



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

**BP - Proposed Rule - Testing and Labeling  
 Pertaining to Product Certification**  
 The contents of this document will be  
 discussed at the Open Commission Meeting  
 on Thursday, April 8, 2010 (afternoon)

**THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.**

**A DECISION MEETING FOR THIS MATTER IS SCHEDULED ON: April 21, 2010**

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

**APR - 1 2010**

**THROUGH:** Cheryl A. Falvey, General Counsel  
 Maruta Budetti, Executive Director

*Handwritten initials: CAF, MB, etc.*

**FROM:** Philip Chao, Assistant General Counsel  
 David M. DiMatteo, Attorney, OGC

**SUBJECT:** Proposed Rule: Testing and Labeling Pertaining to Product Certification

The Office of the General Counsel is providing for Commission consideration the attached draft *Federal Register* notice on a proposed rule that would establish requirements for a reasonable testing program and for compliance and continuing testing for children's products. The proposal would also address labeling of consumer products to show that the product complies with certification requirements under a reasonable testing program for non-children's products or under compliance and continuing testing for children's products. The proposed rule would implement section 14(a) and (d) of the Consumer Product Safety Act, as amended by section 102(b) of the Consumer Product Safety Improvement Act of 2008.

Please indicate your vote on the following options.

- I. Approve publication of the draft proposed rule in the *Federal Register* without change.

\_\_\_\_\_  
 (Signature)

\_\_\_\_\_  
 (Date)

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

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(Signature)

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(Date)

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

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(Signature)

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(Date)

IV. Take other action. (Please specify.)

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(Signature)

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(Date)

Attachments:

Draft *Federal Register* Notice - Proposed Rule: Testing and Labeling Pertaining to Product Certification

Staff Briefing Package from Randy Butturini, Office of Hazard Identification and Reduction to Robert J. Howell, Assistant Executive Director, Office of Hazard Identification and Reduction, *Consumer Product Safety Improvement Act Certification & Testing*, dated April 2010.



**ADDRESSES:** You may submit comments, identified by Docket No. [CPSC docket number], by any of the following methods:

#### Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: <http://www.regulations.gov>.

Follow the instructions for submitting comments.

To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (e-mail) except through [www.regulations.gov](http://www.regulations.gov).

#### Written Submissions

Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions), preferably in five copies, to: Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this proposed rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to <http://www.regulations.gov>. Do not submit confidential business information, trade secret information, or other sensitive or protected information electronically. Such information should be submitted in writing.

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

FOR FURTHER INFORMATION CONTACT: Randy Butturini, Project Manager, Directorate for Engineering Sciences, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; 301-504-7562; e-mail: [RButturini@cpsc.gov](mailto:RButturini@cpsc.gov).

**SUPPLEMENTARY INFORMATION:**

**A. Statutory Authority**

Section 14(a)(1) of the CPSA, (15 U.S.C. 2063(a)(1)), as amended by section 102 of the CPSIA, establishes requirements for the testing and certification of products subject to a consumer product safety rule under the CPSA or similar rule, ban, standard, or regulation under any other Act enforced by the Commission and which are imported for consumption or warehousing or distributed in commerce. Under section 14(a)(1)(A) of the CPSA, manufacturers and private labelers must issue a certificate which "shall certify, 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 the CPSA or any other Act enforced by the Commission." CPSC regulations, at 16 CFR part 1110, limit the certificate requirement to importers and domestic manufacturers. Section 14(a)(1)(B) of the CPSA further

requires that the certificate provided by the importer or domestic manufacturer "specify each such rule, ban, standard, or regulation applicable to the product." The certificate described in section 14(a)(1) of the CPSA is known as a General Conformity Certification.

Section 14(a)(2) of the CPSA (15 U.S.C. 2063(a)(2)) establishes testing requirements for children's products that are subject to a children's product safety rule. (Section 3(a)(2) of the CPSA (15 U.S.C. 2052(a)(2)) defines a children's product, in part, as a consumer product designed or intended primarily for children 12 and younger.) Section 14(a)(2)(A) of the CPSA also states that, before a children's product that is subject to a children's product safety rule is imported for consumption or warehousing or distributed in commerce, the manufacturer or private labeler of such children's product must submit sufficient samples of the children's product "or samples that are identical in all material respects to the product" to an accredited "third party conformity assessment body" to be tested for compliance with the children's product safety rule. Based on such testing, the manufacturer or private labeler, under section 14(a)(2)(B) of the CPSA, must issue a certificate that certifies that such children's product complies with the children's product safety rule based on the assessment of a

third party conformity assessment body accredited to perform such tests.

Section 14(d)(2)(A) of the CPSA requires the Commission to initiate a program by which a manufacturer or private labeler may label a consumer product as complying with the certification requirements. This provision applies to all consumer products that are subject to a product safety rule administered by the Commission.

Section 14(d)(2)(B) of the CPSA requires the Commission to establish protocols and standards for:

- Ensuring that a children's product tested for compliance with a children's product safety rule is subject to testing periodically and when there has been a material change in the product's design or manufacturing process, including the sourcing of component parts;
- Testing of random samples;
- Verifying that a children's product tested by a conformity assessment body complies with applicable children's product safety rules; and
- Safeguarding against the exercise of undue influence on a third party conformity assessment body by a manufacturer or private labeler.

The proposed rule would implement sections 14(a) and (d) of the CPSA, as amended by section 102(b) of the CPSIA, by:

- Defining the elements of a "reasonable testing program" for purposes of section 14(a)(1)(A) of the CPSA;
- Establishing the protocols and standards for continuing testing of children's products under section 14(d)(2)(B) of the CPSA; and
- Describing the label that manufacturers may place on a consumer product to show that the product complies with the certification requirements for purposes of section 14(d)(2)(A) of the CPSA.

The proposed rule also builds upon previous documents and activities by the Commission. For example, on November 3, 2009, Commission staff made available a draft guidance document titled, "Guidance Document: Testing and Certification Requirements Under the Consumer Product Safety Improvement Act of 2008." The draft guidance document, which is available at <http://www.cpsc.gov/library/foia/foia10/brief/102testing.pdf>, was intended to provide the Commission's interpretation of the requirements of section 102 of the CPSIA. Specifically, it sought to describe the Commission's position on a reasonable testing program and how to certify that a product complies with all rules, bans, standards, or other regulations applicable to the product under the laws enforced by the Commission. The guidance document also sought to explain when and how component testing to certain specific requirements would be allowed.

Although the Commission never voted on whether to approve or to not approve the issuance of the draft guidance document, the draft did represent the Commission staff's thinking on the subject. Shortly thereafter, in the FEDERAL REGISTER of November 13, 2009 (74 FR 58611), the Commission announced that it would hold a two-day public workshop to discuss issues relating to the testing, certification, and labeling of consumer products pursuant to section 14 of the CPSA. The workshop was held on December 10 through 11, 2009, in Bethesda, Maryland, and the Commission invited interested parties to attend and participate in the meeting. Commission staff made presentations on specific topics and held breakout sessions on:

- Sampling and statistical considerations;
- Verification of third party test results;
- Reasonable test programs and third party testing;
- Challenges for small manufacturer / low volume production;
- Component testing and material changes; and
- Protection against undue influence.

The notice also stated that the Commission wanted to use the workshop to discuss possible options for implementing section 14 of the CPSA. Several hundred individuals attended the workshop.

**B. Responses to Comments on the Notice of Availability and the Public Workshop**

In connection with the public workshop, the Commission invited public comment on its implementation of various aspects of section 14 of the CPSA.

The FEDERAL REGISTER notice announcing the meeting identified specific issues for public comment; for example, in the section titled, "What are the issues regarding additional third party testing of children's products?" the Commission asked:

- Should the potential hazard (either the severity or the probability of occurrence) be considered in determining how frequently the periodic testing is conducted? For example, should a product subject to a consumer product safety rule, where the potential hazard is death, be tested more frequently than a product where the potential hazard is some lesser degree of harm? If so, how might a rule incorporate potential hazard into testing frequency?
- What changes should constitute a "material change" in a product's design or manufacturing process? Are there criteria by which one might determine whether a change is a "material" change? For example, a material change in a product's design or manufacturing process could be described as a change that affects the product's ability to

comply with a consumer product safety rule. However, as a practical matter, it may be difficult to determine what consumer product safety rules apply to the product and the extent to which compliance with those rules is affected by a change.

See 74 FR at 58614.

The Commission received 38 comments, and we discuss those comments, and our responses, in part B.1 through B.12 of this document. To make it easier to identify comments and our responses, the word *Comments* will appear before the comment's description, and the word *Response* will appear before our response.

#### *1. The Reasonable Testing Program*

In the FEDERAL REGISTER notice announcing the public workshop, the Commission had described a "reasonable testing program" as consisting of:

- Product specifications that describe the consumer product and list the safety rules, standards, etc., with which the product must comply. The product specification should include a complete description of the product and any other information, including, but not limited to, a bill of materials, parts listing, raw material selection and sourcing, and/or model names or numbers of items necessary

to describe the product and differentiate it from other products;

- Certification tests which are performed on samples of the manufacturer's consumer product to demonstrate that the product is capable of passing the tests prescribed by the standard;
- A production testing plan which describes the tests that must be performed and the testing intervals to provide reasonable assurance that the products as produced meet all applicable safety rules;
- A remedial action plan which must be employed whenever samples of the consumer product or results from any other tests used to assess compliance yield unacceptable or failing test results; and
- Documentation of the reasonable testing program and how it was implemented.

See 74 FR at 58613.

*Comments:* Most comments addressed the five elements of the reasonable testing program, either by suggesting that the Commission allow for some flexibility as to what constitutes a reasonable testing program or by suggesting specific exceptions or tests as part of a reasonable testing program.

Several comments expressed concern that many manufacturers may not be able to specify their products down to the component

or raw material level because proprietary information from offshore manufacturers may prevent importers from knowing every component of the products they purchase. One comment noted that importers typically do not control the production process of the products they import, so the Commission should define a reasonable testing program differently to address an importer's special circumstances.

Another comment suggested that "reasonable" for some products would involve less than the five elements outlined by CPSC in the notice for a reasonable testing program. For example, because some regulations require placement of a label, the comment said that "testing" in that circumstance would consist of observing that the label was placed properly.

One comment stated that any testing program that results in an acceptable confidence level that a product complies with the applicable standards should be considered an acceptable reasonable testing program. The comment also suggested that other items, such as factory certification (to recognized standards), audits, risk assessment plans, certification of a manufacturer's quality system, etc., should be allowed as elements of a reasonable testing plan.

One comment suggested allowing process capability testing, where, for a continuous-flow process, first-run samples are tested, as a form of certification testing. The comment urged

the Commission to allow a manufacturer to search "backwards" and "forwards" in continuous-flow process for good product in the event that a test during manufacturing shows noncompliance.

Several comments noted that, for seasonal or short-run products, only prototype samples may exist before production begins. Some comments stated that neither the same materials nor the same manufacturing processes were used to manufacture the prototype samples as would be used to manufacture the consumer product.

Multiple comments stated that the relative hazard should be a factor in determining the test frequency. Some stated that higher risks should necessitate a higher test frequency, and where the perceived risk is low, third party testing should not be mandatory for some products.

One comment suggested that a manufacturer's record of manufacturing products with low-lead levels should result in relaxed testing requirements.

One comment remarked on the differences between conformity assessment and certification. The comment suggested that CPSC regulations should clarify that a "reasonable testing program" means a conformity assessment process such as that in Annex A of ISO/IEC 17000 and describe the five elements in generic terms that avoid the implication that "testing" will always be the evaluation activity. This comment noted that the phrase

"production testing plan" is misleading in that only testing is anticipated, and would expand the interpretation to include activities certification bodies use to assess continuing compliance.

One comment said that the Commission must issue regulations clarifying what will constitute "unacceptable or failing" test results for product testing. Additionally, the comment stated that the Commission's regulations should explicitly allow for retesting prior to remanufacturing or redesigning. One comment specifically stated that the reasonable testing program should be implemented for children's products.

*Response:* The Commission believes that the five elements of a reasonable testing program are adaptable to manufacturers' and importers' circumstances, and are present in most testing programs even if some of the elements might seem trivial and can be accomplished with seemingly little effort. However, the five elements are essential and should be included to ensure a high degree of assurance of compliance to the applicable rules, bans, standards, or regulations.

For the product specification component of a reasonable testing program, a manufacturer is not required to specify every component or raw material of a product. The manufacturer is free to describe its product by model number, general

description, photograph, etc., as long as the product is identifiable and differentiable from other products.

The Commission agrees that other elements such as risk assessment plans, quality system certification, and factory certifications could be added to provide a manufacturer with a high degree of assurance that the product produced complies with all applicable requirements. However many methods suggested in the comments would require CPSC to assess and recognize or certify the certification services providers and require the manufacturer and importer to purchase these certification services. The approach in the proposed rule seeks to identify a method whereby a manufacturer or importer can independently establish a reasonable testing program and to establish a set of minimum requirements for these reasonable testing programs that reflects commonly used elements of a quality assurance/quality control system. If process capability testing can ensure with a high degree of assurance that the product is capable of meeting the applicable rules, bans, standards, or regulations, that form of testing can be used for certification testing. Similarly, techniques used during production to ensure, with a high degree of assurance, that all continuing production is compliant can be considered as acceptable production testing plans.

For children's products, section 14(a)(2) of the CPSA requires manufacturers to submit "sufficient samples of the

children's product, or samples that are identical in all material respects to the product," to third party conformity assessment bodies for testing. A prototype manufactured with different materials or manufacturing processes than the finished product cannot be considered the same in all material respects as the finished product with respect to compliance. Therefore, section 14(a)(2) of the CPSA does not allow for testing of prototype samples unless they are identical in all material respects to the finished product. The proposed rule would extend the requirement to test only prototype samples that are identical in all material respects to the finished product that will be imported for consumption, warehoused, or distributed in commerce to manufacturers of non-children's products under section 14(a)(1) of the CPSA.

While the Commission agrees that a higher risk level should necessitate a greater testing frequency, it should be noted that risk and potential severity are not indicators of the level of compliance to the legal standards, regulations, rules, and bans. Section 14 of the CPSA does not allow for the exclusion of any children's product from third party testing based on a perceived low level of risk. Thus, regardless of other existing means of determining compliance, products must be tested for compliance to the applicable rules, bans, standards, or regulations.

As for the conformity assessment process in ISO/IEC 17000, the Commission does not consider it to be equivalent to a reasonable testing program. In sections 14(a) and 14(d)(2)(B) of the CPSA, testing is specifically mentioned as the evaluation activity. Thus, regardless of other means of determining compliance, products must be tested for compliance to the applicable rules. The conformity assessment process mentioned in Annex A of ISO/IEC 17000 includes attestations in its principles of conformity assessment. However, the CPSA requires the manufacturer to perform the attestation that its products comply with the applicable rules. If the manufacturer uses a third party conformity assessment body to conduct the testing of its products, then the determination and attestation functions would be performed by two separate parties. Thus, the conformity assessment process in ISO/IEC 17000 is not equivalent to the reasonable testing program mentioned in CPSA section 14(a). However, the certification testing and the production testing plan in the reasonable testing program do allow a wide latitude of actions in determining initial and continuing compliance to the applicable rules for a product.

Test results that indicate noncompliance to the applicable rules are unacceptable or failing test results. Retesting, as a general matter, should not be allowed because doing so may tempt unscrupulous parties to attempt to "test the product into

compliance," (i.e., to repeat testing a product until a sample passes the test and then reject the earlier unacceptable or failing test results). The intent of section 14 of the CPSA is to conduct tests to provide assurance that all the products being imported, warehoused, or distributed in interstate commerce comply with all applicable rules.

## *2. Flexibility in Testing*

*Comments:* Many comments stressed the need for flexibility in test protocols. Some comments stated that the types of products are so varied that no one prescribed system could be devised to effectively and efficiently apply to all of them. Other comments noted that determining the number of samples to be tested should be left to the manufacturer, who has intimate knowledge of the product's manufacturing process, to decide.

*Response:* The Commission agrees that it is difficult to develop rigid protocols for testing across all categories of products, manufacturers, and importers. A manufacturer may tailor the tests to the needs of the individual product, and the tests do not need to be the same tests that are specified in the applicable rules, provided that they are at least as effective in assessing compliance. The proposed rule would leave decisions on procedures, such as the number of samples to test, up to the manufacturer provided that the testing plan provides a

high degree of assurance that noncompliant products are not introduced into the stream of commerce.

### *3. Existing Testing Programs*

*Comments:* One comment asked if the Toy Safety Certification Program initiated by the Toy Institute of America (TIA) could be accepted as a reasonable testing program under section 14(a)(1) of the CPSA. Two other comments recommended that CPSC recognize the value of industry-specific certification programs prescribing testing methods for a product category and verifying conformance. Another two comments suggested that CPSC should consider the testing requirements in existing product safety standards to be acceptable in meeting the requirements of section 14 the CPSA, including existing regulations with their own reasonable testing program requirements. One comment noted that, unless the Commission can show that current industry testing programs are insufficient, no prescribed reasonable testing program should be implemented. One comment stated that CPSC should establish a safe harbor enforcement policy regarding recognized programs. The comment noted that an enforcement policy that accepts participation in such programs as demonstrable good faith, without imposition of civil or criminal liability under CPSIA's expanded penalty limits, could act to promote participation in effective certification programs.

*Response:* Manufacturers will need to ensure that any reasonable testing program, whether they are industry-specific programs or not, also conforms to the requirements of the CPSA and any implementing regulations promulgated by the Commission. If, in a manufacturer's determination, a prescribed testing program ensures with a high degree of assurance that all products distributed in commerce will comply with the applicable rules, then the manufacturer is free to choose that program for its product. CPSC cannot generally consider all pre-existing testing regulations to be acceptable for purposes of complying with section 14 of the CPSA. For example, pre-existing CPSC regulations may not mandate third party conformity assessment body testing for children's products because those pre-existing CPSC regulations were promulgated before the CPSIA's enactment. Further, nothing in section 14(a)(1) or 14(b) of the CPSA, nor section 3 of the CPSIA, which gives the Commission the authority to issue regulations to implement the CPSIA, requires the Commission to find industry testing programs to be insufficient before implementing a reasonable testing program.

The proposed rule would not include any provision for a "safe harbor" enforcement policy based on a manufacturer's participation in a voluntary or industry-sponsored program, nor has the Commission recognized any such program as indicating compliance within the requirements of the proposed rule.

Section 14 of the CPSA does not contain a "safe harbor" exception nor does it establish any criteria by which the Commission could "recognize" testing programs for purposes of a "safe harbor."

#### *4. Random Samples*

In the FEDERAL REGISTER notice announcing the public workshop, the Commission explained that section 14(d)(2)(B)(ii) of the CPSA refers to the "testing of random samples to ensure continued compliance" and asked (among other things), "What constitutes a 'random' sample?" See 74 FR at 58614. At the workshop itself, CPSC staff presented a statistically-based rationale for selecting random samples.

*Comment:* Many comments suggested that the word "random" should not be interpreted by its strict statistical definition, but should be adapted to the product type, how it's manufactured, and its intended use. One comment stated that random should be interpreted to mean free from overt selection bias and that it is more important that a sample be reasonably representative of the population from which it is selected. One comment suggested that, with the assistance of industry, the CPSC should develop guidelines regarding the circumstances and elements to consider when determining what constitutes a reasonable random sample. One comment mentioned the problems

associated with random sampling of single-unit production and with very small production volumes (less than 10, for example). One comment noted that some manufacturing processes are of a continuous-flow type, and randomly selecting a sample would be disruptive to the production system. Another comment stated that products that are subjected to continuous testing with a specified frequency should be exempt from any additional random testing.

*Response:* The *Random House Dictionary of the English Language* defines "random sampling" as "a method of selecting a sample from a statistical population in such a way that every possible sample that could be selected has the same probability of being selected." The Commission believes that this is the most appropriate technical definition. It also seems more appropriate to use a definition where both terms (random and sampling) are defined together rather than two separate definitions, one of random and the second of sampling. More generally, terms such as a "representative" sample, a "non-fraudulent" sample, or a "non-golden" sample, do not have the underlying statistical attributes necessary to generalize about compliance of the untested portion of the product population from the tested samples.

With regards to small-volume production, periodic testing, of which random sampling is a feature, the proposed rule would

not require random sampling for production of less than 10,000 units. Regardless of how random sampling is defined, section 14(d)(2)(B) of the CPSA requires samples to be tested. The samples must be selected from products in production or supply and must be tested by a CPSC-recognized third party conformity assessment body.

Products manufactured in a continuous-flow process ultimately create individual products. If those products are subject to periodic testing, the requirement for random samples may constrain where in the manufacturing process periodic testing samples are selected. In general, products tests at a specific frequency are susceptible to transient events that could affect compliance and would be undetected. Random sampling has the capability of detecting such transients and is thus required to ensure continued compliance of the product.

##### *5. Challenges for Small Manufacturers/Low Volume Production*

In the FEDERAL REGISTER notice announcing the public workshop, the Commission asked, "What provisions (if any) should be made for small manufacturers and manufacturers with low production volumes and why?" See 74 FR at 58614. The Commission explained that specifying the frequency of periodic testing or the number of random samples to be tested may be

inappropriate where the volume of children's products being manufactured is low or where the children's product is one-of-a-kind.

*Comments:* Several comments were received specific to small manufacturers who may not have the technical, legal, or financial resources of large-volume manufacturers. One comment stressed the need for step-by-step guidance from the CPSC on how to follow the rules. Another comment noted that, for very small production volumes (often one or two custom items), testing of a representative sample should be allowed to suffice for all items. Two comments concurred with the draft Guidance Policy document text that did not require periodic testing for production volumes less than 10,000 units or once a year, whichever is less. One comment suggested, that due to the economic ramifications associated with the development of a reasonable testing program, the CPSC should convene a Small Business Regulatory Enforcement Fairness Act (SBREFA) panel for this rulemaking.

*Response:* While the Commission will provide general guidance on how to comply with the requirements of the CPSIA, manufacturers are responsible for fully understanding their manufacturing process and knowing how the regulations would apply to their products. Because there may be a disproportionate effect on small-volume manufacturers relative

to large-volume manufacturers, the proposed rule would not require periodic testing for production volumes of less than 10,000 units because certification and periodic testing costs are largely independent of manufacturing volume. Certification testing and testing after a material change are still required and may be performed on portions of the complete product or representative samples that are the same with respect to compliance as the complete product.

As for the comment regarding a SBREFA panel, the requirements for a SBREFA panel only apply to the Environmental Protection Agency and the Occupational Safety and Health Administration (OSHA).

#### *6. Verification of Third Party Conformity Assessment Bodies*

*Comments:* Several comments suggested that the CPSC, rather than manufacturers, should perform any verification of third party conformity assessment bodies. Another comment proposed that, upon demand by the CPSC, the conformity assessment body be required to produce a copy of the mandatory or voluntary standard against which the children's product is being tested, a copy of the test protocol used for the test procedure, and a copy of the test results that can be traced back to the specific sample tested. Another comment noted that variations in sample preparation by conformity assessment bodies can and do lead to

differing test results. One comment, noting lab-to-lab variations in test results for the same product, suggested that CPSC should require CPSC-recognized third party conformity assessment bodies to conduct blind correlation studies and lab audits. Another comment asserted that proficiency testing is the only true outside independent verification option for laboratories and should be limited to chemical tests only.

*Response:* The Commission's limited resources preclude CPSC from directly conducting verification of the numerous CPSC-recognized conformity assessment bodies. Additionally, the activities and requirements for accrediting conformity assessment bodies are outside the scope of this rulemaking.

The Commission acknowledges that variations in sample preparation can lead to some differences in test results. However, these variations should not be significant enough to alter the general determination of whether a product complies with the applicable children's product rule.

As for proficiency testing (by which the Commission means testing conducted by an independent evaluator of the competence of a "body" (organization, person, etc.) to perform specific tasks), the Commission considers proficiency testing to be one option for domestic manufacturers and importers to use for verification purposes. However, the requirements for verifying that a children's product complies with the applicable

children's product safety rules are not limited to only chemical tests.

*7. Protection of Conformity Assessment Bodies Against Undue Influence*

*Comments:* One comment suggested that provisions of ISO Guide 65 be used to prevent undue influence from being exerted over third party testing body by a manufacturer or private labeler. Other comments suggested that laboratory certification beyond ISO 17025 is neither productive nor necessary. Another comment suggested that the Commission should look to OSHA's Nationally Recognized Testing Laboratory (NRTL) program to ensure impartiality and prevent conflict of interest. One comment stated that CPSC should extend existing CPSC fines and penalties that the CPSC can currently impose on manufacturers and retailers to apply to exerting or attempting to exert undue influence on third party conformity bodies.

*Response:* ISO/IEC Guide 65 and OSHA's NRTL program both deal with certifying bodies that perform many functions in addition to the testing functions performed by third party conformity assessment bodies. The ISO/IEC 17025 certification system appears to be working as intended. There is no need to implement duplicative or additional requirements by requiring them in this proposed rule.

With regards to extending fines, section 19 the CPSA already addresses fines and penalties. Section 19(a)(4) of the CPSA prohibits any attempt to exercise undue influence on a third party conformity assessment body. Sections 20 and 21 of the CPSA establish monetary and criminal penalties for violations of section 19 of the CPSA.

#### *8. Certificates*

*Comments:* One comment urged the Commission to recognize the registered certification marks of recognized product certification bodies, like those accredited under the OSHA NRTL program for applicable product scopes, in lieu of paper certificates of conformity. Another comment asserted that the CPSC has no jurisdiction to issue certification regulations except as part of a reasonable labeling rule adopted under section 14 of the CPSA. The comment argued that section 14(a) of the CPSA gives the manufacturer the option to select its own form and medium to convey certification of compliance with a CPSC standard. Finally, the comment contended that section 14 of the CPSA does not authorize the Commission to adopt any rule prescribing the content of the certificate or method of its distribution. Another comment stated that the CPSC has no jurisdiction to require that a certificate be on a separate piece of paper that accompanies the product. The comment also

suggested that at least 180 days would be needed to comply with any new requirements.

*Response:* The Commission does not believe that registered certification marks, by themselves, would provide the information required for certificates under section 14 of the CPSA. With respect to children's products, third party conformity assessment bodies only test children's products for compliance with the applicable children's product safety rules. Third party conformity assessment bodies are not responsible for issuing certificates under section 14(a)(2) of the CPSA; to the contrary, under existing CPSC regulations, only domestic manufacturers and importers are required to issue certificates (see 16 CFR part 1110; see also 73 FR 68328 (November 18, 2008)).

Regarding the Commission's jurisdiction to issue certification regulations, the Commission has the authority to issue implementing regulations under section 3 of the CPSIA, which provides that "[t]he Commission may issue regulations, as necessary, to implement this Act and the amendments made by this Act." The Commission has not required certificates to be only in the form of a separate piece of paper. Certificates can be in electronic form.

As for the effective date of any final rule, the Commission intends that any final rule resulting from this rulemaking

become effective 180 days after its date of publication in the FEDERAL REGISTER. Interested parties who believe that the effective date should be longer or shorter should submit a comment to the proposed rule. The comment should include the specific facts on which they base their conclusion.

#### *9. Reliance on Test Results of Others for Certification*

##### *Purposes*

*Comments:* Two comments noted that a foreign manufacturer may supply the same product to several importers, who would then be required to test the same product. The comments considered such testing of the same product by multiple importers to be wasteful and inefficient. Another comment stated that importers of many products will be overburdened with testing costs, whereas manufacturers making one product can efficiently test their products. The comment added that the importer would still be responsible for the product's certificate, but would use test data furnished by the manufacturer. Finally, the comment noted that importers have little control over the design, manufacturing process, or sourcing of component parts, but manufacturers control all those aspects of production. Two other comments asserted that importers should be allowed to base their certificates on test reports and results of other entities. Another comment proposed that CPSC should recognize

the vendor's assumption of liability in making such certification and deem that retailers, importers and distributors of product subject to such certification may rely upon it without facing civil or criminal liability.

One comment asked for clarification for importers who rely on foreign manufacturers' certificates of conformity regarding what level of diligence can reasonably and effectively be exercised by the importers.

One comment recommended that ink manufacturers be allowed to group, test and certify product families for component testing because product families represent the same core formula. The comment asserted that product family certification provides a reasonable, economically viable, testing model for these ink manufacturers.

*Response:* While an importer is not required to commission testing itself and may use component part test reports from the manufacturer, the importer is responsible for issuing the certificate for a children's product (see 16 CFR part 1110.7(a)). The importer also must ensure that the proper testing was conducted (i.e., a CPSC-recognized third party conformity assessment body accredited for the correct test conducted the testing). The importer is ultimately responsible for ensuring that its product meets CPSC requirements. In those cases in which the importer has little or no control over the

manufacturing process and is relying on the manufacturers test data, the importer should take measures to understand the manufacturing and testing process. An importer needs to ensure that all necessary tests are conducted in an appropriate manner to ensure, with a high degree of assurance, that no noncompliant product is placed into commerce.

As for the comment regarding ink, an ink that has a similar base formula and varies only in color could contain some pigments that contain lead while the same base with different pigments others did not. Thus, families of inks cannot be grouped for compliance testing. However, the Commission has previously made a determination that CYMK inks do not need to be tested since they do not contain lead. See 16 CFR part 1500.91.

10. *Additional Third Party Testing Requirements for Children's Products*

*Comments:* One comment remarked that the Commission should offer guidance on the adequacy of specific programs to firms who request it. The comment also sought clarification on whether a test could be any reasonable, objective method for evaluating compliance with a standard. The comment suggested that any attempt to specify protocols and standards for testing children's products, such as sample size and frequency, should be tied to specific standards. The comment also expressed

interest in having the Commission provide a clearer definition of reasonable certainty, especially in the context of specific standards. Finally, the comment advised against attempting to establish any numerical standard, such as a specified confidence level with a specific number of samples to test.

Another comment requested that the Commission should provide reasonably specific guidelines with regard to both periodic testing frequency and sample size to be used in such testing. The comment suggested a period of at least twice per year or once every 50,000 units in any event, whichever occurs first. With regards to the sample size for periodic testing, the comment suggested (at least for toys) using the 12-unit sample size which has been the requirement of the CPSC Engineering Test Manual for many years as a starting point. A sample size of 18 pieces could be required for higher-risk products such as infant and toddler toys, and a lesser sample could be allowed for large, bulky, or expensive products to minimize cost.

Many comments asserted that risk should be factored into any testing program. A product that poses a higher level of risk should undergo closer scrutiny.

One comment provided a list of activities that would more precisely define a material change. The list included changes

in tooling, product materials, assembly method, or the manufacturing facility.

Another comment contended that once the children's product has passed its certification testing, periodic testing is not required, and that only a material change would require retesting.

One comment noted that first-party production testing is used extensively to control manufacturing and is effective in detecting problems that could lead to nonconforming products. The comment noted that that information can be used to reduce the number of samples required for periodic testing to one.

One comment suggested that, in establishing procedures and standards for periodic testing of children's products, CPSC should consider the potential for lead exposure in order to distinguish between products that pose a reasonable risk of noncompliance with the lead content limits and products that pose only a theoretical risk of noncompliance.

*Response:* Several existing CPSC regulations are product-specific, allowing the Commission to develop guidance for those particular manufactured goods. However, section 14(a) of the CPSA covers all products subject to a consumer product safety standard enforced by the Commission. In light of that fact, the CPSC cannot provide guidance for every product and every manufacturing process. For children's products, only a CPSC-

recognized third party conformity assessment body accredited to perform the required tests is allowed to test for compliance to the applicable children's product safety rules.

The proposed rule would consider non-conformity assessment body tests, such as production tests, process control measurements or other means of assessing compliance to be acceptable if they are as effective in discriminating compliance and noncompliance as the tests specified in the standards as part of a reasonable testing program. Neither the reasonable testing program for non-children's products nor the certification and periodic tests for children's products specify values for sample size or test frequency.

The Commission recognizes that no one-size-fits-all testing program will be sufficient for all manufacturers. The proposed rule would state that if the manufacturer establishes testing programs with sufficient rigor and with testing parameters such as test frequency and the number of samples per test specified such that, if the samples from a production population pass their tests, there is a high degree of assurance that all the untested products in the population will also comply with the applicable product safety rules. If a high degree of assurance is defined to be a statistical likelihood of not producing noncompliant products, the sample size for periodic testing will depend upon the number of samples that need to be tested to

provide that statistical assurance. The number of samples could be fewer than 12 or more than 18. The Commission agrees that products with a higher potential for injury or death should undergo greater scrutiny.

Because of the many types of children's products and manufacturing processes that will be covered by the rule, the description of the activities that would trigger additional third party testing due to material changes need to be described in general terms. A more general description gives manufacturers, who are experts in their product areas and are better suited to understand when a change in their product could affect the product's ability to comply with applicable rules, the flexibility to develop testing programs to suit their products and manufacturing operations. For children's products, section 14(d)(2)(B)(i) of the CPSA says explicitly that the rule is intended to establish protocols and standards to ensure that children's products are tested "periodically," as well as when there has been a material change to the product. Thus, even if no changes are made to a children's product, it must be tested periodically.

For children's products with a reasonable testing program, it may be possible to show that one periodic test sample verifies and validates the program. However, for children's products without a reasonable testing program, in order for

third party testing to provide a high degree of assurance that all products produced comply with the rule, the Commission believes that testing only a single sample would not be acceptable. Other than the exceptions for lead that are specified in section 101 of the CPSIA, all children's products are required to be tested for lead content.

11. *Labeling Program*

As stated earlier in part A of this document, section 14(d)(2)(A) of the CPSA requires the Commission to initiate a program by which a manufacturer or private labeler may label a consumer product as complying with the certification requirements. This provision applies to all consumer products that are subject to a product safety rule administered by the Commission.

*Comments:* One comment recommended that the Commission not initiate a labeling program because it will contribute to confusion within the small business community about the tracking label. Another comment suggested that the Commission should provide examples of allowable text for such labels, but should not have specific requirements for things such as size, color, font or location as these will depend on the product. The comment further noted that it would be a huge burden to impose specifications such as "label" text or size.

One comment noted that some children's products currently must contain a label and that label should be considered sufficient. Two comments stated that, if a consumer compares a children's product with a label stating compliance to all applicable rules to a comparable product with no applicable rules (and thus no label), the absence of the label will be misperceived as noncompliance by the consumer and will thus disadvantage the second product. One comment suggested that the label requirement be harmonized as best as possible with existing federal regulations such as U.S. Customs and Border Production country of origin labeling (19 U.S.C. 1304 and 19 CFR part 134.33) and the Federal Trade Commission's Textile and Wool Products Identification Act's fiber content labeling requirements (15 U.S.C. 70 and 16 CFR part 303). Another comment said that the use of the label should be restricted to identifying the manufacturer/importer and the batch to help facilitate and narrow the scope of recalls. One comment suggested that there needs to be accommodations or exclusions for products that are impossible to mark that are similar to exclusions provided in the J list of the U.S. Customs and Border Protection regulations for country of origin markings or products that would be destroyed by marking. One comment urged CPSC to include the certification requirements of section 14(a) of the CPSA on a label on the product.

*Response:* Section 14(d)(2)(A) of the CPSA requires the Commission to initiate a program by which a manufacturer or private labeler may label their products as complying with the certification requirements. The staff's suggested text and format for the label will make it easier for consumers, small businesses, and any other interested party to notice it, understand its meaning, and distinguish it from tracking labels. Varying the text and the font size and style on the label could lead to greater confusion in understanding than a consistent label. Because the use of the label is optional for manufacturers, similar-looking products, or even units of the same product may or may not contain the label. The label is intended to show compliance with CPSC certification requirements. It is not intended to be a tracking label or demonstrate compliance with laws or regulations administered by other federal agencies. The comment suggesting the Commission should include the certification requirements of section 14(a) of the CPSA on a label on the product is outside the scope of the labeling program in the proposed rule which is being promulgated pursuant to section 14(d)(2)(A) of the CPSA. Additionally, on November 18, 2008, the Commission issued a rule (see 16 CFR part 1110; see also 73 FR 68328) addressing the requirements for certificates under section 14(a) of the CPSA.

12. *Comments outside the scope of the rule*

*Comments:* Several comments addressed issues pertaining to specific tests or other provisions in the CPSIA, such as tracking labels and the interpretation of statutory definitions.

Several comments suggested that X-ray fluorescence (XRF) technology should be an acceptable method to test for the presence of lead.

Two comments suggested that CPSC require a hazard analysis of children's products if manufacturers are permitted to perform the analysis themselves without a third party check of the results.

One comment would interpret the CPSIA's definition of "children's product" as a product with which a child plays.

One comment suggested that the CPSC tracking label require the name of the manufacturer or importer, the production date, the compliance identifier, and the model number.

One comment said that the electronic availability of certificates should satisfy the "accompany" and "furnish" requirements as opposed to requiring a paper certificate. One comment stated that the CPSC cannot require the certificate to contain the specific week of manufacture or the particular unit of equipment used to manufacture the product.

One comment argued that the Commission has no jurisdiction over architectural glass (e.g., glass used in windows and doors).

*Response:* Because these comments address issues that are unrelated to reasonable testing programs, continued testing of children's products, and labels to show that a product complies with the certification requirements in section 14(a) of the CPSA, they are outside the scope of this rule. Consequently, we decline to address them here.

### **C. Description of the Proposed Rule**

The proposal would create a new part in Title 16 of the Code of Federal Regulations: Part 1107, titled "Testing and Labeling Pertaining to Product Certification." The new part 1107 would consist of four subparts: Subpart A would be "General Provisions"; Subpart B would be the requirements for a "Reasonable Testing Program for Non-Children's Products"; Subpart C would be the requirements for "Certification of Children's Products"; and Subpart D would be the requirements for a "Consumer Product Labeling Program."

#### *1. Proposed Subpart A General Provisions*

##### *a. Proposed § 1107.1 - Purpose*

Proposed § 1107.1 would state that part 1107 establishes the requirements for: a reasonable testing program for non-

children's products; third party conformity assessment body testing to support certification and continuing testing of children's products; and labeling of consumer products to indicate that the certification requirements have been met pursuant to sections 14(a)(1), and (a)(2), (d)(2)(B) of the CPSA (15 U.S.C. 2063(a)(1), (a)(2), (d)(2)(B)).

b. Proposed § 1107.2 - Definitions

Proposed § 1107.2 would state that unless otherwise stated, the definitions of the Consumer Product Safety Act and the Consumer Product Safety Improvement Act of 2008 apply to this part. Proposed § 1107.2 also would define certain terms or abbreviations for purposes of part 1107. For example, with respect to abbreviations, proposed § 1107.2(a) would define "CPSA" to mean the Consumer Product Safety Act. Proposed § 1107.2(b) would define "CPSC" to mean the Consumer Product Safety Commission.

Proposed § 1107.2(c) would define "detailed bill of materials" to mean a list of the raw materials, sub-assemblies, intermediate assemblies, sub-component parts, component parts, and the quantities of each needed to manufacture a finished product.

Proposed § 1107.2(d) would define "due care" to mean the degree of care that a prudent and competent person engaged in

the same line of business or endeavor would exercise under similar circumstances.

Proposed § 1107.2(e) would define "high degree of assurance" to mean an evidence-based demonstration of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture. The terms "high degree of assurance" appear in several proposed provisions, and so the concept of what constitutes a "high degree of assurance" would be important for purposes of interpreting and complying with certain proposed sections. We considered several alternative definitions for a high degree of assurance. One alternative definition would be, for quantitative tests, where a high degree of assurance would be at least a 95% probability that all the product produced meets the requirements of the applicable rules; for non-quantitative (pass/fail) tests, a high degree of assurance could mean a 95% confidence that at least 95% of the product produced meets the requirements of the applicable rules. The 95% level is widely used in the natural and social sciences as the minimum acceptable probability for determining statistical significance and has been found to be effective. However, we recognized that defining a "high degree of assurance" as a 95% or greater probability could result in greater testing demands on small manufacturers. For example, for a non-quantitative test, a method such as the "rule of

three" could be used to determine the number of samples needed for testing. For a 95% confidence that no more than 5% of the production fails to comply,  $3/0.05 = 60$  units will be needed for testing. For small production volumes where 60 samples would be considered excessive, alternative methods would be needed. Thus, we decided against defining "high degree of assurance" with respect to a 95% probability or confidence level because there may be difficulty in applying the statistical methods to all manufacturing processes. We invite comment on possible amendments or revisions to the proposed definition of "high degree of assurance."

Proposed § 1107.2(f) would define "identical in all material respects" to mean there is no difference with respect to compliance to the applicable rules between the samples and the finished product.

Proposed § 1107.2(g) would define "manufacturing process" to mean the techniques, fixtures, tools, materials, and personnel used to create the component parts and assemble a finished product.

Proposed § 1107.2(h) would define "production testing plan" to mean a document that shows what tests must be performed and the frequency at which those tests must be performed to provide a high degree of assurance that the products manufactured after certification continue to meet all the applicable safety rules.

Proposed § 1107.2(i) would define "third party conformity assessment body" to mean a third party conformity assessment body recognized by the CPSC to conduct certification testing on children's products.

*2. Proposed Subpart B - Reasonable Testing Program for Non-Children's Products*

Proposed subpart B would consist of one provision and would describe the "reasonable testing program" for non-children's products.

*a. Proposed § 1107.10 - Reasonable Testing Program for Non-Children's Products*

Proposed § 1107.10(a) would state that, except as otherwise provided in a specific regulation under this title or a specific standard prescribed by law, a manufacturer certifying a product pursuant to a reasonable testing program must ensure that the reasonable testing program provides a high degree of assurance that all consumer products covered by the program will comply with all applicable rules, bans, standards or regulations. The proposed exception for specific regulations or standards prescribed by law is meant to recognize that certain pre-existing CPSC regulations or previously voluntary standards which, by statute, are now considered to be mandatory consumer product safety standards or are to be adopted as mandatory

standards may have specific testing requirements or protocols. The reasonable testing program requirements under proposed § 1107.10, are not intended to repeal or revoke those pre-existing testing requirements.

A reasonable testing program serves as the basis for issuance of the general conformity certification for non-children's products unless the manufacturer conducts a test of each product. A reasonable testing program is a program that, when structured with appropriate specifications, measurements, controls, and test intervals, will provide a high degree of assurance that all consumer products manufactured under the reasonable testing program will comply with all the requirements of the applicable rules.

The manufacturer is responsible for establishing a reasonable testing program because it is necessary to support the issuance of a general conformity certificate where a test of each product is not undertaken. All the elements of the reasonable testing program should be in place, and certification tests completed with passing results before a general conformity certificate can be issued for a product.

Several existing non-children's product standards issued by the Commission already contain product-specific testing programs that were developed by the Commission at the time the standard was issued and for which certification was required prior to the

enactment of the CPSIA. For existing rules that contain testing requirements, and do not contain specific testing programs, the reasonable testing program establishes the minimum set of requirements to be met for certification. For the remaining applicable rules, the implementation of reasonable testing programs will vary depending on the product under consideration and the compliance characteristics being tested. Persons issuing general conformity certificates should exercise due care in developing and implementing a reasonable testing program that demonstrates that their products comply with the applicable rules.

Commission staff examined existing CPSC regulations, such as the regulations pertaining to omnidirectional citizens band base station antennas, walk-behind lawn mowers, and automatic residential garage door openers, and selected common features of existing reasonable testing programs that CPSC has found to be effective. The proposed elements of a reasonable testing program would be necessary to demonstrate a product's compliance at the time of certification and as production of the product continues after certification. Because the requirement for a reasonable testing program would apply to a wide variety of product types and manufacturing processes, it is designed to be scalable to production volumes and adaptable to the specifics of the product. A manufacturer may develop the scope and details

of each element of a reasonable testing program based on the manufacturer's knowledge and expertise regarding the product and its manufacturing processes.

The Commission's primary concern is ensuring that manufacturers produce safe and compliant products. Testing is not an end in itself, but rather one part of a process to ensure the safety of consumer products. For this reason, the Commission believes the primary objective in a reasonable testing program is determining whether or not a manufacturer produces safe and compliant products. When CPSC staff discovers unsafe or noncompliant products, CPSC may have reason to examine a manufacturer's programs and processes. Because the Commission recognizes that even the best processes can occasionally yield noncompliant products, the Commission is especially concerned about unsafe or noncompliant products emerging from defective processes.

Proposed § 1107.10(b) would describe the five elements that a reasonable testing program must contain. Proposed § 1107.10(b)(1) would state that a reasonable testing program must have a product specification. The product specification would contain a description of the consumer product and lists the applicable rules, bans, standards or regulations to which the product is subject. A product specification should describe the product listed on a general conformity certification in

sufficient detail to identify the product and distinguish it from other products made by the manufacturer. Proposed § 1107.10(b)(1) would state that the product specification may include, but is not limited to, a color photograph or illustration, model names or numbers, a detailed bill of materials, a parts listing, raw material selection and sourcing requirements. Proposed § 1107.10(b)(1)(i) would state that a product specification must include any component parts that are certified pursuant to 16 CFR Part 1109. (Elsewhere in this issue of the FEDERAL REGISTER, the Commission is issuing a proposed rule regarding component part testing.) Proposed § 1107.10(b)(1)(ii) would state that product specifications that identify individual features of a product as not being materially different may use the same product specification for all products manufactured with those specific features. Features that would be considered as being not materially different include different product sizes, use of different colors, or other features that covers physical variations of the product where those physical variations do not affect the product's ability to comply with applicable rules. For example, several sizes of the same article of clothing made with the same materials would not be considered to materially different. Proposed § 1107.10(b)(1)(iii) would state that each manufacturing site must have a separate product specification

regardless of whether the product is identical in all material respects to a product manufactured at another site. This would be required because a manufacturer cannot assume that units of the same product manufactured in more than one location are identical in all material respects.

Proposed § 1107.10(b)(2) would state that a manufacturer must conduct certification tests on a product before issuing a general conformity certificate for that product. Certification tests provide evidence that a product identified in a product specification complies with the applicable rules, bans, standards, or regulations. Certification tests are required as part of a reasonable testing program in lieu of a test of each product. Proposed § 1107.10(b)(2) would state that a certification test would be a test performed on samples of the product that are identical to the finished product in all material respects to demonstrate that the product complies with the applicable safety rules. Proposed § 1107.10(b)(2) would require certification tests to contain certain elements.

Proposed § 1107.10(b)(2)(i) would state that, for purposes of proposed § 1107.10, a sample means a component part of the product or the finished product which is subjected to testing. Samples submitted for certification testing would be required to be identical in all material respects to the product to be distributed in commerce. The manufacturer would be required to

submit a sufficient number of samples for certification testing so as to provide a high degree of assurance that the certification tests accurately represent the product's compliance with all applicable rules.

Proposed § 1107.10(b)(2)(i)(A) would only allow finished products or component parts listed on the product specification to be submitted for certification testing. Proposed § 1107.10(b)(2)(i)(B) would allow a manufacturer to substitute component part testing for finished product testing pursuant to 16 CFR Part 1109 unless the rule, ban, standard or regulation applicable to the product requires testing of the finished product. If a manufacturer relies upon certification testing of component part(s) (rather than tests of the finished product), the manufacturer would be required to demonstrate how the combination of testing of component part(s), portions of the finished product, and finished product samples demonstrate, with a high degree of assurance, compliance with all applicable rules, bans, standards, or regulations.

Proposed § 1107.10(b)(2)(ii) would state that a material change is any change in the product's design, manufacturing process, or sourcing of component parts that a manufacturer exercising due care knows, or should know, could affect the product's ability to comply with the applicable rules, bans, standards, or regulations. Proposed § 1107.10(b)(2)(ii)(A)

would state that when a previously-certified product undergoes a material change that only affects the product's ability to comply with certain applicable rules, bans, standards, or regulations, certification for the new product specification may be based on certification testing of the materially changed component part, material, or process, and the passing certification tests of the portion of the previously-certified product that were not materially changed. For example, if a material change is limited to using a different paint on the product, new certification testing of that product may be limited to evaluating the paint to the applicable safety rules. Proposed § 1107.10(b)(2)(ii)(B) would require a manufacturer to conduct a certification test of the finished product if a material change affects the finished product's ability to comply with an applicable rule, ban, standard, or regulation. Proposed § 1107.10(b)(2)(ii)(C) would require a manufacturer to exercise due care to ensure that reliance on anything other than retesting of the finished product after a material change occurs does not allow a noncompliant product to be distributed in commerce. A manufacturer should resolve any doubts in favor of retesting the finished product for certification.

Proposed § 1107.10(b)(3) would explain that a production testing plan describes what tests must be performed and the frequency at which those tests must be performed to provide a

high degree of assurance that the products manufactured after certification continue to meet all the applicable safety rules, bans, standards, or regulations. A production testing plan may include recurring testing or the use of process management techniques designed to control potential variations in product manufacturing that could affect the product's ability to comply with the applicable rules, bans, standards, or regulations. Proposed § 1107.10(b)(3)(i) through (iii) would require a production test plan to contain the following elements:

- A description of the production testing plan, including, but not limited to, a description of the tests to be conducted or the measurements to be taken, the intervals at which the tests or measurements will be made, the number of samples tested, and the basis for determining that such tests provide a high degree of assurance of compliance if they are not the tests prescribed in the applicable rule, ban, standard, or regulation.
- A separate production testing plan for each manufacturing site, regardless of whether the product is identical in all material respects to that manufactured at each site; and
- Production testing intervals selected to be short enough to ensure that, if the samples selected for

production testing comply with an applicable rule, ban, standard, or regulation, there is a high degree of assurance that all the untested products manufactured during that interval also will comply with the applicable rule, ban standard, or regulation. Production test intervals should be appropriate for the specific testing or alternative measurements being conducted.

Proposed § 1107.10(b)(3)(iii)(A) would allow a manufacturer to use measurement techniques that are non-destructive and tailored to the needs of an individual product instead of conducting product performance tests to assure a product complies with all applicable rules, bans, standards, or regulations. For example, a manufacturer may have determined that by controlling the particle size and water content of cellulose insulation, it is possible to determine compliance to the cellulose insulation critical radiant flux test (16 CFR part 1209.6) by examination of a sample of a fixed volume under a graduated microscope and measuring its weight. Sizes and weights within certain limits mean that the insulation will pass the critical radiant flux test. As another example, a certifier may choose to determine compliance to the requirements for garage door opener photoelectric sensors (16 CFR part 1211.11) by placing the sensor in a fixture with a calibrated light flux, then measuring

the response voltage of the light-sensitive element directly. An element output voltage above a threshold would indicate passing performance for the tests described in the safety standard. Proposed § 1107.10(b)(3)(iii)(B) would require any production test method used to conduct production testing to be as effective in detecting noncompliant products as the tests used for certification. Proposed § 1107.10(b)(3)(iii)(C) would state that if a manufacturer is uncertain whether a production test is as effective as the certification test, the manufacturer must use the certification test. For example, if the probability that all production products are compliant using the tests methods used for certification is 95%, the probability that all production products are compliant using alternative testing methods should be at least 95%. If there is uncertainty that the test method will not achieve the same level of detection of compliance, then the specific tests required by the applicable rules should be used. Proposed § 1107.10(b)(4) would describe the remedial action plan. Proposed § 1107.10(b)(4)(i) would state that a remedial action plan describes the steps to be taken whenever samples of a product or a component part of a product fails a test or fails to comply with an applicable rule, ban, standard, or regulation. A remedial action plan would be required to contain procedures the manufacturer must follow to investigate and address failing test results. Manufacturers

would be required to take remedial action after any failing test result to ensure with a high degree of assurance that all products manufactured after the remedial action has been taken comply with the applicable rules, bans, standards, or regulations. The type of remedial action may differ depending upon the applicable rule, ban, standard, or regulation.

Proposed § 1107.10(b)(4)(i) would also state that a remedial action can include, but is not limited to, the following:

- Changes to the manufacturing process, the equipment used to manufacture the product, the product's materials, or design;
- Reworking the product produced; or
- Other actions deemed appropriate by the manufacturer, in the exercise of due care, to assure compliant products.

Proposed § 1107.10(b)(4)(ii) would state that any remedial action that results in a material change to a product's design, parts, suppliers of parts, or manufacturing process that could affect the product's ability to comply with any applicable rules would require a new product specification for that product.

Before a product covered by the new product specification can be certified as compliant with the applicable rules, bans, standards, or regulations, a manufacturer would be required to have passing certification test results for the applicable rules, bans, standards, or regulation.

Proposed § 1107.10(b)(5) would impose recordkeeping requirements to document the reasonable testing program. Documentation is necessary to establish the identity of the product, and to demonstrate that the product complies with the applicable rules, when it is certified and on a continuing basis as production progresses. Documentation supports the validity of a general conformity certificate and provides validation that a test of each product produced is not necessary.

Proposed § 1107.10(b)(5)(i)(A) through (b)(5)(i)(E) would identify the records that a manufacturer of a non-children's product would be required to maintain. In brief, these records would be:

- Records of the general conformity certificate for each product;
- Records of each product specification;
- Records of each certification test and, if the manufacturer elected to have a third party conformity assessment body test the product, identification of any third party conformity assessment body on whose testing the certificate depends. Records of certification test would be required to describe how the product was certified as meeting the requirements, including how each applicable rule was evaluated, the test results, and the actual values of the tests;

- Records to demonstrate compliance with the production testing plan requirement, including a list of the applicable rules, bans, standards, or regulations, a description of the types of production tests conducted, the number of samples tested, the production interval selected for performance of each test, and the test results. Records of a production test program would be required to describe how the production tests demonstrate that the continuing production complies with the applicable rules. References to techniques in relevant quality management and control standards, such as ANSI/ISO/ASQ Q9001-2008: Quality management systems - Requirements, ANSI/ASQ Z1.4-2008: Sampling Procedures and Tables for Inspection by Attributes, and/or ANSI/ASQ Z1.9-2008: Sampling Procedures and Tables for Inspection by Variables for Percent Nonconforming, would be allowed to demonstrate that the production tests have the necessary accuracy, precision sensitivity, repeatability, and confidence to distinguish between compliant and noncompliant products. These standards are widely-recognized in industry and were developed by organizations with international exposure and millions of members. Retaining test results can help identify the events that led to the creation of noncompliant products,

the number of products affected, and their disposition;  
and

- Records of all remedial actions taken, including the specific action taken, the date the action was taken, the person who authorized the actions, and any test failure which necessitated the action. Records of remedial action would be required to relate the action taken to the product specification of the product that was the subject of that remedial action and the product specification of any new product resulting from any remedial action.

Proposed § 1107.10(b)(5)(ii) would require a manufacturer to create a new set of records for a product if a remedial action results in a new product specification.

Proposed § 1107.10(b)(5)(iii) would require a manufacturer to maintain the records specified at the manufacturer's main office. The manufacturer would be required to make these records available for inspection by the CPSC upon request.

Proposed § 1107.10(b)(5)(iv) would require a manufacturer to maintain records (except for test records) for as long as the product is being distributed in commerce plus three years. The proposal also would require test records to be maintained for three years and all records to be available in the English language. Records are required for three years to ensure that products have time to clear the distribution channels and get

into consumer use. If there is a compliance problem or defect in a product, three years should provide sufficient time to uncover any problems with the product. The Commission's staff would have time to obtain the records to review the firm's reasonable testing program and take any necessary enforcement action during this three-year period.

Proposed § 1107.10(c) would state that, if any certification test results in a failure, a manufacturer cannot certify a product until the manufacturer has taken remedial action, and the product manufactured after the remedial action passes certification testing.

Proposed § 1107.10(d) would state that a manufacturer of a non-children's product may, but is not required to, use a third party conformity assessment body to conduct certification testing. The third party conformity assessment body would not have to be a third party conformity assessment body recognized by the CPSC to conduct certification testing on children's products.

Proposed § 1107.10(e) would state that manufacturers of children's products may voluntarily establish a reasonable testing program consistent with this subpart.

### *3. Proposed Subpart C - Certification of Children's Products*

Proposed subpart C would contain the requirements pertaining to the certification of children's products. The subpart would consist of eight sections, and most sections would implement the requirements in section 14(d)(2)(B) of the CPSA.

a. Proposed § 1107.20 - General Requirements

Proposed § 1107.20(a) would require manufacturers to submit a sufficient number of samples of a children's product, or samples that are identical in all material respects to the children's product, to a third party conformity assessment body for testing to support certification. The proposal would not specify the exact number of samples to be tested; instead, the proposal would require that the number of samples selected provide a high degree of assurance that the tests conducted for certification purposes accurately demonstrate the ability of the children's product to meet all applicable children's product safety rules.

Proposed § 1107.20(b) would state that, if the manufacturing process for a children's product consistently creates parts that are uniform in composition and quality, a manufacturer may submit fewer samples to provide a high degree of assurance that the finished product complies with the applicable children's product safety rules. If the manufacturing process for a children's product results in

variability in the composition or quality of children's products, a manufacturer may need to submit more samples to provide a high degree of assurance that the finished product complies with the applicable children's product safety rules. An example of a manufacturing process that consistently create highly similar parts would be die casting. Manufacturing processes with greater inherent variability may necessitate testing of more samples to provide a high degree of assurance that the finished product complies with the applicable children's product safety rules. An example of a manufacturing process with greater inherent variability would be hand assembly of the product.

Proposed § 1107.20(c) would state that, except where otherwise specified by a children's product safety rule, a manufacturer may substitute component part testing for finished product testing pursuant to 16 CFR part 1109 if the component part, without the remainder of the finished product, is sufficient to determine compliance for the finished product. For example, assume that a children's product is a cotton sweater with a metal zipper and that the manufacturer wishes to test the sweater for compliance to the lead limits in section 101 of the CPSIA. Because the Commission has determined that textiles, such as cotton, do not exceed the statutory lead limits, the manufacturer would only test the metal zipper for

lead rather than the cotton in the sweater. In this example, therefore, testing the component part (the metal zipper) is sufficient to determine the finished product's compliance with the lead limit.

Proposed § 1107.20(d) would state that, if a product sample fails certification testing, even if other samples have passed the same certification test, the manufacturer must investigate the reasons for the failure and take remedial action. A manufacturer would not be allowed to certify the children's product until the manufacturer establishes, with a high degree of assurance, that the finished product does comply with all applicable children's product safety rules.

b. Proposed § 1107.21 Periodic Testing

Proposed § 1107.21(a) would implement the periodic testing requirement in section 14(d)(2)(B)(i) of the CPSA by requiring all periodic testing to be conducted by a third party conformity assessment body. Each manufacturer would be required to conduct periodic testing at least annually, except as provided in proposed § 1107.21(d) (which we discuss later in this part of the preamble) or as provided in CPSC regulations. The proposal would allow manufacturers to conduct periodic tests more frequently than on an annual basis if they wish. More frequent periodic testing may help a manufacturer identify noncompliant

products more quickly and, as a result, may limit the scope of any potential product recall. In addition, more frequent testing may reduce the manufacturer's liability for civil penalties resulting from a noncompliant product, reduce potential damage to a manufacturer's reputation, and increase the manufacturer's confidence in the effectiveness of the periodic testing.

Proposed § 1107.21(b) would state that, if a manufacturer has implemented a reasonable testing program as described in subpart A of this part, the manufacturer may conduct third party periodic testing on a less frequent basis. The proposal would not specify how less frequently such periodic testing may occur, and the Commission invites comment on this concept.

Proposed § 1107.21(c) would state that, if a manufacturer has not implemented a reasonable testing program, the manufacturer must conduct periodic testing as follows:

Proposed § 1107.21(c)(1) would require the manufacturer to develop a periodic test plan to assure that children's products manufactured after the issuance of a children's product certification, or when the previous periodic testing was conducted, continue to comply with all applicable children's product safety rules. The periodic test plan would have to include the tests to be conducted, the intervals at which the

tests will be conducted, the number of samples tested, and the basis for determining that the periodic testing plan provides a high degree of assurance that the product being tested continues to comply with all applicable children's product safety rules. The proposal would require the manufacturer to have a separate periodic testing plan for each manufacturing site producing a children's product.

Proposed § 1107.21(c)(2) would require the periodic testing interval selected to be short enough to ensure that, if the samples selected for periodic testing pass the test, there is a high degree of assurance that all other untested children's products manufactured during the interval comply with the applicable children's product safety rules. The interval for periodic testing may vary depending upon the specific children's product safety rules that apply to the children's product. For example, the intervals selected to test for small parts where there is variability in the factors assuring that no small parts are created, and for lead in paint, where one tested container is used for a large production volume, may not be the same. Assuring that products do not generate small parts may require more frequent testing than that required to assure that the paint used does not contain lead in excess of the acceptable limits. The appropriate periodic testing interval may vary for a manufacturer depending on the manufacturer's knowledge of the

product and its manufacturing processes. Under proposed § 1107.21(c)(2)(i) through (c)(2)(v), factors to be considered when determining the period testing interval would include, but not be limited to:

- High variability in test results, as indicated by a relatively large sample standard deviation in quantitative tests;
- Measurements that are close to the allowable numerical limit for quantitative tests;
- Known manufacturing process factors which could affect compliance with a rule. For example, if the manufacturer knows that a casting die wears down as the die nears the end of its useful life, the manufacturer may wish to test more often as the casting die wears down;
- Consumer complaints or warranty claims; non-material changes, such as manufacturing or component part/subassembly lot changes and fixed volume production;
- Potential for serious injury or death resulting from a noncompliant children's product;
- The number of children's products produced annually, such that a manufacturer should consider testing a children's product more frequently if the product is produced in

very large numbers or distributed widely throughout the United States;

- The children's product's similarity to other children's products with which the manufacturer is familiar and/or whether the children's product has many different component parts compared to other children's products of a similar type would be a factor to be considered when determining a periodic test interval; and
- The inability to determine the children's product's non-compliance easily through means such as visual inspection.

Proposed § 1107.21(c)(3) would pertain to the periodic testing frequency for low-volume manufacturers. In brief, the proposal would not require a manufacturer to conduct periodic testing until it produces 10,000 units of a product after the time a third party conformity assessment body tested the children's product for certification purposes or conducted periodic testing. The low-volume exception would apply to small manufacturers and importers with low production volume and also to large manufacturers or importers producing small amounts of particular children's products. (See Appendix A of the *Memorandum Requirements for Certification and Continued Testing of Children's Products, Established by the Consumer Product Safety Improvement Act of 2008* from Randy Butturini, Office of

Hazard Identification and Reduction, for Commission staff's rationale for selecting the 10,000 number).

c. Proposed § 1107.22 - Random Samples

Proposed § 1107.22 would implement the testing of random samples requirement in section 14(d)(2)(B)(ii) of the CPSA by requiring each manufacturer to select samples for periodic testing by using a process that assigns each sample in the production population an equal probability of being selected. We recognize that there are alternative approaches for deciding whether something represents a "random" sample. One alternative approach would be to say that a random sample is a sample not intentionally identified beforehand for testing. Another possible approach would be to require only that a random sample adequately represent the production sample pool from which it was chosen. The Commission chose neither alternative because the purpose of random sampling is to establish a basis for inferring compliance about a population of untested products from a set of tested products. If the products selected for testing are not randomly selected, there is no statistical basis for inferring the compliance of the untested products. Manufacturers may select additional samples based on the manufacturer's knowledge of the product and its production to provide greater assurance of compliance. For example, if a certifier knows its control over compliance degrades with

continuing production, the manufacturer may always test the last unit produced. Proposed § 1107.22 would state that the production population is the number of products manufactured or imported after the initial certification or last periodic testing of a children's product. Proposed § 1107.22 would allow a manufacturer to use a procedure that randomly selects items from a list to determine which samples are the random samples for testing before production begins. For example, if the planned production quantity in a period is 50,000, and 12 random samples are to be selected for periodic testing, before the products are manufactured, a random process would have to identify which 12 of the 50,000 will be selected for periodic testing. Manufacturers that produce products that continue to be distributed in commerce as they are manufactured may wish to test the random samples as they are selected to minimize the potential quantity of noncompliant products if a test has failing test results.

Proposed § 1107.22 would allow manufacturers to select samples for testing as they are manufactured. Proposed § 1107.22 would allow manufacturers who produce children's products that continue to be distributed in commerce as they are manufactured to test the samples as they become available instead of waiting until all the random samples have been selected before conducting testing.

d. Proposed § 1107.23 - Material Changes

Proposed § 1107.23 would implement the requirement in section 14(d)(2)(B)(i) of the CPSA to test a children's product when a material change has occurred. Proposed § 1107.23(a) would state that if a children's product undergoes a material change in product design or manufacturing process, including the sourcing of component parts, that a manufacturer exercising due care knows or should know that such material change could affect the product's ability to comply with the applicable children's product safety rules, the manufacturer must submit a sufficient number of samples of the materially changed product for testing by a third party conformity assessment body. Such testing would be required before a manufacturer could certify the children's product. The extent of such testing would depend on the nature of the material change. Proposed § 1107.23(a) would state that, when a material change is limited to a component part of the finished children's product and does not affect the ability of the children's product to meet other applicable children's product safety rules, a manufacturer may issue a children's product certificate based on the earlier third party certification tests and on test results of the changed component part conducted by a third party conformity assessment body. For example, if the paint is changed on a children's product, the

basis for issuing a children's product certificate may be based on previous product testing and on tests of the new paint for compliance to lead, heavy metal, and phthalate concentrations.

Proposed § 1107.23(a) also would state that changes that cause a children's product safety rule to no longer apply to a children's product are not considered to be material changes. For example, assume that a children's product consists of a cotton sweater with metal buttons and that the children's product would be subject to the lead limits in section 101 of the CPSIA. If the manufacturer decided to use wood buttons instead of metal buttons, the use of wood buttons would eliminate the need to test the product for lead, and the change to wood buttons, while arguably a change in the product's component parts, would not be a "material change" under proposed § 1107.23(a).

Proposed § 1107.23(a) would also require a manufacturer to exercise due care to ensure that reliance on anything other than retesting of the finished product after a material change would not allow a noncompliant children's product to be distributed in commerce. A manufacturer should resolve any doubts in favor of retesting the entire product for certification. Additionally, a manufacturer would be required to exercise due care to ensure that any component part undergoing component-part-level testing

is the same as the component part on the finished children's product in all material respects.

Proposed § 1107.23(b) would state that, for purposes of proposed subpart B, the term "product design" includes all component parts, their composition, and their interaction and functionality when assembled. To determine which children's product safety rules apply to a children's product, a manufacturer should examine the product design for the children's product as received by the consumer. For example, if a children's product has a component part that contains lead or has a sharp edge, but is inaccessible when the product is assembled, then the lead and sharp edge requirement would not be applicable to the complete product. Changes to a product's design may result in a product being subject to additional children's product safety rules. For example, if a wooden button on a children's product is replaced with a plastic button, the wooden button previously excluded from testing for lead content has been replaced with a component part that would be subject to testing for compliance with the lead content requirements.

Proposed § 1107.23(c) would state that a material change in the manufacturing process is a change in how the children's product is made that could affect the finished children's product's ability to comply with the applicable rules. For each

change in the manufacturing process, a manufacturer should exercise due care to determine if compliance to an existing applicable rule could be affected or if the change results in a newly-applicable rule. The following are some examples of a material change to the manufacturing process of a children's product:

- A new technique is used to fasten buttons to a doll's dress which could affect the children's products ability to comply with the small parts rule;
- New solvents are used to clean equipment employed in the manufacture of children's products; the new solvents could affect the children's products ability to comply with the lead content and phthalates requirements, and;
- A new mold for an accessible metal component part of a children's product is introduced into the assembly line which could affect the children's products ability to comply with requirements for sharp edges.

Proposed § 1107.23(d) would state that a material change in the sourcing of component parts results when the replacement of one component part of a children's product with another component part that could affect compliance with the applicable children's product safety rules. This would include, but is not limited to, changes in component part composition, component

part supplier, or the use a different component part from the same supplier who provided the initial component part.

e. Proposed § 1107.24 - Verification

Proposed § 1107.24 would implement the requirement in section 14(d)(2)(B)(iii) of the CPSA for verifying that a children's product tested by a conformity assessment body complies with applicable children's product safety rules. Proposed § 1107.24(a) would state that a manufacturer is responsible for verifying that its children's products, as tested by a third party conformity assessment body, comply with applicable children's product safety rules. For purposes of proposed § 1107.24, "verification" would mean testing that demonstrates that the test results from one third party conformity assessment body are consistent with the test results from another third party conformity assessment body for a particular children's product. Proposed § 1107.24(a) would require a manufacturer to send samples of a previously certified children's product or a children's product that previously has been tested periodically pursuant to proposed § 1107.21 to a third party conformity assessment body for verification. Proposed § 1107.24(a) would not allow the third party conformity assessment body conducting tests for verification purposes to be the same third party conformity assessment body that previously

certified the children's product as compliant or the same third party conformity assessment body that conducted the last periodic test for the children's product.

Proposed § 1107.24(b) would require verification to occur on a reoccurring basis and be conducted at a frequent enough interval to provide a high degree of assurance that the children's product that had been certified previously continues to comply with the applicable children's product safety rules or that the periodic test for the children's product was performed correctly. The proposal would not specify a minimum frequency for verification and would not require verification to occur at the same time for all applicable children's product safety rules or be performed by the same alternate third party conformity assessment body. A manufacturer would be allowed to use periodic test results to support verification if an alternate third party conformity assessment body conducts the periodic test.

Proposed § 1107.24(c) would state that if a third party conformity assessment body conducting tests to verify a children's product's compliance with applicable children's product safety standards finds that a children's product fails a children's product safety standard, the manufacturer would be required to investigate the cause(s) for the failure. If, after conducting its investigation, the manufacturer concludes that a

third party conformity assessment body's (whether the third party conformity assessment body that conducted the tests to support a certification for the children's product or a third party conformity assessment body that conducted the verification test), test results were in error, the manufacturer must notify CPSC and describe the occurrence in an electronic mail (email) message to the Assistant Executive Director, Office of Hazard Identification and Reduction at [labaccred@cpsc.gov](mailto:labaccred@cpsc.gov).

f. Proposed § 1107.25 - Undue Influence

Proposed § 1107.25(a) would implement the requirement to safeguard against undue influence, pursuant to section 14(d)(2)(B)(iv) of the CPSA, by requiring each manufacturer to establish procedures to safeguard against the exercise of undue influence by a manufacturer on a third party conformity assessment body.

Proposed § 1107.25(b)(1) would require the procedures established under proposed § 1107.25(a) to include, at a minimum:

- Safeguards to prevent attempts by the manufacturer to exercise undue influence on a third party conformity assessment body, including a written policy statement from company officials that the exercise of undue influence is not acceptable, and directing that

appropriate staff receive annual training on avoiding undue influence

- A requirement to notify the Commission immediately of any attempt by the manufacturer to hide or exert undue influence over test results; and
- A requirement to inform employees that allegations of undue influence may be reported confidentially to the Commission and to describe the manner in which such a report can be made.

g. Proposed § 1107.26 Remedial Action

Proposed § 1107.26(a) would require each manufacturer of a children's product to have a remedial action plan that contains procedures the manufacturer must follow to investigate and address failing test results. A manufacturer would be required to take remedial action after any failing test result to ensure, with a high degree of assurance, that all children's products manufactured after the remedial action has been taken comply with the applicable rules.

Proposed § 1107.26(b) would not permit a manufacturer to certify a product if any certification test by a third party conformity assessment body results in a failure, until the manufacturer has taken remedial action and the product

manufactured after the remedial action passes certification testing.

Proposed § 1107.26(c) would require a manufacturer whose children's product has received a failing test result to take remedial action to ensure, with a high degree of assurance, that the children's product complies with all applicable children's product safety rules. The proposal would state that remedial action can include, is not limited to, redesign, changes in the manufacturing process, or changes in component part sourcing. For existing production, remedial action may include rework, repair, or scrap of the children's product. A manufacturer would be required to have a third party conformity assessment body retest the redesigned or remanufactured product for the manufacturer to be able to certify the product. The proposal also would require a manufacturer to prepare a new product specification for any remedial action that results in a material change in the product design, parts, suppliers of parts, or manufacturing process. A third party conformity assessment body must conduct certification testing for a product covered by a new specification after the manufacturer has completed remedial action.

#### h. Proposed § 1107.27 Recordkeeping

Proposed § 1107.27(a)(1) would require children's product manufacturers to maintain records of the children's product certificate for each product. The children's product covered by the certificate would be required to be clearly identifiable and distinguishable from other products. Additionally, proposed § 1107.27(a)(2) through (a)(7) would require children's product manufacturers to maintain records of:

- Each third party certification test and have separate certification tests records for each manufacturing site;
- The periodic test plan and periodic test results for a children's product;
- Descriptions of all material changes in product design, manufacturing process, and sourcing of component parts, and the certification tests run and the test values;
- Verification of third party test results;
- The undue influence procedures, including training materials and training records of all employees trained on these procedures; and
- All remedial actions taken following a failing test result, including the rule that was tested, the specific remedial action taken, the date the action

was taken, the person who authorized the action, any test failure which necessitated the action, and the results from certification tests showing compliance after the remedial action was taken.

Proposed § 1107.27(b) would require a manufacturer to maintain the records at the manufacturer's main office. The proposal also would require manufacturers to make these records available for inspection by the CPSC upon request.

Proposed § 1107.27(c) would require a manufacturer to maintain records (except for test records) for as long as the product is being distributed in commerce plus 3 years. Test records would be required to be maintained for 3 years. All records would be required to be available in the English language.

#### *4. Proposed Subpart D Consumer Product Labeling Program*

##### *a. Introduction*

Proposed subpart D, consisting of one section, would implement the label provision at section 14(d)(2)(A) of the CPSA. Section 14(d)(2)(A) of the CPSA requires the Commission to initiate a program by which a manufacturer or private labeler may label a consumer product as complying with the certification requirements in section 14(a) of the CPSA.

b. Proposed § 1107.40 Labeling consumer products to indicate that the certification requirements of section 14 of the CPSA have been met

Proposed § 1107.40(a) would allow manufacturers and private labelers of a consumer product to indicate, by a uniform label on or provided with the product, that the product complies with any consumer product safety rule under the CPSA, or with any similar rule, ban, standard or regulation under any other act enforced by the CPSC.

Proposed § 1107.40(b) would require the label to be printed in bold typeface, using an Arial font of not less than 12 points, be visible and legible, and state **"Meets CPSC Safety Requirements."**

The Commission considered whether a shorter label statement would adequately convey the intended message and concluded that it would not. Acronyms such as "CPSIA" or "CPSA" were considered. However, the Commission concluded that the meaning of the acronym might not be known to a sufficient number of people. Further, even those persons who might know what the acronyms stood for would not necessarily know why it was marked on the label or product. The acronym "CPSC" might be more widely recognized, but viewers still may not know why it is present. Further, the Commission does not want the presence of a "CPSC" marking on a label, package, or product to give the

impression that the CPSC has tested, approved, or endorsed the product.

The Commission also considered the statement "Meets CPSC Requirements," but this statement did not seem very informative for persons who did not recognize the term "CPSC." Inserting the word "safety" to form the statement "Meets CPSC Safety Requirements" would convey the message that the product met some safety requirements, even to those persons who are not familiar with CPSC. Giving the full name of the CPSC would make the statement too long to be practical in some cases, and the length could discourage viewers from reading the message. Therefore, the proposal would have the statement say "Meets CPSC Safety Requirements" to indicate that the product has been certified by the manufacturer or private labeler as complying with all applicable safety requirements enforced by CPSC.

Proposed § 1107.40(c) would allow a consumer product to bear the label if the manufacturer or private labeler has certified, pursuant to section 14 of the CPSA, that the consumer product complies with all applicable consumer product safety rules under the CPSA and with all rules, bans, standards, or regulations applicable to the product under any other act enforced by the Consumer Product Safety Commission.

Proposed § 1107.40(d) would allow a manufacturer or private labeler to use another label on the consumer product as

long as such label does not alter or mislead consumers as to the meaning of the label described in proposed § 1107.40(b). A manufacturer or private labeler would not be allowed to imply that the CPSC has tested, approved, or endorsed the product.

#### **D. Regulatory Flexibility Act**

##### *1. Introduction*

The Commission has examined the impact of the proposed rule under the Regulatory Flexibility Act (5 U.S.C. 601-612). The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The Commission has conducted an initial regulatory flexibility analysis of the proposed rule regarding the potential impact on small entities.

##### *2. Objectives and Legal Basis for Proposed Rule*

The Commission is proposing this rule to implement sections 14(a) and 14(d)(2)(A) and (B) of the CPSA, as amended by the CPSIA. The objective of the rule is to reduce the risk of injury from consumer products, especially from products intended for children aged 12 years and younger. The rule will accomplish this objective by requiring that manufacturers of non-children's products that are subject to product safety rules to develop and maintain a reasonable testing program that provides a high degree of assurance that their products conform

to all the applicable safety standards. For children's products, an additional layer of protection is provided by requiring that certain testing be performed by a CPSC-recognized third party conformity assessment body. The proposed testing programs should allow manufacturers to discover noncompliant products and take the necessary corrective actions to keep noncompliant products from entering commerce or to remove them expeditiously if they have been introduced into commerce.

### *3. Number of Small Firms Affected*

The number of firms that could be impacted was estimated by reviewing every category in the North American Industrial Classification System (NAICS) and selecting those firms that manufacture or sell any consumer product that could be covered by a consumer product safety rule. These firms include any establishment that could manufacture or sell a non-children's product or children's products. Firms are classified by an NAICS code that describes their primary activity. Therefore, firms that might manufacture or import consumer products covered by a safety rule as a secondary or tertiary activity might not have been counted. There is no separate NAICS category for importers. Firms that import product might be classified as manufacturers, wholesalers, or retailers.

#### *a. Manufacturers*

According to the criteria established by the Small Business Administration (SBA), manufacturers are generally considered to be small entities if they have fewer than 500 employees. Table 1 shows the number of manufacturers that are classified by the NAICS categories that cover most children's and general use products that are subject to a product safety rule. Although there are more than 36,000 manufacturers that would be considered small in these categories, not all of these firms are engaged in manufacturing children's products or general use products that are subject to a consumer product safety rule. It would be expected that most of the firms engaged in *Doll, Toy, and Game* manufacturing produce some products that are intended for children age 12 and younger. On the other hand, *All Other Miscellaneous Chemical Product and Preparation Manufacturing* includes some products subject to consumer product safety rules such as matchbooks and fireworks, but also includes products that are not subject to consumer product safety rules, such as distilled water and hydraulic fluids. *All Other Miscellaneous Electrical Equipment and Component Manufacturing* includes consumer products such as garage door openers as well as non consumer products such as particle accelerators. The *Surgical Appliance and Supplies Manufacturing* category includes bicycle helmets, but most of the other products in this category are not under CPSC jurisdiction.

**Table 1: Manufacturers**

<b>NAICS Code</b>	<b>Description</b>	<b>Small Firms</b>	<b>Total Firms</b>
31411	Carpet and Rug Mills	261	284
31519	Other Apparel Knitting Mills (Outerwear, Underwear, and Sleepwear)	235	246
3152	Cut and Sew Apparel Manufacturing	9,313	9,388
3159	Apparel Accessories and Other Apparel Manufacturing	907	920
316211	Rubber and Plastic Footwear Manufacturing	52	56
316212	House Slipper Manufacturing	2	2
316219	Other Footwear Manufacturing	68	69
321911	Wood Window and Door Manufacturing	1,241	1,297
32551	Paint and Coating Manufacturing	1,042	1,093
325998	All Other Misc. Chemical Product and Preparation Manufacturing	957	1,045
326191	Plastics Plumbing Fixture Manufacturing	465	488
326299	All Other Rubber Product Manufacturing	633	681
332321	Metal Window and Door Manufacturing	1,071	1,138
332998	Enameled Iron and Metal Sanitary Ware Manufacturing	60	72
333112	Lawn and Garden Tractor and Home Lawn and Garden Equip. Mfg.	117	134
33422	Radio, Television Broadcasting and Wireless Comm. Equip. Mfg.	811	894
335222	Household Refrigerator and Home Freezer Manufacturing	12	18
335999	All Other Misc. Electrical Equipment and Component Mfg.	737	791
336991	Motorcycle, Bicycle, and Parts Manufacturing	456	466
33712	Household and Institutional Furniture Manufacturing	6,052	6,179
33791	Mattress Manufacturing	448	462
339113	Surgical Appliance and Supplies Manufacturing	1,601	1,691
33991	Jewelry and Silverware Manufacturing	2,737	2,752
33992	Sporting and Athletic Goods Manufacturing	1,886	1,930
33993	Doll, Toy and Game Manufacturing	763	776
339999	All Other Miscellaneous Manufacturing	4,440	4,499
	<b>Total Manufacturers</b>	<b>36,367</b>	<b>37,371</b>

Source: U.S. Census Bureau, 2006 County Business Patterns.

b. Wholesalers

Wholesalers would be impacted by the proposed rule if they import any children's products or general use products that are subject to a consumer product safety rule. Wholesalers that obtain their products strictly from domestic manufacturers or from other wholesalers would not be impacted by the proposed rule since the manufacturer would be responsible for testing and certifying the product. Table 2 shows the number of wholesalers by NAICS code that would cover most children's products and general use products that are subject to a consumer product safety rule. According to the SBA criteria, wholesalers are generally considered to be small entities if they have fewer than 100 employees. Although there are more than 77,000 wholesalers that would be considered small in these categories, not all of these firms are engaged in importing children's or general use products that are subject to a consumer product safety rule. A significant proportion of the firms classified as *Toy and Hobby Goods and Supplies Merchant Wholesalers* probably import at least some children's products. However, the only firms classified as *Motor Vehicle and Motor Vehicle Parts and Suppliers* would be those that import all terrain vehicles or

other off-road vehicles, especially those intended for children age 12 years and younger.

**Table 2. Wholesalers**

<b>NAICS Code</b>	<b>Description</b>	<b>Small Firms</b>	<b>Total Firms</b>
4231	Motor Vehicle and Motor Vehicle Parts and Suppliers	16,947	17,858
4232	Furniture and Home Furnishing Merchant Wholesalers	10,534	10,981
42362	Electrical and Electronic Appliance, Television, and Radio Set Merchant Wholesalers	2,147	2,269
42391	Sporting and Recreational Goods and Supplies Merchant Wholesalers	4,397	4,552
42392	Toy and Hobby Goods and Supplies Merchant Wholesalers	2,170	2,248
42394	Jewelry, Watch, Precious Stone, and Precious Metal Merchant Wholesalers	7,735	7,815
42399	Other Miscellaneous Durable Goods Merchant Wholesalers	10,146	10,367
42432	Men's and Boy's Clothing and Furnishings Merchant Wholesalers	3,235	3,393
42433	Women's, Children's, and Infant's Clothing, and Accessories Merchant Wholesalers	5,965	6,186
42434	Footwear Merchant Wholesalers	1,434	1,493
42499	Other Miscellaneous Nondurable Goods Merchant Wholesalers	12,497	12,753
	<b>Total</b>	<b>77,207</b>	<b>79,915</b>

Source: U.S. Census Bureau, 2006 County Business Patterns

c. Retailers

Retailers that obtain all of their products from domestic manufacturers or wholesalers will not be directly impacted by the proposed rule, since the direct impact of the proposed rule would be experienced by the manufacturer. However, there are some retailers that manufacture or directly import some products and, therefore, would be responsible for ensuring that these products are subjected to testing by CPSC-recognized third party conformity assessment body. The number of such retailers is not known. Table 3 shows the number of retailers by NAICS code that would cover most children's products. According to the SBA criteria, retailers are generally considered to be small entities if their annual sales are less than \$7 million (\$27 million in the case of *general merchandise stores*). Because of the way in which the data were reported, Table 3 shows the total number of firms in each of the categories that operated all year and the number with sales of less than \$5 million (\$25 million in the case of *general merchandise stores*). Although there are more than 125,000 that would be considered to be small businesses in these categories, it is not known how many of these firms are engaged in importing or manufacturing children's or general use products that are subject to a consumer product safety rule. Many of these firms probably obtain all of their products from domestic wholesalers or manufacturers and would not be directly impacted by the rule.

**Table 3. Retailers**

NAICS Code	Description	Small Firms	Total Firms
441221	Motorcycle, ATV, and Personal Watercraft Dealers	3,969	4,001
4421	Furniture Stores	16,282	17,542
44813	Children's and Infant's Clothing Stores	2,146	2,200
44814	Family Clothing Stores	5,998	6,240
4482103	Children's & juveniles' shoe stores	300	305
4483	Jewelry, luggage, & leather goods stores	16,341	16,778
45111	Sporting goods stores	14,451	14,831
45112	Hobby, toy, & game stores	4,832	4,903
452	General Merchandise Stores	7,387	7,494
45322	Gift, Novelty, and Souvenir Store	21,412	21,637
453998	All Other Misc. Store Retailers (except Tobacco Stores)	11,934	12,228
4542	Vending machine operators	4,081	4,278
45439	Other direct selling establishments	15,938	16,431
	Total	125,071	128,868

Source: U.S. Census Bureau, 2002 Economic Census, Release date 11/25/2005

#### 4. *The Potential Affects of the Proposed Rule*

##### a. Reasonable Testing Program

The proposed rule would require any manufacturer of a non-children's product to establish a reasonable testing program for the product unless they test every product. Most manufacturers probably have some quality control programs in place that are

intended to demonstrate that the products as manufactured meets the manufacturer's specifications, including their specifications for complying with any safety regulations. In some cases these programs would meet the requirements of the reasonable testing program as described in the proposed rule. Other manufacturers may have to modify their current programs to ensure that they meet the requirements of the proposed rule. For example, some manufacturers might have to modify their programs to ensure that the testing program adequately covers all consumer product safety rules that are applicable to their products. Some manufacturers might have to increase their testing frequency. Some manufacturers might have some informal testing programs that would have to be formalized and better documented. There may also be some manufacturers that do not have a program in place. These firms will have to develop a reasonable testing program from scratch.

Compliance with the proposed rule (assuming that the rule is finalized) would require a variety of professional skills on the part of manufacturers. Lawyers may be required to review CPSC regulations in order to determine which regulations are applicable to a product. Depending upon the specific product and the safety rules that are applicable to it, people with knowledge of subjects such as engineering and chemistry may be required to develop the product specifications, conduct the

certification tests, and to design a program for production testing. Statistical skills or statistical consultants may be required to determine the frequency, sample size, and collection method for production testing. For some production tests, professionals such as engineers or chemists might be required, depending upon the product safety rules applicable to the product. In some cases, the production tests could be carried out by the firm's production workers or technicians, perhaps working under the supervision of an engineer, chemist, or similar professional. When the manufacturer does not have the internal capability to perform some of the required production testing, the testing may need to be performed by a third party testing assessment body.

The cost to firms of complying with this provision of the proposed rule would depend upon the extent of the changes that firms will have to make to their existing testing programs. For firms that already have testing programs that would meet the requirements of the proposed rule, there could be no additional costs. For other firms, the cost of complying with the requirements of the proposed rule will depend upon several factors, including the characteristics of their products and the steps that the firm will have to take to comply with the requirements. Because of the wide variety of products and manufacturers that would be covered by the proposed rule and

because the characteristics of each product and the circumstances of each firm are different, the Commission cannot reliably estimate the cost to manufacturers of the reasonable testing program requirement of the proposed rule. The Commission invites comments that provide more information on the cost and other impacts of this requirement on manufacturers.

b. Third Party Testing of Children's Products

The proposed rule would establish requirements for the continued testing of children's products by third party conformity assessment bodies periodically and when there has been a material change in the products design or manufacturing process, including the sourcing of component parts.

Manufacturers will have to develop and maintain records that demonstrate compliance with the third party testing requirements. The Commission welcomes comment on these requirements, including comments on the possible burden that these recordkeeping requirements might impose.

It is expected that the cost of the third party testing requirements could have a significant impact on a substantial number of small entities. The cost of third party testing is influenced by many factors, including the amount and skill of the labor required to conduct the tests, the cost of the equipment involved, the cost of transporting the product samples to the test facility, and the geographic area where the tests

are conducted. Some tests require a substantial amount of time to conduct the tests including the preparation of the sample. It might take a couple of days, for example, to test a bicycle for compliance with the bicycle standard (16 CFR part 1512). Similarly, a chemist testing the lead content of a product might be able to test only a few components parts a day due to the amount of time required to prepare the samples and to clean and calibrate the equipment between tests.

It should be noted that the price that a given manufacturer pays for testing is often the result of negotiations between the testing laboratory and the manufacturer. Manufacturers that do a large volume of business with a testing laboratory can frequently obtain substantial discounts on the laboratory's normal charges, whereas manufacturers that do only a small volume of business may not.

Some information on the cost of third party testing for some of the applicable tests is provided below. The information was collected from a number of sources, including published price lists from some testing laboratories, conversations with representatives of testing laboratories, and actual invoices provided by consumer product manufacturers. The data are not based upon a statistically valid survey of testing laboratories. Additionally, the costs are only the costs that would be charged by the testing laboratory and do not include the costs of the

products consumed in destructive tests or the cost of shipping the samples to the laboratories.

i. Costs Associated with Various Third Party Tests

*Lead Content and Lead-in-Paint:* The cost per component part for testing for lead content and lead-in-paint using inductive coupled plasma (ICP) analysis will range from a low of about \$20 per test to more than \$100 per test. The lowest per unit cost represents a substantially discounted price charged to a particular customer by a laboratory in China and might not be typical. Within the United States, typical prices range from around \$50 to more than \$100 per test.

The cost of testing for lead content using x-Ray fluorescence (XRF) technology is significantly less expensive. Some firms have offered to screen products for lead content for as little as \$2 per test. These offers were generally directed to stores or businesses that wanted to check their inventory for conformity with the retroactive lead content requirements that were contained in the CPSIA. Some testing laboratories will charge for XRF testing at an hourly rate, which can be around \$100. Ten to 30 components parts can be tested in an hour. However, with the exception of some plastics, XRF is not acceptable for all certification purposes.

*Phthalates:* The cost of testing for phthalate content will range from around \$100 (a discounted price by a laboratory in

China) to about \$350. These are the costs per component part and include testing for all six of the prohibited phthalates specified in the CPSIA.

*Bicycle Standard:* According to one testing laboratory, it takes 1 to 2 days to test a bicycle. The estimated price for testing one bicycle may range from around \$700, if the testing is performed in China, to around \$1,100 if the testing is performed in the United States. A manufacturer that needs several models of bicycle tested at the same time might be able to obtain discounts from these prices. However, this does not include the testing of component parts for lead and phthalates, which would add to the costs of bicycle testing.

*Bicycle Helmets:* One laboratory quoted a price of \$600 for testing one model of a bicycle helmet to the CPSC bicycle helmet standard. A price list from another laboratory stated that conducting the certification testing to the Snell Foundation's bicycle helmet standard (which is similar to the CPSC standard, but considered by some to be more stringent) was \$830.

*Full-Size Cribs:* As with bicycles, testing cribs requires a substantial amount of labor time to assemble the crib, take the appropriate measurements and perform the required tests. The cost of testing a full-size crib will be around \$1,200 in the United States. The cost can vary depending on the features of the individual cribs that require testing and between

laboratories. Some manufacturers might receive discounted prices. This does not include testing the crib for lead and phthalates, which, to the extent necessary, would add to the cost of testing a crib to all applicable safety rules.

*Toys:* The ASTM F963 toy standard was made a mandatory standard by the CPSIA. The standard includes a wide variety of tests, including tests for soluble heavy metals in surface coatings and for various physical and mechanical criteria. Based on the itemized prices on several invoices from testing laboratories that have been provided to CPSC staff or otherwise made public the cost of the physical and mechanical tests range from about \$50 to \$245. The cost of the chemical test for the presence of heavy metals ranges from about \$60 to \$190 per surface coating. Again, these costs do not include testing for lead and phthalates, which add to the total cost.

The flammability requirements of ASTM F963 were not made mandatory by the CPSIA, but the Commission was directed to examine the flammability requirements and consider promulgating rules addressing the issue. If some flammability tests are eventually required, the cost per test could be in the range of \$20 to \$50 based on some observed costs for the ASTM F963 flammability tests.

ii. Cost of Third Party Testing by Product

The cost to obtain the required third party testing for a product depends on the types and number of tests that must be performed on each product, the size of the sample that is required to provide a high degree of assurance that all products comply with the applicable safety rules, and the extent to which component part testing can be used. Because of the wide variety of manufacturers, and importers, and products that would be affected by the proposed rule, we cannot provide comprehensive estimates of the impact of the proposed rule on all products or firms. The discussion immediately below is intended to provide some perspective on the potential impact. The Commission invites additional public comments on the discussion. The Commission invites comments and more specific information on the impact and cost of the third party testing requirements of the proposed rule.

The third party testing costs discussed in this section apply to the costs associated with either the periodic testing requirement or the requirement that additional third party testing be obtained if there is a material change in the product's design or manufacturing process. However, in the latter case, the testing might be limited to those rules where compliance might have been impacted by the change.

*Number of units for testing:* The proposed rule would require the manufacturer to submit enough units to the

conformity assessment body to provide a high degree of assurance that the products in that production lot comply with the applicable product safety rules. The exact number will depend upon the characteristics of the product, the lot size, whether the tests produce quantitative or qualitative data, whether the product has an established reasonable testing program, and the interpretation of a high degree of assurance. A discussion of the statistical aspects of designing a sampling plan was presented by Dr. Michael Greene of the CPSC staff at the Product Testing Workshop on December 10, 2009.

Quantitative testing data is data where the relevant variable can be measured with some degree of precision. For example, the lead content of a substance can be measured in terms of parts per million (ppm). Qualitative data is where the outcome of a test is simply a "pass" or a "fail." For example, in a drop test the result might simply be whether a sharp edge was exposed (a "fail") or a sharp edge was not exposed (a "pass"). When the data is qualitative, the sample size will usually have to be larger than when the data is quantitative.

For example, as of August 14, 2011 the lead content of children's products must be no greater than 100 ppm unless the Commission determines that a limit of 100 ppm is not technologically feasible for a product or product category. If a high degree of assurance means at least a 95% probability that

all products are in compliance and a manufacturer is testing a component part for lead content, then the manufacturer could determine the appropriate sample size if it knew the mean lead content of the component part, the standard deviation about the mean, and the size of the lot that was to be tested. Table 4 shows the sample sizes that would be required to provide a high degree of assurance for different lot sizes by mean and standard deviation (assuming a normal distribution). Larger sample sizes would be required for products with higher means, larger standard deviations, and larger lot sizes. Smaller sample sizes would be required for products with lower means, standard deviations and lot sizes.

**Table 4.** Sample Sizes Required to Provide at Least 95% Probability that the Lot is Compliant (given the availability of quantitative test data).

Mean (ppm)	Standard Deviation (ppm)	Lot Size (units)	Sample Size (units)	Probability that the Lot is Compliant
10	1	1,000	4	.998
10	1	2,500	4	.995
10	1	10,000	4	.992
10	1	25,000	5	.978
10	1	50,000	5	.957
15	3	1,000	5	.993

15	3	2,500	5	.983
15	3	10,000	6	.992
15	3	25,000	6	.981
15	3	50,000	6	.962
35	5	1,000	6	.965
35	5	2,500	7	.976
35	5	10,000	8	.972
35	5	25,000	9	.978
35	5	50,000	9	.957

Where only qualitative (e.g., pass/fail) testing data is available, the sample sizes needed to provide a high degree of assurance will be higher than those in Table 4. Such tests include some of the use and abuse tests for testing children's products (e.g., the drop test). As discussed by Dr. Michael Greene at the CPSIA Product Testing Workshop, more samples may be necessary because there is more uncertainty in the test data. In other words, with only pass/fail data, it is not known if the result was close to the threshold or far from the threshold. In these cases, it might be necessary to define a high degree of assurance as a probability that no more than a given proportion of noncompliant products. For example, as discussed by Dr. Greene at the Product Testing Workshop, a 95% probability that no more than a certain proportion "p" of the units in a lot do

not comply is approximately given by the formula  $p \approx 3/k$ , where "k" is the sample size. Thus, if 50 items were tested and no noncompliant items were found, there is a 95% probability that no more than 6% of the items in the lot do not comply. In other words, if the lot size were 1,000 and 50 units were tested and no noncompliant product were found, there is a 95% probability that no more than 60 units in the entire lot are not in compliance. If the lot size were 10,000 units, there would be a 95% probability that no more than 600 of the products would be noncompliant. If a higher level of assurance were required, the sample size would have to be larger. If a lower level of assurance were acceptable the sample size could be smaller.

The examples in Table 4 illustrate the disproportionate impact that the proposed rule could have on small businesses or businesses with low-volume products. In the first example in Table 4, the same number of units would have to be submitted to a third party testing conformity assessment body whether 1,000 units or 10,000 units were in the lot. In other words, the total third party testing costs would be the same, but the cost per unit for a manufacturer producing only 1,000 units would be 10 times the cost per unit for a manufacturer producing 10,000 units.

The examples in table 4 also illustrate the potential that component part testing could offer for reducing the cost of

testing. For example, assume a manufacturer produces five products in lots of 10,000 units, but uses a common component part on each of the products that it purchases in lots of 50,000, the manufacturer could conduct the applicable chemical tests on the component part rather than on the finished product. If, following the sample sizes in Table 4, the mean of the component was 10 and the standard deviation was 1, this would reduce the cost of testing that component part by a factor of four over the cost that would apply if only tests on the finished product were acceptable. This is because without component part testing, the manufacturer would have had to conduct tests on the component part as it was used in each of the five products. If each product were produced in lots of 10,000 units, this would amount to four tests on the component for each product or 20 total tests on the same component part. With component part testing, the manufacturer could simply conduct the tests on the component part, which was assumed to be purchased in a lot of 50,000 units, which would only require five tests of the component to provide a 95% probability that all of the units in the lot were in compliance.

*Random Samples:* The proposed rule would require that samples for periodic testing for children's products be selected randomly. A random sample is one in which each unit has an equal chance of being included in the sample. The proposed rule

would specify that each unit produced or imported by the firm since the last random sample was drawn must have an equal chance of being selected. There will be some additional cost associated with selecting a random sample rather than a convenience sample. The Commission invites comments on this proposed provision and is especially interested in comments describing the cost or other burdens that this proposed provision would impose.

### iii. Hypothetical Product Testing Examples

To provide some information on what the magnitude of the third party testing costs may be for some manufacturers of children's products, this section discusses the potential cost of obtaining third party testing for two product categories: bicycles and toys. These examples are hypothetical and are intended to illustrate some potential cost implications of the proposed rule but might not be representative of every manufacturer in each category. The costs per test that are assumed in the examples can vary significantly. The Commission invites any comments that provide better information on the potential impacts on individual manufacturers.

*Bicycles:* Children's bicycles must be tested for compliance with the CPSC bicycle standard, which was estimated above to cost between \$700 and \$1,100. Additionally, the paint used on the bicycle must be tested for compliance with the lead-in-paint

standard and the accessible component parts on the bicycle must be tested for lead content. The number of paints and component parts that require testing can vary among different models, but information provided by CPSC Compliance staff suggests that 75 components parts might be a reasonable estimate for the average. This example will use estimates in the middle of these ranges for the testing costs discussed above and assume that the cost of testing to the bicycle standard is \$900 and the cost for testing a component part for lead content is \$50. It is further assumed that quantitative data is available for all applicable tests and that the variation is low enough that testing four units will provide the high degree of assurance desired that products comply with the applicable safety rules. To the extent that some of the tests in the bicycle standard might be qualitative in nature, the sample size for testing would need to be larger.

If component part testing is not available to this manufacturer, the cost of testing the bicycle to each applicable safety rule one time would be about \$4,650 (testing to the bicycle standard itself at \$900 and testing 75 components parts for lead content). If a sample of four units were required to be tested to provide the required high degree assurance, then the cost of the third party testing to the manufacturer would be \$18,600.

The manufacturer in this example might be able to reduce the testing costs with component part testing if some of the components parts were used on more than one model. If component part testing reduced the cost of the lead content testing by this manufacturer by a factor of four, then the cost of testing to the bicycle standard itself would still be \$900, but the average cost of testing the lead content of the component parts would be reduced to \$12.50 per component part. Therefore the cost of testing the bicycle once would be \$1,837.50. The cost to test four units to provide the required high degree of assurance would be \$7,350.

The total cost of the third party testing to the manufacturer would depend upon the number of youth model bicycles that the manufacturer offered. If the manufacturer had five different models, and if component part testing could reduce the costs of the lead-content testing by a factor of four, the total cost of the third party testing to the firm would be about \$36,750.

*Toys:* Toys are subject to the requirements for lead and phthalate content, and to several physical and mechanical requirements, including the requirements of ASTM F963, which was made a mandatory standard by the CPSIA. In this example, it is assumed that the testing costs are at the low to middle part of the ranges and that the hypothesized toy contains one metal

component part that must be tested for lead content using ICP analysis (at \$50) and two plastic component parts for which XRF analysis can be used for determining the lead content (two tests at \$6 each). The plastic component parts also must be tested for phthalate content (two tests at \$225 each). Additionally, it is assumed that the toy contains four different paints that must be tested for both lead content (\$50/test) and soluble heavy metals (\$125/test). Finally, it is assumed that the toy is subject to some mechanical requirements that include use and abuse testing for which only qualitative data is available at \$50 per test. Thus, the cost of testing this toy for compliance to each applicable rule one time would be \$1,262: \$1,212 is associated with the chemical (lead, heavy metal, and phthalate) testing and \$50 is associated with the mechanical testing (including use and abuse testing).

If the means and standard deviations of the lead, heavy metal, and phthalate contents of all of the product components parts are sufficiently low that testing four units could statistically provide the required high degree of assurance, then the cost the chemical testing for this toy would be \$4,848 (\$1,212 x 4). If the means or standard deviations of the lead, heavy metal, or phthalate content were higher, which is likely the case for some materials, more units might have to be tested

to provide the required high degree of assurance and the resulting cost would also be higher.

Because the testing data for mechanical requirements are qualitative in nature, the number of units that might have to be tested to provide the required high degree of assurance would be more than required for the chemical tests. If a high degree of assurance were considered to be a 95% probability that no more than 6% of the units in the lot did not comply, then 50 units would have to be tested. In this case, the cost of mechanical testing would be \$2,500 ( $\$50 \times 50$ ).

Combining the cost of the chemical tests and the cost of the tests for mechanical or physical requirements, the total cost to this hypothetical manufacturer to obtain the required high degree of assurance that all products complied with all applicable safety rules would be \$7,348. If, as in the bicycle example, component part testing could be used to reduce the cost of the chemical testing by a factor of four, then the total cost of testing the toy could be reduced to \$3,712 ( $\$4,848/4 + \$2,500$ ).

Again the total cost to the manufacturer would depend upon factors such as the complexity of the products, the variation in the materials used, the opportunities to use component part testing, and the number of different toys that were offered. For example, if the manufacturer offered five similar toys and

the third party testing costs were similar for each toy and component part testing allowed the manufacturer to reduce the costs of chemical testing by a factor of four, the total cost to the manufacturer for testing the toys would be \$18,560. The annual cost would be higher if the testing had to be repeated more than once annually or there were material changes in the design of the products or production processes during the year.

#### iv. Impact of Third Party Testing on Firms

Whether such costs would have a substantial adverse impact on a firm depends upon the individual circumstances of the firm. One factor that can give an indication of whether something will have a significant impact is the magnitude of the impact in relation to the revenue of the firm. A typical profit rate is about 5% of revenue. In other words, for every \$1 of revenue, only five cents might remain after paying all expenses. Therefore, a new cost that amounted to 1% of revenue could, all other things equal, reduce the profit by 20% and might be considered to be a significant impact by some firms. This would be consistent with what some other agencies consider to be significant. OSHA, for example, considers an impact to be significant if the costs exceed 1% of revenue or 5% of profit.

Using the toy example above, with component part testing, if the third party testing costs were spread over 10,000 units, the cost of the testing would be about \$0.37 per unit

(\$3,712/10,000). According to a toy industry representative, the average retail price of a toy is about \$8. However, depending upon the channels of distribution and the practices in the particular market or industry, the price that a manufacturer receives for a product can be less than half of what the product eventually sells for at retail. Therefore, if the manufacturer received \$4 for the toy that cost \$0.37 per unit to test, the third party testing costs would be 9.2% of revenue ( $\$0.37/\$4$ ) and could exceed the expected profit. Even if the manufacturer received \$30 per unit for the toy (which might indicate a retail price of around \$60 or more), the third party testing cost would still exceed 1% of the revenue per unit and might be considered to be a significant impact.

It is possible that the impact could be reduced if the manufacturer had an established reasonable testing program that met the requirements of the proposed rule and the manufacturer determined that a high degree of assurance did not require a statistical basis. In such cases, some manufacturers may determine that fewer periodic third party tests per rule than were assumed in the above example would provide sufficient evidence that the reasonable testing program was adequate to provide a high degree of assurance that all of the products complied with the applicable safety rules. For example, if the hypothetical manufacturer of the toy used in the above example

determined that obtaining one periodic third party test per applicable rule were sufficient, then the per unit testing cost (without any component testing) would be about \$0.13 (\$1,262/10,000). [However, it should be noted that testing a product for compliance with each applicable rule one time is likely to require that the manufacturer submit more than one sample of the product to the testing laboratory. This is because some required tests cannot be performed on the same sample that has been used for another test. For some chemical tests, it may be necessary to use more than one sample of the product to obtain enough of a component to test.] If the manufacturer received \$4 for each unit, then the periodic third party testing costs would amount to about 3.1% of revenue (\$0.13/\$4), which still could be considered to be a significant impact. If component part testing reduced the cost of the chemical tests by a factor of four, then the cost of the periodic third-party testing could be reduced to \$353 (\$50 + \$1,212/4) or about \$0.04 per unit, if 10,000 units were produced. This would be about 1% of revenue if the manufacturer received \$4 for each unit. This might be considered to be significant by some firms.

It should be noted, that the only costs considered in this hypothetical example is the cost of the third party testing. Any costs associated with the requirements for a reasonable testing program would be in addition to these costs and increase

the impact, as would any additional third party testing costs associated with material changes in the product's design, the manufacturing processes, or the sourcing of component parts. Other costs that were not considered were the cost of the samples consumed in the testing and the cost of shipping the samples to the third-party conformity assessment body.

v. Caveats and Possible Market Reactions to Third Party Testing Requirements

Manufacturers can be expected to react to a significant increase in their costs due to testing requirements in several ways. Some manufacturers might attempt to redesign their products to reduce the number of tests required, by reducing the features or the number of components parts used in their products. Manufacturers could also be expected to reduce the number of children's products that they offer or, in some cases, exit the market for children's products entirely. Some may go out of business altogether.

The requirement for third party certification testing could be a barrier to new firms entering the children's product market, unless they expect to have relatively high volume products. This could be especially important for firms that expected to serve a niche market, including products intended for children with special needs. The requirement for third party testing when there is a material change in a product's

design or manufacturing process could cause some small or low-volume manufacturers to forgo or delay implementing some improvements to a product's design or manufacturing process in order to avoid the cost of the third party testing.

The cost of testing some toys and other children's products could be higher than those in the above examples. The cost would be higher, for example, for products that had more components parts or where the variability in the test results was greater, which would require more samples to be tested. The cost of testing would also be higher if there was less opportunity for component part testing. The cost of testing could be lower for products that were subject to fewer safety rules or that contained fewer component parts. For some apparel articles, for example, the only tests required might be for lead content on some components parts for which component part testing might be permissible.

Although the above examples illustrate the potential for component part testing to reduce the costs of testing, it might not be an option for all products or manufacturers. Component part testing is most likely to be an option for component parts that are common to multiple products (e.g., paints, bolts of a standard size). The potential for component part testing to reduce the cost of testing would be less for products that have component parts that are unique to that product.

*5. Verifying that a Children's Product Tested by a  
Conformity Assessment Body Complies with Children's Product  
Safety Rules*

The proposed rule requires that manufacturers of children's products send samples of the same children's product to an alternate CPSC-recognized third party conformity assessment body for verification at a frequency that provides a high degree of assurance that the children's product complies with the applicable children's product safety rules. This provision would not affect the amount of third party testing required for children's products. While there may be some added costs associated with periodically finding and using a different third party conformity assessment body, the cost of this provision should not be significant for manufacturers.

*6. Protection Against Undue Influence*

The proposed rule would require all manufacturers of children's products to establish procedures to prevent attempts to exercise undue influence on a CPSC-recognized third party conformity assessment body and to report to the Commission immediately of any attempt by any interested party to exert undue influence over test results, and that employees are aware that they may report any allegations of undue influence to the Commission confidentially. There would be some cost to firms to develop the materials or training programs to comply with these

requirements. The Commission invites comments from the public providing information on the cost and other impacts of this provision.

#### *7. Consumer Product Labeling Program*

The consumer product labeling program that would be established by the proposed rule would allow firms to label any product that complies with the certification requirements for the product with a label that states that the product "Meets CPSC Safety Requirements." This provision is not expected to have a significant impact on firms because the program is voluntary and the cost of adding or modifying a label on a product are expected to be low.

#### *8. Summary of Impact on Small Businesses*

The proposed rule, if finalized, could have a significant adverse impact on a substantial number of small businesses. The provisions of the proposed rule that are expected to have the most significant impact are provisions related to requirements for the third party testing of children's products with and without a reasonable testing program. The impact of the proposed rule would be expected to be disproportionate on small and low-volume manufacturers. This is because testing costs are relatively fixed. Therefore, the per unit impact of testing costs will be greater on low-volume producers than on high volume producers.

The provisions of the proposed rule that would require manufacturers of non-children's products to establish and maintain a reasonable testing program also could have an adverse impact on some manufacturers. The impact of these provisions are expected to be less significant than the impact of the provisions related to children's products because many manufacturers are believed to already have at least some quality assurance or testing programs in place. The provisions related to the proposed requirement for a reasonable testing program are intended to provide manufacturers with a high degree of flexibility in designing and implementing the programs, which would also serve to reduce the potential impact on a firm.

The other requirements in the propose rule for verifying that a children's product tested by a CPSC-recognized third party conformity assessment body complies with safety rules, protection against undue influence over a conformity assessment body, and the consumer product labeling program are less likely to have a significant adverse impact on a substantial number of small businesses. The Commission invites comments on these provisions.

*9. Federal Rules which may Duplicate, Overlap, or Conflict with the Proposed Rule*

The proposed rule would establish the minimum requirements for testing and certification of consumer products. Some

individual product safety rules contain specific testing requirements. Manufacturers would be expected to meet the more stringent requirements whether they are the provisions of this proposed rule or the requirements in the specific safety rule. However, the rules would not require manufacturers to duplicate their efforts to comply with both sets of requirements. Testing and recordkeeping required to comply with the more stringent rule would also meet the requirements of the less stringent rule. Manufacturers will not be required to duplicate tests or recordkeeping to comply with both sets of rules. There are no known Federal rules that conflict with the proposed rule.

*10. Alternatives for Reducing the Adverse Impact on Small Businesses*

The Commission recognizes that the proposed rule could have a significant and disproportionate impact on small and low-volume manufacturers. The Commission has incorporated some provisions into the proposed rule that are intended to lessen the impact on small businesses. These include some relief from the periodic testing requirement for children's products, the ability to use component part testing (which will also be addressed by a separate Commission rule in this same issue of the Federal Register). The Commission invites comments on these provisions and other provisions or alternatives that could lessen the adverse impact on small or low-volume businesses.

a. Partial Exemption from Periodic Testing

The proposed rule would require that all children's products be tested periodically by a CPSC-recognized third party conformity assessment body and establishes one year as the maximum interval between periodic tests. However, if fewer than 10,000 units of a product have been manufactured or imported since the last time the product was submitted to a CPSC-recognized third party conformity assessment body, the manufacturer would not be required to obtain additional third party periodic testing until 10,000 units have been manufactured or imported. This provision would allow low-volume manufacturers to spread their periodic testing costs over more units. The exemption would not relieve the manufacturer from the obligation to have the product tested by a CPSC-recognized third party conformity assessment body before the product is introduced into commerce or when there has been a material change in the product's design or production processes.

b. Component Testing

The proposed rule would allow firms to submit component parts for third party testing when the required testing does not need to be performed on the finished product. This can reduce the cost to manufacturers where one component part might be common to more than one product. Such components part might include paints, polymers used in molding different parts, and

standard-sized bolts. In these cases the component parts might be received in larger lots than the production lots of the products in which they are used. Therefore, the testing costs for those component parts will be spread over more units than if they were required to be tested on the finished products.

*11. Alternatives That May Further Reduce the Impact on Small Businesses*

The Commission also invites comments on other alternatives that could provide some relief to small businesses that would be adversely impacted by the proposed rule. Alternatives could include things such as: (1) the establishment of different compliance or reporting requirements that take into account the resources available to small businesses; (2) the clarification, consolidation, or simplification of compliance and reporting requirements for small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part of the rule thereof, for small entities. In providing such comments, the Commission requests that the comments provide specific suggestions and well developed justifications for the suggestions. Some possible alternatives that could be considered are discussed below.

*a. Less Stringent Requirements for Third Party Testing*

The proposed rule would require that enough third party tests be conducted to provide a high degree of assurance that

all of products in the lots tested comply with the applicable rules. This could require most manufacturers to submit multiple samples for third party testing each year, especially if they have not implemented a reasonable testing program. However, the Commission could adopt an alternative that would limit the number of samples required for third party testing. For example, the Commission could simply require that manufacturers submit sufficient samples to a CPSC-recognized third party conformity assessment body so that compliance with each rule could be assessed at least once annually.

The proposed rule would require that periodic third party testing be conducted at least once a year. A year was chosen as the maximum interval between periodic testing because many children's products are produced on an annual or seasonal cycle. The Commission could, however, consider a different maximum interval between the periodic tests. For example, the Commission could consider requiring that periodic tests be conducted at least once every two years or once every five years.

The advantage of less stringent requirements is that they could significantly reduce the cost of the third party testing requirement. The disadvantage is that the testing would provide less information about whether all of the products produced were in compliance with the applicable safety rules.

The Commission invites comments on these and similar alternatives. For example, should the Commission consider a less stringent requirement? If so, what should the alternative requirement be? Should the less stringent requirement apply to all manufacturers or only those that meet certain criteria, such as to small or low-volume manufacturers?

b. Limits on Third Party Testing for Small or Low Volume  
Manufacturers

The Commission could consider additional alternatives that would provide relief to small or low-volume manufacturers. Substantial relief could be provided to small or low-volume manufacturers. For example, the Commission could exempt them from the third party testing requirements altogether. (The proposed rule does not address this issue). Alternatively, it could limit the third party testing required to no more than a certain percentage of the firm's revenue, or similar criteria. The Commission invites comments on this or similar alternatives. For example, should the Commission adopt criteria that put a maximum limit on the required third party testing costs by small or low-volume manufacturers? If so, what should the criteria be? If such a provision were adopted, how should the manufacturer allocate its limited testing funds? For example, should the same priority be given to all safety rules? Should the manufacturer give a higher priority to testing for

compliance to some safety rules than to others? For example, should the manufacturer give a higher priority to testing for compliance with the lead-in-paint standard than to the phthalate standard?

c. Alternative Test Methods for Small or Low-Volume  
Manufacturers

Some small manufacturers have encouraged the Commission to allow alternative test methods such as those relying on XRF technology. XRF testing methods are significantly less expensive than the ICP analysis that the Commission currently requires for most lead content testing (with the exception of homogenous polymer products). The Commission staff does use XRF for screening samples.

The Commission invites comments on the possibility of using alternative testing technologies for reducing the burden on small and low-volume manufacturers. For example, could the Commission allow small or low-volume manufacturers to use less expensive, but potentially less accurate third party testing methods? If so, under what conditions?

**E. Paperwork Reduction Act**

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork

Reduction Act of 1995 (44 U.S.C. 3501-3520). We describe the provisions in this section of the document with an estimate of the annual reporting burden. Our estimate includes the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We particularly invite comments on: (1) Whether the collection of information is necessary for the proper performance of the CPSC's functions, including whether the information will have practical utility; (2) the accuracy of the CPSC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Testing and Labeling Pertaining to Product  
Certification

Description: The proposed rule would implement section 102(b) of the CPSIA, which requires certifications of compliance with safety standards for each product subject to a consumer product safety rule, ban, standard, or regulation promulgated

and/or enforced by the CPSC. A certification that a non-children's product complies with applicable safety rules, bans, standards, and regulations must be supported by a reasonable testing program. A certification that a children's product complies with applicable safety rules, bans, standards, and regulations must be supported by testing performed by an approved third party conformity assessment body. The proposed rule would impose recordkeeping requirements related to those testing and certification requirements. The recordkeeping requirements are intended to allow one to uniquely identify each product and establish that it was properly certified before it entered commerce and has been properly retested for conformity with all applicable rules on a continuing basis, including after a material change in the product's design or manufacturing processes, including the sourcing of component parts.

Each manufacturer or importer of a consumer product subject to an applicable safety rule would be required to establish and maintain the following records.

- A copy of the certificate of compliance for each product. In the case of non-children's products the required certificate is a general conformity certificate. In the case of children's products, the certificate must be based upon testing by a CPSC-approved third party

conformity assessment body. (Proposed §§

1107.10(a)(5)(i)(A), 1107.26(a)(1))

- For non-children's products, a record of each product specification, including any new product specification resulting from remedial action. (Proposed §

1107.10(a)(5)(i)(B))

- Records of each certification test, including identification of the third party conformity assessment body, if any, that conducted the test. (Proposed §§

1107.10(a)(5)(i)(C), 1107.26(a)(2))

- Records of the periodic test plan and results.

(Proposed §§ 1107.10(a)(5)(i)(D), 1107.26(a)(3))

- For children's products, records relating to all material changes. (Proposed § 1107.26(a)(4))

- Records of all remedial actions taken. (§§

1107.10(a)(5)(i)(E), 1107.26(a)(7))

- For children's products, records of verification of third party test results. (Proposed § 1107.26(a)(5))

- For children's products, records of undue influence procedures. (Proposed § 1107.26(a)(6))

Description of Respondents: The recordkeeping requirements contained in this proposed rule would apply to all manufacturers or importers of consumer products that are covered by one or

more product safety rules promulgated and/or enforced by the CPSC. The CPSC reviewed every category in the NAICS and selected those that included firms that could manufacture or sell any consumer product that could be covered by a consumer product safety rule. Using data from the U.S. Census Bureau, we determined that there were over 37,000 manufacturers, almost 80,000 wholesalers, and about 128,000 retailers in these categories. However, not all of the firms in these categories manufacture or import products that are covered by product safety rules. Therefore, these numbers would constitute a high estimate of the number of firms that are subject to the recordkeeping requirements.

Estimate of the Burden: The hour burden of the recordkeeping requirements will likely vary greatly from product to product depending upon such factors as the complexity of the product and the amount of testing that must be documented. CPSC staff does not have comprehensive data on the universe of products that will be impacted. Therefore, estimates of the hour burden of the recordkeeping requirements are somewhat speculative. The CPSC invites comments that can provide more information about the number of hours required for the recordkeeping requirements of the proposed rule.

Previously, the CPSC staff estimated that the recordkeeping burden of the mattress open flame flammability standard would be

about one hour per model (prototype) per year. Many of the recordkeeping requirements in that standard are comparable to the requirements in this proposed rule. However, that rule concerned only the recordkeeping requirements for only one rule (mattress flammability) while manufacturers of children's products will frequently have to document their compliance with more than one product safety rule (e.g., lead-in-paint, lead content, phthalates, and some product specific rules, such as the ASTM F963 toy standard). Therefore, one can assume the burden of the proposed rule could be twice the hour burden of the recordkeeping required for the mattress flammability rule. (Information on the product safety rules that apply to different consumer products can be found at <http://www.cpsc.gov/businfo/regsbyproduct.html>.)

According to a representative of a trade association, there are an estimated 50,000 to 60,000 individual toys on the market. It is likely that there are at least that many other children's products in product categories such as wearing apparel, accessories, jewelry, juvenile products, children's furniture, etc. Additionally non-children's products that are subject to product safety rules include paints, nonmetal furniture (for lead-in-paint), all terrain vehicles, bicycles, and bunk beds. Therefore, we estimate that there are approximately 100,000 to

150,000 individual products to which the recordkeeping requirements would apply.

Assuming the annual recordkeeping burden per product will be two hours and that there are between 100,000 and 150,000 products to which the recordkeeping requirements would apply, the total hour burden for the recordkeeping requirements is estimated to be between 200,000 and 300,000 hours.

The total cost burden of the recordkeeping requirements is expected to be between \$9.8 and \$14.7 million. This estimate is obtained by multiplying the total burden hours by \$48.91, which is the total hourly compensation for private sector workers in management, professional, and related occupations. The recordkeeping requirements are not expected to result in any additional cost to the Federal government. The CPSC will likely request access to these records only when it is investigating potentially defective or non-complying products. Investigating potentially defective or non-complying product is a regular ongoing activity of the Commission. It is anticipated that access to the records required by this rule will make it easier for the investigators to narrow the scope of their investigations to particular production or import lots.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection requirements of this rule to OMB for review. Interested persons

are requested to fax comments regarding information collection by [insert date 30 days after date of publication in the FEDERAL REGISTER], to the Office of Information and Regulatory Affairs, OMB (see ADDRESSES).

#### **F. Environmental Considerations**

This proposed rule falls within the scope of the Commission's environmental review regulations at 16 CFR part 1021.5(c)(2) which provides a categorical exclusion from any requirement for the agency to prepare an environmental assessment or environmental impact statement for product certification rules.

#### **G. Executive Order 12988**

Executive Order 12988 (February 5, 1996), requires agencies to state in clear language the preemptive effect, if any, of new regulations. The proposed regulation would be issued under authority of the CPSA and the 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 in a court of competent jurisdiction.

## H. Effective Date

The Commission is proposing that any final rule based on this proposal become effective 180 days after its date of publication in the FEDERAL REGISTER.

### List of Subjects in 16 CFR Part 1107

For the reasons stated in the preamble, the Commission proposes to amend Title 16 of the Code of Federal by adding a new part 1107 to read as follows:

PART 1107 - TESTING AND LABELING PERTAINING TO PRODUCT  
CERTIFICATION

SUBPART A GENERAL PROVISIONS

Sec.

1107.1 Purpose.

1107.2 Definitions.

SUBPART B REASONABLE TESTING PROGRAM FOR NON-CHILDREN'S  
PRODUCTS

1107.10 Reasonable Testing Program for Non-Children's products.

SUBPART C CERTIFICATION OF CHILDREN'S PRODUCTS

1107.20 General Requirements.

1107.21 Periodic Testing.

1107.22 Random Samples.

- 1107.23 Material Changes.
- 1107.24 Verification.
- 1107.25 Undue Influence.
- 1107.26 Remedial Action.
- 1107.27 Recordkeeping.

#### SUBPART D CONSUMER PRODUCT LABELING PROGRAM

1107.40 Labeling consumer products to indicate that the certification requirements of section 14 of the CPSA have been met.

Authority: 15 U.S.C. 2063, Sec. 3, 102 Pub. L. 110-314, 122 Stat. 3016, 3017, 3022.

#### SUBPART A - GENERAL PROVISIONS

##### § 1107.1 Purpose.

This part establishes the requirements for: a reasonable testing program for non-children's products; third party conformity assessment body testing to support certification and continuing testing of children's products; and labeling of consumer products to indicate that the certification requirements have been met pursuant to sections 14(a)(1), and (a)(2), (d)(2)(B) of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2063(a)(1), (a)(2), (d)(2)(B)).

§ 1107.2 Definitions.

Unless otherwise stated, the definitions of the Consumer Product Safety Act and the Consumer Product Safety Improvement Act of 2008 apply to this part. The following definitions apply for purposes of this part:

- (a) *CPSA* means the Consumer Product Safety Act.
- (b) *CPSC* means the Consumer Product Safety Commission.
- (c) *Detailed bill of materials* means a list of the raw materials, sub-assemblies, intermediate assemblies, sub-components parts, component part, and the quantities of each needed to manufacture a finished product.
- (d) *Due care* means the degree of care that a prudent and competent person engaged in the same line of business or endeavor would exercise under similar circumstances.
- (e) *High degree of assurance* means an evidence-based demonstration of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture.
- (f) *Identical in all material respects* means there is no difference with respect to compliance to the applicable rules between the samples and the finished product.

- (g) *Manufacturing process* means the techniques, fixtures, tools, materials, and personnel used to create the component parts and assemble a finished product.
- (h) *Production testing plan* means a document that shows what tests must be performed and the frequency at which those tests must be performed to provide a high degree of assurance that the products manufactured after certification continue to meet all the applicable safety rules.
- (i) *Third party conformity assessment body* means a third party conformity assessment body recognized by the CPSC to conduct certification testing on children's products.

SUBPART B - REASONABLE TESTING PROGRAM FOR  
NON-CHILDREN'S PRODUCTS

§ 1107.10 Reasonable Testing Program for Non-Children's Products.

(a) Except as otherwise provided in a specific regulation under this title or a specific standard prescribed by law, a manufacturer certifying a product pursuant to a reasonable testing program must ensure that the reasonable testing program provides a high degree of assurance that all consumer products covered by the program will comply with all applicable rules, bans, standards, or regulations.

(b) A reasonable testing program must consist of the following elements:

(1) Product Specification. The product specification is a description of the consumer product and lists the applicable rules, bans, standards or regulations to which the product is subject. A product specification should describe the product listed on a general conformity certification in sufficient detail to identify the product and distinguish it from other products made by the manufacturer. The product specification may include, but is not limited to, a color photograph or illustration, model names or numbers, a detailed bill of materials, a parts listing, raw material selection and sourcing requirements.

(i) A product specification must include any component parts that are certified pursuant to 16 CFR Part 1109.

(ii) Product specifications that identify individual features of a product as not being materially different may use the same product specification for all products manufactured with those specific features. Features that are considered as being not materially different include different product sizes, use of different colors, or other features that covers physical variations of the product where those physical

variations do not affect the product's ability to comply with applicable rules, bans, standards, or regulations.

(iii) Each manufacturing site must have a separate product specification regardless of whether the product is identical in all material respects to a product manufactured at another site.

(2) Certification Tests. A manufacturer must conduct certification tests on a product before issuing a general conformity certificate for that product. A certification test is a test performed on samples of the product that are identical to the finished product in all material respects to demonstrate that the product complies with the applicable safety rules, bans, standards, or regulations. Certification tests must contain the following elements:

(i) Samples. For purposes of this section, a sample means a component part of the product or the finished product which is subjected to testing. Samples submitted for certification testing must be identical in all material respects to the product to be distributed in commerce. The manufacturer must submit a sufficient number of samples for certification testing so as to provide a high degree of assurance that the certification tests accurately represent the product's compliance with all applicable rules.

(A) Only finished products or component parts listed on the product specification can be submitted for certification testing.

(B) A manufacturer may substitute component part testing for finished product testing pursuant to 16 CFR Part 1109 unless the rule, ban, standard or regulation applicable to the product requires testing of the entire product. If a manufacturer relies upon certification testing of component part(s) (rather than tests of the finished product), the manufacturer must demonstrate how the combination of testing of component part(s), portions of the finished product, and finished product samples demonstrate, with a high degree of assurance, compliance with all applicable rules, bans, standards, or regulations.

(ii) Material Changes. A material change is any change in the product's design, manufacturing process, or sourcing of component parts that a manufacturer exercising due care knows, or should know, could affect the product's ability to comply with the applicable rules, bans, standards, or regulations.

(A) When a previously-certified product undergoes a material change that only affects the

product's ability to comply with certain applicable rules, bans, standards, or regulations, certification for the new product specification may be based on certification testing of the materially changed component part, material, or process, and the passing certification tests of portion of the previously-certified product that were not materially changed.

(B) A manufacturer must conduct certification test of the finished product if a material change affects the finished product's ability to comply with an applicable rule, ban, standard, or regulation.

(C) A manufacturer must exercise due care to ensure that reliance on anything other than retesting of the finished product after a material change occurs does not allow a noncompliant product to be distributed in commerce. A manufacturer should resolve any doubts in favor of retesting the finished product for certification.

(3) Production Testing Plan. A production testing plan describes what tests must be performed and the frequency at

which those tests must be performed to provide a high degree of assurance that the products manufactured after certification continue to meet all the applicable safety rules, bans, standards, or regulations. A production testing plan may include recurring testing or the use of process management techniques designed to control potential variations in product manufacturing that could affect the product's ability to comply with the applicable rules, bans, standards, or regulations. A production testing plan must contain the following elements:

(i) A description of the production testing plan, including, but not limited to, a description of the tests to be conducted or the measurements to be taken, the intervals at which the tests or measurements will be made, the number of samples tested, and the basis for determining that such tests provide a high degree of assurance of compliance if they are not the tests prescribed in the applicable rule, ban, standard, or regulation;

(ii) Each manufacturing site must have a separate production testing plan regardless of whether the product is identical in all material respects to that manufactured at each site;

(iii) The production testing interval selected must be short enough to ensure that, if the samples selected for production testing comply with an applicable rule, ban, standard, or regulation, there is a high degree of assurance that all the untested products manufactured during that interval also will comply with the applicable rule, ban standard, or regulation. Production test intervals should be appropriate for the specific testing or alternative measurements being conducted.

(A) A manufacturer may use measurement techniques that are non-destructive and tailored to the needs of an individual product instead of conducting product performance tests to assure a product complies with all applicable rules, bans, standards, or regulations.

(B) Any production test method used to conduct production testing must be as effective in detecting noncompliant products as the tests used for certification.

(C) If a manufacturer is uncertain whether a production test is as effective as the certification test, the manufacturer must use the certification test.

(4) Remedial Action Plan.

(i) A remedial action plan describes the steps to be taken whenever samples of a product or a component part of a product fails a test or fails to comply with an applicable rule, ban, standard, or regulation. A remedial action plan must contain procedures the manufacturer must follow to investigate and address failing test results.

Manufacturers must take remedial action after any failing test result to ensure with a high degree of assurance that all products manufactured after the remedial action has been taken comply with the applicable rules, bans, standards, or regulations. The type of remedial action may be different depending upon the applicable rule, ban, standard, or regulation. Remedial action can include, but is not limited to:

- (A) changes to the manufacturing process, the equipment used to manufacture the product, the product's materials, or design;
- (B) reworking the product produced; or
- (C) other actions deemed appropriate by the manufacturer, in the exercise of due care, to assure compliant products.

(ii) Any remedial action that results in a material change to a product's design, parts, suppliers of parts, or

manufacturing process that could affect the product's ability to comply with any applicable rules requires a new product specification for that product. Before a product covered by the new product specification can be certified as compliant with the applicable rules, bans, standards, or regulations, a manufacturer must have passing certification test results for the applicable rules, bans, standards, or regulation.

(5) Recordkeeping.

(i) A manufacturer of a non-children's product must maintain the following records:

(A) Records of the general conformity certificate for each product;

(B) Records of each product specification;

(C) Records of each certification test and, if the manufacturer elected to have a third party conformity assessment body test the product, identification of any third party conformity assessment body on whose testing the certificate depends. Records of certification test must describe how the product was certified as meeting the requirements, including how each applicable rule was evaluated, the test results, and the actual values of the tests;

(D) Records to demonstrate compliance with the production testing plan requirement, including a list of the applicable rules, bans, standards, or regulations, a description of the types of production tests conducted, the number of samples tested, the production interval selected for performance of each test, and the test results. Records of a production test program must describe how the production tests demonstrate that the continuing production complies with the applicable rules. References to techniques in relevant quality management and control standards, such as ANSI/ISO/ASQ Q9001-2008: Quality management systems - Requirements, ANSI/ASQ Z1.4-2008: Sampling Procedures and Tables for Inspection by Attributes, and/or ANSI/ASQ Z1.9-2008: Sampling Procedures and Tables for Inspection by Variables for Percent Nonconforming, may be used to demonstrate that the production tests have the necessary accuracy, precision sensitivity, repeatability, and confidence to distinguish between compliant and noncompliant products;

(E) Records of all remedial actions taken, including the specific action taken, the date the action was taken, the person who authorized the actions, and any

test failure which necessitated the action. Records of remedial action must relate the action taken to the product specification of the product that was the subject of that remedial action and the product specification of any new product resulting from any remedial action;

(ii) If a remedial action results in a new product specification, the manufacturer must create a new set of records for the product.

(iii) A manufacturer must maintain the records specified in this subpart at the manufacturer's main office. The manufacturer must make these records available for inspection by the CPSC upon request.

(iv) A manufacturer must maintain records (except for test records) for as long as the product is being distributed in commerce plus 3 years. Test records must be maintained for 3 years. All records must be available in the English language.

(c) If any certification test results in a failure, a manufacturer cannot certify a product until the manufacturer has taken remedial action, and the product manufactured after the remedial action passes certification testing.

(d) Manufacturers of a non-children's product may use a third party conformity assessment body to conduct certification

testing but are not required to use a third party conformity assessment body recognized by the CPSC to conduct certification testing on children's products.

(e) Manufacturers of children's products may voluntarily establish a reasonable testing program consistent with this subpart.

#### SUBPART C CERTIFICATION OF CHILDREN'S PRODUCTS

##### § 1107.20 Children's Product Certification.

(a) Manufacturers must submit a sufficient number of samples of a children's product, or samples that are identical in all material respects to the children's product, to a third party conformity assessment body for testing to support certification. The number of samples selected must provide a high degree of assurance that the tests conducted for certification purposes accurately demonstrate the ability of the children's product to meet all applicable children's product safety rules.

(b) If the manufacturing process for a children's product consistently creates parts that are uniform in composition and quality, a manufacturer may submit fewer samples to provide a high degree of assurance that the finished product complies with the applicable children's product safety rules. If the manufacturing process for a children's product results in

variability in the composition or quality of children's products, a manufacturer may need to submit more samples to provide a high degree of assurance that the finished product complies with the applicable children's product safety rules.

(c) Except where otherwise specified by a children's product safety rule, a manufacturer may substitute component part testing for complete product testing pursuant to 16 CFR part 1109 if the component part, without the remainder of the finished product, is sufficient to determine compliance for the entire product.

(d) If a product sample fails certification testing, even if other samples have passed the same certification test, the manufacturer must investigate the reasons for the failure and take remedial action. A manufacturer cannot certify the children's product until the manufacturer establishes, with a high degree of assurance, that the finished product does comply with all applicable children's product safety rules.

#### § 1107.21 Periodic Testing.

(a) General Requirements. All periodic testing must be conducted by a third party conformity assessment body. Each manufacturer must conduct periodic testing at least annually, except as otherwise provided in paragraph (d) of this section or

as provided in regulations under this title. Manufacturers may conduct periodic tests more frequently than on an annual basis.

(b) If a manufacturer has implemented a reasonable testing program as described in subpart A of this part, the manufacturer may conduct third party periodic testing on a less frequent basis.

(c) If a manufacturer has not implemented a reasonable testing program as described in subpart A of this part, the manufacturer must conduct periodic testing as follows:

(1) Periodic Test Plan. Manufacturers must develop a periodic test plan to assure that children's products manufactured after the issuance of a children's product certification, or when the previous periodic testing was conducted, continue to comply with all applicable children's product safety rules. The periodic test plan must include the tests to be conducted, the intervals at which the tests will be conducted, the number of samples tested, and the basis for determining that the periodic testing plan provides a high degree of assurance that the product being tested continues to comply with all applicable children's product safety rules. The manufacturer must have a separate periodic testing plan for each manufacturing site producing a children's product.

(2) Testing Interval. The periodic testing interval selected must be short enough to ensure that, if the samples selected for periodic testing pass the test, there is a high degree of assurance that all other untested children's products manufactured during the interval comply with the applicable children's product safety rules. The interval for periodic testing may vary depending upon the specific children's product safety rules that apply to the children's product. Factors to be considered when determining the period testing interval include, but are not limited to, the following:

(i) High variability in test results, as indicated by a relatively large sample standard deviation in quantitative tests;

(ii) Measurements that are close to the allowable numerical limit for quantitative tests;

(iii) Known manufacturing process factors which could affect compliance with a rule. For example, if the manufacturer knows that a casting die wears down as the die nears the end of its useful life, the manufacturer may wish to test more often as the casting die wears down;

(iv) Consumer complaints or warranty claims; non-material changes, such as manufacturing or component

part/subassembly lot changes and fixed volume production;

(v) Potential for serious injury or death resulting from a noncompliant children's product;

(vi) The number of children's products produced annually, such that a manufacturer should consider testing a children's product more frequently if the product is produced in very large numbers or distributed widely throughout the United States;

(vii) The children's product's similarity to other children's products with which the manufacturer is familiar and/or whether the children's product has many different component parts compared to other children's products of a similar type; or

(viii) Inability to determine the children's product's non-compliance easily through means such as visual inspection.

### (3) Periodic Testing Frequency for Low-Volume

Manufacturers. A manufacturer is not required to conduct periodic testing until it produces 10,000 units of a product after the time a third party conformity assessment body tested the children's product for certification purposes or conducted periodic testing.

§ 1107.22 Random Samples.

Each manufacturer must select samples for periodic testing by using a process that assigns each sample in the production population an equal probability of being selected. For purposes of this section, the production population is the number of products manufactured or imported after the initial certification or last periodic testing of a children's product. A manufacturer may use a procedure that randomly selects items from a list to determine which samples are the random samples used for periodic testing before production begins. A manufacturer may select samples for testing as they are manufactured. Manufacturers who produce children's products that continue to be distributed in commerce as they are manufactured may wish to test the samples as they become available instead of waiting until all the random samples have been selected before conducting testing.

§ 1107.23 Material Changes.

(a) General Requirements. If a children's product undergoes a material change in product design or manufacturing process, including the sourcing of component parts, that a manufacturer exercising due care knows, or should know, could affect the product's ability to comply with the applicable children's product safety rules, the manufacturer must submit a

sufficient number of samples of the materially changed product for testing by a third party conformity assessment body. Such testing must occur before a manufacturer can certify the children's product. The extent of such testing may depend on the nature of the material change. When a material change is limited to a component part of the finished children's product and does not affect the ability of the children's product to comply with other applicable children's product safety rules, a manufacturer may issue a children's product certificate based on the earlier third party certification tests and on test results of the changed component part conducted by a third party conformity assessment body. Changes that cause a children's product safety rule to no longer apply to a children's product are not considered to be material changes. A manufacturer must exercise due care to ensure that reliance on anything other than retesting of the finished product after a material change would not allow a noncompliant children's product to be distributed in commerce. A manufacturer should resolve any doubts in favor of retesting the entire product for certification. Additionally, a manufacturer must exercise due care to ensure that any component part undergoing component-part-level testing is the same as the component part on the finished children's product in all material respects.

(b) Product Design. For purpose of this subpart, the term product design includes all component parts, their composition, and their interaction and functionality when assembled. To determine which children's product safety rules apply to a children's product, a manufacturer should examine the product design for the children's product as received by the consumer.

(c) Manufacturing Process. A material change in the manufacturing process is a change in how the children's product is made that could affect the finished children's product's ability to comply with the applicable rules. For each change in the manufacturing process, a manufacturer should exercise due care to determine if compliance to an existing applicable rule could be affected, or if the change results in a newly-applicable rule.

(d) Sourcing of Component Parts. A material change in the sourcing of component parts results when the replacement of one component part of a children's product with another component part that could affect compliance with the applicable children's product safety rules. This includes, but is not limited to, changes in component part composition, component part supplier, or the use a different component part from the same supplier who provided the initial component part.

§ 1107.24 Verification.

(a) A manufacturer is responsible for verifying that its children's products, as tested by a third party conformity assessment body, comply with applicable children's product safety rules. For purposes of this section, verification means testing that demonstrates that the test results from one third party conformity assessment body are consistent with the test results from another third party conformity assessment body for a particular children's product. A manufacturer must send samples of a previously certified children's product or a children's product that has previously been tested periodically pursuant to section 1107.21 to a third party conformity assessment body for verification. The third party conformity assessment body conducting tests for verification purposes cannot be the same third party conformity assessment body that previously certified the children's product as compliant or the same third party conformity assessment body that conducted the last periodic test for the children's product.

(b) Verification must occur on a reoccurring basis and be conducted at a frequent enough interval to provide a high degree of assurance that the children's product that had been certified previously continues to comply with the applicable children's product safety rules or that the periodic test for the children's product was performed correctly. Verification does not have to occur at the same time for all applicable children's

product safety rules or be performed by the same alternate third party conformity assessment body. A manufacturer may use periodic test results to support verification if an alternate third party conformity assessment body conducts the periodic test.

(c) If a third party conformity assessment body conducting tests to verify a children's product's compliance with applicable children's product safety standards finds that a children's product fails a children's product safety standard, the manufacturer must investigate the cause(s) for the failure. If, after conducting its investigation, the manufacturer concludes that a third party conformity assessment body's (whether the third party conformity assessment body that conducted the tests to support a certification for the children's product or a third party conformity assessment body that conducted the verification test), test results were in error, the manufacturer must notify CPSC and describe the occurrence in an electronic mail (email) message to the Assistant Executive Director, Office of Hazard Identification and Reduction at [labaccred@cpsc.gov](mailto:labaccred@cpsc.gov).

§ 1107.25 Undue Influence.

(a) Each manufacturer must establish procedures to safeguard against the exercise of undue influence by a manufacturer on a third party conformity assessment body.

(b) The procedures required in subsection (a), at a minimum, must include:

- (1) Safeguards to prevent attempts by the manufacturer to exercise undue influence on a third party conformity assessment body, including a written policy statement from company officials that the exercise of undue influence is not acceptable, and directing that appropriate staff receive annual training on avoiding undue influence;
- (2) A requirement to notify the Commission immediately of any attempt by the manufacturer to hide or exert undue influence over test results; and
- (3) A requirement to inform employees that allegations of undue influence may be reported confidentially to the Commission and to describe the manner in which such a report can be made.

§ 1107.26 Remedial Action.

(a) Each manufacturer of a children's product must have a remedial action plan that contains procedures the manufacturer must follow to investigate and address failing test results. A

manufacturer must take remedial action after any failing test result to ensure, with a high degree of assurance, that all children's products manufactured after the remedial action has been taken comply with the applicable rules.

(b) A manufacturer must not certify a product if any certification test by a third party conformity assessment body results in a failure until the manufacturer has taken remedial action and the product manufactured after the remedial action passes certification testing.

(c) Following a failing test result, a manufacturer must take remedial action to ensure, with a high degree of assurance, that the children's product complies with all applicable children's product safety rules. Remedial action can include, is not limited to, redesign, changes in the manufacturing process, or changes in component part sourcing. For existing production, remedial action may include rework, repair, or scrap of the children's product. A manufacturer must have a third party conformity assessment body retest the redesigned or remanufactured product for the manufacturer to be able to certify the product. A manufacturer must prepare a new product specification for any remedial action that results in a material change in the product design, parts, suppliers of parts, or manufacturing process. A third party conformity assessment body must conduct certification testing for a product covered by a

new specification after the manufacturer has completed remedial action.

§ 1107.26 Recordkeeping.

(a) A manufacturer of a children's product subject to an applicable children's product rule must maintain the following records:

- (1) Records of the children's product certificate for each product. The children's product covered by the certificate must be clearly identifiable and distinguishable from other products;
- (2) Records of each third party certification test. The manufacturer must have separate certification tests records for each manufacturing site;
- (3) Records of the periodic test plan and periodic test results for a children's product;
- (4) Records of descriptions of all material changes in product design, manufacturing process, and sourcing of component parts, and the certification tests run and the test values;
- (5) Records of verification of third party test results;

(6) Records of the undue influence procedures, including training materials and training records of all employees trained on these procedures; and

(7) Records of all remedial actions taken following a failing test result, including the rule that was tested, the specific remedial action taken, the date the action was taken, the person who authorized the action, any test failure which necessitated the action, and the results from certification tests showing compliance after the remedial action was taken.

(b) A manufacturer must maintain the records at the manufacturer's main office. The manufacturer must make these records available for inspection by the CPSC upon request.

(c) A manufacturer must maintain records (except for test records) for as long as the product is being distributed in commerce plus 3 years. Test records must be maintained for 3 years. All records must be available in the English language.

#### SUBPART D CONSUMER PRODUCT LABELING PROGRAM

§ 1107.40 Labeling consumer products to indicate that the certification requirements of section 14 of the CPSA have been met.

(a) Manufacturers and private labelers of a consumer product may indicate, by a uniform label on or provided with the product, that the product complies with any consumer product safety rule under the CPSA, or with any similar rule, ban, standard or regulation under any other act enforced by the CPSC.

(b) The label must be printed in bold typeface, using an Arial font of not less than 12 points, be visible and legible, and consist of the following statement:

**Meets CPSC Safety Requirements**

(c) A consumer product may bear the label if the manufacturer or private labeler has certified, pursuant to section 14 of the CPSA, that the consumer product complies with all applicable consumer product safety rules under the CPSA and with all rules, bans, standards, or regulations applicable to the product under any other act enforced by the Consumer Product Safety Commission.

(d) A manufacturer or private labeler may use another label on the consumer product as long as such label does not alter or mislead consumers as to the meaning of the label described in paragraph (b) of this section. A manufacturer or private labeler must not imply that the CPSC has tested, approved, or endorsed the product.

Dated: \_\_\_\_\_

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Todd A. Stevenson,

Secretary