



# **U.S. Consumer Product Safety Commission**

## ***FY 2013 Third-Party Laboratory Accreditation Program Performance Audit***

### ***Audit Report***

**February 20, 2015**

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COMPANY**

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**U.S. CONSUMER PRODUCT SAFETY COMMISSION  
BETHESDA, MD 20886**

Date: February 23, 2015

**TO :** Elliot F. Kaye, Chairman  
Robert S. Adler, Commissioner  
Marietta S. Robinson, Commissioner  
Ann Marie Buerkle, Commissioner  
Joseph P. Mohorovic, Commissioner

**FROM :** Christopher W. Dentel, Inspector General

**SUBJECT:** Third-Party Laboratory Accreditation Performance Audit

On August 14, 2008, the Consumer Product Safety Improvement Act (CPSIA) of 2008, Public Law (P.L.) 110-34, was signed into law. The CPSIA constituted a comprehensive overhaul of consumer product safety rules, which significantly affected nearly all children's products entering the U.S. market. The CPSIA imposed a third-party testing requirement on all consumer products primarily intended for children twelve years of age or younger. Every manufacturer (including importers) or private labeler of children's products must have the product tested by an accredited independent testing laboratory and, based on the testing, must be issued a certificate stating that the product meets all applicable CPSC requirements. The CPSC was given authority under the CPSIA to either directly accredit third-party conformity assessment bodies to complete the required testing of children's products, or designate independent accrediting organizations to accredit the testing laboratories. The CPSC has the authority to suspend or terminate a laboratory's accreditation in appropriate circumstances, and is required to periodically assess whether or not laboratories should continue to be accredited. The statute requires that the CPSC issue laboratory accreditation regimes for a variety of different categories of children's products.

Section 205(a)(2) of the CPSIA requires the CPSC's Office of Inspector General (OIG) to review the adequacy of the CPSC's procedures for accrediting conformity assessment bodies. In accordance with this requirement, the CPSC OIG completed reviews over the CPSC's compliance with third-party accreditation requirements in fiscal years (FY) 2011 and 2012. The initial review found that while the CPSC had established a laboratory accreditation program within a short time period, the program lacked certain aspects to ensure that it operated efficiently and effectively to meet its stated objectives. Findings included the absence of documented policies and procedures, a subjective review process, and weak program management internal controls. In response to the OIG's review, the CPSC's management took aggressive steps to address the program's deficiencies and, upon completion of the FY 2012

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follow-up review, most of the OIG's recommendations were found to have been fully implemented. This resulted in the overall conclusion that the CPSC was in compliance with CPSIA and agency regulations.

The CPSC OIG retained the services of Kearney & Company, P.C. (Kearney), an external audit firm, to conduct a performance audit of the CPSC's compliance with relevant Consumer Product Safety Act requirements, as amended by the CPSIA. Under a contract monitored by the OIG, Kearney conducted a performance audit to assess the compliance of the CPSC's program for accrediting laboratory assessment bodies with the CPSIA and the applicable sections of the Federal Register. Kearney found that to accredit testing laboratories, the CPSC relies on accreditation bodies that are signatories to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement. Kearney also found that the CPSC has a process in place for accepting accredited laboratories (and also auditing them on a periodic basis). The CPSC website, which is used to display public information regarding the accepted laboratories, was found to be up-to-date and current.

Finally, Kearney found that over the past year, the CPSC has made several improvements to its Third-Party Laboratory Accreditation Program, to include updating written policies and procedures, addressing prior/open findings identified from OIG reviews, and updating the Laboratory Approval System to automate manual processes/controls. However, Kearney noted several instances in which the CPSC performed certain controls it did not have documented in its written policies and procedures.

In connection with the contract, we reviewed Kearney's report and related documentation and inquired of its representatives. Our review, as differentiated from an audit in accordance with generally accepted government auditing standards, was not intended to enable us to express, and we do not express, an opinion on the matters contained in the report. Kearney is responsible for the attached report. However, our review disclosed no instances where Kearney did not comply, in all material respects, with generally accepted government auditing standards.

If you have any questions please feel free to contact me.

  
CHRISTOPHER W. DENTEL  
Inspector General

Attached: Audit Report

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## **1. EXECUTIVE SUMMARY**

### **1.1 Background**

Enacted on August 14, 2008, the Consumer Product Safety Improvement Act (CPSIA) constituted a comprehensive overhaul of consumer product safety rules and regulations and expanded the United States (U.S.) Consumer Product Safety Commission's (CPSC or Commission) authority to regulate consumer products and enforce higher civil penalties. The CPSIA significantly affected all children's products entering the U.S. market.

The main subject of this performance audit was the Third-Party Laboratory Accreditation Program. In summary, all manufacturers and importers of children's products must certify, in a Children's Product Certificate, that their children's products comply with all applicable children's product safety rules. Third-party testing means testing performed by a third-party accredited laboratory that the CPSC has accepted to perform the specific tests for each children's product safety rule.

Section 205(a)(2) of the CPSIA requires the Commission's Office of Inspector General (OIG) to conduct audits to assess the adequacy of procedures for accrediting conformity assessment bodies, as authorized by Section 14(a)(3) of the Consumer Product Safety Act (CPSA). In accordance with this requirement, Kearney & Company, P.C. (Kearney), an external audit firm acting on the OIG's behalf, conducted a performance audit of the CPSC compliance with CPSA, as amended by CPSIA during fiscal year (FY) 2013.

### **Results of Evaluation and Findings**

Kearney conducted this performance audit to assess the compliance of the CPSC's program for accrediting laboratory assessment bodies with CPSIA and the applicable Federal Register (F.R.). Kearney found that to accredit testing laboratories, the CPSC relies on accreditation bodies that are signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA). As such, the CPSC assesses the risk of this reliance and notes that the reliance on ILAC member accreditation bodies to assess CPSC-accepted laboratories is small, in terms of potential for allowing incompetent or problematic laboratories in the CPSC program. Kearney also found that the CPSC has a process in place for accepting accredited laboratories (and also auditing them on a periodic basis). The CPSC website, which is used to display public information regarding the accepted laboratories, was found to be up-to-date and current.

Over the past year, the CPSC has made several improvements to its Third-Party Laboratory Accreditation Program, to include updating written policies and procedures via the F.R., addressing prior/open findings identified from OIG reviews, and updating the Laboratory Approval System to automate manual processes/controls. Kearney noted instances in which the CPSC performed certain controls; however, the CPSC did not document them in its written policies and procedures. The section below outlines what Kearney noted.

## Status of Prior/Open Findings

The CPSC OIG conducted a review, as authorized by Section 14(a)(3) of CPSA, on December 10, 2010 in response to the CPSIA. The initial review identified seven findings. The CPSC OIG then conducted a follow-up review in 2012 to determine whether the CPSC management had addressed the prior seven findings. During this review, which was issued on September 24, 2012, the CPSC OIG determined that five of the seven findings were closed. The following findings were still considered open at the time of the follow-up:

### 1. The CPSC Failed to Meet a Number of Accreditation Timeline Requirements

Current Year Follow-up: Kearney discussed the prior finding with CPSC management during the performance audit. We were informed that the rule pertaining to baby bouncers, walkers, and jumpers was established in 1971 by the Food and Drug Administration (FDA) (15 United States Code [U.S.C.] 1261 – 1278 and 36 F.R. 21809, dated November 16, 1971). During that time period, these three juvenile products included similar mechanisms and could be lumped into the same grouping. However, over the years, these products have become more distinct and now include separate mechanisms. CPSC management determined that the initial rule from 1971, which was cited within CPSIA, was no longer applicable; therefore, in 2009, management proposed that this rule be revoked (74 F.R. 45714). Since the rule's revocation, only a mandatory standard for walkers was established (16 Code of Federal Regulations [C.F.R.] Part 1216, in compliance with American Society for Testing and Materials [ASTM] F977-12). The mandatory standard allowed the CPSC to publish a notice of requirement. Until rules are mandated for bouncers and jumpers, the Laboratory Accreditation Program cannot publish notice of requirements for them.

As the rule established in 1971 was no longer applicable and revoked, Kearney determined that CPSC management is unable to publish a notice of requirement pertaining to bouncers and/or jumpers at this time.

Kearney discussed the results of these conversations and testwork related to timeline accreditations with the CPSC OIG. They concurred that this rule was no longer applicable, and this prior year finding is subsequently closed.

### 2. Assurance ILAC Standards Conform to CPSIA Standards

Current Year Follow-up: Kearney discussed the prior finding with CPSC management during the FY 2013 performance audit. We were informed that the CPSC was still fully reliant on ILAC. They were also comfortable with the use of International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 as the standard that all laboratories were held against. Kearney tested both aspects of this prior year finding: 1) ISO/IEC 17025 comparison to CPSIA standards, and 2) ILAC reliance. We determined that CPSIA did not include any incremental standards above ISO/IEC 17025. However, we determined that the CPSC lacks controls to complement its reliance

on ILAC when determining whether laboratories should be accredited as compliant with CPSC standards. See the current year finding related to ILAC reliance at #2 (Lack of Complementary Controls) below.

## **Current Year Findings**

Kearney conducted this performance audit to assess the CPSC's compliance with CPSA, as amended by the CPSIA and the applicable provisions of the F.R. During the audit, Kearney noted the following (see *Section 3 – Results and Findings* below for additional detail):

### **1. Insufficient Documentation**

The CPSC lacks documented policies and procedures to address the actions taken when a third-party accreditation laboratory's certification lapses in order to confirm that the laboratory remains in good standing with its accreditation body.

#### **Management's Response**

Management concurs with the finding and recommendation.

### **2. Lack of Complementary Controls**

The CPSC lacks controls to complement its reliance on ILAC when determining whether laboratories should be accredited as compliant with the CPSC's standards.

#### **Management's Response**

Management concurs with the finding and recommendation.

Kearney has included CPSC management's responses to our findings in the audit report (see *Appendix B*). We did not audit management's responses, and accordingly, we do not express an opinion on them.

## **2. INTRODUCTION**

### **2.1 Project Background**

On August 14, 2008, the CPSIA of 2008, Public Law (P.L.) 110-34, was signed into law. The CPSIA constituted a comprehensive overhaul of consumer product safety rules, which significantly affected nearly all children's products entering the U.S. market.

The CPSIA imposed a third-party testing requirement on all consumer products primarily intended for children twelve years or younger. Every manufacturer (including importers) or private labeler of children's products must have the product tested by an accredited independent testing laboratory and, based on the testing, must be issued a certificate that the product meets all

applicable CPSC requirements. The CPSC was given authority to either directly accredit third-party conformity assessment bodies to complete the required testing of children's products or designate independent accrediting organizations to accredit the testing laboratories. The CPSC is required to maintain an up-to-date list of accredited laboratories on its website. The CPSC has the authority to suspend or terminate a laboratory's accreditation in appropriate circumstances, and is required to periodically assess whether or not laboratories should continue to be accredited. The third-party testing and certification requirements for children's products are phased in on a rolling schedule. The statute requires the CPSC to issue laboratory accreditation regimes for a variety of different categories of children's products.

The CPSC OIG completed reviews over the CPSC's compliance with third-party accreditation requirements in FYs 2011 and 2012. The initial review found that while the CPSC had established a laboratory accreditation program within a short time period, the program lacked certain aspects to ensure that it operates efficiently and effectively to meet its stated objectives. Aspects lacking included the absence of documented policies and procedures, a subjective review process, and weak program management internal controls. In response to the OIG's review, the CPSC management took aggressive steps to address the program's deficiencies and, upon completion in the FY 2012 follow-up review, most of the OIG's recommendations were fully implemented. This resulted in the overall conclusion that the CPSC is in compliance with CPSIA and agency regulations.

## **2.2 Performance Audit Objectives**

The purpose of this performance audit was to assess the adequacy of the CPSC's program for accrediting laboratory assessment bodies, as authorized by Section 14(a)(3) of the CPSA, and amended by the CPSIA and the applicable F.R. The primary objective of the audit was to ascertain the CPSC's compliance with Section 14 of the CPSA as well as determine whether internal controls had been placed into operation and were functioning efficiently and effectively to meet the objectives of the program. Further, this was a statutory audit required under Section 205(a)(2) of the CPSIA.

This audit and resulting report should provide sufficient findings and recommendations to allow it to serve as:

- A rigorous evaluation of the CPSC's laboratory accreditation program, to include compliance with CPSIA and evaluation of related internal controls
- A consistent and understandable mechanism for reporting the results of the performance audit in accordance with Generally Accepted Government Auditing Standards (GAGAS)
- Recommendations that the CPSC can follow in improving its laboratory accreditation program for compliance with CPSIA.

## **2.3 Performance Audit Scope**

This performance audit covers the FY 2013 (October 1, 2012 – September 30, 2013) program for accrediting laboratory assessment bodies. This program is led by the CPSC’s Office of Executive Director Safety Operations Staff. The scope of this performance audit included:

1. Notice of requirements for time line accreditation
2. Requirements for application by third-party assessment bodies
3. Published CPSC rules and test methods
4. Review process for third-party conformity assessment bodies applications
5. Public information provided on CPSC’s website
6. Inspections of third-party conformity assessment bodies
7. Audits of third-party conformity assessment bodies
8. ISO/IEC 17025 standards.

Kearney conducted the work from May 2015 through November 2015 at the CPSC’s Headquarters in Bethesda, MD. In the audit, CPSC identified six categories of timeline accreditations, zero governmental applicants (as no governmental laboratories applied during the period under audit), three firewalled applicants, 39 independent applicants, and 51 audited laboratories.

## **2.4 Performance Audit Standards**

Kearney planned and performed this audit in accordance with performance audit requirements in GAGAS. Those standards required that Kearney obtain sufficient, appropriate evidence to provide a reasonable basis for findings and conclusions. Sufficiency and appropriateness of evidence needed and tests of evidence varied based on the audit objectives, findings, and conclusions. Kearney designed the audit to obtain insight into the CPSC’s current processes, procedures, and organizational structure with regards to compliance with CPSIA requirements.

## **3. RESULTS AND FINDINGS**

### **3.1 Lack of Documented Policies and Procedures Related to the Grace Period Follow an Expired Certification of Accreditation and Scope of Accreditation**

The CPSC is required to periodically assess whether third-party conformity assessment bodies (laboratories) should continue to be accredited. A Certificate of Accreditation and Scope of Accreditation issued to a third-party testing laboratory is a declaration that the accreditation body has determined that the laboratory meets all of the requirements for accreditation. The declaration is based on an assessment of compliance with ISO/IEC 17025 as well as an assessment of the competence of the laboratory for its scope. The assessment is based on a review of the laboratory management system documentation and an onsite visit by subject matter experts for both the management system and technical aspects.

Based on FY 2013 testwork and discussions with CPSC management, it was noted that it is not uncommon for an accreditation body to issue updated official certificate and scope documentation a month or more after the expiration date shown on the official certificate copy attached to the latest approved CPSC application. According to the CPSC, a certificate with a past due expiration date is not an indication of cessation of competence, nor is it a sign that a laboratory's accreditation has lapsed with its accreditation body. The laboratory remains accredited and stays on the accreditation body's published list of accredited laboratories. A laboratory holds a valid accreditation continuously unless the accreditation body officially suspends or withdraws a laboratory's accreditation.

When there is a delay in a laboratory's submittal of a valid CPSC Audit or Update Certificate application, the CPSC staff investigates the causes by contacting the laboratory, the accreditation body, or other sources, if needed, to confirm whether the laboratory remains in good standing with the accreditation body and currently maintains its status with the CPSC. The CPSC may take different actions depending on what is learned from the investigation. If the laboratory's accreditation has been suspended or withdrawn by the accreditation body, the CPSC will take action to withdraw or suspend the laboratory from CPSC-accepted status. However, these policies and procedures related to the grace period are not formally documented.

As a result of a lack of documented policies and procedures to address the certification lapses for the CPSC's accreditation laboratories, a third-party testing laboratory continues to be accepted by CPSC with an expired accreditation certificate without formal criteria to confirm that it is in good standing with its accreditation body. This could lead to laboratories' accreditation statuses not being suspended or terminated in a timely manner and adds risk that the expired laboratories do not comply with the accreditation requirements.

Kearney recommended that the CPSC establish policies and procedures to document: 1) the actions performed by the CPSC when there is a delay in a laboratory's submission of a valid CPSC Audit or Update Certificate application, and 2) criteria for deregistration. Actions pertaining to a laboratory's delay in submission of a valid CPSC Audit or Update Certificate application should include, but not be limited to, the following:

1. Investigate the cause by contacting the laboratory, the accreditation body, or other sources, if needed
2. Adjust the due date for the CPSC Audit application
3. Verify that the laboratory is still in good standing with its accreditation body
4. Withdraw or suspend the laboratory's CPSC-accepted status if its accreditation has been suspended or withdrawn
5. Maintain appropriate documentation of the above actions.

### **3.2 Lack of Documented Policies and Procedures Related to CPSC Reliance on the International Laboratory Accreditation Cooperation**

The CPSC relies on ILAC-MRA signatory accreditation bodies to perform assessments of third-party laboratories in accordance with ISO/IEC 17025. These assessments are completed as part

of the process for the laboratories to become accredited with CPSC in order for them to conduct testing over consumer products. Assessments of the laboratories include onsite visits, review of internal audits, document review, review of complaints from any source, and feedback from the marketplace and relevant regulatory bodies.

The CPSC may investigate a CPSC-accepted laboratory. It may also withdraw or suspend a laboratory from CPSC-accepted status, if warranted, after a CPSC investigation.

Based on FY 2013 testwork and discussions with CPSC, it was noted that CPSC lacks documented controls to complement the reliance on ILAC when determining whether laboratories should be accredited as compliant with CPSC standards. The CPSC does not conduct its own testing or review to monitor that ILAC standards and policies conform to CPSC standards.

Because of a lack of documented policies and procedures that verify if ILAC standards and policies conform to CPSC standards for complementary controls, emerging issues may exist with testing laboratories that are not known and further investigated. In addition, testing of laboratories could be inadequate and lead to inappropriate certifications.

Kearney recommended that the CPSC establish policies and procedures to document its due diligence over ensuring that ILAC is carrying out its testing and accreditation of laboratories to support certification by CPSC. This could take the form of the following:

1. Reviewing import/export data for abnormal trends that could trigger a request for ILAC audit workpapers
2. Engaging with ILAC to review the details of ILAC's audit/testing/assessment results
3. Conducting field site visits or inspections of third-party laboratories
4. Establishing other mechanisms to verify the validity and quality of ILAC testing, such as coordination between CPSC's Laboratory Accreditation Program and Directorate of Epidemiology to implement complementary controls in order to rely on a third-party service organization. These policies and procedures should include, at a minimum, criteria considered to: 1) trigger an investigation, and 2) obtain and review information and reports collected and produced by the Directorate for Epidemiology from the National Injury Information Clearinghouse.

#### **4. OPINION**

In our opinion, the CPSC is in compliance with CPSA, as amended by CPSIA, and internal controls have been placed into operation and are functioning efficiently and effectively to meet the objectives of the program, as of September 30, 2013. The CPSC has made significant strides in the development of its Third-Party Laboratory Accreditation Program since CPSIA was enacted in 2008. The Commission continues to enhance the program and has plans for further improvements during the upcoming FYs. Kearney has discussed our recommendations with CPSC management; they indicated that the CPSC plans to take the proper actions to remediate the issues noted, and will address Kearney's recommendations to strengthen the program.

**APPENDIX A – ACRONYM LIST**

Acronym	Definition
APLAC	Asia Pacific Laboratory Accreditation Cooperation
ASTM	American Society for Testing and Materials
BIEC	Border Interagency Executive Council
C.F.R.	Code of Federal Regulations
CPSA	Consumer Product Safety Act
CPSC	Consumer Product Safety Commission
CPSIA	Consumer Product Safety Improvement Act of 2008
EA	European Cooperation on Accreditation
FDA	Food and Drug Administration
F.R.	Federal Register
FY	Fiscal Year
GAGAS	Generally Accepted Government Auditing Standards
IAAC	InterAmerican Accreditation Cooperation
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
Kearney	Kearney & Company, P.C.
MLA	Multilateral Agreement
MRA	Mutual Recognition Arrangement
NIST	National Institute of Standards and Technology
OIG	Office of Inspector General
P.L.	Public Law
U.S.	United States
U.S.C.	United States Code
USTR	Office of the United States Trade Representative

**APPENDIX B – MANAGEMENT’S RESPONSES**

## 1. Insufficient Documentation

The CPSC lacks documented policies and procedures to address the actions taken when a third-party accreditation laboratory’s certification lapses in order to confirm that the laboratory remains in good standing with its accreditation body.

**Management’s Response**

Management concurs with the finding and recommendation.

The CPSC staff has been conducting all the actions outlined in the Audit Recommendations 1 through 4 (see *Section 3.1* for this listing), but the policies, procedures, and tracking have not been formally documented.

The CPSC staff will develop an internal report to track late submissions of CPSC Audit applications, report on CPSC steps taken to investigate the cause of the late submittal, check on the accredited status of the laboratory, and report CPSC actions related to the investigation. The report will be transmitted at regular intervals to CPSC management and as requested.

Internal CPSC procedures and processes will be developed and documented related to the handling of late CPSC Audit applications and CPSC follow-up actions.

## 2. Lack of Complementary Controls

The CPSC lacks controls to complement its reliance on ILAC when determining whether laboratories should be accredited as compliant with CPSC standards.

**Management’s Response**

Management concurs with the finding and recommendation.

The documented policies and controls related to CPSC acceptance of testing laboratories are in rule 16 C.F.R. Part 1112, the standards ISO/IEC 17025 and ISO/IEC 17011, and in ILAC’s rules for accreditation bodies to become ILAC-MRA signatories and to maintain that status. CPSC Management considers that the risk of relying on ILAC Signatory accreditation bodies to conduct assessments of CPSC-accepted laboratories to be small, in terms of potential for allowing incompetent or problematic laboratories in the CPSC program and in terms of overall potential for introducing substantial and unreasonable risks of injury associated with consumer products.

ILAC is the established worldwide accepted body for the accreditation of testing and calibration laboratories.

There is a rapidly growing demand for conformity assessment entities that can facilitate the acceptance of products across nations' borders, i.e., increase international trade with less tariffs and delays in getting products to markets. This demand has resulted in the establishment of international organizations and the development of international standards related to all aspects conformity assessment. ILAC was formed to promote international acceptance of test results performed by accredited laboratories. ILAC is the international body to which accreditation bodies become members upon application and evaluation by their peers. ILAC has observer status with the World Trade Organization and ILAC members participate in the writing of standards for conformity assessment.

A series of standards developed by the ISO/IEC provides standards for organizations that conduct conformity assessment activities. The ISO/IEC is a specialized system for worldwide standardization that in part enables increased trade in the global economy. Technical committees comprised of members from across the globe (including the United States) collaborate to develop these conformity assessment standards to facilitate acceptance of testing results between countries.

The most relevant ISO/IEC standards for testing laboratories and the accreditation of such laboratories are: 1) ISO/IEC 17025:2005 International Standard -General Requirements for the Competence of Testing and Calibration Laboratories, and 2) ISO/IEC 17011:2004 Conformity Assessment -General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies.

MRAs for laboratory testing began in the 1980s through a series of bilateral arrangements between accreditation bodies. A group of five bilateral participating accreditation bodies in the Asia-Pacific region formed a group to establish a multilateral arrangement. Similar activity occurred in Europe.

In 1997, the Asia Pacific Laboratory Accreditation Cooperation (APLAC) established its MRA for testing laboratories and calibration laboratories. Also in the 1990s, the Europeans established their Multilateral Agreement (MLA). In 2000, the ILAC MRA was established with APLAC and the European Cooperation on Accreditation (EA) as regional bodies and members of the APLAC MRA and EA MLA eligible for ILAC MRA membership. Later, the InterAmerican Accreditation Cooperation (IAAC) became a regional member of ILAC.

Members of ILAC, EA, APLAC, and other accreditation bodies around the world meet multiple times per year to review the MRA/MLA signatories, work on standards, and to improve the art and science of conformity assessment.

The ILAC MRA helped establish a global network of accredited testing and calibration laboratories that are assessed and determined to be competent by an ILAC arrangement signatory accreditation body. There are over 60 ILAC-MRA signatory accreditation bodies located throughout the world. This includes MRA signatory organizations in North America, South America, Europe, Asia, Australia, and Africa.

ILAC MRA signatory accreditation bodies undergo peer evaluations conducted by multinational teams of experts every four years. The evaluation teams observe the conduct of a selection of on-site assessments performed by the accreditation body. The evaluation of an accreditation body to establish its qualifications to be a signatory involves a team of peers (including senior staff of experienced accreditation bodies and subject matter experts) who conduct evaluations in accordance with ISO/IEC 17011. The evaluations include audits at the headquarters office of the accreditation body. Additionally, the evaluators witness the performance of the assessors during actual assessments/reassessments of laboratories to determine compliance with ISO/IEC 17025.

ILAC, regional member bodies, and accreditation bodies conduct training for assessors on all aspects of ILAC MRA requirements including all of the applicable ISO/IEC standards.

ILAC's uniform approach, based on ISO/IEC standards, allows countries to establish agreements based on mutual evaluation and acceptance of each other's laboratory accreditation systems. Each partner in such an arrangement recognizes the other partner's accredited laboratories as if they themselves had undertaken the accreditation of the other partner's laboratories.

#### ISO/IEC 17025

The ISO/IEC 17025 standard sets out requirements for testing laboratories to demonstrate that they operate a management system (which includes quality management), are technically competent, and are able to generate technically valid results.

Laboratories are accredited to ISO 17025 for a specified technical scope. This statement of scope comprises part of the laboratory's accreditation, and can include testing in accordance with mandatory standards, voluntary standards, or other types of testing regimes.

In concert with technical requirements, the ISO/IEC 17025 standard has management requirements including organization, management systems, document control, audits, and management reviews.

To ensure continued compliance, accredited laboratories are regularly reassessed, to ensure that they maintain their standards of independence and technical expertise.

#### ISO/IEC 17011

The ISO/IEC 17011 standard establishes requirements for accrediting organizations that evaluate testing laboratories for conformance with ISO/IEC 17025.

ISO/IEC 17011 was created to be used within a framework of international MRAs that implement a peer evaluation mechanism among nations' accreditation bodies. The peer

evaluation process provides assurance that accreditation bodies are operating in accordance with the 17011 standard. The standard provides specifications for accreditation body procedures for conducting laboratory assessments, and also provides the procedures for the peer evaluation of operations among accreditation bodies.

Major elements of the ISO/IEC 17011 standard include requirements for the structure, management, and supervision of the accreditation body organization, including documentation of responsibilities, and demonstration of expertise. A related section of requirements addresses impartiality of the accreditor's operations. For example, the standard requires that the accreditation body shall ensure a balanced representation of interested parties with no single party predominating. All accreditation body personnel must act objectively and shall be free from any undue commercial, financial, and other pressures that could compromise impartiality.

#### CPSC's Program of Acceptance of Testing Laboratories Based on Accreditation by ILAC MRA Signatory Accreditation Bodies

CPSC staff consulted with other Federal agencies to learn the rigors of the accreditation process and the peer review evaluations of ILAC MRA accreditation bodies. The agencies consulted included the National Institute of Standards and Technology (NIST) and the Office of the U.S Trade Representative (USTR). NIST is recognized as the primary federal resource for federal Government agencies that are considering programs related to third-party conformity assessment. This includes providing information related to conformity assessment bodies, the applicable international standards, and practical input on feasibility and the impacts on the regulated entities.

The CPSC staff recommended the current CPSC program that relies on accreditation by ILAC MRA signatory accreditation bodies. The Commission voted to approve this approach through Notices of Requirements starting in 2008 and through the rule at 16 C.F.R. Part 1112 that took effect in June 2013. This approach met several objectives:

1. Designate the core elements of a CPSC accreditation program to an entity that is established and has acceptance on a multinational level. The entity should follow internationally recognized standards for assessing the competence of laboratories and for the processes and standards used by accreditation bodies that evaluate such laboratories
2. Designate one entity that could bring on board, on a multinational level, a large number of peer-reviewed accreditation bodies that could begin the process of accrediting laboratories in accordance with the CPSC-specific requirements for a children's product safety rule
3. Avoid designation to accreditation programs or entities that are recognized only in a specific region, nation, or locality. The reasons for this objective are to:
  - a. Keep the program as simple as possible for use by manufacturers, private labelers, importers, laboratories, and other interested parties
  - b. Avoid any perceived notions of barriers to fair trade practices

- c. Establish a program that is manageable within agency resources
- d. Maintain a degree of consistency in the procedures used by the designated accreditation bodies.

CPSC Management Recommendations in Response to the Auditor’s Finding:

I. Collect and Analyze Data from Electronic Certificates

In February 2014, the President signed Executive Order 13659, Streamlining the Export/Import Process for America’s Businesses. The Executive Order requires an electronic information exchange capability, or “single window” through which businesses will transmit data required by participating agencies for the importation or exportation of cargo. The CPSC is a single window participating agency and serves as the vice-chair of the Border Interagency Executive Council (BIEC) that oversees the implementation of the Executive Order. The CPSC embraces the single window concept and will collect CPSC import specific data accordingly, including electronic certificates of compliance. The CPSC is actively working on the technical requirements to collect the electronic certificates through the single window portal, and plans to update 16 C.F.R. Part 1110 accordingly.

Staff believes the collection of electronic certificates will facilitate the review of third-party testing data of imported violative products to identify abnormal trends that could trigger the need for further investigation. Should the Commission approve inclusion of this data collection into a revision to 16 C.F.R. Part 1110, staff will explore new ways to search the data that have the potential to identify problems with individual laboratories. These types of investigations may also serve to support reliance on ILAC or identify opportunities for improvement to the CPSC program for laboratory acceptance.

II. Monitor ILAC Activities and Changes in Policies

CPSC staff will prepare and implement written procedures that call for regular monitoring of ILAC activities and changes in ILAC policies and procedures, especially those that could adversely affect ILAC-MRA conditions for acceptance or contradict with CPSC rules. As warranted, CPSC staff will engage with ILAC through its Executive or Other Committees to emphasize CPSC rules and policies and make recommendations to support CPSC positions that will support the CPSC program for acceptance of competent and independent laboratories for testing of children’s products in accordance with CPSC safety rules.



U.S. CONSUMER PRODUCT SAFETY COMMISSION  
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February 18, 2015

Kearney & Company  
1701 Duke Street, Suite 500  
Alexandria, VA 22314

Dear Kearney & Company,

CPSC Management concurs with the audit opinion rendered by Kearney and Company, in connection with its "FY 2013 Third Party Laboratory Accreditation Program Performance Audit," that determined "the CPSC is in compliance with CPSA, as amended by CPSIA, and internal controls have been placed into operation and are functioning efficiently and effectively to meet the objectives of the program as of September 30, 2013." CPSC Management also agrees that documentation of the policies and procedures noted in the audit report can be improved upon as noted in management's response to the audit findings.

We would like to acknowledge the work of Adam Pantano in conducting this truly collaborative audit engagement. If you require additional information, please contact me at (301) 504-7621 or rhowell@cpsc.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Howell", written over a horizontal line.

Robert J. Howell

\*These comments are those of CPSC staff, have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.