

# INFORMATION COLLECTION REQUEST

## Supporting Statement

### Audit Requirements for Third Party Conformity Assessment Bodies

#### A. Justification

##### 1. Circumstances Necessitating Information Collection

Section 14(a)(1) of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2063(a)(1)), as amended by the Consumer Product Safety Improvement Act of 2008 (CPSIA (Pub. L. 110-314, 122 Stat. 3016)), requires that the manufacturer (including the importer) and the private labeler, if any, of a product that is subject to an applicable consumer product safety rule under the CPSA, or any similar rule, ban, standard, or regulation under any other Act enforced by the Commission, issue a certificate which certifies “based on a test of each product or upon a reasonable testing program, that such product complies with all rules, bans, standards, or regulations applicable to the product under this Act or any other Act enforced by the Commission” and specifies each rule, ban, standard, or regulation applicable to the product. This requirement applies to any such product manufactured on or after November 12, 2008.

Section 14(a)(2) of the CPSA establishes a third party testing requirement for children’s products that are subject to a children’s product safety rule. In general, section 14(a)(2) of the CPSA states, in part, that every manufacturer or private labeler (if the children’s product bears a private label) of such products shall submit sufficient samples of the product, or samples that are identical in all material respects to the product, to an accredited third party conformity assessment body to be tested for compliance with such children’s product safety rule.

Section 14(a)(3) of the CPSA establishes various time lines for accreditation and requires the Commission to publish notice of the requirements for accreditation of third party conformity assessment bodies to assess conformity with specific laws or regulations, and the Commission has published four notices of requirements in the *Federal Register* (see 73 FR 54564 (September 22, 2008) (Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity with part 1301 of Title 16, Code of Federal Regulations)); 73 FR 62965 (October 22, 2008) (Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity With Part 1508, Part 1509, and/or Part 1511 of Title 16, Code of Federal Regulations)); 73 FR 67838 (November 17, 2008) (Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity With part 1501 of Title 16, Code of Federal Regulations); and 73 FR 78331 (December 22, 2008) (Notice of requirements for accreditation of third party conformity assessment bodies to assess conformity with the 600 parts per million (“ppm”) and 300 ppm lead content limits in metal and metal alloy parts of children’s metal jewelry established by

the Consumer Products Safety Improvement Act of 2008)).

Section 14(d)(1) of the CPSA, as added by the CPSIA, requires the Commission to establish “requirements for the periodic audit of third party conformity assessment bodies as a condition for the continuing accreditation of such conformity assessment bodies” under section 14(a)(3)(C) of the CPSA. The proposed rule would establish the audit requirements pursuant to section 14(d)(1) of the CPSA.

The proposed rule would require third party conformity assessment bodies to comply with the audit requirements. As part of these requirements, the proposed rule would, if finalized, require the third party conformity assessment bodies to complete an on-line form to begin the examination portion of the audit process. This form asks for certain identifying information pertaining to the third party conformity assessment body, information concerning whether the third party conformity assessment body is owned, managed, or controlled by manufacturers or private labelers of children’s products, whether the third party conformity assessment body is owned or controlled by a government entity, the laboratory accreditation certificate for the third party conformity assessment body, and, for “firewalled” conformity assessment bodies, training materials.

Additionally, the proposed rule would require third party conformity assessment bodies to retain records relating to a reassessment and all records pertaining to the third party conformity assessment body’s resolution or plans for resolving nonconformities identified by the reassessment. The proposal would require third party conformity assessment bodies to retain such records relating to the last three reassessments (or however many reassessments have been conducted if the third party conformity assessment body has been reassessed less than three times) and to make such records available to the Consumer Product Safety Commission upon request.

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

The CPSC will use the information to conduct part of the audit process. The information may help the CPSC identify changes in a third party conformity assessment body’s ownership or operations that cause the third party conformity assessment body to no longer comply with the applicable notice of requirements or statutory requirements pertaining to that particular type of third party conformity assessment body.

3. Consideration of Information Technology

The collection of information would occur through a form that is available on the CPSC’s website. The CPSC is developing new software to improve a respondent’s ability to submit and to revise information, but cannot anticipate when the new software will become operational.

4. Efforts to Identify Duplication and Similar Information Already Available

Section 14(a)(3) and (d)(1) of the CPSA expressly require the Commission to establish

notices of requirements for the accreditation of third party conformity assessment bodies and to establish periodic audit requirements. While some of these third party conformity assessment bodies may perform testing for products outside the Commission's jurisdiction, the statutory framework in the CPSA makes it unlikely that duplication of data exists.

5. Impact on Small Business

The Small Business Administration considers a testing laboratory to be a small business if its annual revenue is less than \$12.5 million. According to the 2002 Economic Census, a very high percentage of testing laboratories ("third party conformity assessment bodies" under section 14 of the CPSA) would be considered small businesses. In 2002, almost 97 percent of all testing laboratories had revenue of less than \$10 million, and almost 50 percent had revenue of less than \$500,000. In addition, about 63 percent of the third party conformity assessment bodies that have been accredited so far for testing children's products appear to be small businesses. Therefore, it is likely that the collection of information will affect a substantial number of small businesses. However, it is unlikely that the collection of information will have significant adverse impact on many third party conformity assessment bodies. The only third party conformity assessment bodies that will seek accreditation for testing children's products are those that expect to receive substantial revenue from the testing required by the CPSIA. Those third party conformity assessment bodies that do not expect substantial revenue from the testing required by the CPSIA will not seek to be accredited for the testing or they will not renew their accreditation if they had initially sought accreditation, but the expected revenue did not materialize.

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 third party conformity assessment bodies continued to meet the appropriate statutory requirements. Failure to retain the records sought by the proposed rule would limit the CPSC's ability to detect whether third party conformity assessment bodies took appropriate actions in response to deficiencies identified in the reassessment process.

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

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

8. Consultation Outside the Agency

Given the nature of the information being collected, the CPSC's experience with third party conformity assessment bodies, and the fact that the information is collected on a CPSC form, no consultation outside the agency was necessary.

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

Questions regarding ownership, business, and governmental relationships, and third party conformity assessment body personnel may be considered sensitive. Such information could appear through proposed § 1112.9(b).

12. Estimates of Burden Hours and Explanation

We estimate the burden of this collection of information as follows:

Table 1 – Estimated Annual Reporting Burden

16 CFR Section	Number of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Hours
1112.9(b)(1)	150	1	150	1	150
1112.9(b)(2)	3	1	3	0.25	0.75
1112.13	150	1	150	4	600
Total					750.75

There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimates are based on the following information:

- As of June 5, 2009, 153 third party conformity assessment bodies had registered with the CPSC. However, because we expect to receive additional registrations and because section 14(a)(3)(B)(vi) of the CPSA requires the Commission to issue a notice of requirement for “all other children’s product safety rules,” we anticipate that many more third party conformity assessment bodies will register. Therefore, we tentatively estimate the number of third party conformity assessment bodies to be 300.
- Under proposed § 1112.9(b)(1), third party conformity assessment bodies would be required to resubmit CPSC Form 223. At a minimum, assuming there are no changes to the information that a third party conformity assessment body has submitted previously in its CPSC Form 223, the resubmission would occur every two years from the date of the previous submission. As all third party conformity assessment bodies have not submitted their first CPSC Form 223s at the same time, only some would be expected to resubmit a CPSC Form 223 in any one year. We do not know what percentage of third party conformity assessment bodies will resubmit a CPSC Form 223 in a given year, so, for purposes of this analysis, we will assume that half of the third party conformity assessment bodies will resubmit a CPSC Form 223 in any given year. Thus, the estimated number of respondents for proposed § 1112.9(b)

- (1) is 150 (300 total third party conformity assessment bodies x 0.5 resubmissions per year per third party conformity assessment bodies = 150 resubmissions per year). Furthermore, we estimate the burden hour for each resubmission to be one hour, so the total burden associated with proposed § 1112.9(b)(1) would be 150 hours (150 resubmissions x 1 hour per resubmission = 150 hours).
- Under proposed § 1112.9(b)(2), third party conformity assessment bodies would be required to ensure that the information submitted on CPSC Form 223 is current and to submit a new CPSC Form 223 whenever the information changes. Based on current experience with third party conformity assessment bodies, we estimate that only one percent of third party conformity assessment bodies will revise or update their information, so the estimated number of respondents is 3 (300 third party conformity assessment bodies x 0.01 revisions per conformity assessment body = 3 revisions per year).
  - Under proposed § 1112.13, third party conformity assessment bodies will have to retain records pertaining to an audit and their resolution of or plans for resolving nonconformities identified through a reassessment by an accrediting body or through an examination by the CPSC. The proposal also would require third party conformity assessment bodies to retain records relating to the last three reassessments (or however many reassessments have been conducted if the number of reassessments is less than three). We do not know how many third party conformity assessment bodies will be reassessed in a given year, but, for purposes of this analysis, we will assume that half will be reassessed in any given year. Thus, the estimated number of respondents is 150 (300 third party conformity assessment bodies x 0.5 reassessments per year per third party conformity assessment bodies = 150 reassessments per year). As for the time required to retain such records, it is difficult to estimate such time with precision because the amount of time is likely to vary among the third party conformity assessment bodies. Third party conformity assessment bodies that are accredited in more than one field or that have scopes that include a large number of tests are likely to require more time to manage the records generated during an audit than those who are accredited in only one field or whose scopes are limited to only a few tests. It is also likely that third party conformity assessment bodies at which a large number of nonconformities are discovered during a reassessment audit will require more time to maintain the records since more records are likely to be generated in correcting the nonconformities. Nevertheless, we tentatively estimate that it will take 4 hours per third party conformity assessment body, so the overall recordkeeping burden will be 600 hours (150 reassessments per year x 4 hours per record per reassessment = 600 hours). Most respondents probably will need less time to maintain records, but some can be expected to require more time due to factors such as the number of nonconformities found that might require the preparation of additional documents.

The total burden, therefore, is 750.75 hours, which we will round up to 751 hours.

### 13. Annual Cost to Respondents

There are no total capital or start-up costs or service costs projected.

The annual reporting cost is estimated to be \$51,068. This estimate is based on the estimated total burden hours (751 hours) multiplied by an estimated wage of \$68 per hour (751 hours x \$68 per hour = \$51,068) and assumes that a manager will complete the form. (The median hourly wage of a general or operations managers in testing laboratories (NAICS code 541380) is \$48.73 (U.S. Department of Labor, Bureau of Labor Statistics, National Occupational Employment and Wage Estimates, May 2008 (data extracted on June 17, 2009 from <http://www.bls.gov/data/>)). In 2008, wages and salaries represented about 71.9 percent of total compensation for professional and related occupations in private industry (U.S. Department of Labor, Bureau of Labor Statistics, *Employer cost for Employee Compensation* (data extracted on June 17, 2009)).) The cost could be somewhat higher than average for “firewalled” and government-owned or government-controlled conformity assessment bodies. “Firewalled” conformity assessment bodies will need to provide the CPSC staff with the updated information and documents that describe the training that the “firewalled” conformity assessment body employees receive for reporting to the Commission any allegation of an attempt by a manufacturer, private labeler, or other interested party to hide or exert undue influence over test results. Government-owned or government-controlled conformity assessment bodies might need to provide updated information to demonstrate that the government entity does not exert undue influence on the operation of the third party conformity assessment body or the testing results and that the third party conformity assessment body is not treated more favorably than other accredited third party conformity assessment bodies in the same nation.

14. Annual Cost to the Government

The annualized cost to the CPSC is estimated to be \$4,544.79. This figure is based on the following calculations and assumptions. For the resubmitted forms: (a) the employee reviewing the forms will be a GS-13 level employee; (b) the hourly wage for a mid-level GS-13 employee in the Washington, DC metropolitan area (effective as of January 2009) is \$47.21 (GS-13 step 5); and (c) a total of 30 minutes will be needed to review a resubmitted form. As we estimate that there will be 150 resubmissions, a total of 75 hours would be needed to examine all resubmitted forms (150 resubmissions x 0.5 hours per resubmission = 75 hours). The annual cost associated with the resubmitted forms under the audit provision, therefore, is \$3,540.75 (75 hours x \$47.21 per hour = \$3,540.75).

For the review of records: (a) the employee reviewing the records will be a GS-14 level employee; (b) the hourly wage for a mid-level GS-14 employee in the Washington, DC metropolitan area (effective as of January 2009) is \$55.78 (GS-14, step 5); and (c) six hours will be needed to review records. As we have no experience in this area yet, we tentatively estimate that we will review the records of one percent of the third party conformity assessment bodies in a given year or 3 reviews (300 third party conformity assessment bodies x 0.01 record reviews per third party conformity assessment bodies = 3 record reviews). The annual cost associated with the review of records under the audit provision, therefore, is \$1,004.04 ((3 reviews x 6 hours per review) x \$55.78 per hour =

\$1,004.04).

Therefore, the total annual cost to the government is \$4,544.79 (\$3,540.75 + \$1,004.04).

15. Changes in Burden

The form and recordkeeping would represent a new collection of information and increase the overall information collection burden for the CPSC by 751 hours.

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.