

INFORMATION COLLECTION REQUEST

Supporting Statement

Requirements Pertaining to Third Party Conformity Assessment Bodies RIN: 3041-AC97

A. Justification

1. Circumstances Necessitating Information Collection

Section 14(a)(2) of the Consumer Product Safety Act (“CPSA”), 15 U.S.C. 2063(a)(2), requires manufacturers and private labelers of any children’s product that is subject to a children’s product safety rule to submit samples of the product, or samples that are identical in all material respects to the product, to a third party conformity assessment body accredited by the U.S. Consumer Product Safety Commission (“CPSC” or “Commission”) to be tested for compliance with such children’s product safety rule.

Section 14(a)(3)(C) of the CPSA, as amended by section 102 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the Commission to accredit third party conformity assessment bodies or designate an independent accreditation organization.

Section 14(e) of the CPSA authorizes the Commission to withdraw the accreditation or acceptance of accreditation of a third party conformity assessment body if:

- a manufacturer, private labeler, or governmental entity has exerted undue influence on such conformity assessment body or otherwise interfered with or compromised the integrity of the testing process with respect to the certification of a children's product; or
- such conformity assessment body failed to comply with an applicable protocol, standard, or requirement established by the Commission.

Section 14(e)(3) of the CPSA authorizes the Commission to suspend the accreditation of a conformity assessment body if it fails to cooperate with the Commission in an investigation.

Section 14(f)(2)(B) of the CPSA lists additional requirements for including governmental third party conformity assessment bodies as CPSC-accepted third party conformity assessment bodies.

Section 14(f)(2)(D) of the CPSA lists additional requirements for including firewalled third party conformity assessment bodies as CPSC-accepted third party conformity assessment bodies.

Section 14(i)(1) requires the CPSC to establish requirements for the periodic audit of third party conformity assessment bodies as a condition for the continuing accreditation or acceptance of accreditation of such conformity assessment bodies.

The rule is codified at 16 CFR part 1112. This rule establishes the accreditation and audit requirements for third party conformity assessment bodies so that their testing results may be used as a basis for a manufacturer to issue a Children's Product Certificate. This rule establishes procedures by which a third party conformity assessment body may have its CPSC acceptance of that accreditation withdrawn or suspended. Additionally, the rule codifies the notices of requirements third party conformity assessment bodies need to meet in order to have their accreditation accepted by the Commission for test methods for children's products certification, and includes new or modified notices of requirements.

A third party conformity assessment body must keep all test reports and technical records related to tests conducted for purposes of section 14 of the CPSA for a period of at least five years from the date the test was conducted. Any and all third party conformity assessment body internal documents describing testing protocols and procedures (such as instructions, standards, manuals, guides, and reference data) that applied to a test conducted for purposes of section 14 of the CPSA must be retained for a period of at least five years from the date such test was conducted. A third party conformity assessment body must keep records relating to its reassessment by an accreditation body for the last three reassessments.

The rule does not require the records to be available in the English language if they can be provided to the CPSC within 48 hours and translated into English within 30 days of a request by the CPSC. The documentation and records are needed to enable the Commission to investigate manufacturers if noncomplying yet certified products are found or to investigate an allegation of undue influence on the third party conformity assessment body.

2. How, by Whom, and for What Purpose Information Is Used

The recordkeeping requirements are intended to allow a third party conformity assessment body to support a manufacturer's claim that children's products are properly tested before being certified and entered in commerce, and have been properly retested for conformity with all applicable rules on a continuing basis.

3. Consideration of Information Technology

The rule allows records to be maintained electronically and provided in that form to the Commission, upon request.

4. Efforts to Identify Duplication and Similar Information Already Available

The recordkeeping requirements are intended to indicate whether third party conformity assessment body is complying with the accreditation and audit requirements of section 14

of the CPSA and the requirements of the rule. . Consequently, it is unlikely that the required information is duplicated or already available from other sources. Given the statutory requirements for testing and certification, the nature of the information being collected, and the CPSC's experience with certification programs for consumer products, no consultation regarding recordkeeping outside the agency was necessary.

5. Impact on Small Business

The recordkeeping requirements in the rule would likely not have a significant impact on third party conformity assessment bodies that are small businesses because the rule does not prescribe any particular method for establishing and maintaining records. Thus, third party conformity assessment bodies have the flexibility to establish and maintain the records in the manner that suits their needs. Most of the records required by the rule are already maintained by third party conformity assessment bodies as a normal business practice.

6. Consequences of Less Frequent Information Collection and Technical or Legal Obstacles

Failure to provide the information would impair the CPSC's ability to determine whether a third party conformity assessment body is complying with the accreditation and audit requirements of section 14 of the CPSA and the requirements of the rule. Less frequent information collection could investigations regarding whether a third conformity assessment body's accreditation is current and continues to meet CPSC requirements.

7. Consistency with the Guidelines in 5 CFR §1320.5(d)(2)

The rule is consistent with the guidelines in 5 CFR §1320.5(d)(2).

8. Consultation Outside the Agency

Given the statutory requirements for third party conformity assessment body accreditation, other agencies' methods for accreditation were examined for their suitability. Among the accreditation methods examined were:

- the National Institute of Standards and Technology's (NIST's) National Voluntary Laboratory Accreditation Program (15 CFR part 285);
- Customs and Border Protection's (CBP's) Accreditation of Commercial Labs (19 CFR part 151); and
- The Occupational Safety and Health Administration's (OSHA's) Nationally Recognized Testing Laboratories (NRTL) program (29 CFR part 1910).

The agency published a notice in the Federal Register announcing the intention to renew this collection. The comment period closed April 12, 2016. No comments were received.

9. Payment or Gift to Respondents

The CPSC did not, and will not, provide any payment or gifts to respondents.

10. Confidentiality of Information

The information submitted would be subject to the Freedom of Information Act and its exemptions to public disclosure.

11. Sensitive Questions

Information regarding ownership, business and governmental relationships, and third party conformity assessment body personnel may be considered sensitive. Such information could appear through the records and documentation required by the rule. However, the rule does not require the disclosure of such information.

12. Estimates of Burden Hours and Explanation

Because applying for CPSC acceptance of accreditation by uploading a completed Form 223 to the CPSC is voluntary, we anticipate that only third party conformity assessment bodies expecting an economic benefit will undertake this task.

For independent third party conformity assessment bodies, the estimated time to complete the initial application materials is 75 minutes. For governmental and firewalled third party conformity assessment bodies, the estimate is longer because of their additional requirements. Firewalled third party conformity assessment bodies will require an estimated 8.4 hours to develop and upload their additional requirements to the CPSC. Governmental third party conformity assessment bodies will require an extra 3 hours to develop and upload their additional requirements to the CPSC.

Based on applications received from FY 2013 to date, we estimate that about 40 new applications from third party conformity assessment bodies will be submitted each year for the next few years. All types of third party conformity assessment bodies will be required to expend the initial 75 minutes, leading to an estimated 50 hours per year. Based on recent experience, we estimate that about 3 firewalled third party conformity assessment bodies will apply per year, with a total annual added burden of 25.2 hours. Based on recent experience, we estimate that about 4 governmental third party conformity assessment bodies will apply per year, with a total annual added burden of 12 hours.

If a third party conformity assessment body needs to update the information on CPSC Form 223, they will not need to fill out an entirely new CPSC Form 223 to submit new information. The third party conformity assessment body can access its existing CPSC Form 223 via the third party conformity assessment body application program on the CPSC's website and change only those elements that need updating. We estimate that it will take a third party conformity assessment body 15 minutes to update its information. We estimate that only about 1 percent of approximately 540 third party conformity assessment bodies will do this per year, leading to an estimated 1.35 hours per year total.

It is our understanding that third party conformity assessment bodies maintain records as a normal course of their business. However, we would also require that when a test conducted for purposes of section 14 of the CPSA is subcontracted, a prime contractor's report must identify clearly which test(s) was performed by a CPSC-accepted third party conformity assessment body acting as a subcontractor, and the test from the subcontractor must be appended to the prime contractor's report. We estimate that an average third party conformity assessment body conducts 10,188 tests annually for purposes of section 14 of the CPSA. Based on our experience, to date, with the third party conformity assessment body program, we estimate that 5 percent of third party conformity assessment bodies will subcontract tests to other CPSC-accepted third party conformity assessment bodies. It is difficult to estimate exactly how many tests will be subcontracted, but for current purposes, we will estimate that of the third party conformity assessment bodies who subcontract, they will subcontract 25 percent of their tests. To comply with the recordkeeping requirements related to subcontracted tests, we estimate that a third party conformity assessment body will take 7 minutes. If 5 percent of 540 third party conformity assessment bodies subcontract 25 percent of 10,188 tests per year, that is a total of 68,769 subcontracted tests per year. Seven minutes times 68,769 subcontracted tests produces an estimate of 481,383 minutes, or approximately 8,023 hours per year to comply with the subcontracting recordkeeping requirement.

If a third party conformity assessment body wishes to discontinue voluntarily its participation with the CPSC, an estimated 30 minutes is needed to create and submit the required documentation. Based on past experience, an estimated 8 third party conformity assessment bodies may do so in a year, leading to an estimated 4 hours per year.

Because the CPSC portion of the audit is required no less than once every 2 years, we estimate that 50 percent of third party conformity assessment bodies each year will go through audit. Based on the number of independent third party conformity assessment bodies that have already been accepted by the CPSC and based upon our experience with the rate of new successful applications, we predict that the total number of independent third party conformity assessment bodies will be 455. Half of those, or 228, will be audited annually. We estimate that independent laboratories will spend approximately 4 minutes to resubmit their Form 223 and accreditation certificate. Therefore, the total amount of time spent by independent conformity assessment bodies will be 15.2 hours complying with this requirement.

Firewalled third party conformity assessment bodies do not need to re-create their documentation to comply with the audit requirements. We estimate that a third party conformity assessment body will spend 226 minutes collecting and preparing the documentation to submit at audit. Based on the number of firewalled third party conformity assessment bodies that have already been accepted by the CPSC and our experience with the rate of new successful applications, we predict that the total number of firewalled third party conformity assessment bodies will be 35. Half of those, or 18, will be audited annually. If half of the firewalled third party conformity assessment bodies spend 226 minutes to comply with this aspect of audit annually, that is an annual paperwork burden of 4,068 minutes, or about 68 hours.

Similar to firewalled third party conformity assessment bodies, governmental third party conformity assessment bodies do not need to re-create their documentation to comply with the audit requirements. Therefore, we estimate that a third party conformity assessment body will spend 1 hour in support of submitting the accompanying documentation at audit. Based on the number of governmental third party conformity assessment bodies that have already been accepted by the CPSC and our experience with the rate of new successful applications, we predict that the total number of governmental third party conformity assessment bodies will be 50. Half of those, or 25, will be audited annually. If 25 third party conformity assessment bodies spend 1 hour to comply with this aspect of audit annually, that is an annual paperwork burden of about 25 hours.

Adding the aforementioned annual burden hours results in a total of 8,224 hours for third party conformity assessment bodies per year.

For the rule, to calculate the cost of the recordkeeping burden, we used the average of the total hourly compensation for private sector workers in management, professional, and related occupations, and the total hourly compensation for “sales and office” occupations, which is \$38.78 (<http://www.bls.gov/news.release/ecec.t09.htm>)¹. This is based on the assumption that workers in management and professional occupations (e.g., chemists, engineers, and quality control managers) will be responsible for about half the record keeping and administrative personnel will be responsible for the other half. At \$38.78 per hour (*i.e.*, the revised hourly compensation rate), the total cost of the recordkeeping associated with the testing and certification rule is approximately \$318,927 (8,224 hours x \$38.78 = \$318,927).

13. Annual Cost to Respondents

There are no costs to respondents beyond those presented in Section A.12. There are no other operating, maintenance, or capital costs associated with the collection.

14. Annual Cost to the Government

In the CPSC document, *Feasibility Study of User Fees*,² estimates were developed for the agency’s costs associated with accepting the accreditation of independent, firewalled, and governmental third party conformity assessment body applicants. Also, agency costs were developed for the activities associated with conducting the examination portion of third party conformity assessment body audits.

The agency cost estimates were \$500 for independent applicants and \$4,400 each for firewalled and governmental applicants. Because audit activities are essentially the same

1 U.S. Department of Labor, Bureau of Labor Statistics, “Employer costs for Employee Compensation –September 2015, Table 9”. Available at: <http://www.bls.gov/news.release/ecec.t09.htm>. Last accessed December 23, 2015. The total hourly compensation for “management, professional, and related” occupations was \$54.01; the total hourly compensation for “sales and office” occupations was \$23.55.

2 Inserra, Anne E, and Ray, Dale R. “Feasibility Study of User Fees,” May, 2011.

as an initial application, the same estimates were used for third party conformity assessment body audits. We estimate that there will be about 40 initial applications from conformity assessment bodies annually, about 12 percent of whom are expected to be either firewalled or governmental. This estimate results in an estimated agency cost of \$38,720 to examine or evaluate initial applications. We expect that about 228 independent conformity assessment bodies and about 43 firewalled or governmental conformity assessment bodies will be audited annually. Therefore, estimated cost to the government to examine and evaluate the documents submitted in connection with the audits is expected to be about \$303,200. Therefore, the total annual cost to the government associated with these requirements is estimated to be \$341,920.

15. Changes in Burden

The documentation and recordkeeping requirements have been updated based on data from the last three years' registration information.

16. Statistical Reporting

Information collected under this requirement will not be published.

17. Exemption for Display of Expiration Date

The agency does not seek an exemption from displaying the expiration date.

18. Exemption to Certification Statement

N/A.

B. Statistical Methods

The information collection requirements do not employ statistical methods.