receive any comments on this proposed definition and are finalizing the definition as proposed.

The other definition from the audit rule that the Commission proposed to amend is "CPSC." The rule discusses certain tasks that must be accomplished by the 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, revised the definition of "CPSC" to mean the U.S. Consumer Product Safety Commission as an agency. The definition of "CPSC" in the final rule is unchanged from the proposed rule.

(ii) Other Definitions

Final § 1112.3 creates the following nine definitions; all are the same as proposed:

Accept accreditation: The rule defines this term consistent with its use in section 14 of the CPSA. *See, e.g.*, 15 U.S.C. 2063(e)(1). The definition 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.

Commission: The rule defines "Commission" to mean the body of Commissioners appointed to the U.S. Consumer Product Safety Commission. In contrast, the agency as a whole was referred to, in this part, as the CPSC.

CPSA: The rule defines this acronym to mean the Consumer Product Safety Act, 15 U.S.C. 2051–2089.

Notice of requirements: The rule defines this term to 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.

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

Third party conformity assessment body: The rule defines this term to mean a laboratory. The preamble to the proposed rule discusses the development of this definition in detail. *See* 77 FR at 31109. In the preamble to this rule, for ease of reference, and for the convenience of the reader, the word "laboratory" is used interchangeably with "third party conformity assessment body." In the regulatory text, for clarity, only the full term, "third party conformity assessment body" is used.

Undue influence: The rule defines "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. The preamble to the proposed rule discusses the development of this definition in detail. *See* 77 FR at 31109.

Withdraw: The rule defines this term consistent with its use in section 14(e) of the CPSA. The proposed rule defined "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

1. What Are the Types of Third Party Conformity Assessment Bodies? (§ 1112.11)

This section describes, for purposes of part 1112, the three types of third party conformity assessment bodies: independent, firewalled, and governmental. Section 1112.11(a) describes 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.

Section 1112.11(b) describes the circumstances that result in firewalled status. The rule considers a laboratory "firewalled" if it is owned, managed, or controlled by a manufacturer or private labeler of a children's product. The rule considers a laboratory owned by a trade association to be firewalled. 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 by discouraging reports of attempted undue influence by an association member.

A laboratory would be considered to be "owned, managed, or controlled" by a manufacturer or private labeler if one (or more) of three characteristics apply. The first is if the manufacturer or private labeler of the children's product holds a 10 percent or greater ownership interest, whether direct 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 chose the 10 percent threshold ownership amount because it is our estimation that a manufacturer or private labeler who possesses less than a 10 percent ownership interest in a laboratory and 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 3 years indicates that applicants understand it easily 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 rule also includes indirect ownership because an entity that owns a manufacturer or private labeler that, 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.

The second circumstance that signifies that a laboratory is firewalled arises when the laboratory and a manufacturer or private labeler of a 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 firewalled to ensure that its testing processes are independent.

The third circumstance that results in firewalled status occurs 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 levels 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 preamble to the proposed rule discusses in more detail the development of the firewalled requirements in proposed §§ 1112.11(b)(1)(ii)(A)-(C). *See* 77 FR at 31109-10. Proposed §§ 1112.11(b)(1)(ii)(A)-(C) of the final rule are unchanged from the proposed rule.

The fourth circumstance described in the proposed rule that would have resulted in firewalled status arises 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 customers of the laboratory. As discussed in the response to Comment 13 in section II.B. of the preamble, the Commission has decided to delete proposed § 1112.11(b)(1)(ii)(D) from the final rule.

Section 1112.11(c) implements the CPSA section 14(f)(2)(B) definition of a "governmental" laboratory as one "owned or controlled in whole or in part by a government."

The proposed rule stated that, for purposes of this part, "government" includes any unit of a national, territorial, provincial, regional, state, tribal, or local government. "Government" includes domestic, as well as foreign governmental entities. 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 specified "in whole or in part" in section 14(f)(2)(B) of the CPSA. For that reason, the rule describes the ways in which 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.

As in the proposal, § 1112.11(c) lists six characteristics, any one of which triggers governmental laboratory status:

- A governmental entity holds a 1 percent or greater ownership interest, whether direct or indirect, in the laboratory (§ 1112.11(c)(1)). 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;
- A governmental entity provides any direct financial investment or funding (other than fee-for-work) to the laboratory (§ 1112.11(c)(2)). This circumstance triggers

governmental status because operational control of an enterprise may be affected by control or influence over its resources;

- 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 limited to, the 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 , at least in part, control of the laboratory (§ 1112.11(c)(3));
- If any of the laboratory's management or technical personnel are government employees (§ 1112.11(c)(4)). Direct involvement by government personnel in the operation of a laboratory would represent control, in part;
- If the laboratory has a subordinate position to a governmental entity in its external organizational structure (§ 1112.11(c)(5)). We consider 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; or
- If a government can determine, establish, alter, or otherwise affect the laboratory's testing outcomes, its budget or financial decisions, its organizational structure, or continued existence, or determines whether the laboratory may accept particular offers of work, then the laboratory would be considered governmental (§ 1112.11(c)(6)). The preamble to the proposed rule discusses the criteria for governmental laboratory status in

further detail. *See* 77 FR at 31110-11. This provision of the final rule is unchanged from the proposed rule.

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

Section 1112.13 describes how a third party conformity assessment body may apply for CPSC acceptance of its accreditation. We are finalizing this section as proposed. Section 1112.13(a) describes the initial baseline requirements for any laboratory to apply. The laboratory must submit the following:

- A completed application, CPSC Form 223. The laboratory also must update its CPSC Form 223 whenever any information previously supplied on the form changes.
- A certificate of accreditation to ISO/IEC Standard 17025:2005(E), "General requirements for the competence of testing and calibration laboratories."
- Accreditation by an accreditation body that is a signatory to the ILAC-MRA. All laboratories also are required to furnish their statement of scope, and the statement of scope would have to identify clearly the CPSC rule(s) and/or test method(s) for which CPSC acceptance is sought.

The preamble to the proposed rule discusses the baseline requirements for accreditation in further detail. *See* 77 FR at 31111.

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

> (i) [acceptance] of the accreditation 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 conformity assessment body; and

> (ii) the 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 Commission is notified immediately of any attempt by the manufacturer, private labeler or other interested party to hide or exert undue influence over test results; and
> (III) allegations of undue influence may be reported confidentially to the Commission.

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

To evaluate whether a laboratory satisfies these criteria, the rule requires that a laboratory seeking CPSC-accepted firewalled status submit copies of various documents to the CPSC. Such laboratories must 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. 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, in addition to submitting the laboratory's policies and procedures explaining that an allegation of undue influence may be reported confidentially to the CPSC.
- Copies of training documents, including a description of the training program content, showing how employees are trained on the three policies just described. The rule requires this training annually.
- Training records listing staff members who received the training and bearing their signatures. The training records must include training dates, location, and the name and title of the individual providing the training.

- For firewalled laboratory applicants, two organizational charts. One chart must be an organizational chart(s) of the laboratory itself. It must include the names of all personnel, both temporary and permanent, and their reporting relationship within the laboratory. The other organizational chart must identify the reporting relationships of the laboratory within the broader organization (using both position titles and staff names).
- 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.

The preamble to the proposed rule discusses the additional requirements for firewalled laboratories in further detail. *See* 77 FR at 31112.

Section 14(f)(2)(B) of the CPSA mandates that the Commission may accept the accreditation of a governmental laboratory if:

> (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 [section 14];
> (iv) the 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) 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).

The rule restates these statutory requirements and provides that, in order for the CPSC to make the necessary determinations, governmental laboratories must submit the following:

- A description that can be in the form of a diagram. The description should illustrate the laboratory's relationships with other entities, such as government agencies and joint venture partners.
- Questionnaires completed by the governmental laboratory and the relevant governmental entity. The questionnaires are designed to elicit information related to the five statutory criteria.
- A copy of an executed memorandum that addresses undue influence. The memorandum must 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 must be displayed prominently at the laboratory for as long as the laboratory's accreditation is accepted by the CPSC. The memorandum must state certain policies and require that the laboratory's policy is to reject undue influence. Additionally, the memorandum must require employees to report immediately, to their supervisor or to another designated laboratory official, any attempt at undue influence. Finally, the memorandum must state that the laboratory will not tolerate violations of the undue influence policy.
- An attestation by a senior official of the governmental laboratory, who has the authority to make binding statements of policy on behalf of the laboratory. The official must attest to several statements related to the application, including that the laboratory does not

receive and will not accept favorable treatment from any governmental entity with regard to products that are subject to CPSC jurisdiction and that are for export to the United States. Among other things, the senior official of the governmental laboratory must attest that the information in the laboratory's application continues to be accurate, unless the laboratory notifies the CPSC otherwise.

- If CPSC 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, the CPSC may require the relevant governmental entity to attest to the details of the new relationship or policy.

The preamble to the proposed rule discusses the additional requirements for firewalled laboratories in further detail. *See* 77 FR at 31112-13. This section of the final rule is unchanged from the proposed rule, with one exception. Proposed § 1112.13(c)(2)(iii)(3) would have required an executed memorandum, "From senior management," addressing undue influence. The description of the rule in the preamble to the proposed rule noted that the executed memorandum was required to be "from the senior management of the governmental laboratory." 77 FR at 31112. Final § 1112.13(c)(2)(iii)(3) has been revised by adding "of the third party conformity assessment body" after "from senior management," to clarify what "senior management" refers to in the codified text.

Section 1112.13(d) states 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. This provision of the final rule is unchanged from the proposed rule.

As in the proposal, § 1112.13(e) requires all application materials to be in English.

Section 1112.13(f) requires that CPSC Form 223 and all required accompanying documentation be submitted electronically via the CPSC website. We have established an electronic application system that can be accessed via our Internet site at: http://www.cpsc.gov/about/cpsia/labaccred.html. This provision of the final rule is unchanged from the proposed rule.

Section 1112.13(g) reserves the authority to require additional information from an applicant laboratory to determine whether the laboratory meets the relevant criteria. This provision allows us to gather additional information if the initial information supplied by an applicant laboratory is insufficient. The rule also states that the CPSC, before acting on an application, may verify the accreditation certificate and statement of scope directly from the laboratory's accreditation body. This provision of the final rule is unchanged from the proposed rule.

Section 1112.13(h) provides that a laboratory may retract an application at any time before the CPSC has acted on it. The rule notes, however, that a retraction would not end or nullify any enforcement action that the CPSC is authorized to pursue. This provision of the final rule is unchanged from the proposed rule.

Section 1112.13(i) contains the incorporation by reference language for ISO/IEC Standard 17025:2005(E): "General requirements for the competence of testing and calibration laboratories," which is required by the Office of the Federal Register.

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

a. Regulatory Text

Section 1112.15(a) states, 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. This section notes that a laboratory may apply for acceptance for more than one CPSC rule and/or test method at a time. 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. Finally, this section states for purposes of section 14 of the CPSA, a laboratory may be authorized to issue test results only for tests that fall within the CPSC rules and/or test methods for which its accreditation has been accepted by the CPSC. This provision of the final rule is unchanged from the proposed rule.

Section 1112.15(b) lists the rules and test methods for which the Commission has published the requirements for accreditation of laboratories. The list in the final rule is current through the publication date of the final rule in the *Federal Register*. After the final rule publishes in the *Federal Register*, additions or revisions to this list in the future will be proposed as amendments to this section. The preamble to the proposed rule contains a more detailed discussion of the list of rules and test methods. *See* 77 FR at 31134-36. We are finalizing § 1112.15(b), as proposed, with the following exceptions.

The preamble to the proposed rule (77 FR at 31135) noted that proposed §§ 1112.15(b)(28) and (29), would contain two proposed revisions, which provided 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 in its scope of accreditation either Test Method CPSC-CH-E1001-08 (the original test method) and/or Test Method CPSC-CH-

E1001-08.1 (the revised test 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).

Comment 3 in section II.A of the preamble notes that CPSC test method CPSC–CH–E1001–08.2 was not included as an acceptable test method in the codified text of proposed § 1112.15(b)(28). In the codified text of proposed § 1112.15(b)(28), test method CPSC–CH–E1001–08.2 was omitted inadvertently, although it was discussed in the preamble to the proposed rule, and we intended that test method CPSC–CH–E1001–08.2 be allowed under § 1112.15(b)(28). Therefore, § 1112.15(b)(28) of the final rule expressly allows for the use of test method CPSC–CH–E1001–08.2.

Additionally, as discussed in response to Comment 8 in section II.A of the preamble, CPSC staff has posted two new test methods, CPSC-CH-E1001-08.3 (http://www.cpsc.gov/about/cpsia/CPSC-CH-E1001-08_3.pdf) and CPSC-CH-E1002-08.3 (http://www.cpsc.gov/about/cpsia/CPSC-CH-E1002-08_3.pdf), on the CPSC website. Sections 1112.15(b)(28) and (29) of the final rule have been revised to add test method CPSC-CH-E1001-08.3 as an option for laboratory accreditation for lead content in metal jewelry and children's metal products. Section 1112.15(b)(30) of the final rule has also been revised to add test method CPSC-CH-E1002-08.3 as an option for laboratory accreditation for nonmetal products.

Finally, editorial changes have been made to §§ 1112.15(b)(28), (29), and (30) of the final rule. In §§ 1112.15(b)(28) and (29) of the final rule, the full name of the 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)" is used the first time it appears in the provision; and thereafter, reference is made to the number of the test method because the

name of the test method is clear from the context of the provision. The same change has been made to § 1112.15(b)(30) regarding the reference to CPSC Test Method CPSC-CH-E1002-08, "Standard Operating Procedure for Determining Total Lead (Pb) in Nonmetal Children's Products." These changes are not intended to change those provisions substantively. Other than the changes just discussed, §§ 1112.15(b)(28) and (29) of the final rule have been finalized as proposed.

b. Retrospective Testing

In order to ease the transition to new third party testing requirements and to avoid a "bottlenecking" of products at laboratories at or near the effective date of required third party testing for children's product, the Commission, in the past, and under certain conditions, has accepted certifications based on testing that occurred prior to the effective date for third party testing. The CPSC will accept retrospective testing under certain conditions for six new or revised requirements for accreditation listed in § 1112.15(b) of the final rule. The retrospective testing conditions listed here are based on other standards that previously allowed for retrospective testing. The details for retrospective testing for particular standards or tests methods are discussed below.

Standards for Play Yards, Infant Swings, and Bed Rails (16 CFR parts 1221, 1223, and 1224)

We will accept retrospective testing for 16 CFR parts 1221 (play yards), 1223 (infant swings), and 1224 (portable bed rails) for the tests contained in those standards, 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(E) by a signatory to the ILAC-MRA at the time of the test. The

scope of the third party conformity body accreditation must include testing in accordance with the applicable standard. 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 the applicable standard at the time of initial Commission acceptance. For governmental third party conformity assessment bodies, accreditation of the body must be accepted by the Commission, even if the scope of accreditation did not include the tests contained in the applicable standard at the time of initial CPSC acceptance.

- The third party conformity assessment body's application for acceptance of its accreditation is accepted by the CPSC on or after May 24, 2012, and before [INSERT DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].
- The test results show compliance with the applicable standard(s).
- 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 1221, Play Yards (published August 29, 2012);
    - 16 CFR part 1223, Infant Swings (published November 7, 2012); and/or
    - 16 CFR part 1224, Portable Bed Rails (published February 29, 2012);

  and before [INSERT DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].
- The laboratory's accreditation remains in effect through [INSERT DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

Testing for Nonmetal Children's Products (Test Methods CPSC-CH-E1001-08.2 and CPSC-CH-E1002-08.2)

We will accept retrospective testing using test methods CPSC-CH-E1001-08.2 (for testing children's metal products) and CPSC-CH-E1002-08.2 (for testing nonmetal children's products), 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(E) by a signatory to the ILAC-MRA at the time of the test. The scope of the third party conformity body accreditation must include test methods CPSC-CH-E1001-08.2 and/or CPSC-CH-E1002-08.2. For firewalled third party conformity assessment bodies, the Commission, by order, must have accredited it on or before the time that the children's product was tested, even if the order did not include the test methods CPSC-CH-E1001-08.2 and/or CPSC-CH-E1002-08.2 at the time of initial Commission acceptance. For governmental third party conformity assessment bodies, accreditation of the body must be accepted by the Commission, even if the scope of accreditation did not include at the time of initial CPSC acceptance the test methods CPSC-CH-E1001-08.2 and/or CPSC-CH-E1002-08.2.
- The third party conformity assessment body's application for acceptance of its accreditation to the revised test methods is accepted by the CPSC on or after May 24, 2012, and before [INSERT DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].
- The test results show compliance with limits on total lead content, as established in section 101 of the CPSIA.

- The children's product was tested on or after April 10, 2012 (the date the revised test methods were posted on the CPSC website) and before [INSERT DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].
- The laboratory's accreditation remains in effect through [INSERT DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

Toy Standard (ASTM F963-11)

We will accept retrospective testing on children's products conducted by a third party conformity assessment body accepted by the Commission for those tests in ASTM F963-11 that have no equivalent, or functionally equivalent, test in ASTM F963-08, 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(E) 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 F963-11. For firewalled third party conformity assessment bodies, the Commission, by order, must have accredited it, on or before the time that the children's product was tested, even if the order, at the time of initial Commission acceptance, did not include the nonequivalent tests contained in ASTM F963-11. For governmental third party conformity assessment bodies, accreditation of the body must be accepted by the Commission, even if the scope of accreditation at the time of initial CPSC acceptance did not include the nonequivalent tests methods contained in ASTM F963-11.

- The third party conformity assessment body's application for acceptance of its accreditation is accepted by the CPSC on or after May 24, 2012, and before [INSERT DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].
- The test results show compliance with the nonequivalent section(s) of ASTM F963-11.
- The children's product was tested on or after February 22, 2012 (the date that the Commission voted to approve ASTM F963-11 as a mandatory standard), and before [INSERT DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].
- The third party conformity assessment body's accreditation remains in effect through [INSERT DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

4. How Will the CPSC Respond to Each Application? (§ 1112.17)

This section establishes the procedures related to CPSC action on a third party conformity assessment body's application for CPSC acceptance of its accreditation. We are finalizing this section as proposed.

CPSC staff will review each application and may contact applicant laboratories with questions or to request submission of missing information.

Consistent with section 14(f)(2)(D) of the CPSA, 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.

The CPSC will communicate its decision on each application, in writing, to the applicant; the written decision may be by electronic mail.

5. How Does the CPSC Publish Information Identifying Third Party Conformity Assessment Bodies that Have Been Accepted? (§ 1112.19)

In accordance with section 14(a)(3)(E) of the CPSA, § 1112.19 provides 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. The rule states that the CPSC will 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, the CPSC will 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 its acceptance of a laboratory's accreditation. This provision of the final rule is unchanged from the proposed rule.

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

We are finalizing this section as proposed. It requires 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 purposes of section 14 of the CPSA. The CPSC is requiring that test methods be specified 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 is a common understanding between the CPSC and CPSC-accepted laboratories. Second, by specifying the test method, greater consistency among tests conducted at different CPSC-accepted laboratories is established. Variations between laboratories are reduced. Finally, the specified test method 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,

accreditation bodies can determine whether the laboratory meets competency requirements to carry out a particular test.

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

This section of the final rule is unchanged from the proposed rule. It prohibits subcontracting of tests conducted for purposes of section 14 of the CPSA, unless the work is subcontracted 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. The purpose of requiring a third party conformity assessment body subcontractor to be a CPSC-accepted laboratory is to promote competent and consistent test results across all laboratories that conduct testing of children's products under section 14 of the CPSA.

The provisions of part 1112 apply to all CPSC-accepted laboratories, even if they are a prime contractor and/or a subcontractor.

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

This section requires third party conformity assessment bodies to retain certain records related to the tests conducted for purposes of section 14 of the CPSA. All required records must be legible. 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 5 years from the date the test was conducted. These requirements are unchanged from the proposed rule.

Proposed § 1112.25(a)(2) required, in the case of a test report for a test conducted by a CPSC-accepted laboratory acting as a sub-contractor, that the prime contractor's test report identify clearly 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. This provision of the final rule has been changed to require only that the subcontractor's laboratory test report be made available to the CPSC, upon request, but not necessarily appended to the prime contractor's test report, as discussed in the response to Comment 28 in section II.F of the preamble.

The remaining subsections of § 1112.25(a) are unchanged from the proposed rule. For purposes of section 14 of the CPSA, where a report, 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 5 years from the date the test was conducted.

Any and all laboratory internal documents describing testing protocols and procedures (such as instructions, standards, manuals, guides, and reference data) that have been 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.

As noted in the response to comment section of this preamble, we are modifying § 1112.25(b). The proposed rule stated 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. If the records are not in English, copies of the original records must be made available to the CPSC within 48 hours, and an English translation of the records must be made available by the laboratory within 30 calendar days of the date the CPSC requested an English translation. As discussed in the response to Comment 29 in section II.F of the preamble, we are revising § 1112.25(b) to remove the "within 48 hours" language in the proposed rule and replacing it with: "such as through an Internet website." The revised language is being added to be consistent with the recordkeeping language in 16 CFR part 1107 (testing and

labeling rule) and 16 CFR part 1109 (component part testing rule), which require submission of records, upon request, but do not specify a time frame within which the records must be submitted and allows for electronic records "such as through an Internet website." Implicit in the requirement to submit records to the CPSC upon request, is the commenter's concept of "within a reasonable time given the particular circumstances." The time frame necessary to respond to a document request by the CPSC, by its nature, is required to be determined on a case-by-case basis. Therefore, stating an explicit time frame, such as "48 hours," as the proposed rule specified, would not fit the many different circumstances that might occur when the CPSC requests records.

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

This section of the final rule is unchanged from the proposal. It requires 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. The CPSC will 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 § 1112.45. The preamble to the proposed rule discusses this condition of CPSC-acceptance in further detail. *See* 77 FR at 31118.

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

This section is unchanged from the proposed rule. It provides 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. To discontinue voluntarily its participation as a CPSC-accepted laboratory, the laboratory must notify the CPSC in writing. This notification may be sent electronically. The notice must include the name, address, phone number, and electronic mail address of the laboratory and the person responsible for submitting the request. The notice also must include the scope of the discontinuance; the beginning date for the discontinuance; a statement that the laboratory understands that in the future, if desired, it must reapply for acceptance of the accreditation scope for 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.

The CPSC may verify the information submitted in a notice of voluntary discontinuance. 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, the CPSC will update its website to indicate that the CPSC no longer accepts the accreditation of the third party conformity assessment body as of the date provided, and for the scope indicated in the notice. 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. When Must an Audit Be Conducted? (§ 1112.35(b))

As explained in the audit final rule published in the *Federal Register* on May 24, 2012 (77 FR 30704), 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 reassessment portion of an audit is conducted, at a minimum, at the frequency established by its

accreditation body. 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.

We are finalizing these provisions as proposed. Section 1112.35(b) established when the examination portion of an audit must be conducted. This section requires each laboratory to submit a new CPSC Form 223 and applicable accompanying documentation no less than every 2 years.

This section notes that 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. 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 § 1112.35(b)(1). If the laboratory also intends to satisfy the audit requirement of § 1112.35(b)(1), it must indicate that intent clearly when it submits a CPSC Form 223. In addition, the laboratory must upload all applicable accompanying documentation.

Section1112.35(b)(3) states 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, CPSC 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

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

This section lists the possible adverse actions that the CPSC may take against a third party conformity assessment body: denial of acceptance of accreditation; suspension of acceptance of accreditation; or withdrawal of acceptance of accreditation. It also states 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. This section of the final rule is unchanged from the proposed rule.

2. What Are the Grounds for Denial of an Application? (§ 1112.43)

This section, unchanged from the proposal, lists the grounds for denying an application for acceptance of accreditation from a third party conformity assessment body. It notes that 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 deficiency, constitute grounds for denial of an application.

Submission of false or misleading information concerning a material fact(s) on an application, or concerning any other information provided to the CPSC related to a third party conformity assessment body's ability to become or remain a CPSC-accepted third party conformity assessment body are grounds for denial of an application.

The CPSC may deny an application if the applicant laboratory fails to satisfy the necessary requirements described in § 1112.13, such as ISO/IEC 17025:2005(E) accreditation by

an ILAC-MRA signatory accreditation body for the scope for which acceptance of accreditation is being sought.

The CPSC's denial of an application will follow the process described in § 1112.51 of this part.

3. What Are the Grounds for Suspension of CPSC Acceptance? (§ 1112.45)

This section, unchanged from the proposal, provides that the CPSC may suspend 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. 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 the laboratory fails to cooperate with an investigatory inspection under § 1112.27.

A suspension will last until the laboratory complies, to CPSC's satisfaction, with required actions, as outlined in the initial notice described in proposed § 1112.51(b), or until the CPSC withdraws acceptance of the laboratory. The suspension of CPSC acceptance will be lifted if the CPSC determines that the third party conformity assessment body is cooperating sufficiently with the investigation. The suspension would be lifted as of the date of the CPSC's written notification to the laboratory, which may be by electronic mail, indicating that the CPSC is lifting the suspension.

4. What Are the Grounds for Withdrawal of CPSC Acceptance? (§ 1112.47)

This section, unchanged from the proposal, establishes the grounds upon which the CPSC may withdraw acceptance of the accreditation of a third party conformity assessment body for any portion of its CPSC scope.

One basis for withdrawal is when 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. The preamble to the proposed rule discusses the exertion of undue influence in further detail. 77 FR at 31120.

A second ground for withdrawal occurs when a third party conformity assessment body has failed to comply with an applicable protocol, standard, or requirement under subpart C of this part.

Finally, the CPSC may withdraw its acceptance of the accreditation of a laboratory if the laboratory fails to comply with any provision in subpart B of this part. Subpart B establishes 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.

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

This section, unchanged from the proposal, allows 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. This section also lists the information to be included in a submission alleging grounds for adverse action.

- The submission should include the name and contact information of the person making the allegation.

- 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.
- 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.
- 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 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.
- A submission of grounds for adverse action should include a description of the impact of the acts and/or omissions, where known.

Upon receiving the information, the CPSC will review the information to determine if it is sufficient to warrant an investigation. The CPSC 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. What Are the Procedures Relevant to Adverse Actions? (§ 1112.51)

This section, unchanged from the proposal, describes the process by which the CPSC 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. The CPSC would use the *Procedures for Investigations, Inspections, and Inquiries*, 16 CFR part 1118, subpart A, to investigate under this part.

An investigation under this part may include: any act the CPSC may take 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 we receive, which relates to a laboratory's ability to become or remain a CPSC-accepted laboratory.

The CPSC will begin an investigation by providing written notice, which may be electronic, to the laboratory. The notice will inform the laboratory that we have received information sufficient to warrant an investigation, and describe the information received by the CPSC, as well as describe the investigative process. The notice also will inform the laboratory that failure to cooperate with a CPSC investigation is grounds for suspension.

Any 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, constitutes a notice of investigation for purposes of this section. The examination portion of an audit under § 1112.33(c) of this part (which is currently in effect) constitutes an investigation for purposes of this section.

If, after investigation, the CPSC determines that grounds for adverse action exist, and the CPSC proposes to take an adverse action against a laboratory, the CPSC will 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 begin a proceeding to suspend or withdraw our acceptance of its accreditation, as described in section 14(e) of the CPSA. The notice must:

- Include the proposed adverse action;
- Specify the grounds upon which the proposed adverse action is based;
- Provide findings of fact to support the proposed adverse action;
- When appropriate, specify actions a third party conformity assessment body must take to avoid an adverse action;
- Include consideration of the criteria set forth in § 1112.51(d)(1), when the proposed adverse action is withdrawal; and
- Specify 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.

Under § 1112.53, 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.

Section 1112.51(c) addresses how a laboratory may respond to the initial notice. The proposed rule required the laboratory's response to be in writing, which may be by electronic mail, and in English. The response may 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 matter, and action(s) taken as a result; or a detailed plan and schedule for an internal review.

The written response from the laboratory must state the laboratory's reasons why the ground(s) for adverse action do 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, the CPSC will 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, the CPSC may proceed, without further delay, to a Final Notice, as described in § 1112.51(e).

Section 1112.51(d) addresses proceedings for adverse actions. The CPSC 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.

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 § 1112.51(d)(3), the CPSC will determine what action is appropriate under the circumstances. Any suspension or withdrawal of a firewalled laboratory would occur by order of the Commission.

The CPSC may withdraw its acceptance of the accreditation of a laboratory on a permanent or temporary basis.

If the CPSC withdraws its acceptance of accreditation of a laboratory, it may establish requirements for the reacceptance of the laboratory's accreditation. Any such requirements would be related to the reason(s) for the withdrawal.

Section 1112.51(e) describes the Final Notice for an adverse action. If, after reviewing a laboratory's response to a notice, and conducting additional investigation, where necessary, the CPSC determines that grounds for adverse action exist, the CPSC will send a Final Notice to the laboratory, in writing, which may be electronic. The Final Notice will state:

- The adverse action that we are taking;
- The specific grounds on which the adverse action is based;
- 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 set forth in § 1112.51(d)(1);
- When the adverse action is withdrawal, whether the withdrawal is temporary or permanent, and, if the withdrawal is temporary, the duration of the withdrawal.
- The Final Notice will 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 will inform the laboratory that the CPSC website will be updated to reflect adverse actions taken against a previously CPSC-accepted laboratory.
- The Final Notice will inform the laboratory whether it may submit a new application.

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.

Section 1112.51(g) addresses Administrative Appeals. Except for cases covered in § 1112.51(g)(2), a laboratory could file an Administrative Appeal with the CPSC Office of the Executive Director. The Administrative Appeal must be sent by mail within 30 calendar days of the date on the Final Notice; § 1112.51(g) provides the appropriate mailing and electronic mail addresses. The rule requires 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, the Executive Director 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.

Section1112.51(g)(2) addresses 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 CPSC Office of the Secretary by mail within 30 calendar days of the date on the Final Notice. The rule requires 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. Can the CPSC Immediately Withdraw its Acceptance of the Accreditation of a Third Party Conformity Assessment Body? (§ 1112.53)

This section, unchanged from the proposal, establishes a means of withdrawing immediately and temporarily 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 § 1112.51.

When it is in the public interest to protect health and safety, and notwithstanding any other provision of this part, the CPSC may immediately and temporarily withdraw our acceptance of a laboratory's accreditation for any portion of its CPSC scope while it pursues an investigation and potential adverse action. "In the public interest to protect health and safety" means 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 noncompliant with CPSC rules, bans, standards, and/or regulations, constitutes an imminently hazardous consumer product under section 12 of the CPSA.

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 time frames described in § 1112.51, the following time frames 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.

If the laboratory is already the subject of an investigation or adverse action process, the immediate and temporary withdrawal will remain in effect until either the CPSC communicates in writing that the immediate and temporary withdrawal has been lifted, the investigation concludes, and the CPSC does not propose an adverse action, or the adverse action process concludes with denial, suspension, or withdrawal.

If the laboratory 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.

8. Will the CPSC Publish Adverse Actions? (§ 1112.55)

This section, unchanged from the proposal, states that, 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. In addition, after issuance of a final adverse action, the CPSC will amend its website listing of CPSC-accepted laboratories to reflect the nature and scope of such adverse action.

E. *Conduct and Scope of Inspections (16 CFR 1118.2)*

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 sought to amend § 1118.2(a) in two ways. First, it included firewalled third party conformity assessment bodies as entities that the CPSC may inspect. This amendment is necessary to conform § 1118.2(a) with the statutory language in section 16(a) of

the CPSA and the inspection provision at § 1112.27. Second, it removed 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. To be consistent with the inspection provision at § 1112.27, the references to "product" must be broad enough to include more than just products subject to CPSA safety standards. The final rule is unchanged from the proposed amendments to the existing provisions of § 1118.2 of the proposed rule.

IV. Regulatory Flexibility Act

A. Introduction

The Regulatory Flexibility Act (RFA) requires that final rules be reviewed for their potential economic impact on small entities, including small businesses. Section 604 of the RFA generally requires that the Commission prepare a final regulatory flexibility analysis when it promulgates a final rule. The final regulatory flexibility analysis must describe the impact of the rule on small entities. Specifically, the final regulatory flexibility analysis must contain:

- a succinct statement of the objectives of, and legal basis for, the rule;
- a summary of the significant issues raised by public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
- a description of, and where feasible, an estimate of, the number of small entities to which the rule will apply;
- a description of the projected reporting, recordkeeping, and other compliance requirements of the 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

- a description of the steps the agency has taken to reduce the significant economic impact on small entities, consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the rule, and why each one of the other significant alternatives to the rule considered by the agency, which affect the impact on small entities, was rejected.

B. Comments on the Initial Regulatory Flexibility Analysis

The preamble to the proposed rule contained the initial regulatory flexibility analysis (IRFA). The CPSC received six public comments in response to the notice of proposed rulemaking. None of the comments addressed the content of the IRFA or its findings.

C. Description and Estimate of the Small Entities to Which the Final Rule Applies

The final rule applies to laboratories that intend to test children's products for conformance to children's product safety rules under Section 14 of the CPSA. The final rule does not impose any requirements on laboratories that do not intend to provide this service.

Although there are 5,198 firms in the United States classified as "testing laboratories" (NAICS code 54138), only a small subset of these laboratories is expected to provide third party conformity assessments of children's products for purposes of section 14 of the CPSA. As of October 5, 2012, the CPSC has accepted the accreditation of 92 laboratories located in the United States.[3] This number could increase, somewhat, over the next year or so, as new notices of requirements for accreditation are issued.

[3] The CPSC has recognized the accreditation of 410 laboratories worldwide (as of January 15, 2013). However, most of the laboratories are located in other countries. Only domestic firms are considered for the purposes of the RFA.

According to criteria established by the U.S. Small Business Administration (SBA), a laboratory is considered small if its revenue is less than $14 million a year. Of the 92 laboratories located in the United States with CPSC-accepted accreditations, 58 (or 63 percent) could be small businesses, according to the SBA criteria.

D. Compliance and Recordkeeping Requirements of the Rule

1. Acceptance of Accreditation

The final rule establishes 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 final rule does not impose any requirements on laboratories that do not intend to provide these services.

The final rule requires that, as a condition of CPSC acceptance of its accreditation, the laboratory must be accredited to ISO/IEC 17025:2005(E). The accreditation must be made by an accreditation body that is a signatory to the 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 requirements that are required as the basis for certifying that children's products conform to the applicable product safety rules. This aspect of the final rule would simply codify the existing conditions for CPSC acceptance of accreditation that have been stated in every NOR published previously by the Commission.

The final rule requires that laboratories provide the Commission with their accreditation and scope documents. These records are normally 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, an electronic application form. All

of the information that is required to be supplied on the form should be readily available to the laboratory. The professional skills required to complete Form 223, and the related documents, are skills that a competent, accredited laboratory would be expected to possess.

The final rule also requires laboratories that are managed, owned, or controlled by a manufacturer or private labeler (or, firewalled laboratories) to submit additional materials, as described in § 1112.13(b). The acceptance of a firewalled laboratory's accreditation occurs, by Commission order, only after the Commission has made certain findings based on the additional documents.

The final rule also establishes additional requirements as described in § 1112.11 for Commission acceptance of the accreditation of laboratories that are owned or controlled, in whole or in part, by a government. The CPSC has accepted the accreditation of three conformity assessment bodies located in the United States that are owned by or affiliated with government entities, none of which meet the definition of a "small entity." Laboratories that are owned or controlled by foreign governments do not meet the definition of a "small entity" under the RFA.

In addition to the baseline requirements (accreditation to ISO/IEC 17025:2005(E) by a signatory to the ILAC-MRA and 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, as described in § 1112.11, so that the CPSC can determine whether the laboratory satisfies the criteria for the acceptance of the accreditation of a governmental laboratory.

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 to 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(E) 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 travel, lodging, and meal expenses. The cost could be higher if the assessment takes longer 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(E) 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 what would be required for a full initial assessment.

For most children's product safety rules, the required test methods were specified in the regulation that established the safety rule. However, in the case of the requirements for lead content of children's products, the test methods are specified in the notices of requirements for accreditation, which are included in the final rule. The final rule expands 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, 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.

Each ILAC-MRA signatory accreditation body has requirements for the periodic reassessment of accredited laboratories. The Commission has established the auditing requirements for maintaining CPSC acceptance of a laboratory's accreditation in the separate, but related, rule on periodic audits (16 CFR §§ 1112.30 through 1112.39), which is currently in effect.

2. Recordkeeping Requirements

The final rule requires 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 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. 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, 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.

3. Grounds and Procedures for Adverse Actions Against Laboratories

The final rule also establishes 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 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 establishes 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 may open is not known.

E. Economic Impact on Small Entities and Significant Alternatives Considered

1. Expected Economic Impact on Small Entities

Laboratories that intend to provide the third party testing services required by section 14 of the CPSA will incur some costs to obtain CPSC acceptance of their accreditation. If the laboratory is not already accredited to ISO/IEC 17025:2005(E) 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. The costs could be significantly lower for laboratories that are already accredited to ISO/IEC 17025:2005(E) by a body that is an ILAC-MRA signatory. 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 final rule requires laboratories to maintain certain records for 5 years, which could also add to a laboratory's costs, 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 certifying children's products under 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 testing services 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.

2. Alternatives Considered

Although the final rule is not expected to have a significant adverse impact on a substantial number of small entities, CPSC staff considered alternatives that could have reduced the costs associated with the accreditation process or providing the testing services to some laboratories. The alternatives considered were accepting the accreditation of laboratories that were not accredited by a signatory to the ILAC-MRA and allowing the use of XRF techniques for determining compliance with the lead content requirements for more materials.

a. Accepting the Accreditation of Laboratories Not Accredited by ILAC-MRA Signatories

CPSC staff considered accepting the accreditation of laboratories that have been accredited by accreditation bodies that are not signatories to the ILAC-MRA. This alternative could have reduced the cost of obtaining CPSC acceptance of their accreditation for laboratories accredited by bodies that were not ILAC-MRA signatories. Under the final 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, despite being accredited by an accrediting body that was not a signatory to the ILAC-MRA. This alternative would not have any impact on laboratories that are not accredited by any accreditation body.

This alternative was not included in the final rule because it would not meet the objectives that CPSC staff have identified for a program to meet the laboratory accreditation requirements in the CPSA. In establishing the requirements for the laboratory accreditation program, the CPSC staff considered timelines established by the CPSA and the fact that children's products destined for the U.S. market are manufactured in nations throughout the world and established several objectives for the laboratory accreditation program. These objectives were to:

- Delegate the core elements of a CPSC accreditation program to an entity that was established and had acceptance on a multinational level and that followed internationally recognized standards for assessing the competence of laboratories and for the processes and standards used by accreditation bodies that evaluate such laboratories. In addition, CPSC staff sought a program that included regular evaluation of the accreditation bodies to ensure those bodies continued to follow the same, internationally recognized, set of standards and procedures;
- Designate one entity that could bring on board, on a multinational level, a large 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
- Avoid designation to accreditation programs or entities that are recognized only in a specific region, nation, or locality.

In addition to the objectives outlined above, the Commission also seeks to keep the program as simple as possible, avoid any perceived notions of barriers to fair trade practices, and ensure that the program established would be manageable with agency resources. The

Commission staff found that the ILAC-MRA signatory program met those objectives. Although CPSC staff recognizes that there are other types of accreditation organizations and accreditation bodies for different types of conformity assessment programs, some of these organizations are for very specific industry or governmental sectors or are only applicable to certain regions. Designations to such organizations would not meet all of the objectives established by CPSC staff for the laboratory accreditation program.

b. Allowing XRF Test Methods for Lead Content for More Materials

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 the CPSC's 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 final 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, CPSC staff has not determined that XRF is as effective, precise, and reliable as the approved methods. Therefore, the final rule does not expand the approved use of XRF to cover all materials or substances.

V. Paperwork Reduction Act

This rule contains information collection requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The preamble to the proposed rule (77 FR at 31126-30) discussed the information collection burden of the proposed rule and specifically requested comments on the accuracy of our estimates. We did not receive any comments concerning the information collection burden of the proposal, and the final rule does not make any changes to

that burden. The OMB has approved the information collection requirements in this rule, and the OMB control number for such approval is OMB 3041–0156.

VI. Environmental Considerations

The final 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.

VII. Preemption

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.

VIII. Effective Date

The Commission proposed that the final rule would become effective 90 days after publication in the *Federal Register*. We received no comments regarding the effective date. Therefore, the final rule will become effective 90 days after publication of the final rule in the *Federal Register*.

List of Subjects

16 CFR Part 1112

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

16 CFR Part 1118

Administrative practice and procedure, Consumer protection, Investigations.

Therefore, the Commission amends Title 16 of the Code of Federal Regulations by adding:

PART 1112 – REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

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

Authority: Pub. L. 110-314, section 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 whose accreditations 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 CPSC-accepted 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.

3. Amend § 1112.3 by:

a. Revising the definitions of "Audit" and "CPSC," and

b. Adding definitions for "Accept accreditation," "Commission," "CPSA," "Notice of requirements," "Scope," "Suspend," "Third party conformity assessment body," "Undue Influence," and "Withdraw"

The additions read as follows:

§ 1112.3 Definitions.

* * * * *

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 (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 have its accreditation accepted to test children's products for conformity with a particular children's product safety rule.

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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 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.

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 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; or

(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;

(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 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:

(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) *Accreditation certificate*. (A) 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*.

(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 paragraph (b)(2)(i) of this section;

(iii) Training records, including a list and corresponding signatures, of the staff members who received the training identified in paragraph (b)(2)(ii) of this section. 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 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;

(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 paragraph (c)(1), and in addition to the baseline accreditation requirements in paragraph (a) of this section, a governmental third party conformity assessment body seeking CPSC-accepted status must submit:

(i) *Description.* 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) *Executed memorandum*. 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 of the third party conformity assessment body;

(*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 whose accreditation 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 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 this part, 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 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 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 paragraph (a)(2)(i) 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), "General requirements for the competence of testing and calibration laboratories," Second Edition, May 15, 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/home.htm. You may 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.

§ 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 parts 1221, 1223, and 1224, and ASTM F963-11 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;

(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 1223, Safety Standard for Infant Swings

(9) 16 CFR part 1224, Safety Standard for Portable Bed Rails;

(10) 16 CFR part 1303, Ban of Lead-Containing Paint and Certain Consumer Products Bearing Lead-Containing Paint. 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:

(i) 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;

(ii) ASTM F2853-10, "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."

(11) 16 CFR part 1420, Safety Standard for All-Terrain Vehicles;

(12) 16 CFR 1500.86(a)(5), Exceptions from Classification as a Banned Toy or Other Banned Article for Use by Children (Clacker Balls);

(13) 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);

(14) 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;

(15) 16 CFR part 1505, Requirements for Electrically Operated Toys or Other Electrically Operated Articles Intended for Use by Children;

(16) 16 CFR part 1510, Requirements for Rattles;

(17) 16 CFR part 1511, Requirements for Pacifiers;

(18) 16 CFR part 1512, Requirements for Bicycles;

(19) 16 CFR part 1513, Requirements for Bunk Beds;

(20) 16 CFR part 1610, Standard for the Flammability of Clothing Textiles;

(21) 16 CFR part 1611, Standard for the Flammability of Vinyl Plastic Film;

(22) 16 CFR part 1615, Standard for the Flammability of Children's Sleepwear: Sizes 0 Through 6X (FF 3–71);

(23) 16 CFR part 1616, Standard for the Flammability of Children's Sleepwear: Sizes 7 Through 14 (FF 5-74);

(24) 16 CFR part 1630, Standard for the Surface Flammability of Carpets and Rugs (FF 1-70);

(25) 16 CFR part 1631, Standard for the Surface Flammability of Small Carpets and Rugs (FF 2-70);

(26) 16 CFR part 1632, Standard for the Flammability of Mattresses and Mattress Pads (FF 4-72, amended);

(27) 16 CFR part 1633, Standard for the Flammability (Open Flame) of Mattress Sets;

(28) 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 revision CPSC Test Method CPSC-CH-E1001-08.1; and/or the revision CPSC Test Method CPSC-CH-E1001-08.2; and/or CPSC Test Method CPSC-CH-E1001-08.3;

(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;

(29) 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 revision CPSC Test Method CPSC-CH-E1001-08.1; and/or the revision CPSC Test Method CPSC-CH-E1001-08.2; and/or the revision CPSC Test Method CPSC-CH-E1001-08.3;

(30) Limits on Total Lead in Children's Products: Nonmetal Children's Products. For its accreditation to be accepted by the Commission to test for lead content in nonmetal 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 Nonmetal Children's Products"; and/or the revision CPSC Test Method CPSC-CH-E1002-08.1; and/or the revision CPSC Test Method CPSC-CH-E1002-08.2; and/or the revision CPSC Test Method CPSC-CH-E1002-08.3;

(31) 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:

(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;"

(32) ASTM F963-11 "Standard Consumer Safety Specification for Toy Safety," and section 4.27 (toy chests) from ASTM F963-07ε1 "Standard Consumer Safety Specification for Toy Safety." The CPSC only requires certain provisions of ASTM F963–11 and Section 4.27 of ASTM F963–07ε1 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 F963–07ε1; Section 4.27—Toy Chests (except labeling and/or instructional literature requirements)

(ii) ASTM F963–11

(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)

(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)

(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 paragraph (b) 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) You may obtain a copy of the following standards from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428: *http://www.astm.org*.

(i) ASTM F2853-10, "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," July 1, 2010;

(ii) ASTM F963-07ε1 "Standard Consumer Safety Specification for Toy Safety," March 15, 2007;

(iii) ASTM F963-11 "Standard Consumer Safety Specification for Toy Safety," December 28, 2010.

(2) You may obtain a copy of GB/T 22048-2008, "Toys and Children's Products – Determination of Phthalate Plasticizers in Polyvinyl Chloride Plastic," June 18, 2008 from Code of China, Room 2118, New Fortune International Plaza, No.71 Chaoyang Road, Chaoyang District, Beijing, 100123, China; http://www.codeofchina.com/.

§ 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 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 whose accreditation has 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?

(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 available upon request by CPSC.

(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 electronically, such as through an Internet website. 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 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 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;

(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?

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(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, 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.

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 § 1112.53.

§ 1112.43 What are the grounds for denial of an application?

(a) The CPSC may deny an application for any of the following reasons:

(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(E) 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.

§ 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 § 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 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 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.

§ 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.

(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

(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 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;

(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 paragraph (d)(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 its 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 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 paragraph (g)(2) of this section, the third party conformity assessment body may file an Administrative Appeal with the Office of the Executive Director.

(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, and must be 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 be issued (?).

(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, and must be in English.

(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,

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.

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:

§ 1118.2 Conduct and scope of inspections.

(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, firewalled 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, firewalled 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

(3) To have access to and to copy all relevant records, books, documents, papers, packaging, or labeling which:

(i) Are 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.

* * * * *

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Todd A. Stevenson,

Secretary, Consumer Product Safety Commission

United States
Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

Memorandum

This document has been electronically approved and signed.

Date: January 16, 2013

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel
Kenneth R. Hinson, Executive Director
Robert J. Howell, Deputy Executive Director for Safety Operations

FROM: J. DeWane Ray
Assistant Executive Director
Office of Hazard Identification and Reduction

Randy S. Butturini
Office of Hazard Identification and Reduction

SUBJECT: Draft Final Rule for 16 CFR parts 1112 and 1118, Requirements Pertaining to Third Party Conformity Assessment Bodies

Table of Contents

1 Introduction

On August 14, 2008, the Consumer Product Safety Improvement Act (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 children's product safety rule. The U.S. Consumer Product Safety Commission (CPSC) has established requirements for acceptance of accreditation of third party conformity assessment bodies (laboratories) for assessing conformity with certain children's product safety rules. Section 14(a)(3)(C) of the CPSA (as amended by section102(a)(3)(C) of the CPSIA) states that accreditation of laboratories may be conducted by the Commission or an independent accreditation organization designated by the Commission. Section 14(e) of the Consumer Product Safety Act (CPSA) authorizes the Commission to withdraw or suspend its accreditation or acceptance of accreditation of a laboratory under certain conditions. Section 14(f) of the CPSA describes additional requirements for governmental and firewalled laboratories.

To implement these provisions, the Commission published a notice of proposed rulemaking (NPR) in the *Federal Register* on May 24, 2012 (77 FR 31086). The proposed rule included requirements and procedures for CPSC acceptance of the accreditation of laboratories, adverse actions that may be imposed against CPSC-accepted laboratories, and audit requirements; it also proposed to amend the Commission's regulation on inspections to include firewalled laboratories as entities that may be inspected under the CPSA.

The draft final rule codifies previously published notices of requirements (NORs). An NOR specifies the requirements that laboratories must satisfy to qualify for CPSC acceptance of accreditation for a particular CPSC standard or test method. Once an NOR is issued for a children's product safety rule, the NOR establishes an effective date for when the domestic manufacturer, importer, or private labeler is required to have third party testing performed by a CPSC-accepted laboratory as a basis for issuing a Children's Product Certificate (CPC). Future NORs will require amendments to this draft final rule, if adopted.

Finally, the draft final rule would add the following test methods: CPSC-CH-E1001-08.2 and CPSC-CH-E1001-08.3, *Standard Operating Procedure for Determining Total Lead (Pb) in Metal Children's Products (including Children's Metal Jewelry)*, and CPSC-CH-E1002-08.2 and CPSC-CH-E1002-08.3, *Standard Operating Procedure for Determining Total Lead (Pb) in Non-Metal Children's Products* to the list of NORs found in the codified text.

2 Public Comments

CPSC received submissions from six commenters in response to the NPR (Docket CPSC-2012-0026). CPSC staff's summarization of the submissions and responses to the comments are provided in Tab A. Tab B contains a list of the commenters, their affiliation, and their commenter number.

2.1 Comment topics

Among the topics covered by the commenters' submissions are:

- Sample Homogeneity and X-Ray Fluorescence Spectrometry;
- Laboratory Accreditation;
- Inspections and Investigations;
- Undue Influence;
- Adverse Actions;
- Recordkeeping;
- Definitions; and
- Retrospective Testing.

All of the public comments pertained to 16 CFR part 1112. We received no comments on the proposed change to 16 CFR part 1118. Based on the comments received and a review of the proposed rule, CPSC staff recommends making five changes to the proposed rule, as described in Section 3.

2.2 Retrospective testing

One commenter discussed the use of retrospective testing, which is not a provision in the draft final rule but pertains to CPSC recognition of certification based on testing using a new standard and/or test method after its date of publication, but before the effective date for required third party testing. If certain criteria are met, retrospective testing is allowed for the six CPSC rules and test methods for which retrospective testing was not addressed in previous NORs. These provisions are patterned after provisions used for 16 CFR parts 1217, 1219, and 1220, regarding retrospective testing.

The six rules and test methods are:

- 16 CFR part 1221, Safety Standard for Play Yards
- 16 CFR part 1223, Safety Standard for Infant Swings
- 16 CFR part 1224, Safety Standard for Portable Bed Rails
- ASTM F963-11, Standard Consumer Safety Specification for Toy Safety
- Standard Operating Procedure for Determining Total Lead (Pb) in Children's Metal Products (CPSC-CH-E1001-08.2)
- Standard Operating Procedure for Determining Total Lead (Pb) in Nonmetal Children's Products (CPSC-CH-E1002-08.2).

The draft final rule, if approved, for part 1112 will establish the effective date for required third party testing for 16 CFR parts 1221, 1223, and 1224, and for ASTM F963-11. The draft final rule provides an effective date for 16 CFR part 1112 that is 90 days after the final rule is published in the *Federal Register*. Therefore, play yards, infant swings, and portable bed rails that are manufactured after 90 days following the publication in the *Federal Register* of the final rule for 16 CFR part 1112 must be tested by a CPSC-accepted laboratory to support a certificate of compliance to the safety standards for those products. Toys manufactured after 90 days

following the publication in the *Federal Register* of the final rule for 16 CFR part 1112 must be tested by a CPSC-accepted laboratory to support a certificate of compliance to ASTM F963-11.

We recommend the following retrospective testing allowances for the other rules and test methods:

We recommend accepting retrospective testing for 16 CFR part 1221(play yards), 16 CFR part 1223 (infant swings), and 16 CFR part 1224 (portable bed rails) under certain circumstances. For the tests contained in these standards, testing before the effective date of 16 CFR part 1112 will be accepted, if the following conditions are met:

- The product was tested by a laboratory accredited to the international standard International Standards Organization/International Electrotechnical Commission (ISO/IEC) 17025:2005(E) by a signatory to the International Laboratory Accreditation Cooperation-Mutual Recognition Arrangement (ILAC-MRA) at the time of the test. The scope of the third party conformity body accreditation must include testing in accordance with the applicable standard. For firewalled laboratories, the firewalled laboratory 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 the applicable standard at the time of initial Commission acceptance. For governmental laboratories, the governmental laboratory must be one whose accreditation was accepted by the Commission, even if the scope of accreditation did not include the tests contained in the applicable standard at the time of initial CPSC acceptance.
- The laboratory's application for acceptance of its accreditation is accepted by the CPSC before the effective date of 16 CFR part 1112.
- The test results show compliance with the applicable standard(s).
- The children's product was tested on or after the date of publication in the *Federal Register* of the final rule for:
    - play yards, 16 CFR part 1221 (published August 29, 2012);
    - infant swings, 16 CFR part 1223 (published November 7, 2012); and/or
    - portable bedrails, 16 CFR part 1224 (published February 29, 2012);

  and before the effective date of 16 CFR part 1112.
- The laboratory's accreditation remains in effect through the effective date of 16 CFR part 1112.

The draft final rule includes an NOR for ASTM F963-11. Testing to requirements of ASTM F963-08 that are performed by a CPSC-accepted laboratory to support children's product certifications to ASTM F963-11 requirements would be accepted only for those sections of ASTM F963-08 that are considered equivalent or functionally equivalent to ASTM F963-11. We recommend accepting retrospective testing on children's products conducted by a laboratory accepted by the Commission for those tests in ASTM F963-11 that have no equivalent or functionally equivalent test in ASTM F963-08, before the effective date of mandatory third party testing for ASTM F963-11, if the following conditions are met:

- The children's product was tested by a laboratory accredited to ISO/IEC 17025:2005(E) by a signatory to the ILAC-MRA at the time of the test. The scope of the laboratory's

accreditation must include the tests conducted. For firewalled laboratories, the 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 at the time of initial Commission acceptance. For governmental laboratories, the laboratory must be one whose accreditation was accepted by the Commission, even if the scope of accreditation did not include the nonequivalent test methods at the time of initial CPSC acceptance.

- The laboratory's application for acceptance of its accreditation is accepted by the CPSC by the effective date of 16 CFR part 1112.
- The test results show compliance with ASTM F963-11.
- The children's product was tested on or after February 22, 2012 (this is the date of publication in the *Federal Register* notice of CPSC acceptance of ASTM F963-11 as a Mandatory Consumer Product Safety Standard), and before the effective date of 16 CFR part 1112.
- The laboratory's accreditation remains in effect through the effective date of 16 CFR part 1112.

For testing for total lead in children's metal products and children's nonmetal products, testing currently must be conducted by a CPSC-accepted laboratory by using any of the earlier versions of CPSC test methods (CPSC-CH-E1001-08 or CPSC-CH-E1001-08.1 for children's metal products and CPSC-CH-E1002-08 or CPSC-CH-E1002-08.1 for children's nonmetal products). These earlier versions of the test methods remain acceptable for testing for total lead in substrate materials.

We will accept retrospective testing using the updated test methods CPSC-CH-E1001-08.2 and CPSC-CH-E1002-08.2 if the following conditions are met:

- The children's product was tested by a laboratory accredited to ISO/IEC 17025:2005(E) by a signatory to the ILAC-MRA at the time of the test. The scope of the third party conformity body accreditation must include test method CPSC-CH-E1001-08.2 (for testing of a children's metal product) and/or test method CPSC-CH-E1002-08.2 (for testing a children's nonmetal product). For firewalled laboratories, the firewalled laboratory 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 test methods CPSC-CH-E1001-08.2 and/or CPSC-CH-E1002-08.2 at the time of initial Commission acceptance. For governmental laboratories, the governmental laboratory must be one whose accreditation was accepted by the Commission, even if the scope of accreditation did not include the test methods CPSC-CH-E1001-08.2 and/or CPSC-CH-E1002-08.2 at the time of initial CPSC acceptance.
- The laboratory's application for acceptance of its accreditation to the revised test methods is accepted by the CPSC before the effective date of 16 CFR part 1112.
- The test results show compliance with the limits on total lead content, as established in section 101 of the CPSIA.
- The children's product was tested on or after April 10, 2012 (the date the revised test methods were posted on the CPSC website) and before the effective date of 16 CFR part 1112.

- The laboratory's accreditation remains in effect through the effective date of 16 CFR part 1112.

3 Recommended Changes in the Draft Final Rule

The CPSC staff's draft final rule is substantially the same as the proposed rule but with the following recommended modifications. These recommended changes are in response to the comments received.

3.1 Addition of the CPSC-CH-E1001-08.2 test method as acceptable to test for lead in children's metal jewelry

The proposed rule specified the test methods CPSC–CH–E1001–08 and CPSC-CH-E1001-08.1 for use in determining the lead content of children's metal jewelry. The draft final rule allows an additional test method, CPSC–CH–E1001–08.2, to be used as an acceptable means to test for the lead content of children's metal jewelry. The "-08.2" version of the test method includes the use of X-Ray fluorescence spectrometry (XRF) for homogeneous glass materials, crystals, and some metals.

3.2 Addition of the test methods CPSC-CH-E1001-08.3 and CPSC-CH-E1002-08.3

These new versions of the CPSC test methods for the lead content of children's metal and nonmetal products include a change in the limitations when using XRF. The current test methods, CPSC-CH-E1001-08.2 and CPSC-CH-E1002-08.2, contain a test for homogeneity, where a relative standard deviation (RSD) is calculated. If the RSD is above a threshold of 30 percent, the sample tested is considered nonhomogeneous, and wet chemistry methods are required to determine the lead content. However, for very small lead content values, the calculation of the RSD could be affected by instrument measurement variability (as opposed to actual nonhomogeneity in the sample tested) and result in a calculated RSD that is not indicative of sample homogeneity. Therefore, the revised test methods include language stating that if all the measurements are below one-half of the required limit (50 ppm for lead content), then XRF measurements are allowed to indicate compliance. Variation in lead content measurements above this level are considered to be dominated by sample inhomogenieties rather than by potential instrument variability.

3.3 Subcontractor test reports can be made available when requested, rather than require them to be appended to the primary contractor report

If a laboratory (prime contractor) uses a subcontractor laboratory to conduct tests for children's product certification purposes, § 1112.25(a)(2) of the proposed rule required the subcontractor's test report to be appended to the prime contractor's test report. The draft final rule allows the subcontractor's report to be "available" with the prime contractor's test report but not necessarily "appended" to it. However, appending a subcontractor's test report would satisfy the requirement to make the report available.

3.4 Contractual relationships and control determinations for laboratories

Under §1112.11(b)(1)(ii)(D) of the proposed rule, a laboratory that was limited by a manufacturer in the services it may perform for other customers would be considered a

firewalled laboratory. The draft final rule revises that section. In the draft final rule, a contractual relationship between a manufacturer and a laboratory that explicitly limits which or how many other entities may also be customers of the laboratory would not be considered a form of "control," under section 14(f)(2)(D) of the CPSA and would not therefore result in the designation of the laboratory as firewalled. Such a designation would result in little benefit to consumer safety beyond that already accounted for in the criteria for firewalled laboratories set forth in the proposed rule.

3.5 Document requests

Section 1112.25(b) in the draft final rule removes the "within 48 hours" requirement for records to be supplied to the CPSC and replaces it with: "such as through an Internet website," in order to be consistent with the recordkeeping language in 16 CFR part 1107 (testing and labeling rule) and 16 CFR part 1109 (component part testing rule). These rules, which allow for electronic records, require submission of records, upon request, but do not specify a time frame within which the records must be submitted.

4 Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) generally requires that an agency prepare a final regulatory flexibility analysis when promulgating a final rule, describing the impact of the rule on small entities. Among other things, the final regulatory flexibility analysis must contain a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis and the agency's assessment of the issues raised. Although six public submissions were received in response to the NPR, none of the comments addressed the initial regulatory flexibility analysis or questioned its conclusions. The final regulatory flexibility analysis, provided in Tab C, concludes that the draft final rule is not expected to have a significant impact on a substantial number of small entities.

5 Effective Date of Final Rule

CPSC staff recommends that the Requirements Pertaining to Third Party Conformity Assessment Bodies become effective 90 days after publication of the final rule in the *Federal Register*.

6 Commission Options

The following options are available for Commission consideration:

1. Publish the final rule, as drafted by the Office of the General Counsel.
2. Publish the final rule, with changes, as directed by the Commission.
3. Specify other options, as directed by the Commission.

7 Staff Recommendation

CPSC staff recommends that the Commission publish the final rule, as drafted by the Office of the General Counsel.

Tab A: Response to Comments Received from the Notice of Proposed Rulemaking on Requirements Pertaining to Third Party Conformity Assessment Bodies

United States
Consumer Product Safety Commission
Washington, DC 20814

Memorandum

Date: December 18, 2012

TO: J. DeWane Ray
Assistant Executive Director
Office of Hazard Identification and Reduction

FROM: Randy S. Butturini
Office of Hazard Identification and Reduction

SUBJECT: Response to Comments Received on the Notice of Proposed Rulemaking, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, 16 CFR part 1112

1 Introduction

On May 24, 2012, a notice of proposed rulemaking (NPR), *Requirements Pertaining to Third Party Conformity Assessment Bodies*, Docket CPSC-2012-0026, was published in the *Federal Register* (77 FR, 31086). The NPR proposed general requirements pertaining to the acceptance of accreditation of third party conformity assessment bodies (laboratories) that are authorized to test children's products in support of their certification. The proposed rule included requirements and procedures for U.S. Consumer Product Safety Commission (CPSC) acceptance of the accreditation of laboratories, adverse actions that may be imposed against CPSC-accepted laboratories, and audit requirements; it also proposed to amend the Commission's regulation on inspections.

The CPSC received submissions from six commenters in response to the NPR.

2 Background

On August 14, 2008, the Consumer Product Safety Improvement Act of 2008 (CPSIA) was signed into law. Section 102 of the CPSIA, which amended section 14 of the Consumer Product Safety Act (CPSA), requires that manufacturers of children's products subject to an applicable children's product safety rule submit samples to a CPSC-accepted laboratory for testing, and based on those tests, issue a certificate that such product complies with the applicable children's product safety rules.

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 assessment bodies to assess conformity'' with specific laws or regulations. Section 14(a)(3)(C) of the CPSA states that accreditation of laboratories may be conducted either by the Commission or by an independent accreditation organization designated by the Commission. Section 14(e) of the CPSA established conditions under which the CPSC's acceptance of a laboratory's accreditation may be withdrawn.

3 Comments Received and Staff Responses

The comments are summarized with the CPSC staff response after each summary. For ease of reading, each comment is prefaced with a numbered "Comment," and each response is prefaced by a numbered "Response." The comments are grouped by topic. There are eight topics:

- Sample Homogeneity and X-Ray Fluorescence Spectrometry;
- Laboratory Accreditation;
- Inspections and Investigations;
- Undue Influence;
- Adverse Actions;
- Recordkeeping;
- Definitions; and
- Retrospective Testing.

The commenters are identified by a number in parentheses after "commenter"; the identification of the commenter associated with these numbers can be found in Tab B.

Several commenters make general statements supporting the overall purpose of the proposed rule. For example, one commenter predicts that with the allowance of XRF testing under 16 CFR part 1112, the lower costs and personnel requirements of XRF technology would permit reduced third party testing costs and allow companies "to concentrate on building in safeguards for products."

3.1 Sample Homogeneity and X-Ray Fluorescence Spectrometry

Comment 1: With regard to the proposed test methods for determining lead content on component parts,[1,2] a commenter (2) notes the proposed requirement that three or more

[1] *Test Method: CPSC-CH-E1001-08.2 Standard Operating Procedure for Determining Total Lead (Pb) in Children's Metal Products (Including Children's Metal Jewelry), Revision*, which can be found at: http://www.cpsc.gov/about/cpsia/CPSC-CH-E1001-08_2.pdf.

[2] *Test Method: CPSC-CH-E1002-08.2 Standard Operating Procedure for Determining Total Lead (Pb) in Nonmetal Children's Products*, which can be found at: http://www.cpsc.gov/about/cpsia/CPSC-CH-E1002-08_2.pdf.

measurements be made when using the x-ray fluorescence spectrometry (XRF, or EDXRF[3]) method described in ASTM F2853-10, also known as Energy Dispersive XRF Spectrometry Using Multiple Monochromatic Excitation Beams (currently allowed for lead in paint testing). As described in the proposed test method, the three measurements are intended to ensure some degree of spatial homogeneity or assurance that the material tested does not falsely indicate compliance with the lead content limit of 100 parts-per-million (ppm) because a "local" area, unrepresentative of the component part, was tested. The commenter recommends that the requirement to sample three or more areas using the lead content testing method described in ASTM F 2853-10 be removed.

The commenter states that any empirical evidence of nonhomogeneities resulting in a false determination of compliance is "questionable at best." The commenter adds that the "wet chemistry" method (Inductively Coupled Plasma, or ICP, using various spectrometric techniques) includes a procedural step where 30 to 100 milligrams (mg) of a sample is collected and subjected to testing. The commenter points out that the ICP method does not require samples from three areas of the component part to be tested and questions why the XRF method should be subject to that requirement. The commenter opines that this is a policy issue to be determined by the Commission and not a technical issue to be determined by CPSC staff. The commenter states that if a component part "appears not to have visual anomalies, it can reasonably be presumed to in fact be homogeneous with respect to its lead content." The commenter adds that very small component parts may pose practical difficulties in providing locations for three measurements and that the proposed testing method has no allowance for very small component part testing. The commenter concludes that the test method, ASTM F2853-10, requires only one measurement when used to determine the lead content of a paint sample.

Another commenter (4) expresses concern that the small spot size (on the order of 1 mm^2) increases the sensitivity of the test method ASTM F2853-10 to nonhomogeneities in the lead content of the component part under test.

Another commenter (5) expresses concern that the test for homogeneity requires the use of XRF in the test methods for lead content determination, specifically, the requirement that at least three spatially separated measurements be made. The commenter points out that the ICP method requires only 30 to 100 mg of material, which the commenter considers "incongruous" with respect to homogeneity.

Another commenter (7) remarks that the CPSC test method CPSC-CH-E1001-08.2 (total lead (Pb) in nonmetal children's products), states that a homogenized aliquot[4] should be prepared after grinding a sufficient sample of a component part for ICP testing. The commenter states that there is no clear guidance for how to determine what "sufficient" is. The commenter further notes that if a sample is not homogeneous, ICP testing is required (instead of XRF). However, the commenter asserts that if the component part is nonhomogeneous, the ICP testing results can

[3] EDXRF is an acronym for "energy dispersive x-ray fluorescence" spectrometry. Most XRF spectrometry devices used to detect lead in paint and component parts use this technology.

[4] An aliquot in chemistry is a portion of a sample.

vary, depending on from where the sample is taken. The commenter opines that ICP testing of nonhomogeneous component parts may not adequately reflect the component part's lead content, and XRF testing, using multiple locations, is better at determining the component part's lead content.

Response 1: We decline to revise the test method for determining lead content that requires multiple sample areas to be tested when using forms of XRF based on these comments. CPSC staff believes that XRF has the potential, with certain limitations, to measure reliably lead content in some homogeneous metal and glass materials at the concentrations necessary to certify compliance with the 100 parts per million (ppm) limit now required under the CPSIA for children's products. With the appropriate test methods and reference materials, staff considers homogeneous substrates to be necessary in order for the XRF methods included in ASTM F2853-10, or in the proposed CPSC test methods, to be effective in determining the compliance of the sample under test. Multiple measurements are required to determine that such homogeneity exists, which allows the use of the XRF measurements for children's product certification purposes. CPSC staff agrees that it is important to obtain a sufficient sample for wet chemistry testing. The CPSC wet chemistry test methods for determining lead in a substrate include instructions for the user to make every effort to homogenize the sample prior to taking 30 to 100 mg for testing. Thus, a sufficient sample would be an amount that ensures that the portion selected for testing actually represents the total lead content of the component part under evaluation.

With respect to small parts and the need to determine homogeneity, there are no limitations on using XRF for testing small component parts. Small parts may be rotated so that different surface areas would be tested. If three completely distinct areas could not be tested, three separate tests could still be done on overlapping areas.

Comment 2: A commenter (4) suggests that when testing for lead content of component parts, using other types of XRF spectrometers that do not meet the requirements of ASTM F2853-10, an alternative to the testing of three areas on the component part should be considered. The commenter states that all XRF techniques are being subject to additional homogeneity requirements that are really intended for the ASTM F2853-10 method. The commenter asserts that the relatively large spot size of other XRF methods mitigates the need for the repeated measurements in the proposed test method. The commenter recommends that in order to mitigate some of the heterogeneity effect:

> . . . an 8 mm diameter x-ray surface shot (HHXRF),[5] with a scatter that widens in three dimensions, should be as much of a heterogeneity correction as the 100 mg sample size for wet chemistry to be considered quantitative under EN 71-3[6] and others.

[5] HHXRF is an acronym for "handheld x-ray fluorescence spectrometry," and is used to distinguish this type of handheld device from other forms of XRF spectrometry.
[6] EN71-3 is a European Safety Standard, titled: *Safety of toys - Part 3: Migration of certain elements*.

The commenter adds that even though other types of XRF spectrometers that do not meet the requirements of ASTM F2853-10 are far less vulnerable to nonhomogeneities in a test sample, a homogeneity test for XRF methods should be retained, rather than eliminated, "because the need to limit all EDXRF techniques to materials that are proven to be homogeneous is beyond question."

Response 2: We decline to remove that requirement to test multiple areas from the test method for lead content when using XRF. CPSC staff believes that for dense materials, like metals and glass materials, typical XRF instruments sample a very small mass of the sample because the penetration of the x-rays is limited. Thus, it is appropriate when testing dense materials, to measure multiple areas to ensure homogeneity when using these test methods as the basis for issuing a Children's Product Certificate.

Comment 3: A commenter (5) notes that in § 1112.15(b)(29) of the proposed rule, in order for a laboratory to have its accreditation accepted by the Commission to test for lead content in children's metal products, a third party conformity assessment body must have the CPSC test method CPSC–CH–E1001–08, CPSC–CH–E1001–08.1, or CPSC–CH–E1001–08.2, in its statement of scope. The commenter further notes that in § 1112.15(b)(28) of the proposed rule, in order for a laboratory to have 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 the CPSC test method CPSC–CH–E1001–08, or CPSC–CH–E1001–08.1, in its statement of scope. The commenter requests that the "-08.2" version of the test method be allowed to be used by a laboratory for the testing of lead in children's metal jewelry, adding that this method allows the use of XRF testing.

Response 3: We agree with the commenter that CPSC test method CPSC–CH–E1001–08.2 should be allowed in § 1112.15(b)(28) of the draft final rule. In the proposed rule, test method CPSC–CH–E1001–08.2 was inadvertently not included in proposed § 1112.15(b)(28), although it was intended that the test method be allowed. Therefore, in the draft final rule, § 1112.15(b)(28) expressly allows use of test method CPSC–CH–E1001–08.2.

Comment 4: A commenter (2) requests that a procedure for plated metals and glazed ceramics be developed for XRF using the ASTM F2853-10 method. This procedure would involve grinding a plated metal or glazed ceramic sample, as is done in preparation for an ICP test, and then testing the blended sample using the ASTM F2853-10 method.

Another commenter (5) requests that the CPSC make explicit that XRF can be used to test electroplated metals for lead content. The commenter notes that electroplating does not fall into the definition of a "paint or other similar surface-coating material" described in 16 CFR § 1303.2(b)(1).

Response 4: Staff disagrees with the commenters' requests to develop a procedure using the ASTM F2853-10 method for plated metals and glazed ceramics because the method has not been validated for use on ground metals, which behave differently than solids when tested with XRF, due to different scattering behavior and the presence of interstitial air gaps. Electroplated metals and glazed ceramics pose an especially difficult analysis challenge for XRF. Because

such coatings become part of the substrate and are not subject to the lead paint ban, it is necessary to consider the single, nonhomogeneous material that results from the electroplating or ceramic glaze bonding with the substrate. The idea for a method suggested by commenter (2) could potentially be developed by some party in the future. CPSC staff is particularly concerned that the small volume and mass of a sample probed by XRF would not adequately serve to indicate the homogeneity of the sample.

We decline the request to allow XRF to be used to test electroplated materials because currently it is not possible to determine the correct lead content in such materials with this method. The commenter is correct that electroplated coatings that become part of the substrate are not considered paint under 16 CFR part 1303. The combined electroplated metal (*i.e.*, the electroplating and the substrate together) must meet the 100 ppm lead limit. The x-rays used in XRF penetrate only a very small distance through metals, and as such, tend to sample the outer surface to a much higher degree than the base metal (substrate). The limited depth of x-ray penetration means that the electroplating can screen the base metal from being properly measured by XRF. Additionally, because the x-rays do penetrate somewhat into the base metal, such a measurement also is not suitable for determining the lead in the electroplated coating itself, although it is only the combination of the two that is required to meet the 100 ppm lead content limit.

Comment 5: A commenter (4) states that there is not any difference between the XRF method described in ASTM F2853-10 and other methods of XRF in terms of the ability to detect lead in paint. Currently, only ICP techniques, or the XRF method described in ASTM F2853-10, are allowed to be used to determine the lead content in paint for purposes of children's product certification. The commenter asserts that improvements in detector technology have improved the performance of handheld XRF instruments. The commenter adds that work is under way to convert the traditional lead in paint measurement of "Mass Loading," or micrograms per cm^2, into a concentration measurement of ppm.

Response 5: We decline to amend the draft final rule based on this comment. At present, no XRF method, other than ASTM F2853-10, is recognized by the CPSC to determine accurately the lead content of painted surfaces of consumer products. The lead paint ban in 16 CFR part 1303 is based on the definition of "lead paint" as paint containing in excess of 0.009 percent lead by weight. Measurements in micrograms per cm^2 cannot be used to make such a determination without knowing the density and thickness of the paint, neither of which is generally known at the time of testing.

Comment 6: A commenter (4) states that other forms of XRF are at least as accurate as the ASTM F2853-10 method, and they disagree with the use of the phrase "may be," rather than the same language used for the ASTM F2853-10 method of describing suitable instruments for the accurate determination of lead in glass materials and homogeneous metals.

Response 6: We do not agree with the commenter regarding the use of the phrase "may be." The commenter is referring to Tab C in the Staff Briefing Package, *Requirements Pertaining to*

Third Party Conformity Assessment Bodies,[7] for the proposed rule. Tab C, titled, *Study on the Applicability of X-ray Fluorescence Spectrometry for Measuring Lead in Metal and Glass Substrate*, describes how XRF potentially could be used to test homogeneous metal and glass materials found in children's products. The report examines extending the use of XRF beyond the already-approved method for polymeric materialsto include glass and metal substrates.

At the time the report was prepared, the CPSC test methods for determining the lead content of metal and nonmetallic component parts did not include procedural steps or limitations on the use of XRF for homogeneous glass materials, crystals, and some metals. Section 5.1 of Tab C states: "Standard test methods with scopes that cover the CPSIA lead limit of 100 ppm in metal or glass are not currently available." The section includes the recommendation that the 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 limitations.

Thus, the use of the phrase, "may be," refers to the potential use of XRF before the CPSC test methods had been updated, and at that time, the possibility still existed that a factor could be uncovered that would further limit or preclude the use of XRF. The phrase "may be" is not used in the context of XRF in either the draft final rule or the proposed CPSC test methods, other than stating: "Destructive sample preparation techniques may be required for certain components to create a uniform sample for testing."

Comment 7: A commenter (7) states that the limitations applied to other forms of XRF listed in the test methods, CPSC-CH-E1001-08.2 and CPSC-CH-E1002-08.2, should apply to the form of XRF described in ASTM F2853-10. According to the commenter, the CPSC test methods apply only four limitations to the form of XRF described in ASTM F2853-10. The commenter recommends the following additional limitations be applied to the form of XRF described in ASTM F2853-10:

- Verifying 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. This is limitation number 3, listed on page 7 of the test method, CPSC-CH-E1001-08.2, and on page 5 of test method CPSC-CH-E1002-08.2.
- For testing metals, if the form of XRF described in ASTM F2853-10 deviates from the method described in the ASTM test method, all of the limitations in test method CPSC-CH-E1001-08.2 applied to other forms of XRF should be applied to the form of XRF described in ASTM F2853-10.
- Because uncoated wood and fabrics were not evaluated in the interlaboratory study of the form of XRF described in ASTM F2853-10, all of the limitations in test method CPSC-CH-E1002-08.2 applied to other forms of XRF should be applied to the form of XRF described in ASTM F2853-10.

Response 7: Staff does not recommend changing the proposed rule based on this comment. With regard to the first bullet point in the commenter's recommendations, we agree that it is

[7] The Staff Briefing Package can be found at http://www.cpsc.gov/library/foia/foia12/brief/tprequirements.pdf.

important for reasonable quality assurance/quality control (QA/QC) requirements to be a part of all types of XRF testing. However, we find that section 13.3 of ASTM 2853-10 provides guidance on quality control samples that should be followed to verify system control. The absence of an applicable existing standard for other XRF methods, and the wide variety of XRF instrumentation used in the more general case, lead us to make the specific QA/QC directions discussed. Staff included in the lead test methods, quality control guidelines described in section 6 of International Electrotechnical Commission (IEC) Method 62321 ED 1.0 B; but because that method is designed for higher lead concentrations, we added the requirement for verifying XRF spectrometer performance daily, by analyzing a reference material with 50−300 ppm lead content.

The second and third bullet points in the commenter's recommendations suggest that additional limitations should be placed on ASTM F2853-10 testing for metals other than zinc. CPSC staff believes that the staff study presented in Tab C of the Staff Briefing Package for the NPR was sufficient and that CPSC-CH-E1001-08.2 adequately deals with other metals for XRF testing using the method described in ASTM F2853-10. The third bullet point suggests that for natural wood and for fabric, ASTM F2853-10 testing should have the same requirements as traditional XRF testing, and staff believes that is the case as the method is written.

Comment 8: A commenter (7) requests clarification on several technical issues related to XRF testing.

First, the commenter asks if the term "matrix" means "metal" or the specific alloy used as a reference material in the test method CPSC-CH-E1001-08.2.

Second, the commenter asks for guidance on how many glass or other substrate standards should be used daily to verify instrument performance in the test method CPSC-CH-E1002-08.2.

Finally, the commenter questions the value of a relative standard deviation (RSD) of 30 percent for very low instrument readings using the XRF method described in ASTM F2853-10. The commenter provides the example of three readings of 10, 15, and 25 ppm. While these readings are substantially below the lead limit of 100 ppm, the RSD is 46 percent. In the commenter's opinion, this proposed requirement does not take instrument repeatability into account and makes more expensive ICP testing necessary, even though the readings are not close to the compliance limits. The commenter recommends that when the testing results are well below the concentration limit that would render a reading inconclusive, the XRF results should not be excluded from indicating compliance with the lead content limit.

Response 8: With regard to the commenter's first and second questions, it is not possible to know the exact alloy that is to be tested or to have sample standards that match exactly its chemical composition. Thus, "matrix" is used as a generic term to include metals and alloys similar to the sample to be tested. Laboratories should develop their QA/QC procedures, including having various relevant metals, glass, and plastic standards, to verify instrument performance. Exactly how extensive such a collection must be should be left up to the individual laboratories, their accreditation bodies, and their customers.

Staff agrees with the final comment by the commenter. Notably, this comment illustrates that at very low lead concentrations, differences of just a few ppm in measurements can result in an RSD indicating nonhomogeneity, where possibly, the instrumental variability is dominating the calculation. Staff believes that it is appropriate to allow XRF use where at least three measurements are taken by XRF, as described in this method, and the result of each of those measurements is below 50 percent of the limit (*i.e.*, below 50 ppm), subject to the remaining limitations given for all types of XRF. Variation in lead content measurements above this level are considered to be dominated by sample inhomogenieties rather than by potential instrument variability.

Staff has posted two new test methods, CPSC-CH-E1001-08.3 and CPSC-CH-E1002-08.3, on the CPSC website,[8,9] which includes this change, and the draft final rule allows this as an option for laboratory accreditation.

Comment 9: One commenter (4) refers to the requirement in Public Law 112-28 for the CPSC to provide alternative testing requirements for small batch manufacturers for testing compliance with some product safety rules and to exempt small batch manufacturers from the third party testing requirements, if no alternative testing requirement is available or economically practicable. The commenter proposes that the Commission allow handheld XRF, which the commenter notes that the Commission recognizes is less expensive than other approved test methods, and allow it to be used for third party testing of other substrates, in addition to the homogenous polymer substrates, for which it has already been approved. The commenter is willing "to work with the Commission on the execution of a plan that will prevent the needless exemption of an entire subset of the market that we all agree is in need of this regulatory oversight."

Response 9: The CPSC has proposed the use of XRF to determine the lead content of glass materials, crystals, and some metals. At this time, we are not recommending that handheld XRF be approved for the third party testing of other substrates. CPSC staff has not determined that handheld XRF possesses enough accuracy, precision, and reliability required for the determination of the lead content of substrates other than in homogenous polymer products and the proposed materials.

Public Law 112-28 requires the Commission to provide alternative testing requirements for small batch manufacturers for certain children's product safety rules. If no alternative method is available, the Commission, with some exceptions, is to exempt small batch manufacturers from the third party testing requirements. However, developing alternative testing requirements for small batch manufacturers is not within the scope of the current rulemaking proceeding, which concerns the accreditation requirements for third party conformity assessment bodies.

[8] The revised test method for determining total lead in children's metal products (including children's metal jewelry) can be found at http://www.cpsc.gov/about/cpsia/CPSC-CH-E1001-08_3.pdf.
[9] The revised test method for determining total lead in children's nonmetal products can be found at http://www.cpsc.gov/about/cpsia/CPSC-CH-E1002-08_3.pdf.

Comment 10: A commenter (5) asks that the CPSC propose a technical, rather than a proprietary solution, for lead content testing. The commenter insists that the CPSC should allow new and emerging technologies the same access to the proposed test methods.

Response 10: We do not recommend a change to the proposed rule based on this comment. The CPSC does not endorse one product or technique over another, equally effective product or technique. For lead content testing, multiple methods and technologies are available for use by a laboratory. Each acceptable method has been proven to meet the technical requirements (*e.g.*, precision, accuracy, repeatability) needed to determine compliance to the lead content limit of 100 ppm. CPSC staff supports the development of new technologies for achieving the goals of improved product safety and reduced costs to manufacturers.

3.2 Laboratory Accreditation

Comment 11: A commenter (6) emphasizes the importance of the CPSC's evaluation of the integrity of each laboratory's independence and its compliance with the requirements of ISO/IEC 17025. The commenter states:

> By making the accreditation and audit requirements more focused on the authentication of independence, the CPSC will be able to adopt requirements that will further its commitment to ensure that all approved laboratories are meeting the conditions for their continuing accreditation.

Response 11: Staff does not recommend a change to the proposed rule based on this comment because the rule already addresses the commenter's concerns. We agree that a laboratory's independence should be reassessed on a regular basis. The final rule on the audit of laboratories (16 CFR part 1107, subpart C) 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.

If the Commission has already accepted a laboratory as firewalled, the Commission considers it to have shown previously that it has policies and procedures in place consistent with laboratory independence and impartiality.

To evaluate whether a laboratory satisfies these criteria on independence and impartiality, the draft final rule requires that a laboratory seeking CPSC-accepted firewalled status submit copies of various documents to the CPSC. The applicant 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 CPSC's purpose in reviewing such documents would be to assess whether the laboratory has established the necessary written procedures to maintain its independence from the manufacturer or private labeler. We also 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, as well as policies and procedures explaining that an allegation of undue influence may be reported confidentially to the CPSC. Our purpose in 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.

Comment 12: A commenter (6) recommends that reciprocity provisions be built into the accreditation and audit provisions for laboratories. The commenter asserts that in the absence of aligned standards and compliance protocols, accreditation for foreign laboratories from countries with reciprocity provisions is the optimum approach to third party testing.

The commenter opines that reciprocity provisions provide a "level playing field" for manufacturers and laboratories, without compromising the accreditation program's integrity. The commenter adds that for trade purposes, U.S.-based laboratories should be allowed to provide their services in any market that contains foreign-based laboratories seeking CPSC-acceptance of their accreditation.

The commenter adds that the Occupational Safety and Health Administration (OSHA) Nationally Recognized Laboratories (NTRL) program and the Federal Communications Commission (FCC) accreditation program for Telecommunications Certification Bodies include reciprocity provisions. The commenter states that such reciprocity provisions benefit U.S. manufacturers by streamlining compliance requirements across markets and allowing laboratories to bundle services.

Response 12: We decline to adopt reciprocity as a criterion in the CPSC third party conformity assessment body program.

In implementing the CPSIA's requirement that products subject to CPSC children's product safety rules be third party tested, the CPSC's interest is to establish an effective and efficient program through which we recognize laboratories worldwide that are competent to conduct these third party tests. The use of ILAC-MRA signatory accreditation bodies creates a level playing field by providing an internationally available, consistent, accreditation process for laboratories, regardless of where they are located. Any CPSC-accepted laboratory, whose scope includes the tests conducted, may test children's products for compliance to the applicable CPSC children's product safety rules. Reciprocity provisions regarding U.S.-based laboratory activities in other nations are not necessary to ensure the technical competence and objective assessment of compliance from a CPSC-accepted laboratory.

Comment 13: Two commenters (3, 7) note that the proposed rule defines a "firewalled" laboratory, in part, as one that "is under a contract to a manufacturer or private labeler . . . that explicitly limits the services [it] may provide for other customers and/or limits which or how many other entities may also be customers of the [laboratory]." (Proposed § 1112.11(b) (1) (ii) (D)). The commenters assert that the definition constitutes an unnecessary and unwarranted intrusion into the private contractual rights of independent laboratories and their customers.

One commenter (3) notes that absent any indication that such a contractual relationship, in fact, constitutes "ownership or control" by a manufacturer over a laboratory, the proposed rule/staff justification offers no foundation for this provision, and in fact, there appears to be no valid purpose (including any based on congressional intent in this regard) to having such an

overly broad definition of "firewalled lab." Another commenter (7) recommends that this provision be modified to reflect that, absent any indication that such a contractual relationship, in fact, constitutes "ownership or control" by a manufacturer over a laboratory, the laboratory should not be considered to be a "firewalled lab."

Response 13: Staff recommends that the element regarding contractual relationships be removed as one of the criteria that define a "firewalled" laboratory in the draft final rule.

The preamble to the proposed rule included a discussion noting that a contractual relationship between a manufacturer and a laboratory that explicitly limits which or how many other entities may also be customers of the laboratory would grant the manufacturer such a significant interest in the work of the laboratory that the Commission would consider the interest "controlling." Section 1112.11(b)(1)(ii)(D) of the proposed rule would designate a laboratory with such a contractual relationship with a manufacturer as "firewalled."

After reviewing the comments regarding this section of the proposed rule, we agree with the commenters that this type of contractual relationship would not necessarily result in a situation where the manufacturer controls the laboratory. Because the specific details of these types of contracts are highly variable, it would be impractical and complex to assess independently each contract on a case-by-case basis. Further, staff considers that such a contract assessment would result in little benefit to consumer safety, above the other elements in the proposed rule that define a firewalled laboratory, and above the criteria for CPSC acceptance of a laboratory's accreditation.

Comment 14: One commenter (6) recommends that the provision stating that a "one percent or greater ownership or control" for a governmental laboratory (proposed § 1112.11(c)(1)), should instead be a higher percentage and/or a fact-based determination based on the "undue influence" definition whereby the governmental ownership or control causes the laboratory to "compromise the integrity of its testing processes or results."

Response 14: We decline to choose another percentage of ownership or control to designate a governmental laboratory based on this comment. Section 14(f)(2)(B) of the CPSA states that a governmental third party conformity assessment body is an entity that is owned or controlled in whole or in part by a government. "In part" can be interpreted as any proportion of ownership or control, and therefore, it is not limited to a minimum value. As stated in the proposed rule, "Selecting one percent as an ownership threshold is a practical matter of selecting the smallest whole number as an expression of ownership." The commenter does not provide a recommended value greater than one percent to indicate governmental ownership or control. Nor does the commenter provide a rationale for choosing an ownership percentage other than one percent.

We decline to adopt the commenter's recommendation with regard to considering a fact-based determination. The definition of a "governmental third party conformity assessment body" in section 14(f)(2)(B)(ii) of the CPSA states that the laboratory's test results are not

"subject to undue influence."[10] We interpret "subject to undue influence" to mean being liable, or vulnerable to undue influence, not to an after-the-fact determination that undue influence had actually been exerted to compromise the integrity of testing results. Thus, we consider being vulnerable to the exercise of undue influence, not whether the undue influence has occurred, as being "subject to undue influence."

Comment 15: One commenter (6) recommends eliminating the provision that a laboratory will be classified as "governmental" if any of that laboratory's "management or technical personnel include any government employees." (Proposed § 1112.11(c)(4)). The commenter asks whether the phrase "technical personnel" should be deleted or clarified to indicate that such individuals cannot be employees of both the government and the laboratory, or whether another modification should be provided because some government employees might be assigned temporarily to a laboratory for specific training/oversight/similar legitimate function.

Response 15: We decline the commenter's recommendation. We assume that a government management or technical employee is present in the laboratory to perform a function essential to the laboratory's testing operations. If the management or technical position is controlled by the government, then the government has control over some aspect of the laboratory's testing and test results. Therefore, additional safeguards against the exercise of undue influence are warranted.

Comment 16: One commenter (6) recommends that the Commission modify proposed § 1112.43 to clarify that only "material" omissions or "materially incorrect" information in an application for acceptance be grounds for denial of the application and that the laboratory is to be afforded a reasonable opportunity to correct an omission or error in its application.

Response 16: We decline the commenter's recommendation to change the proposed rule because all of the information described as grounds for denial of an application in § 1112.43 of the proposed rule are considered material. If any of the information described in proposed § 1112.43(a) is not provided, that would be considered to be a material omission. Any inaccurate information would be considered materially incorrect. Clarification to this section is not necessary because the plain language of proposed § 1112.43(a) includes the omissions of information considered to be material.

We do not agree with the commenter that changes are needed to the proposed rule to provide an applicant a reasonable opportunity to correct an omission or error in its application because the language in the proposed rule already provides such opportunity. Section 1112.17(a) of the proposed and draft final rule allows CPSC staff to contact a laboratory with any questions regarding an application or to request the submission of missing information. Section 1112.43(b) in the draft final rule provides that "the CPSC's denial of an application will follow the process described in § 1112.51 of this subpart." Section 1112.51 of the draft final rule stipulates that the CPSC will provide an initial notice that notifies the laboratory of the specific grounds for a denial of an application. Some common reasons for denial of an application

[10] The definition of *subject* in the *Random House Dictionary of the English Language*, Library of Congress Catalog Car number 74-129255, New York, includes "to make liable or vulnerable; lay open; expose (usually fol. by *to*)."

include a missing scope document or a missing or incorrect test method reference within a scope document.

In § 1143(a)(1) of the draft final rule, a laboratory will be given 30 calendar days to respond and correct the issue. Further, the procedures in the draft final rule allow for a laboratory to request an extension of time with an explanation and an estimate of how much additional time is needed. Even in cases in which an applicant cannot correct the issue within an allotted extension and an application is denied, the applicant is notified that it may reapply for CPSC acceptance when all required elements are fulfilled.

Comment 17: One commenter (6) recommends that the Commission specify that only a "material" failure "to comply with an applicable [test method] protocol, standard or requirement . . ." (proposed § 1112.47(b)) or a "material" failure "to comply with any provision of Subpart B" (1112.47(c)) may provide grounds for CPSC withdrawal of a laboratory's accreditation, not just any minor/technical failure, which the commenter asserts the proposed rule now seems to allow.

Response 17: Staff declines the commenter's recommendation to add the additional language in section 1112.47(b) or (c) of the proposed rule because the plain language of those sections already addresses the commenter's concerns. Any failure "to comply with an applicable protocol, standard or requirement . . ." is grounds for withdrawal of CPSC acceptance listed in § 1112.47(b) of the proposed rule (and unchanged in the draft final rule) because the applicable protocol, standard, or requirement is considered to be "material" or it would not have been included in the rule. Similarly, any failure "to comply with any provision of Subpart B" in § 1112.47(c) of the draft final rule may be grounds for withdrawal of CPSC acceptance because those requirements would not be included in the rule unless they were considered "material."

Comment 18: A commenter (3) recommends that § 1112.53 of the proposed rule should specify in more detail the circumstances under which the CPSC may immediately suspend its acceptance of a laboratory's accreditation.

Response 18: We disagree that the changes suggested by the commenter are needed to this section of the proposed rule because the proposed rule at § 1112.53 already clearly describes, in detail, the circumstances when the CPSC may withdraw immediately and temporarily its acceptance of a laboratory's accreditation. The CPSC may take such action when it is in the public interest to protect health and safety. The section defines "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 noncompliant with CPSC rules, bans, standards, and/or regulations, constitutes an imminently hazardous consumer product under section 12 of the CPSA.

We believe this language clearly defines the threshold for the CPSC to consider immediate withdrawal of its acceptance of accreditation.

Comment 19: A commenter (6) requests that the status of CPSC-accepted laboratories should be disclosed publicly and readily ascertainable on the CPSC's website.

The list of CPSC-accepted laboratories on the CPSC website at: www.cpsc.gov/labsearch, currently does not display whether a laboratory is categorized as independent, firewalled, or governmental. The commenter asserts that it is in the interest of commercial customers and consumers to display this information and that the proposed rule should be modified to require that in applying for acceptance by the CPSC, "a lab must accede to the public disclosure of its acceptance status" (independent, firewalled, governmental) on the website display of CPSC-accepted laboratories.

Response 19: We decline the request to list the independent, firewalled, or governmental status of accepted laboratories on the CPSC website. Section 14 of the CPSA does not differentiate between "third party conformity assessment bodies" based on whether they are independent, governmental, or firewalled laboratories, provided the laboratory complies with the applicable criteria established in sections 14(f)(2)(A), (B), and (D). To list CPSC-accepted governmental and firewalled laboratories differently than independent laboratories might confuse manufacturers into thinking that the CPSC has assigned them a different status of acceptance of accreditation, which is not the case. Once its accreditation is accepted by the CPSC, a laboratory may conduct tests within its scope for children's product certification purposes, regardless of its status as an independent, governmental, or firewalled laboratory.

Many of the CPSC-accepted governmental laboratories have a small portion of government ownership and little-to-no government involvement in their operations. These laboratories operate essentially as independent laboratories, but by law, they must be categorized as "governmental" because they have partial government ownership, such as through a joint venture. Other governmental laboratories are associated with state-funded institutions. Because forms of governmental involvement can vary, listing a laboratory as "governmental" would not necessarily convey any meaningful information to the public.

For firewalled laboratories, firewalled status applies only to a manufacturer or private labeler who owns, manages, or controls the laboratory. The laboratory is considered independent for any other manufacturer or private labeler who may wish to use the laboratory's services. Further, notices of CPSC approval of firewalled laboratories are already published elsewhere on the CPSC website and are publicly available.[11]

[11] The notices of Commission acceptance of accreditation are posted by fiscal year under "Staff Briefing Packages" at http://www.cpsc.gov/library/foia/foia.html.

3.3 Inspections and Investigations

Comment 20: One commenter (6) recommends modifying proposed § 1112.27 to clarify that laboratories must allow on-site inspections by CPSC personnel or their designated representative, without exception. The commenter notes that this should be enforced uniformly to allow participation in the program.

Response 20: We decline the commenter's recommendation. The language in proposed § 1112.27 states: "A third party conformity assessment body, *as a condition of its accreditation, must allow* an officer or employee duly designated by CPSC to enter and inspect the third party conformity assessment body for purposes of an investigation under this part." (emphasis added). The language in proposed § 1112.27 is clear regarding the compulsory nature of allowing on-site inspections, when asked by CPSC personnel, for the purpose of an investigation as a condition of accepting the laboratory's accreditation. Therefore, it is unnecessary to add additional language, such as: "without exception," because that language would not add any further clarity.

Comment 21: Two commenters (3 and 6) request that "failure to cooperate" should be defined to address specifically only the actions or inactions that are within the scope of an investigation and should not be defined in regard to any other request from CPSC staff. The commenters opine that "a request to receive a subpoena for requested documents or the assertion of any other legal rights or procedures available to the lab in question should explicitly not be considered 'failure to cooperate.'"

Response 21: Because both the CPSA and the draft final rule specifically state that suspension of accreditation is for failing to cooperate with an investigation, we believe that the current text of the draft final rule already meets the commenters' request to limit the suspension to the scope of the investigation.

Section 14(e)(3) of the CPSA states:

> The Commission may suspend the accreditation of a conformity assessment body if it fails to cooperate with the Commission in an investigation under this section.

Section § 1112.45 of the draft final rule: *What Are the Grounds for Suspension of CPSC Acceptance?* implements section 14(e)(3) of the CPSA by stating:

> (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.

Finally, a laboratory that exercises any legal procedural right available under law would not be considered to have "failed to cooperate" under the draft final rule. This legal procedural right would include a laboratory request for the issuance of a subpoena before providing documents to the CPSC.

Comment 22: One commenter (6) states that the suspension of acceptance of accreditation of a laboratory should be warranted only when a laboratory exhibits a pattern of evading legitimate CPSC requests or inquiries related to an inspection or investigation. This commenter states that a "failure to cooperate" should specifically exclude: "reasonable delays in providing requested information or documents, considering all the circumstances." The commenter asks that the phrase "failure to respond to CPSC inquiries or requests" (section 1112.45(a) of the proposed rule) be defined more specifically, to specify, for example, a 20-day period or other reasonable time, based on the circumstances.

Response 22: Staff declines to adopt the commenter's recommendations. We agree with the commenter that evasive responses to CPSC inquiries could be grounds for suspension of the CPSC's acceptance of the laboratory's accreditation. Section 1112.45 of the draft final rule states:

> 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.

Because the text of the proposed and draft final rule already includes suspension of acceptance of accreditation for responding evasively to investigations, we believe that the current text already meets the commenter's concerns. It is not necessary for a pattern of evasion to be established before suspension of acceptance of accreditation is considered. Requiring a pattern of evasion would allow laboratories to respond to inquiries in a manner that is evasive some of the time, until a pattern is established. Because inspections or investigations frequently pertain to the presence of noncompliant children's products in the marketplace, evasive responses are never acceptable.

With regard to the commenter's statement regarding "reasonable delays," what is considered "reasonable" varies, based on the nature of the request; therefore, specifying a period is impractical. For example, a request for a corrected phone number, compared to a request for testing records covering a multiyear period will have different "reasonable" expected response periods. Thus, 20 days may be excessive for a telephone number correction, while that period may be unreasonably short for the collection and transmission of voluminous records. Further, the phrase "other reasonable time based on the circumstances" does not add specificity to what is considered "reasonable."

Comment 23: Two commenters (3 and 6) state that a request by the CPSC for a laboratory's "protocols and procedures" should relate only to the specific grounds for the investigation, not to testing in general.

Response 23: We decline the commenters' request because the rule, as proposed, already addresses the commenters' concerns.

Section 1112.25(a)(4) of the proposed rule: *What are a third party conformity assessment body's recordkeeping responsibilities?* requires laboratories to maintain internal documents

describing testing "protocols and procedures" that have applied to a test conducted for purposes of section 14 of the CPSA. Section 1112.51 of the rule, as proposed (and in the draft final rule), limits investigations to applications for acceptance of accreditation, submissions alleging grounds for an adverse action, or other information received by the CPSC that relates to a laboratory's ability to become or remain CPSC-accepted.

Comment 24: Two commenters (3 and 6) recommend that the term "investigation" should be defined to mean more than a nonspecific request for information, with one commenter (6) proposing a definition of "investigation" as a "formal inquiry based on specific and sufficient facts that give rise to a reasonable belief by the CPSC that a material violation of this rule has occurred." This commenter also suggests that "investigations" should be limited to the scope and the specific, material violation implicated by those facts. The commenter adds that "investigations" "should only be allowed when something akin to "probable cause" arises about a specific violation of a lab and should not be allowed to be fishing expeditions by the agency."

Response 24: We decline to add a formal pleading requirement or the equivalent of a "probable cause" requirement because determining whether an investigation is warranted is a fact-based judgment best made on a case-by-case basis.

Section 1112.49(a) of the draft final rule (and as proposed) allows any person to submit information alleging grounds for adverse action, as set forth in part 1112. The submitter is required to allege that one or more of the grounds for adverse action set forth in part 1112 exist. Section 1112.49(a) of the draft final rule describes the kind of information necessary for the CPSC to substantiate an allegation for an adverse action. Any investigation resulting from the information submitted under § 1112.49 would be instituted under the procedures described in § 1112.51. If a person submitting information does not provide sufficient information to investigate an allegation, it will be difficult for the agency to substantiate the allegation, as is indicated in § 1112.49(b), which states:

> Upon receiving the information, the CPSC will review the information to determine if it is sufficient to warrant an investigation. The CPSC may deem the information insufficient to warrant an investigation if the information fails to address the categories of information outlined in paragraph (a) of this section above.

The language of § 1112.49(a) sets the threshold regarding the types and sufficiency of the information necessary to warrant an investigation. Therefore, it is unnecessary to define the term "investigation" as the commenters have requested.

3.4 Undue Influence

Comment 25: One commenter (6) recommends that the Commission specify that the exercise of "undue influence" over the laboratory sufficient to justify CPSC "withdrawal" of its acceptance of the laboratory (proposed § 1112.47(a)) must be "directly related and material to the scope of the testing for which the laboratory was accepted by the CPSC." The commenter notes that this is particularly important in regard to the requirements for "firewalled" laboratories.

Response 25: We decline to adopt the commenter's recommendation. The current language of §§ 1112.47(a) and 1112.51 of the draft final rule (which is the same as that in the proposed rule) permits CPSC flexibility in assessing the nature of various undue influences acting upon conformity assessment bodies, whereas the commenter's recommendation would narrow this flexibility. This could have unintentional and unforeseeable consequences affecting the CPSC's ability to address instances of undue influence for testing under the jurisdiction of CPSC.

The commenter does not explain why the withdrawal of CPSC acceptance of a firewalled laboratory should be treated differently than other types of laboratories. The CPSC regards any exercise of undue influence on the integrity of a laboratory's test results as calling into question the integrity of all of the laboratory's test results, including those related to the testing of children's products.

If a laboratory disagrees with a CPSC final notice of adverse action, § 1112.51 of the draft final rule describes procedures for filing an administrative appeal. In addition, for firewalled laboratories, any suspension or withdrawal of CPSC acceptance of accreditation must be done by order of the Commission. These procedures allow a laboratory to present its case if there is disagreement with the CPSC staff findings that support an adverse action.

3.5 Adverse Actions

Comment 26: One commenter (6) recommends that the Commission clarify in the rule that, except for situations that warrant an "immediate suspension" of a laboratory, a laboratory may be suspended or withdrawn from acceptance only after a formal "investigation" and an adequate opportunity for the laboratory to respond under the rule.

The commenter further recommends that the Commission should allow "immediate withdrawal" of a laboratory's acceptance of accreditation (proposed § 1112.53) only upon an affirmative vote of the Commission (not a mere staff determination that withdrawal is necessary "to protect the public health and safety"). The commenter notes that Commission action is necessary for the analogous action by the CPSC to waive the 6(b) notification rights of a company to disclose immediately product-specific information to the public, and likewise, should be required here.

Response 26: We decline the commenter's recommendation of an "immediate suspension" because the draft final rule, which is unchanged from the proposed rule, already includes a section describing the procedures to be used during an investigation, and further clarification is not necessary.

Subpart D of the proposed rule, *Adverse Actions: Types, Grounds, Allegations, Procedural Requirements, and Publication,* includes § 1112.51, *What are the procedures relevant to adverse actions?* This section describes the procedures that will be used to conduct an investigation, and it also includes established procedures and opportunities for the laboratory to respond.

We decline to adopt the commenter's recommendation that we should allow "immediate withdrawal" of a laboratory's acceptance of accreditation (proposed § 1112.53) only upon an

affirmative vote of the Commission (not a mere staff determination that withdrawal is necessary "to protect the public health and safety"). Section 14(a)(3)(C) of the CPSA states that accreditation of third party conformity assessment bodies may be conducted by the Commission or an independent accreditation organization designated by the Commission. Currently, staff has been tasked with reviewing and accepting the accreditation of independent and governmental laboratories. While staff also reviews accreditation and application materials from firewalled applicants, section 14(f)(2)(D) of the CPSA provides that the Commission may accept a firewalled laboratory's accreditation, by order of the Commission, after determining that the firewalled applicant meets statutory requirements.

Section 14(e) of the CPSA authorizes the Commission to withdraw or suspend its accreditation or acceptance of accreditation of a laboratory under certain conditions. To parallel the acceptance process to accredit firewalled laboratories, the withdrawal of acceptance of accreditation of firewalled laboratories occurs by Commission vote. In order to maintain the parallel structure of Commission acceptance of accreditation, the Commission does not require a vote to withdraw or suspend acceptance of accreditation of independent or governmental laboratories.

3.6 Recordkeeping

Comment 27: One commenter (7) suggests modifying the document retention requirement of proposed § 1112.25(a) (1) to specify that only "test reports and technical records that are directly related and material to the scope of the laboratory's acceptance related to that testing" must be retained under the rule.

Response 27: Staff does not recommend making a change to the proposed rule in response to this comment. The proposed rule requires laboratories to keep "test reports and technical records *related* to tests conducted for purposes of section 14 of the CPSA" (emphasis added). The commenter does not provide any information regarding the advantage of limiting the retention to those records that are "directly related and material" to the laboratory's testing for purposes of section 14 of the CPSA. Moreover, staff is not sure that the suggested change would make a difference in the records that conformity assessment bodies would be required to keep.

Comment 28: One commenter (7) suggests modifying proposed § 1112.25(a) (2) to require only that the subcontractor laboratory's test report be "available with the prime contractor laboratory's test report" and not necessarily "appended to" it.

Response 28: We agree with the commenter and will revise § 1112.25(a) (2) of the proposed rule to require making the subcontractor's laboratory test report available to CPSC upon request but not necessarily appended to the prime contractor's test report (this is reflected in the draft final rule). We note that appending a subcontractor's test report would satisfy the requirement to make the report available.

Comment 29: One commenter (6) recommends modifying proposed § 1112.25(b) to require that documents required to be retained be provided to the CPSC, upon request, within "48 hours or within a reasonable time given the particular circumstances." The commenter also asserts that

we should require only that English translations of documents be supplied to the CPSC "that are relevant and reasonably necessary with regard to the CPSC's specific inquiry or investigation."

Response 29: We decline to make the commenter's recommended change to § 1112.25(b) regarding changing "48 hours" to "48 hours or within a reasonable time given the particular circumstances" when records are requested by the CPSC. However, we are revising § 1112.25(b) of the proposed rule to remove the "within 48 hours" language and replace it with "such as through an Internet website." This change is reflected in the draft final rule. The revised language is being added to be consistent with the recordkeeping language in 16 CFR part 1107 (testing and labeling rule) and 16 CFR part 1109 (component part testing rule), which require submission of records upon request but does not specify a time frame within which the records must be submitted and allows for electronic records "such as through an Internet website." Implicit in the requirement to submit records to the CPSC upon request is the commenter's concept of "within a reasonable time given the particular circumstances." The time frame necessary to respond to a document request by the CPSC, by its nature, is required to be determined on a case-by-case basis. Therefore, stating an explicit time frame, such as "48 hours," as the proposed rule specified, would not fit the many different circumstances that might be present when CPSC requests records.

Regarding the commenter's suggestion that we should require English translations only of documents "that are relevant and reasonably necessary with regard to the CPSC's specific inquiry or investigation," the documents required in §§ 1112.25(a)(1)-(4) of the draft final rule are always considered to be "relevant and reasonably necessary with regard to the CPSC's specific inquiry or investigation," hence, that is the reason for the requirement to maintain those records. Therefore, we decline to make the commenter's recommended change because the proposed and draft final rules inherently require maintaining records "that are relevant and reasonably necessary with regard to the CPSC's specific inquiry or investigation."

Comment 30: One commenter (6) recommends that we modify the proposed rule to clarify generally that:

> except for the status of an accepted laboratory, confidential business information, copyrighted information and trademarks, trade secrets and other information and documents provided to the CPSC by a laboratory under this rule is strictly protected from any third party disclosure under the all applicable laws, including, without limitation, the Consumer Product Safety Act.

Response 30: We decline the commenter's recommendation because it is unnecessary to clarify the draft final rule by adding the language requested by the commenter. Confidential business information, copyrighted information and trademarks, trade secrets, and other information and documents provided to the CPSC by a laboratory are all subject to protections from third party disclosure or others protections under existing applicable laws, and the draft final rule does not change that.

3.7 Definitions

Comment 31: A commenter (6) notes that the proposed rule defined a "quality manager" for an accredited laboratory as having "defined responsibility and authority for ensuring the management system related to quality is implemented and followed at all times." The commenter states that a laboratory may institute an ISO 9000-compliant management system and "may not address the fulfillment of ISO/IEC 17025, which may NOT include competence requirements for testing." The commenter continues that the definition appears to refer only to compliance with the management system and not to all sections of ISO/IEC 17025.

Response 31: The definition of a "quality manager" provided in the Audit Final Rule (16 CFR §1112.3, *Definitions*), is the same as the definition of a "quality manager" in section 4.1.5.i of ISO/IEC 17025:2005(E).

We agree with the commenter that, regardless of the definition of a "quality manager," a laboratory must comply with all the requirements of ISO/IEC 17025:2005(E) in order for its accreditation to be accepted by the CPSC.

3.8 Retrospective Testing

Comment 32: One commenter (2) notes that most of the previous NORs have provided for "retrospective testing" by laboratories, *i.e.*, CPSC recognition of testing and certification using the new standard after the date of the method's initial publication by the agency and before the NOR formally goes into effect. The commenter also notes that the two new CPSC lead substrate test methods have already been posted on the CPSC website, including a reference in the laboratory accreditation application page of that site, which indicates that laboratories can now begin applying for private accreditation. Thereafter, CPSC acceptance, to these new methods, should be allowed, despite the fact that there has been no retrospective testing allowance provided for in the proposed rule. The commenter recommends that the final rule allow retrospective testing using the new methods, effective back to April 10, 2012, the date those new methods were first published by the CPSC.

Response 32: We agree with the commenter and recommend including provisions allowing Children's Product Certificates to be based on testing performed by an ISO/IEC 17025:2005(E)-accredited laboratory prior to the CPSC's acceptance of its accreditation for lead content test methods for which retrospective testing was not previously addressed. The preamble to the draft final rule includes information on accepting retrospective testing.

The proposed rule for Part 1112 introduced two CPSC test methods that were not in previously published NORs. These are:

- Standard Operating Procedure for Determining Total Lead (Pb) in Children's Metal Products (CPSC-CH-E1001-08.2); and
- Standard Operating Procedure for Determining Total Lead (Pb) in Nonmetal Children's Products (CPSC-CH-E1002-08.2).

We recommend the following retrospective testing allowances for the lead content test methods:

For testing for total lead in children's metal products and children's nonmetal products, testing must be conducted by a laboratory that has been CPSC-accepted for any of the earlier versions of CPSC test methods (CPSC-CH-E1001-08 or CPSC-CH-E1001-08.1 for children's metal products and CPSC-CH-E1002-08 or CPSC-CH-E1002-08.1 for children's non-metal products). These earlier versions of the test methods will remain acceptable for testing for total lead in substrate materials.

We will accept retrospective testing using the updated test methods, CPSC-CH-E1001-08.2 and CPSC-CH-E1002-08.2, if the following conditions are met:

- The children's product was tested by a laboratory accredited to ISO/IEC 17025:2005(E) by a signatory to the ILAC-MRA at the time of the test. The scope of the laboratory's accreditation must include test method CPSC-CH-E1001-08.2 for testing of a children's metal product. The scope of the laboratory's accreditation must include test method CPSC-CH-E1002-08.2 for testing a children's nonmetal product. For firewalled laboratories, the firewalled laboratory 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 test methods CPSC-CH-E1001-08.2 and CPSC-CH-E1002-08.2. For governmental laboratories, the governmental laboratory must be one whose accreditation was accepted by the Commission, even if the scope of accreditation did not include the test methods CPSC-CH-E1001-08.2 and CPSC-CH-E1002-08.2.
- The laboratory's application for acceptance of its accreditation to the revised test methods is accepted by the CPSC before the effective date of 16 CFR part 1112.
- The test results show compliance with limits on total lead content, as established in section 101 of the CPSIA.
- The children's product was tested on or after April 10, 2012 (the publication date of the updated test methods) and before the effective date of 16 CFR part 1112.
- The laboratory's accreditation remains in effect through the effective date of 16 CFR part 1112.

Tab B: Commenters Submitting Comments to Docket CPSC-2012-0026

Commenters to Docket CPSC-2011-0026 on www.regulations.gov

Commenter Number	Commenter	Affiliation	Docket Comment Number
1	Proposed Rule		CPSC-2012-0026-0001
2	Satbir Nayar	XOS, Inc.	CPSC-2012-0026-0002
3	Gene Rider	Intertek, Consumer Goods North America	CPSC-2012-0026-0003
4	Michael J. Gray	Thermo Scientific Portable Analytical Instruments	CPSC-2012-0026-0004
5	Steve Lamar	American Apparel & Footwear Association	CPSC-2012-0026-0005
6	Maarten van der Dussen	International Federation of Inspection Agencies	CPSC-2012-0026-0006
7	Jiaxin Chen	Olympus NDT	CPSC-2012-0026-0007

Tab C: Final Regulatory Flexibility Analysis for Requirements Pertaining to Third Party Conformity Assessment Bodies

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

Memorandum

Date: 10/16/2012

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: Final Regulatory Flexibility Analysis for Draft Final Rule Establishing Requirements for Third Party Conformity Assessment Bodies

Introduction

This memorandum provides a final regulatory flexibility analysis of the draft final rule that would establish requirements for third party conformity assessment bodies (laboratories). Previously, the staff analyzed the impact of the proposed rule on small entities and prepared an initial regulatory flexibility analysis (IRFA), which was included in the notice of proposed rulemaking (NPR)(77 FR 31123 – 31126). The Regulatory Flexibility Act (RFA) generally requires agencies to prepare a final regulatory flexibility analysis when promulgating a final rule, which describes the impact of the rule on small entities. The final regulatory flexibility analysis must contain –

(1) a succinct statement of the need for, and objectives of, the rule;
(2) a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
(3) a description of and an estimate of the small entities to which the rule will apply or an explanation of why no such estimate is available;

(4) a description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for the preparation of the report or record; and
(5) a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

The Need for, and Objectives of, the 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 (laboratory). The draft final rule would establish the requirements that laboratories must meet in order to test children's products under Section 14 of the CPSA, including procedures for becoming a U.S. Consumer Product Safety Commission (CPSC) -accepted third party conformity assessment body. Many of the requirements in the final rule regarding the acceptance of laboratory accreditation are the same requirements that the CPSC has been using since the CPSIA was passed in 2008. The draft final rule also would establish the process for a laboratory to discontinue voluntarily its participation as a CPSC-accepted third party conformity assessment body, the grounds and procedures by which the CPSC may suspend or withdraw its acceptance of the accreditation of a third party conformity assessment body, and the procedures by which a person may submit allegations against a third party conformity assessment body to the CPSC.

Significant Issues Raised by the Public Comments in Response to the IRFA

The CPSC received six public comments in response to the (NPR). CPSC staff are addressing the issues raised in the comments in another memorandum. None of the comments questioned the content of the IRFA or its findings.

Description and Estimate of the Small Entities to which the Draft Final Rule Would Apply

The draft final rule would apply to laboratories that intend to test children's products for conformance to children's product safety rules under Section 14 of the CPSA. The draft final rule would not impose any requirements on laboratories that do not intend to provide this service.

Although there are 5,198 firms in the United States classified as "laboratories" (NAICS code 54138),[12] 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 October 5, 2012, the CPSC has accepted the accreditation of 92 laboratories located in the United States.[13] This number could increase, somewhat, over the next year or so, as new notices of requirements (NORs) for accreditation are issued.

According to criteria established by the U.S. Small Business Administration (SBA), a laboratory is considered small if its revenue is less than $14 million a year. Of the 92 laboratories located in the United States with CPSC-accepted accreditations, 58 (or 63 percent) could be small businesses according to the SBA criteria.

Projected Reporting, Recordkeeping, and Other Compliance Requirements

Requirements for CPSC Acceptance of Accreditation

The draft final rule would establish the requirements for CPSC acceptance of the accreditation of a laboratory. Therefore, the rule would apply 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 final rule would not impose any requirements on laboratories that do not intend to provide these services.

The draft final rule would require that, as a condition of CPSC acceptance of its accreditation, the laboratory must be accredited to the International Organization for Standardization/International Electrotechnical Commission Standard (ISO/IEC) 17025:2005(E)–*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 requirements (NORs) that are required as the basis for certifying that children's products conform to the applicable product safety rules. This aspect of the draft final rule would simply codify the existing conditions for CPSC acceptance of accreditation that have been stated in every NOR published previously by the Commission.

The draft final rule would require that laboratories provide the Commission with their accreditation and scope documents. These records are normally generated during the accreditation process and can be provided to the CPSC electronically. The application for

[12] United States Census Bureau, 2009 County Business Patterns (available at: http://www.census.gov/econ/susb/).

[13] The CPSC has recognized the accreditation of almost 400 laboratories worldwide (as of October 15, 2012). However, most of the laboratories are located in other countries. Only domestic firms are considered for the purposes of the RFA.

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 to complete Form 223 and the related documents are skills that a competent, accredited laboratory would be expected to possess.

The draft final 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 made certain findings based on the additional documents. The additional documents that "firewalled" laboratories must 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 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 final rule also would establish additional requirements for Commission acceptance of the accreditation of laboratories that are owned or controlled, in whole or in part, by a government. CPSC has accepted the accreditation of three conformity assessment

bodies located in the United States that are owned by or affiliated with government entities, none of which meet the definition of a "small entity." Laboratories that are owned or controlled by foreign governments do not meet the definition of a small entity under the RFA.

In addition to the baseline requirements (accreditation to ISO/IEC 17025:2005(E) by a signatory to the ILAC-MRA and 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 third party conformity assessment body 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 third party conformity assessment body 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;
        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:
        i. 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;
        ii. 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;

iii. 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 third party conformity assessment body by the CPSC as a governmental third party conformity assessment body;

iv. 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;

v. 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 third party conformity assessment bodies in the same country or administrative area are not permitted to perform those same functions;

vi. 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 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;

vii. 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; and

viii. 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(E) 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 longer 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(E) 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.

For most children's 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 NORs for accreditation, which are one of the subjects of the draft final rule. The draft final rule would expand the list of acceptable test methods for measuring lead content to include the use of X-ray fluorescence spectrometry (XRF) 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.

Each ILAC-MRA signatory accreditation body has requirements for the periodic reassessment of accredited laboratories. The Commission has established the auditing requirements for maintaining CPSC acceptance of a laboratories accreditation in the separate, but related, rulemaking on periodic audits (16 CFR §§1112.30–1112.39), which is currently in effect.

Recordkeeping Requirements

The draft final 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 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 laboratory must make any and all of the records required by this section available for inspection, either in hard copy or electronic form. If the records are not in the English language, the laboratory must make copies of the original (non-English language) records available to the CPSC, 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 final rule also would establish the grounds and procedures that the CPSC could 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 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; 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 may open is not known.

Economic Impact on Small Entities and Significant Alternatives Considered

Expected Economic Impact on Small Entities

Laboratories that intend to provide the third party testing services required by section 14 of the CPSA will incur some costs to obtain CPSC acceptance of their accreditation. If the laboratory is not already accredited to ISO/IEC 17025:2005(E) 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. The costs could be significantly lower for laboratories that are already accredited to ISO/IEC 17025:2005(E) by a body that is an ILAC-MRA signatory. 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 draft final 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 laboratories that intend to provide the third party testing services for purposes of certifying children's products under 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 testing services 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.

Alternatives Considered

Although the draft final rule is not expected to have a significant adverse impact on a substantial number of small entities, CPSC staff considered alternatives that could have

reduced the costs associated with the accreditation process or providing the testing services to some laboratories. The alternatives considered were accepting the accreditation of laboratories that were not accredited by a signatory to the ILAC-MRA and allowing the use of XRF techniques for determining compliance with the lead content requirements for more materials.

Accepting the Accreditation of Laboratories not Accredited by ILAC-MRA Signatories

CPSC staff considered accepting the accreditation of laboratories that have been accredited by accreditation bodies that are not signatories to the ILAC-MRA. This alternative could have reduced the cost of obtaining CPSC acceptance of their accreditation for laboratories accredited by bodies that were not ILAC- MRA signatories. Under the draft final 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, despite being accredited by an accrediting body that was not a signatory to the ILAC-MRA. This alternative would not have any impact on laboratories that are not accredited by any accreditation body.

This alternative was not included in the draft final rule because it would not meet the objectives that CPSC staff had identified for a program to meet the laboratory accreditation requirements in the CPSA. In establishing the requirements for the laboratory accreditation program, CPSC staff considered timelines established by the CPSA and the fact that children's products destined for the U.S. market are manufactured in nations throughout the world. Ultimately, staff established several objectives for the laboratory accreditation program, which were to:

(1) Delegate the core elements of a CPSC accreditation program to an entity that was established and had acceptance on a multinational level and that followed internationally recognized standards for assessing the competence of laboratories and for the processes and standards used by accreditation bodies that evaluate such laboratories. In addition, CPSC staff sought a program that included regular evaluation of the accreditation bodies to ensure those bodies continued to follow the same, internationally recognized, set of standards and procedures;
(2) Designate one entity that could bring on board, on a multinational level, a large 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.

In addition to the objectives outlined above, the CPSC also sought to keep the program as simple as possible, avoid any perceived notions of barriers to fair trade practices, and to ensure that the program established would be manageable with agency resources. Commission staff found that the ILAC-MRA signatory program met its objectives. Although CPSC staff recognizes that there are other types of accreditation organizations and accreditation bodies for different types of conformity assessment programs, some of these organizations are for very specific industry or governmental sectors, or are only applicable to certain regions. Designations to such organizations would not meet all of the objectives established by CPSC staff for the laboratory accreditation program.

Alternative Test Methods for Lead

Allowing the use of XRF to determine compliance with the lead content requirements for more materials - 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 final rule would further allow the use of certain XRF methods for determining the lead content of glass materials, crystals, and particular metals. However, for other materials, CPSC staff has not determined that XRF has the required accuracy, precision, and reliability to determine their lead content, and therefore, the draft final rule does not expand the approved use of XRF to cover all materials or substances.