

United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, DC 20814

OFFICE OF INSPECTOR GENERAL

**Review of the Consumer Product Safety Commission's Laboratory Accreditation
Program**

10 December 2010



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: December 10, 2010

TO : Inez Tenenbaum
Chairman

FROM : Christopher W. Dentel
Inspector General

SUBJECT : Review of the CPSC Laboratory Accreditation Program

The Office of Inspector General has completed its review of the CPSC's Laboratory Accreditation Program. A copy of the report is attached.

Management has been briefed regarding the findings and recommendations of this review and given an opportunity to respond to them. Management's response may be found as an attachment to the report. Management generally concurred with the findings of the review and agreed to implement corrective actions regarding these findings. Many of their corrective actions have already been initiated.

If you have any questions about this report or wish to discuss it, please feel free to contact me at 301-504-7644 or cdentel@cpsc.gov.

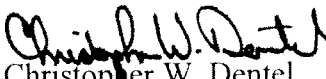

Christopher W. Dentel
Inspector General

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ABBREVIATIONS

| | |
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| CIGIE | Council of Inspectors General on Integrity and Efficiency |
| CPSC | Consumer Product Safety Commission |
| CPSIA | Consumer Product Safety Improvement Act |
| EXIP | Office of International Programs and Intergovernmental Affairs |
| GAGAS | Generally Accepted Government Audit Standards |
| ILAC | International Laboratory Accreditation Corporation |
| ISO | International Organization for Standardization |
| OIG | Office of Inspector General |

EXECUTIVE SUMMARY

On August 14, 2008, the “Consumer Product Safety Improvement Act of 2008” (CPSIA) was signed into law. The CPSIA constituted a comprehensive overhaul of consumer product safety rules, and significantly impacted nearly all children’s products entering the United States market.

In relevant part, 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 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 CPSC was given the authority to either directly accredit third party conformity assessment bodies (hereafter referred to as “third party laboratories”) to do the required testing of children’s products or to designate independent accrediting organizations to accredit the testing laboratories. The CPSC is required to maintain an up-to-date list of accredited labs on its web site. The CPSC has 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.

Inspector General Review: The CPSIA also requires that the CPSC Office of Inspector General (OIG) review the adequacy of procedures the CPSC has established for accrediting conformity assessment bodies and overseeing the third party testing required by the CPSIA (henceforth this program will be referred to as “laboratory accreditation”).¹ This report summarizes the results of that review.

This review focuses on two specific areas. First, it evaluates if internal controls were adequately designed and properly executed in the management of the laboratory accreditation program. Second, it assesses the CPSC’s compliance with the the CPSIA in its 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) standards issued by the Government Accountability Office.

Background: The CPSC quickly determined that it lacked the necessary infrastructure to directly accredit the testing laboratories. So, in order to leverage its available resources, the CPSC decided to utilize an independent accrediting organization to accredit the testing laboratories. The requirements for CPSC recognition include 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); the laboratory scope of accreditation must include the test methods required by CPSC laws and regulations; and the laboratory must apply to the CPSC for recognition and must agree to fulfill the requirements of the CPSC program.

¹ As authorized by section 14(a)(3) of the Consumer Product Safety Act (CPSA)

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

The CPSIA expanded both 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, much less been faced with the daunting task of developing a program to accredit laboratories and oversee 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 aggressiveness of the CPSIA has had both positive and negative effects on the agency. It has spurred on a greater degree of regulatory activity than would have existed without the passage of the act. At the same time, it established implementation timelines that required the CPSC to move at a pace that the agency has not always been able to accommodate.

Results in Brief: The OIG 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 areas of the program that could be improved. In particular, perhaps because of the rate at which the program was created, written policies and procedures were often lacking, certain aspects of the review process appear to be subjective, and internal control design was weak in some aspects of the program's management. As noted in the agency's responses to findings 1, 4, 5, and 7, the agency began taking aggressive measures to address a number of the findings detailed in this report even before the report was issued.

Management Response: CPSC management generally agreed with the recommendations made. This report contains both a summary of management's response to each of the individual findings and recommendations, set out immediately following the findings and recommendation in question, and management's verbatim response as an appendix to this report.

RESULTS OF THE REVIEW

Finding 1. No Published Methodology or Detailed Criteria had been Developed for the Evaluation of Government Labs

We found that there was neither a published methodology nor a detailed criteria established for the evaluation of government labs. The criteria for evaluating third-party and firewalled labs was spelled out fairly clearly and available to the public at the CPSC web site. However, no such criteria had been published for government controlled labs and it appeared that no such criteria existed, at least in a written form.^{2 3}

As a result of the lack of visible criteria, the evaluation of government labs may appear subjective. This may increase the chances that an unsuccessful applicant could successfully challenge the agency's decision as arbitrary and capricious.

Beyond the issue of appearance, the methodology and criteria used for evaluating government-controlled labs was in fact more subjective than the methodology and criteria used to evaluate third-party and firewalled labs. It was determined that at the time of fieldwork no detailed written procedures were in place to standardize the way evaluations of government labs were conducted. Laboratories in one country were asked to respond to a different set of questions than laboratories in another country. These procedures may well have a reasonable and rationale basis, but it is not one that had been committed to writing. A review of the physical application files determined that they contained a variety of documents with little consistency from application package to application package.

General guidance set out in a memo from the Office of International Programs and Intergovernmental Affairs (EXIP) to the Commission dated March 19, 2009 stated, "The number of attestations will depend on the specific case. For example, a single attestation from a senior ministry official might be sufficient in cases where the lab is operated directly by that ministry. A joint venture would likely require attestations from the company operating the lab and from their related government entity."

This might well be good and appropriate general policy guidance, but the agency needs to develop specific guidance on how this policy will be applied to specific cases.

Clearly, some degree of professional judgment will need to be exercised in the evaluation process and a "one size fits all" approach would be counterproductive. However, there should be written criteria documenting the process used and the process itself should be regularized and made as objective as possible. For example, if the CPSC is going to rely on information provided by employees of other Federal agencies, the relationship between the CPSC and those agencies should be formalized in writing.

² The CPSIA establishes the underlying criteria to be evaluated (the existence of "undue influence" etc), but not how that evaluation should take place (independent investigation, information provided by other Federal agencies, etc).

³ 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. See "Response" below.

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

Agency Response: As a result of the OIG's early informal recommendations, the agency has developed a standard set of questions and requests for documentation that it uses for all governmental lab applicants. These standard requests are being published. Requests for information from U.S. missions abroad also have a standard form. All applicants are reviewed using a standardized review document that provides grounds and reasoning for a finding relative to each of the five criteria for governmental labs set forth in the statute. All EXIP staff are being trained in the standard procedures. EXIP does not agree that the relationship between CPSC and other federal agencies providing assistance should be formalized in writing. Other agencies are under no obligation to assist us in our analysis of an applicant and there is no evidence that a formal relationship would result in better information than we currently receive. Feedback from our Embassies and Consulates to date has been extremely helpful. Creating a formal relationship with multiple agencies would, however, create a new demand on our own scarce agency resources and could result in the creation of new bureaucratic procedures without clear benefits.

Finding 2. No Policies or Procedures have been Developed to Audit Third Party Laboratories as a Condition for their Continuing Accreditation

The agency does not have written policies or procedures in place for auditing third party laboratories as a condition for their continuing accreditation.

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

The CPSC does not yet have written withdrawal policies or procedure in place to audit third party laboratories.

As a result, the CPSC has no way of verifying whether or not the third party laboratories that it has accredited in the past are currently complying with the accreditation requirements.

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

Agency Response: The CPSC did publish a proposed rule to implement the audit provision in the CPSIA (74 FR 40784 (August 13, 2009)). The final rule is in progress and must be coordinated with a proposed rule that would address third party conformity assessment body requirements, including suspension and withdrawal of accreditation.

Finding 3. Inadequate Monitoring of Certification Expiration Dates

The CPSC lacks documented procedures for monitoring laboratory certification expiration dates. We also observed that whatever “ad hoc” monitoring was taking place was failing to identify laboratories with expired certificates. Our review of the database found seven laboratory certificates that had expired and 16 laboratories that had certificates without 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 for expired certifications or certificate renewals and instead conducts the checks - which are not documented or recorded - on an ad hoc basis. As a result, the agency failed to identify those laboratories which were out of compliance with applicable protocols due to their certification having expired. Additionally, files were found in which laboratories had been accredited despite failing to provide expiration dates for their certification. These problems were not detected by the agency.

The lack of documented procedures for monitoring certificate expiration dates increases the risk of a laboratory continuing to be recognized by the CPSC incorrectly. As of the end of field work for this review, the list of accredited laboratories on the CPSC website was not reconciled with the accreditation database.

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

Agency Response: Accreditation bodies across the world have somewhat different conventions on the issuance of an expiration date. These different conventions are within the allowable framework established by the ISO standards and by ILAC, so long as the accreditation body is complying with its designated reassessment schedule for a laboratory. In all cases, the laboratory maintains its accreditation unless there is a formal notice from an accreditation body that a laboratory’s accreditation is suspended or withdrawn. The CPSC application process collects certificate expiration dates for information purposes (for those labs that are issued expiration dates). However, there has not been a case where the absence of an expiration date or the passing of an expiration date has indicated a suspension of accreditation by the accreditation body. While a certificate expiration date may be useful in certain circumstances to trigger a CPSC follow-up with the laboratory, it has been determined that this should not be a stand-alone criteria for the CPSC to remove a laboratory from the “CPSC-accepted” list.

The most important factor is that a laboratory has not been formally issued a “suspension or withdraw” by its accreditation body, and therefore is still in good standing with its accreditation body.

Through the continued maturation of the CPSC application and review process and the laboratory community's increasing familiarity of the CPSC application process, the CPSC has several ways to ensure that laboratories continue to meet their accreditation requirements. CPSC staff is currently developing a proposed rule that would address third party conformity assessment body requirements, including suspension and withdrawal of accreditation.

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

The agency does not have written withdrawal policies or procedures in place for withdrawing a third party laboratory's certification.

The CPSIA contemplates two situations which may lead to the withdrawal of a third party laboratory's certification. 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 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. 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 withdrawal policies or procedure in place to implement either CPSIA, Section 102(e)(1)(A) or (B).

As a result, the withdrawal process is not standardized and runs the risk of not being applied uniformly. Any effort by the agency to withdraw accreditation would run the risk of being found to be arbitrary and capricious by a court if challenged. In addition, it is unclear when and how the CPSC will decide to withdraw its recognition or acceptance of a third party laboratory's accreditation.

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

Agency Response: The CPSC is developing a proposed rule that would address third party conformity assessment body requirements, including suspension and withdrawal of accreditation.

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

In addition to the baseline accreditation requirements, firewalled laboratories must submit to the CPSC copies, in English, of their training documents. These documents should demonstrate that their employees have been trained that they may notify the CPSC immediately and confidentially of any attempt by the 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 ten percent or more in the laboratory in question.

During our fieldwork we noted that the CPSC was not consistent in applying its standards regarding minimum laboratory employee training requirements and attendance records to its review of Firewall Laboratory Application packages.

No written policy or procedure exists 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 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 if the listed attendees actually received the training in question.

The management of the Firewalled laboratories are required to provide an ethics phone list to their employees, to allow them to report undue influence, and to indicate that they have done so in their application packages. However, upon review of these packages, some application packages contained copies of the phone list while others did not. Specifically, of eleven (11) firewall applications received by CPSC, seven (7) applications (64%) did not include an ethics phone list as part of the package. As a result, the phone list's existence, much less whether or not it had in fact been provided to the employees, could not be validated.

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

Agency Response: All points in Finding 5 are currently in development and will be presented to the Commission for its consideration in a proposed rule and policies and procedures.

Finding 6: The CPSC Failed to Meet a 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 (i.e. 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 (i.e. June 14, 2009). The CPSIA also

required that the CPSC establish by regulation requirements for the periodic audit of third party laboratories as a condition for the continuing accreditation of such bodies. This requirement was supposed to be met not later than 10 months after the date of enactment of the CPSIA.

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

The following product classes had laboratory accreditation requirements which the CPSC did not post until after the August 2009 deadline set out in the CPSIA.

- Infant bath seats - 11 months late
- Clacker balls - 8 months late
- Electrically operated toys - 8 months late
- Vinyl plastic film - 11 months late
- Carpets and rugs - 11 months late
- Small carpets and rugs - 11 months late

There does not appear to have been a single overarching reason for the agency's not meeting timelines requirements set out in the CPSIA. In some cases (baby bouncers, walkers, and jumpers) staff has indicated that they desired to produce a "better" rule than had currently existed and chose to place quality over timeliness. In other cases (audit of third party laboratories) staff indicated that the project was simply viewed as having a low priority when considered against the other requirements that needed to be met.

Recommendation: Increase the emphasis on meeting Congressional mandates.

Agency Response: The CPSIA represents the most substantial change in consumer product safety since the creation of the Agency in 1973. Since August 2008, CPSC staff has worked diligently to implement the CPSIA through rulemaking, enforcement, and other safety standard activities. In 2010 we have completed over 30 rules or other documents required by the CPSIA. The number of completed assignments required by the CPSIA, however, is only a partial accounting of Commission staff's actual workload. For example, in some cases, a statutory requirement under the CPSIA triggered additional work and the need for the Commission staff to issue a proposed rule (before it could issue the CPSIA required final rule), an interpretive rule, a statement of policy, or a guidance document. These other rules and documents constitute an additional 50 items completed since August 2008 (20 items completed in 2009, 30 items completed in 2010). We also held numerous public briefings to help stakeholders understand their obligations under the law, created a special Web site devoted to CPSIA, and responded to thousands of inquiries from affected manufacturers, retailers, resellers, and consumers.

At the same time the CPSC was working on the implementation of the CPSIA it was called upon to deal with two other challenges. Staff resources had to be reallocated to work on the unplanned and unbudgeted drywall problem and in December 2008, the Virginia Graeme Baker Pool and Spa Safety Act (Pool and Spa Safety Act) became effective. In working to implement the Pool and Spa Safety Act CPSC staff participated in Webinars, held meetings, and disseminated information on the Pool and Spa Safety Act to all pool and spa owners, operators, technicians, manufacturers, state and local health officials, and other organizations concerned with children's safety and drowning. CPSC staff inspected over 1,200 public pools and spas in 38 states for compliance with drain cover requirements of the Act. We also entered into a partnership with the Centers for Disease Control to provide states in 2010 with enforcement grants and funded a major information campaign to begin in 2010.

The CPSC did not publish a notice of requirements pertaining to walkers, bouncers, and jumpers in 2009 because, at the time, staff intended to revoke the regulation (see "Revocation of Regulation Banning Certain Baby-Walkers and Similar Products," 74 FR 45714 (September 3, 2009)) and issue a new standard for walkers. However, after publication of the proposed rule to revoke the regulation, CPSC staff reconsidered their position and elected to revoke only those aspects of the rule pertaining to walkers. The issuance of a final rule establishing a new standard for walkers was accompanied by a notice of requirements for walkers ("Third Party Testing for Certain Children's Products; Infant Walkers; Requirements for Accreditation of Third Party Conformity Assessment Bodies," 75 FR 35282 (June 21, 2010)), and CPSC staff intends to issue a notice of requirements pertaining to bouncers and jumpers when it develops final standards for those products.

Finding 7. Assurance ILAC Standards 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 conform 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, we still have concerns regarding whether or not the CPSC adequately demonstrated and documented that ILAC standards/test methods conform to CPSIA standards prior to the agency opting to use ILAC as the independent accreditation organization.

Based on our findings it appears that, due to a tight deadline and other resource constraints, the CPSC may be relying too heavily on ILAC's accreditation when determining whether or not to accredit laboratories as being CPSIA compliant.

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

Agency Response: The IG recommendation to conduct field visits/onsite inspections to “limit reliance on the ILAC certification” is noted and considered an appropriate action for CPSC to take, as circumstances dictate.

**APPENDIX I
MANAGEMENT'S RESPONSE**

APPENDIX II OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The objectives of this review included evaluating if internal controls were adequately designed and properly executed in the management of the laboratory accreditation program and determining if the CPSC complied with the terms of the relevant portions of the CPSIA in its operation of its conformity assessment program.

Scope

OIG conducted audit fieldwork to determine if the CPSC had developed and published requirements for the accreditation of third party laboratories on specified children products, CPSIA mandates, CPSC requirements for meeting accreditation, implemented the proper level of internal controls to accredit third party laboratories and oversee third party testing requirements from August 2008 – September 2009.

Methodology

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 GAGAS standards issued by the GAO. Fieldwork included interviewing personnel responsible for formulating and publishing the accreditation requirements, reviewing documentation, reviewing the database and recordkeeping, and documenting findings in the work papers and draft/final audit report.

**APPENDIX I
MANAGEMENT'S RESPONSE**



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

Memorandum

November 29, 2010

TO: Christopher Dentel
Inspector General

FROM: Jay Howell
Assistant Executive Director
Office of Hazard Identification and Reduction

SUBJECT: Lab Accreditation Notice of Proposed Finding

This memo provides responses to your notice of proposed finding received in your email of November 12, 2010. The responses have been developed by the members of the lab accreditation team that includes members from EXHR, EXIP, and GC. The responses from the team are indicated in italic and colored red.

Finding 1: There is at least the appearance of subjectivity in the methodology used for evaluating government labs

We found that there were no published methodology or detailed criteria established for the evaluation of government labs. The criteria for evaluating third-party and firewalled labs was spelled out fairly clearly and available to the public at the CPSC web site at cpsc.gov. However, no such criteria had been published for government controlled labs and it appears that no such criteria existed, at least in a written form.¹²

A staff member stated that due to sensitive political issues with government labs, not present with the other types of labs, it is difficult to provide concrete criteria for how these labs will be evaluated.

As a result of the lack of visible evaluation criteria the valuation of government labs may appear subjective and arbitrary and this may increase the chances that an unsuccessful applicant could challenge the agency's decision as arbitrary and capricious.

Beyond the issue of appearance, compared to third-party and firewalled labs, the methodology and criteria for evaluating government-controlled labs was in fact more subjective. It was

¹ The CPSIA establishes the underlying criteria to be evaluated (the existence of "undue influence" etc), but not how that evaluation should take place (independent investigation, information provided by other Federal agencies, etc).

² Since the completion of field work the agency has developed . . . (I anticipate that the agency response will cover new procedures now in effect and new documents either now in effect or soon to be adopted.)

determined that at the time of fieldwork no detailed written procedures were in place to standardize the way evaluations were conducted. Laboratories in one country were asked to respond to a different set of questions than laboratories in another country. These procedures may well have a reasonable and rationale basis, but it is not one that had been committed to writing. A review of the physical application files determined that they contained a variety of documents with little consistency from application package to application package.

General guidance set out in a memo from EXIP to the Commission dated March 19, 2009 stated, "The number of attestations will depend on the specific case. For example, a single attestation from a senior ministry official might be sufficient in cases where the lab is operated directly by that ministry. A joint venture would likely require attestations from the company operating the lab and from their related government entity."

This might well be good and appropriate general policy guidance, but the agency needs to develop specific guidance on how this policy will be applied to specific cases.

Clearly, some degree of professional judgment will need to be exercised in the evaluation process and a "one size fits all" approach would be counterproductive. However, there should be written criteria documenting the process used and the process itself should be regularized and made as objective as possible. For example, if the CPSC is going to rely on information provided by employee's of other Federal agencies, the relationship between the CPSC and those agencies should be formalized in writing.

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

***Response:** As a result of the OIG's early informal recommendations, the agency has developed a standard set of questions and requests for documentation that it uses for all governmental lab applicants. These standard requests are being published. Requests for information from U.S. missions abroad also have a standard form. All applicants are reviewed using a standardized review document that provides grounds and reasoning for a finding relative to each of the five criteria for governmental labs set forth in the statute. All EXIP staff are being trained in the standard procedures. EXIP does not agree that the relationship between CPSC and other federal agencies providing assistance should be formalized in writing. Other agencies are under no obligation to assist us in our analysis of an applicant and there is no evidence that a formal relationship would result in better information than we currently receive. Feedback from our Embassies and Consulates to date has been extremely helpful. Creating a formal relationship with multiple agencies would, however, create a new demand on our own scarce agency resources and could result in the creation of new bureaucratic procedures without clear benefits.*

Finding 2: No policies or procedures have been developed to audit third party laboratories as a condition for their continuing accreditation

The agency does not have written policies or procedures in place for auditing third party

laboratories as a condition for their continuing accreditation.

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

The CPSC does not yet have written withdrawal policies or procedure in place to audit third party laboratories.

As a result, the CPSC has no way of verifying whether or not the third party laboratories that it has accredited are in fact complying with the accreditation requirements.

Recommendation: The CPSC should develop and implement written policies and procedures for the audit of a third party laboratories.

***Response:** The CPSC did publish a proposed rule to implement the audit provision in the CPSIA (74 FR 40784 (August 13, 2009)). The final rule is in progress and must be coordinated with a proposed rule that would address third party conformity assessment body requirements, including suspension and withdrawal of accreditation.*

Finding 3: Inadequate monitoring of certification expiration dates

The CPSC lacks documented procedures for monitoring laboratory certification expiration dates. We also observed that whatever “ad hoc” monitoring was taking place was failing to identify laboratories with expired certificates. Our review of the database found seven laboratory certificates that had expired and 16 laboratories had certificates without expiration dates.

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

However, the CPSC does not have written procedures to monitor for expired certification/certificate renewals and instead conducts the checks – which are not documented or recorded - on an ad hoc basis. As a result, the agency failed to identify those laboratories which were out of compliance with applicable protocols due to their certification having expired. Additionally, files were found in which laboratories had been accredited despite failing to provide expiration dates for their certification. These problems were not detected by the agency.

The lack of documented procedures for monitoring certificate expiration dates increases the risk of a laboratory continuing to be recognized by the CPSC incorrectly. As of the end of field work for this review, the list of accredited laboratories on the CPSC website was not reconciled with the accreditation database.

Recommendation: The CPSC should develop and implement procedures for monitoring certificate renewals and detecting expired certifications on a regular basis and

maintain records of these reviews. Laboratories with expired certifications should be removed from the accredited laboratory list maintained electronically by the CPSC.

Response: *All accreditation bodies that are signatories to the International Laboratory Accreditation - Mutual Recognition Arrangement (ILAC-MRA) follow strict procedural ISO standards for assessing testing laboratories and issuing accreditation certificates. Accreditation bodies across the world have somewhat different conventions on the issuance of an expiration date. These different conventions are within the allowable framework established by the ISO standards and by ILAC, so long as the accreditation body is complying with its designated reassessment schedule for a laboratory. Some accreditation bodies do not issue expiration dates. In all cases, the laboratory maintains its accreditation unless there is a formal notice from an accreditation body that a laboratory's accreditation is suspended or withdrawn. The CPSC application process collects certificate expiration dates for information purposes (for those labs that are issued expiration dates). However, there has not been a case where the absence of an expiration date or the passing of an expiration date has indicated a suspension of accreditation by the accreditation body. While a certificate expiration date may be useful in certain circumstances to trigger a CPSC follow-up with the laboratory, it has been determined that this should not be a stand-alone criteria for the CPSC to remove a laboratory from the CPSC-accepted list.*

The most important factor is that a laboratory has not been formally issued a suspension or withdraw by its accreditation body, and therefore is still in good standing with its accreditation body.

Through the continued maturation of the CPSC application and review process and the increasing familiarity of the CPSC application process by the laboratory community, the CPSC has several ways to ensure that laboratories continue to meet their accreditation requirements. CPSC staff is currently developing a proposed rule that would address third party conformity assessment body requirements, including suspension and withdrawal of accreditation.

Finding 4: No written withdrawal policies or procedures for removing a third party laboratory's certification

The agency does not have written withdrawal policies or procedures in place for withdrawing a third party laboratory's certification.

The CPSIA contemplates two situations which may lead to the withdrawal of a third party laboratory's certification. 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 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. 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 yet have written withdrawal policies or procedure in place to implement either CPSIA, Section 102(e)(1)(A) or (B).

As a result, the withdrawal process is not standardized and runs the risk of not being applied uniformly. Any effort by the agency to withdraw accreditation would run the risk of being found to be arbitrary and capricious by a court if challenged. In addition, it is unclear when and how CPSC will decide to withdraw its recognition or acceptance of a third party laboratory's accreditation.

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

Response: The CPSC is developing a proposed rule that would address third party conformity assessment body requirements, including suspension and withdrawal of accreditation.

Finding 5: No written policies or procedures for reviewing the employee training records contained in Firewalled Laboratory Accreditation application packages

In addition to the baseline accreditation requirements, firewalled laboratories must submit to the CPSC copies, in English, of their training documents showing how employees are trained to notify the CPSC immediately and confidentially of any attempt by the 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 ten percent or more in the laboratory in question.

During our fieldwork we noted that the CPSC was not consistent in applying its standards regarding minimum laboratory employee training requirements and attendance records to its review of Firewall Laboratory Application packages.

No written policy or procedure exists 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. In addition, the lack of employee's signatures on the training attendance list leaves open the question of the verification of the training list.

All training documents reviewed, with one exception, indicated employees had taken training on reporting undue influence over laboratory's test results to the CPSC, as shown by their signature on the sign-in training sheet. However, it was difficult for us to evaluate the compliance of the relevant laboratories as the training was not recorded in a consistent manner.

The management of the Firewalled laboratories indicated in their application packages that an ethics phone list was provided to industry employees to report undue influence. However, upon review of these packages, some application packages provided copies of the phone list while

others did not. Specifically, of 11 firewall applications received by CPSC, 7 applications (64%) did not include an ethics phone list as part of the package. As a result, the phone list's existence, much less whether or not it had in fact been provided to the employees, could not be validated.

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

Response: All points in Finding 5 are currently in development and will be presented to the Commission for its consideration in a proposed rule and policies and procedures.

Finding 6: The CPSC failed to meet a number of accreditation timeline requirements

The CPSIA and related regulations created a number of timeline requirements for the establishment of accreditation requirements, for example, the accreditation requirements for baby bouncers, walkers and jumpers was to be established not later than 210 days after enactment of the CPSIA (i.e. 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 (i.e. June 14, 2009). The CPSIA also required that the CPSC establish by regulation requirements for the periodic audit of third party laboratories as a condition for the continuing accreditation of such bodies. This requirement was supposed to be met not later than 10 months after the date of enactment of the CPSIA,

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

The following product classes had laboratory accreditation requirements posted after the August 2009 deadline set out in the CPSIA.

- Infant bath seats - 11 months late
- Clacker balls - 8 months late
- Electrically operated toys - 8 months late
- Vinyl plastic film - 11 months late
- Carpets and rugs - 11 months late
- Small carpets and rugs - 11 months late

The CPSC also continued to post laboratory accreditation requirements for classes of products that were not specifically listed in the CPSIA regulation well after the 10 month deadline listed in the CPSIA. As of August 2010, the agency planned to continue posting laboratory accreditation requirements for additional classes of children's products although not specifically required by the legislation. The CPSC has not yet determined the point at which it will stop

releasing new laboratory accreditation requirements for additional product classes. As a result, manufacturers remain uncertain as to lab testing requirements that will be introduced by CPSC.

There does not appear to have been a single overarching reason for the agency's not meeting timelines requirements set out in the CPSIA. In some cases (baby bouncers, walkers, and jumpers) staff have indicated that they desired to produce a "better" rule than had currently existed and chose to place quality over timeliness. In other cases (audit of third party laboratories) staff indicated that the project was simply viewed as having a low priority.

Recommendation: Increase the emphasis on meeting Congressional mandates. Consider terminating the practice of adding more laboratory accreditation requirements for additional product classes, perhaps merely refining and updating those rules already released as needed.

***Response:** The CPSIA represents the most substantial change in consumer product safety since the creation of the Agency in 1973. Since August 2008, CPSC staff have worked diligently to implement the CPSIA through rulemaking, enforcement, and other safety standard activities. In 2010 we have completed over 30 rules or other documents required by the CPSIA. The number of completed assignments required by the CPSIA, however, is only a partial accounting of Commission staff's actual workload. For example, in some cases, a statutory requirement under the CPSIA triggered additional work and the need for the Commission staff to issue a proposed rule (before it could issue the CPSIA required final rule), an interpretive rule, a statement of policy, or a guidance document. These other rules and documents constitute an additional 50 items completed since August 2008 (20 items completed in 2009, 30 items completed in 2010). We also held numerous public briefings to help stakeholders understand their obligations under the law, created a special Web site devoted to CPSIA, and responded to thousands of inquiries from affected manufacturers, retailers, resellers, and consumers.*

Staff resources were also reallocated to work on the unplanned and unbudgeted drywall problem. CPSC staff has worked tirelessly with U.S. Environmental Protection Agency, the Centers for Disease Control and Prevention, Agency for Toxic Substance and Disease Registry, the U.S. Department of Housing and Urban Development, and numerous state departments of health to bring answers and solutions to these affected families. CPSC staff has conducted more than 700 telephone interviews with affected homeowners and over 809 in-depth investigations. CPSC field investigators have responded to the imported drywall issue, collected samples, and followed up on hundreds of consumer complaints. In an effort to go to the source of the problems, a special team traveled to China to get a first-hand look at various mines and plants that make drywall. Additionally, CPSC staff developed an online Drywall Information Center (www.DrywallResponse.gov), which provides the latest information on technical developments, news about the investigation, a way for homeowners to report incidents to CPSC and established an e-mail distribution (listserv) to disseminate noteworthy developments directly to interested parties. CPSC and our federal and state partners also conducted several studies of drywall samples, chamber emission studies and air quality studies. The results of the studies have been delivered to Congressional leaders and the CPSC will continue to work with Congress to develop an appropriate plan for affected homeowners.

In December 2008, the Virginia Graeme Baker Pool and Spa Safety Act became effective. CPSC staff participated in Webinars, held meetings, and disseminated information on the Pool and Spa Safety Act to all pool and spa owners, operators, technicians, manufacturers, state and local health officials, and other organizations concerned with children's safety and drowning. CPSC staff inspected over 1,200 public pools and spas in 38 states for compliance with drain cover requirements of the Act. We also entered into a partnership with the Centers for Disease Control to provide states in 2010 with enforcement grants and funded a major information campaign to begin in 2010.

The CPSC did not publish a notice of requirements pertaining to walkers, bouncers, and jumpers in 2009 because, at the time, staff intended to revoke the regulation (see "Revocation of Regulation Banning Certain Baby-Walkers and Similar Products," 74 FR 45714 (September 3, 2009)) and issue a new standard for walkers. However, after publication of the proposed rule to revoke the regulation, CPSC staff reconsidered their position and elected to revoke only those aspects of the rule pertaining to walkers. The issuance of a final rule establishing a new standard for walkers was accompanied by a notice of requirements for walkers ("Third Party Testing for Certain Children's Products: Infant Walkers; Requirements for Accreditation of Third Party Conformity Assessment Bodies," 75 FR 35282 (June 21, 2010)), and CPSC staff intends to issue a notice of requirements pertaining to bouncers and jumpers when it develops final standards for those products.

Finding 7: Assurance ILAC standards 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 conform 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, we still have concerns regarding whether or not the CPSC adequately demonstrated and documented that ILAC standards/test methods conform to CPSIA standards prior to the agency opting to use ILAC as the independent accreditation organization.

Based on our findings it appears that, due to a tight deadline and other resource constraints, the CPSC selected ILAC as the independent accreditation organization for the recognizing of third party laboratories without doing any substantive independent work to verify the quality of ILAC's work.

As a result, the CPSC may be relying too heavily on ILAC's accreditation when determining whether or not to accredit laboratories as being CPSIA compliant.

Recommendation:

Consider conducting field visits/onsite inspections or some other monitoring mechanism to verify the validity and quality standards of third party laboratories. Perform these visits on a random basis or when other concerns arise to help limit reliance on the ILAC certification.

Response: *As stated, the CPSIA does permit the CPSC to accredit third party laboratories through an independent accreditation organization. The IG staff has correctly noted the "tight deadline", less than 60 days, given to CPSC staff to assess the mandated laboratory accreditation requirements, identify options, decide on an approach, develop and staff the processes, and provide notice to the affected parties.*

This IG report claims no "substantive independent work" was undertaken to verify the quality of ILAC's work. During the course of this IG audit, IG staff was told that CPSC staff consulted with, and relied upon the advice of, experts from the National Institute of Standards (NIST) staff as alternatives were identified and discussed. The NIST experts are involved in the work of the Interagency Committee on Standards Policy (ICSP), which seeks to promote effective and consistent standards policies while fostering cooperation between government, industry, and other private organizations involved in standards activities. ICSP membership consists of Federal Standards Executives and their designated representatives from 32 agencies.

In the absence of any evidence of waste, fraud, abuse, or any other substantive issue arising out of CPSC's reliance on the ILAC process, relative to the overall risk associated with an ILAC process failure, CPSC staff reliance on the knowledge and advice of another federal agency that has specific expertise in the fields of conformity assessment and laboratory accreditation, seems to be an appropriate and efficient use of resources and taxpayer funding.

The IG recommendation to conduct field visits/onsite inspections to "limit reliance on the ILAC certification" is noted and considered an appropriate action for CPSC to take, as circumstances dictate.

APPENDIX II OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The objectives of this review included evaluating if internal controls were adequately designed and properly executed in the management of the laboratory accreditation program and determining if the CPSC complied with the terms of the relevant portions of the CPSIA in its operation of its conformity assessment program.

Scope

OIG conducted audit fieldwork to determine if the CPSC had developed and published requirements for the accreditation of third party laboratories on specified children products, CPSIA mandates, CPSC requirements for meeting accreditation, implemented the proper level of internal controls to accredit third party laboratories and oversee third party testing requirements from August 2008 – September 2009.

Methodology

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 GAGAS standards issued by the GAO. Fieldwork included interviewing personnel responsible for formulating and publishing the accreditation requirements, reviewing documentation, reviewing the database and recordkeeping, and documenting findings in the work papers and draft/final audit report.