United States CONSUMER PRODUCT SAFETY COMMISSION Bethesda, MD 20814

OFFICE OF INSPECTOR GENERAL

2010 Consumer Product Safety Improvement Act Report to Congress

Issued: 14 January 2011 Minor Revisions: 11 February 2011

TABLE OF CONTENTS

Executive Summary	1
Introduction	2
Assessment of the Capital Improvement Efforts by the Commission	3
Assessment of the Third Party Laboratory Accreditation Program	6
Employee Complaints	11

Executive Summary

The Consumer Product Safety Improvement Act (CPSIA) of 2008 requires that the Office of Inspector General (OIG) of the U.S. Consumer Product Safety Commission (CPSC) include in an annual report to the appropriate congressional committees, the findings, conclusions, and recommendations from its reviews and audits performed under section 205 of the CPSIA. This year's report deals with the CPSC's capital improvement efforts involving information technology and the CPSC's laboratory accreditation program.

Capital Improvements: The CPSIA requires that the CPSC improve its information technology (IT) architecture in general, and that it establish and maintain a database on the safety of consumer products and other products or substances regulated by the Commission. The database must be publicly available, searchable, and accessible through the Internet website of the Commission. The development of this database will constitute, by a wide margin, the largest single IT project ever undertaken by the CPSC.

To meet these requirements, the CPSC has begun aggressively implementing a structured IT investment management process. This has proven to be particularly challenging because historically the CPSC dealt with the design and acquisition of its IT systems in an ad hoc manner. So in many ways, it had to start its implementation of a structured IT investment management process from scratch. To assess the CPSC's progress in this area, and to help provide the agency with guidance on how to continue to improve its processes, the CPSC OIG contracted with the public accounting firm of Withum, Smith+Brown (WS+B) to use the Information Technology Investment Maturity (ITIM) model developed by the Government Accountability Office (GAO) to audit the ITIM of the CPSC. WS+B found that the CPSC had taken several key steps in improving its ITIM processes, including the creation of an Investment Review Board and the adoption of its charter; the development of an IT investment portfolio; the formation of a Capital Planning and Investment Control Guide; the creation of a System Development Life Cycle Guide; and the implementation of IT Investment Classification Guidance. As a result of these and other activities, WS+B concluded that the CPSC had reached Stage 1 of the five-stage ITIM model, as defined by the GAO. In addition, WS+B found that the CPSC had implemented several of the key practices and critical processes that constitute Stage 2, but had yet to achieve that state. Based upon their assessment, WS+B provided a set of specific actions that the CPSC must accomplish to continue to improve its ITIM processes.

Laboratory Accreditation Program: The OIG's review of the CPSC's laboratory accreditation program focused on the program's internal controls. It found that although CPSC management had done a remarkable job of creating a laboratory accreditation program out of whole cloth at the time field work was being done, there were still areas of the program that needed improvement. In particular, perhaps because of the rate at which the program was created, written policies and procedures often were found to be lacking; aspects of the review process appeared to be subjective; and internal control design was deemed weak in certain areas of the program's management. The agency began taking aggressive measures to address several of these findings before the initial report was issued. Moreover, a number of these corrective measures have been implemented already; and it is anticipated that when this program is reviewed next year, the majority of this year's findings will have been addressed.

Introduction

This report has been prepared in accordance with the Consumer Product Safety Improvement Act (CPSIA) of 2008. The CPSIA constituted a comprehensive overhaul of consumer product safety rules, and it significantly impacted nearly all children's products entering the U.S. market.

The CPSIA also required that the Inspector General of the U.S. Consumer Product Safety Commission (CPSC) include in an annual report to the appropriate congressional committees, the Inspector General's findings, conclusions, and recommendations from the reviews and audits performed under subsections (a) and (b) of section 205 of the CPSIA. Those sections read as follows:

SEC. 205. INSPECTOR GENERAL AUDITS AND REPORTS.

- (a) IMPROVEMENTS BY THE COMMISSION.—The Inspector General of the Commission shall conduct reviews and audits to assess—
 - (1) the Commission's capital improvement efforts, including improvements and upgrades of the Commission's information technology architecture and systems and the development of the database of publicly available information on incidents involving injury or death required under section 6A of the Consumer Product Safety Act, as added by section 212 of this Act; and
 - (2) the adequacy of procedures for accrediting conformity assessment bodies as authorized by section 14(a)(3) of the Consumer Product Safety Act (15 U.S.C. 2063(a)(3)), as amended by this Act, and overseeing the third party testing required by such section.
- (b) EMPLOYEE COMPLAINTS.—Within 1 year after the date of enactment of this Act, the Inspector General shall conduct a review of—
 - (1) complaints received by the Inspector General from employees of the Commission about failures of other employees to enforce the rules or regulations of the Consumer Product Safety Act or any other Act enforced by the Commission or otherwise carry out their responsibilities under such Acts if such alleged failures raise issues of conflicts of interest, ethical violations, or the absence of good faith; and
 - (2) actions taken by the Commission to address such failures and complaints, including an assessment of the timeliness and effectiveness of such actions.

This report fulfills the above-referenced requirements.

Assessment of Capital Improvement Efforts by the Commission

To meet this requirement in FY 2010, the CPSC OIG focused on the development of the database of publicly available information on incidents involving injury or death, required under section 6A of the Consumer Product Safety Act. Because this database is not operational yet—it is scheduled to be operational in spring 2011—it was impossible to assess its operational effectiveness.

However, a method was found to assess objectively the current status of the CPSC's efforts in this area, as well as provide the agency with a road map to meet the goals set out in the CPSIA. That method was the Government Accountability Office's (GAO) Information Technology Investment Maturity (ITIM) framework.

Background: The ITIM framework is a maturity model consisting of five progressive stages of maturity that allow an agency to achieve its ITIM capabilities. The maturity stages are cumulative; that is, in order to attain a higher stage of maturity, the agency must have institutionalized each of the requirements for that stage, in addition to those for each of the lower stages. The framework can be used to assess the maturity of an agency's investment management processes, leading to overall organizational improvement.

The GAO's ITIM maturity model framework offers organizations a guide for improving their IT investment management processes in a systematic and organized manner. These process improvements are intended to: increase the likelihood that investments will be completed on time, within budget, and with the expected functionality; promote better understanding and management of related risks; ensure that investments are selected based on their merits by a well-informed decision-making body; implement ideas and innovations to enhance process management; and increase the business value and mission performance of investments.

Under a contract monitored by the Office of Inspector General (OIG), Withum, Smith+Brown, PC (WS+B), an independent certified public accounting firm, performed an audit of the CPSC's ITIM processes, using the GAO's ITIM framework.¹

Findings: WS+B found that the current condition of the CPSC's ITIM processes is primarily a function of the length of time that the CPSC has been working to fully develop and implement these processes. The passage of the Consumer Product Safety Improvement Act of 2008 (CPSIA) provided the impetus for the CPSC to upgrade its ITIM processes. Prior to that time, many of these processes were carried out in an *ad hoc* manner. To fund the public database project, the CPSC was required to submit an Exhibit 300,² to the OMB, which it submitted in September 2008. The CPSC has provided several updates on the database project to the OMB since then. As a result of the passage of the CPSIA, the CPSC received a mandate to:

¹ The audit report, upon which this portion of the report is based, can be found at the CPSC OIG webpage at http://www.cpsc.gov/about/oig/oig.html.

² Exhibit 300 provides summary information and justification; summary of funding, acquisition and contract strategy; and earned value management, performance information, security, and enterprise architecture information related to capital investments.

- establish and maintain a database on the safety of consumer products that is publicly available, searchable, and accessible through the Internet;
- provide a detailed plan for establishing and maintaining the database, including plans for the operation, content, maintenance, and functionality of the database and details on the integration of the database into the Commission's overall information technology improvement objectives and plans; and
- expedite efforts to upgrade and improve the information technology systems in use by the Commission.

Since the passage of the CPSIA, the CPSC has been working to improve its ITIM practices. A year after passage of the CPSIA, the CPSC retained a capital planning manager from another federal agency, who is also serving as the Investment Review Board (IRB) chair. Because ITIM maturity stages are cumulative, where each stage is dependent upon completion of the previous stage, the CPSC has not been able to implement fully all of the Stage 2 critical processes and key practices.

As a result of these and other activities, WS+B concluded that the CPSC has reached Stage 1 of the five-stage ITIM model, as defined by the GAO. The CPSC has implemented several of the key practices and critical processes that constitute Stage 2. However, without adequate ITIM practices and procedures in place, the CPSC may not be able to reduce risk and heighten investment return; thus, the possibility exists that investments may not meet mission needs in the most cost-effective and efficient manner.

This takes on greater importance and urgency because the public database project is scheduled for implementation in spring 2011; currently, the launch of the public database is the most costly project in the CPSC's portfolio. The CPSC has performed additional activities and continues to develop and refine key practices following substantial completion of WS+B's assessments in July 2010.

Recommendations: WS+B determined that the following specific items need to be achieved for the CPSC to reach Stage 2 of ITIM maturity:

- 1. Ensure that the IRB has adequate resources, people, funding, and tools to support its operations and that these resources are identified and dedicated. The CPSC should identify the resources required for the effective operation of the IRB and ensure that the same is made available for investment execution and management.
- 2. Ensure that IRB members understand the CPSC's ITIM policies and procedures, as well as tools and techniques. The CPSC should organize a formal orientation session for its IRB members in areas such as economic evaluation techniques, capital budgeting methods, performance measurement strategies, and risk management approaches. The CPSC should provide training to the IRB on the Capital Planning and Investment Control Guide (CPIC), focusing on the policy and criteria for identification and selection of IT projects.

- 3. Implement project management procedures for all projects and systems, including a dedicated project management office (PMO) modeled after CPSRMS's; although the extent of management procedures can vary, depending on the classification of the project. CPSC staff should continue to use the PMO dashboard as a tool to provide oversight and monitoring functions to ensure that projects receive the required oversight based upon the investment size and classification.
- 4. Establish procedures to ensure that users participate in project management throughout an IT project's life cycle, as CPSRMS has done. WS+B recommend that the CPSC provide additional resources to form an integrated Program Team or designated liaison within the program area to facilitate understanding of business needs. Internal user signoffs should be documented formally to evidence participation of the user departments.
- 5. Facilitate and enforce use of the CPIC Guide and the selection process for IT investments, as defined in the CPIC Guide for all projects.
- 6. Develop procedures to ensure that funding decisions are aligned with selection decisions, and that the IRB's IT portfolio recommendations are integrated more closely in the CPSC's budget process.
- 7. Develop procedures to ensure that all IT investment expenditures and acquisitions are made within the ITIM framework.
- 8. Ensure that the CPSC's IT projects and systems, including those in steady-state (operations and maintenance), are identified and that the required documents are collected in accordance with the CPIC Guide (including expected cost and schedule milestones, measurable benefit and risk expectations) to support decisions. These documents should be made available on the CPSC portal and updated, as necessary.
- 9. Ensure that data on actual performance, utilizing dashboards (including cost, schedule, benefit and risk performance), is made available to the IRB and reviewed regularly.
- 10. For each underperforming IT project or system, ensure that appropriate actions are taken to correct or terminate the project or system, in accordance with defined criteria and the documented policies and procedures for IRB oversight.
- 11. Ensure that the IRB regularly tracks the implementation of corrective actions for each underperforming project until the actions are completed.

Due to the cumulative nature of the ITIM maturity framework, Stages 3, 4, and 5 cannot be achieved until all of the critical processes in Stage 2 have been achieved. Therefore, it would be premature to propose a road map for Stages 3, 4, and 5. GAO research has shown that agency efforts to improve investment management capabilities should focus on implementing all lower-stage practices before addressing the higher-stage practices.

Conclusion: Although it is too early to tell how effective the public database will be when it becomes operational, the steps taken by CPSC management to improve its ITIM processes certainly constitute movement in a positive direction. In FY 2011, after the publicly available database becomes operational, CPSC OIG will conduct a review of the public database project's effectiveness in meeting the criteria set forth in the CPSIA. To ensure that the CPSC has the appropriate investment management processes in place for the implementation of the public database project, and to improve its IT investment management processes over its entire investment portfolio, the OIG has recommended that the Chairman of the CPSC direct the Chief Information Officer to develop a plan of action and milestones (POA&M) to include timeframes for the completion of the remaining Stage 2 processes, as well as the subsequent stages.

Assessment of the Third Party Laboratory Accreditation Program

To assess the adequacy of procedures for accrediting conformity assessment bodies as authorized by section 14(a)(3) of the Consumer Product Safety Act (15 U.S.C. 2063(a)(3)), as amended by the CPSIA, and to oversee the third party testing required by such section, this office conducted a review of the CPSC's Laboratory Accreditation Program.

Background: In relevant part, the CPSIA imposed a third-party testing requirement on all consumer products intended primarily for children 12 years of age or younger. Every manufacturer (including an importer) or private labeler of a children's product must have its product tested by an accredited independent testing laboratory and, based on the testing, must issue a certificate that the product meets all applicable Consumer Product Safety Commission (CPSC) requirements. The CPSIA gave the CPSC the authority to directly accredit third party conformity assessment bodies (hereafter referred to as "third party laboratories") to do 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 authority to suspend or terminate a laboratory's accreditation, in appropriate circumstances, and is required to periodically assess whether 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 OIG's review focused on two specific areas. First, it evaluated whether internal controls were designed adequately and executed properly in the management of the laboratory accreditation program. Second, it assessed the CPSC's compliance with the CPSIA in the operation of its conformity assessment program. This review was completed in accordance with the Quality Standards for Inspections issued by the Council of Inspectors General on Integrity and Efficiency's (CIGIE) Inspection and Evaluation Committee and not the Generally Accepted Government Audit Standards (GAGAS) issued by the Government Accountability Office.

The CPSC determined quickly that it lacked the necessary infrastructure to directly accredit the testing laboratories. So, to leverage its available resources, the CPSC used an independent accrediting organization to accredit the testing laboratories. The requirements for CPSC recognition include the following: (1) that the laboratory be accredited by a laboratory

accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA); (2) that the laboratory scope of accreditation include the test methods required by CPSC laws and regulations; and (3) that the laboratory apply to the CPSC for recognition and agree to fulfill the requirements of the CPSC program.

In implementing the CPSIA, in general, and the laboratory accreditation program, in particular, the CPSC faced challenges created not only by the requirement that it promulgate rules within mandatory timelines, but also by the complex scientific, technical, and procedural issues surrounding the rules. For example, the first in the series of rules dealing with laboratory accreditation (not a subject traditionally within the CPSC's jurisdiction) had to be promulgated within 30 days of the enactment of the CPSIA.

The CPSIA expanded the authority and the responsibilities of the CPSC. Prior to the passage of the CPSIA, the agency had never participated in the accreditation of laboratories, and had not been confronted with the daunting task of developing a program to accredit laboratories and overseeing their testing of certain consumer products. The CPSIA established an aggressive regulatory agenda and set deadlines to ensure that results were achieved in a timely fashion. The vigorous requirements of the CPSIA have had positive as well as negative effects on the agency. The CPSIA has spurred a greater degree of regulatory activity. Meanwhile, it established implementation deadlines requiring the CPSC to move at a pace that it has not always been able to achieve.

Summary of Findings: The OIG found that although the CPSC has done a remarkable job of creating a laboratory accreditation program out of whole cloth at a time when field work was ongoing, there were other areas of the program that needed improvement. In particular, perhaps because of the rate at which the program was created, written policies and procedures often were lacking; certain aspects of the review process appeared to be subjective; and internal controls design was weak in certain areas of the program's management. As noted in the CPSC's responses to these findings, the agency began taking aggressive measures to address a number of the findings detailed in the report, even before the report was issued. Summaries of the specific findings made in the OIG's report are set forth below.³

Finding 1. No Published Methodology or Detailed Criteria Developed for Evaluation of Government Laboratories

We found that there was neither a published methodology nor detailed criteria established for the evaluation of government laboratories. The criteria for evaluating third-party and firewalled laboratories were spelled out fairly clearly and made available to the public on the CPSC's website. However, no such criteria have been published for government-controlled laboratories, and it appeared that no such criteria existed, at least in a written form.^{4,5}

³ The report containing the results of the review upon which this portion of this report is based, as well as management's responses to same, may be found at the CPSC OIG webpage at http://www.cpsc.gov/about/oig/oig.html.

⁴ The CPSIA establishes the underlying criteria to be evaluated (e.g., the existence of "undue influence"), but not how that evaluation should take place (e.g., independent investigation, information provided by other federal agencies).

As a result of the apparent lack of criteria, the evaluation of government laboratories may appear subjective. This appearance of subjectivity could increase the chances that an unsuccessful applicant would challenge the agency's decision to deny accreditation.

Recommendation: Develop a baseline or minimum set of documents and requirements that government laboratories must meet to be accredited; continue to use the current multi-person panel to evaluate applications to reduce subjectivity.

Finding 2. No Policies or Procedures Developed to Audit Third Party Laboratories as Condition of Continuing Accreditation

The CPSIA requires that no later than 10 months after the date of enactment of the CPSIA, the CPSC, by regulation, should establish requirements for the periodic audit of third party laboratories, as a condition of the continuing accreditation of such bodies. This requirement was to be completed by June 2009.

The CPSC does not have written policies or procedures in place to audit third party laboratories. As a result, the CPSC has no way of verifying whether the third party laboratories that it has accredited previously currently are complying with the accreditation requirements.

Recommendation: The CPSC should develop and implement written policies and procedures for auditing third party laboratories.

Finding 3. Inadequate Monitoring of Certification Expiration Dates

In accordance with section 102(e)(1)(B) of the CPSIA, the CPSC may withdraw its accreditation or its acceptance of the accreditation of a third party laboratory if the CPSC finds such laboratory failed to comply with an applicable protocol, standard, or requirement established by the CPSC.

However, the CPSC does not have written procedures to monitor whether certifications have expired certifications or whether certificates are up for renewal. Instead, the CPSC conducts follow-up checks—which are not documented or recorded—on an *ad hoc* basis.

The lack of documented procedures for monitoring certificate expiration dates increases the risk that an unauthorized laboratory will continue to be recognized as an accredited laboratory by the CPSC.

Recommendation: The CPSC should develop and implement procedures for regularly monitoring certification/certificate renewals and detecting expired certifications and maintain records of these reviews. Laboratories with expired certifications should be removed from the accredited laboratory list maintained electronically by the CPSC.

⁵ Since the completion of field work, the agency has made improvements in this area, including developing a standard set of questions and requests for documentation that it uses for all governmental lab applicants.

Finding 4. No Written Policies or Procedures Exist for Removing Third Party Laboratory's Certification.

The CPSIA contemplates two situations that may lead to the withdrawal of a third party laboratory's certification. First, in accordance with CPSIA, Section 102(e)(1)(A), the CPSC may withdraw its accreditation or its acceptance of the accreditation of a third party laboratory if the CPSC finds that 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. Second, CPSIA, Section 102(e)(1)(B) states that the CPSC may withdraw its accreditation or its acceptance of the accreditation of a third party laboratory if the CPSC finds such laboratory failed to comply with an applicable protocol, standard, or requirement established by the CPSC.

The CPSC does not have written policies or procedures to address the requirements of CPSIA, Section 102(e)(1)(A) or (B).

As a result, its process of withdrawing accreditation is not standardized, leaving the agency subject to a claim in court that it acted in an arbitrary and capricious manner when it withdraws accreditation from a laboratory. It is unclear what policies and procedures the CPSC will implement to withdraw recognition or acceptance of a third party laboratory's accreditation.

Recommendation: The CPSC should develop and implement written policies and procedures for withdrawing a third party laboratory's certification.

Finding 5. No Written Policies or Procedures Exist for Reviewing Employee Training Records Contained in Firewalled Laboratory Accreditation Application Packages

In addition to the baseline accreditation requirements, firewalled laboratories must submit in English, copies of their training documents to the CPSC. These documents should demonstrate that the laboratory's employees have been trained to understand that they may notify the CPSC immediately and confidentially of any attempt by a manufacturer, private labeler, or other interested party to hide or exert undue influence over the third party laboratories' test results. This additional requirement applies to any third party laboratory in which a manufacturer or private labeler of a children's product to be tested by the third party laboratory, owns an interest of 10 percent or more in the laboratory in question.

No written policies or procedures exist on how to implement the above-described requirements. During field work, we observed that there was little standardization or uniformity in the evaluation process. As a result, there is a lack of consistent enforcement or implementation of application requirements. For example, not all application packages examined contained the actual signatures of the employees who allegedly attended the training. The lack of employees' signatures on the training attendance list increases the difficulty of establishing whether the listed attendees actually received the training in question.

Recommendation: Develop and implement written policies and procedures to describe what constitutes acceptable training documents and related minimum requirements for firewalled laboratory application packages.

Finding 6. CPSC Failed to Meet Number of Accreditation Timeline Requirements

The CPSIA and related regulations created a number of timeline requirements for the establishment of accreditation requirements. The accreditation requirements for baby bouncers, walkers, and jumpers were to be established not later than 210 days after enactment of the CPSIA, or March 12, 2009. All other current CPSC children's product safety rules were to be created not later than 10 months after enactment of the CPSIA, or June 14, 2009). The CPSIA also required the CPSC to establish, by regulation, requirements for the periodic audit of third party laboratories, as a condition of the continuing accreditation of such bodies. The periodic audit requirement was supposed to be met not later than 10 months after the date of enactment of the CPSIA, June 14, 2009.

The CPSC did not publish *Federal Register* notices of accreditation requirements for baby bouncers, walkers, and jumpers by March 2009, as required by the CPSIA timeline.

Of the five classes of children's products mentioned specifically in the CPSIA regulation, four of the classes successfully met the timeline requirements, and only one class (baby bouncers, walkers, and jumpers) did not post before the required timeline expired. The rule for infant walkers finally posted to the *Federal Register* in June 2010, 15 months after the CPSIA timeline required.

There does not appear to be a predominate reason for the agency's failure to meet certain required timelines set forth in the CPSIA. In the case of baby bouncers, walkers, and jumpers, staff indicated the desire to produce a "better" rule than the previous rule. In the case of auditing third party laboratories, staff completed other projects demanding more immediate attention.

Recommendation: Increase the emphasis on meeting congressional mandates.

Finding 7. Overreliance on ILAC to Ensure Laboratories Conform to CPSIA Standards

At the time fieldwork was conducted, the CPSC was relying nearly exclusively on ILAC to ensure that the laboratories accredited by the CPSC actually conformed to CPSIA standards.

Although the CPSIA (Section 102(a)(1)(3)(C)) does permit the CPSC to accredit third party laboratories directly or through an independent accreditation organization, concerns exist about whether the CPSC demonstrated adequately and documented completely—prior to the agency opting for ILAC as the independent accreditation organization—that ILAC standards/test methods conform to CPSIA standards.

Based upon our findings, it appears that the CPSC may be relying too heavily on ILAC's accreditation process to determine whether to accredit laboratories as CPSIA compliant. It appears that tight deadlines and other resource constraints may be contributing factors in the CPSC's reliance on ILAC accreditation.

Recommendation: Consider conducting field visits or onsite inspections or employing some other monitoring mechanism to verify the validity and quality standards of third party laboratories. Perform these visits randomly, or when concerns arise, to limit reliance on ILAC certification.

Conclusion: Prior to the release of our original review, the CPSC already had undertaken aggressive measures to address our findings and recommendations. These included formal rulemaking—a rule is being developed that would address third party conformity assessment body requirements, including suspension and withdrawal of accreditation, as well as the development of internal agency procedures for overseeing accreditation. For example, the agency has developed a standard set of questions and requests for documentation to use for all governmental lab accreditation applicants. These standard requests are being published. Requests for information from U.S. missions abroad now also have a standard form. Thus, all applicants are reviewed using a standardized review document that provides the grounds for the agency's findings regarding the five criteria for governmental laboratories set forth in the statute. All relevant staff are being trained in these new procedures. In FY 2011, the OIG anticipates that a follow-up review will be completed to determine the effectiveness of these new policies and procedures.

Employee Complaints

No complaints fitting the definitions set forth in section 205(b) of the CPSIA have been filed with this office.

Christopher W. Dentel

Inspector General

U.S. Consumer Product Safety Commission