



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

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approved and signed.

BALLOT VOTE SHEET

DATE: January 22, 2020

TO: The Commission
Alberta E. Mills, Secretary

THROUGH: Mary T. Boyle, Executive Director
J. Gibson Mullan, General Counsel
Patricia M. Pollitzer, Assistant General Counsel

FROM: David M. DiMatteo, General Attorney

SUBJECT: Accreditation of the Step 2 Company LLC Conformity Assessment
Body as a "Firewalled" Third Party Laboratory and Related
Delegation of Authority

Ballot Vote Due: Tuesday, January 28, 2020

CPSC staff is forwarding to the Commission a memorandum recommending that the Commission accredit the Step 2 Company LLC conformity assessment body as a firewalled third party laboratory to perform tests for:

- Section 4.6, *Small Objects*, (ASTM F963-17);
- Section 4.7, *Accessible Edges*, (ASTM F963-17);
- Section 4.8, *Projections (except bath toy projections)* (ASTM F963-17);
- Section 4.9, *Accessible Points*, (ASTM F963-17);
- Section 4.12, *Plastic Film*, (ASTM F963-17);
- Section 4.13, *Folding Mechanisms and Hinges*, (ASTM F963-17);
- Section 4.14, *Cords, Straps, and Elastics* (Except 4.14.12, 4.14.4, *Strings and Lines for Flying Devices*), (ASTM F963-17);
- Section 4.15, *Stability and Overload Requirements*, (ASTM F963-17);
- Section 4.16, *Confined Spaces*, (ASTM F963-17);
- Section 4.17, *Wheels, Tires, and Axles*, (ASTM F963-17);
- Section 4.18, *Holes, Clearances, and Accessibility of Mechanisms*, (ASTM F963-17);
- Section 4.32, *Certain Toys with Nearly Spherical Ends*, (ASTM F963-17);
- Section 4.36, *Hemispheric-Shaped Object*, (ASTM F963-17);

- Section 4.39, *Jaw Entrapment in Handles and Steering Wheels*, (ASTM F963-17);
- Section 4.41, *Toy Chests (Except 4.41.1)*, (ASTM F963-17);
- 16 CFR part 1501, *Small Parts Regulation*.

A. Please indicate your vote below:

1. _____ Approve accreditation and order, as staff recommends.

(Signature) _____
(Date)

2. _____ Approve accreditation and order, with the specified changes:

(Signature) _____
(Date)

3. _____ Do not approve accreditation and order.

(Signature) _____
(Date)

4. Take other action specified below.

(Signature) _____
(Date)

B. Staff also requests that the Commission authorize the Deputy Executive Director for Operations, Office of the Executive Director, to grant or deny subsequent applications by the Step 2 Company LLC (*e.g.*, to be accredited for additional requirements or test methods or to renew their accreditation information and CPSC acceptance). (If the Commission does not grant this authority to the Deputy Executive Director for Safety Operations, Office of the Executive Director, we will delete the paragraph in the draft order granting such authority.)

Please indicate your vote below:

1. _____ Authorize the Deputy Executive Director for Operations, Office of the Executive Director, to grant or deny subsequent applications by the Step 2 Company LLC (*e.g.*, to be accredited for additional requirements or test methods or to renew their accreditation information and CPSC acceptance).

(Signature)

(Date)

2. _____ Do not authorize the Deputy Executive Director for Operations, Office of the Executive Director to grant or deny subsequent applications by the Step 2 Company LLC (*e.g.*, to be accredited for additional requirements or test methods or to renew their accreditation information and CPSC acceptance).

(Signature)

(Date)

3. Take other action as specified.

(Signature)

(Date)

UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

In the Matter of the Application for Accreditation as a Firewalled Third Party Conformity Assessment Body)	
)	
of)	CPSC Docket No. _____
)	
The Step 2 Company LLC)	
10010 Aurora-Hudson Rd)	
Streetsboro, OH)	
44214)	
United States)	
)	
)	

ORDER

Having considered the application of the Step 2 Company LLC (the applicant) to be accredited by the U.S. Consumer Product Safety Commission as a “third party conformity assessment body,” as that term is defined in 15 U.S.C. § 2063(f)(2)(D), and having considered the analysis and recommendations of CPSC staff, the Commission, by order, finds that:

1. The applicant is owned, managed, or controlled by the manufacturer or private labeler of products that would be assessed by the applicant, if the applicant is accredited as a third party conformity assessment body.
2. The applicant is accredited by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation-Mutual Recognition Arrangement.
3. The applicant has established procedures to ensure that:
 - a. its test results are protected from undue influence by the manufacturer, private labeler, or other interested party;
 - b. the Consumer Product Safety Commission is notified immediately of any attempt by the manufacturer, private labeler, or other interested party to hide or exert undue influence over test results; and

c. allegations of undue influence may be reported confidentially to the Consumer Product Safety Commission;

and

4. In view of the findings numbered 2 and 3 above, the accreditation of the applicant will provide equal or greater consumer safety protection than the manufacturer's or private labeler's use of an independent third party conformity assessment body for the requirements and test method(s) for which accreditation is ordered.

Accordingly, it is

ORDERED that the applicant is accredited as a third party conformity assessment body for testing children's products for:

- Section 4.6, *Small Objects*, (ASTM F963-17);
- Section 4.7, *Accessible Edges*, (ASTM F963-17);
- Section 4.8, *Projections (except bath toy projections)* (ASTM F963-17);
- Section 4.9, *Accessible Points*, (ASTM F963-17);
- Section 4.12, *Plastic Film*, (ASTM F963-17);
- Section 4.13, *Folding Mechanisms and Hinges*, (ASTM F963-17);
- Section 4.14, *Cords, Straps, and Elastics* (Except 4.14.12, 4.14.4, *Strings and Lines for Flying Devices*), (ASTM F963-17);
- Section 4.15, *Stability and Overload Requirements*, (ASTM F963-17);
- Section 4.16, *Confined Spaces*, (ASTM F963-17);
- Section 4.17, *Wheels, Tires, and Axles*, (ASTM F963-17);
- Section 4.18, *Holes, Clearances, and Accessibility of Mechanisms*, (ASTM F963-17);
- Section 4.32, *Certain Toys with Nearly Spherical Ends*, (ASTM F963-17);
- Section 4.36, *Hemispheric-Shaped Object*, (ASTM F963-17);
- Section 4.39, *Jaw Entrapment in Handles and Steering Wheels*, (ASTM F963-17);
- Section 4.41, *Toy Chests* (Except 4.41.1), (ASTM F963-17);
- 16 CFR part 1501, *Small Parts Regulation*; and it is

FURTHER ORDERED that the applicant will be placed on the list of entities on the CPSC's Internet website that have been accredited to assess conformity with children's product safety rules in accordance with the requirements in 16 CFR part 1112; and it is

FURTHER ORDERED that if the applicant does not continue to meet the requirements of 16 CFR part 1112, the applicant would be subject to suspension or withdrawal in accordance with the procedures provided in 16 CFR part 1112; and it is

FURTHER ORDERED that the authority to grant or deny subsequent applications by this applicant (*e.g.*, to be accredited for additional requirements or test methods or to renew their accreditation information and CPSC acceptance) is delegated to the Deputy Executive Director for Operations, Office of the Executive Director.

Order issued on the ____ day of _____, 2020.

BY ORDER OF THE COMMISSION:

Alberta E. Mills, Secretary
U.S. Consumer Product Safety Commission



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

This document has been electronically
approved and signed.

Date: January 22, 2020

TO: The Commission
Alberta E. Mills, Secretary

THROUGH : John G. Mullan, General Counsel
Mary T. Boyle, Executive Director
DeWane Ray, Deputy Executive Director for Operations

FROM: Duane E. Boniface, Assistant Executive Director
Office of Hazard Identification and Reduction

Scott Heh
Program Manager, Third Party Laboratory Accreditation
Directorate for Laboratory Sciences

SUBJECT: The Step 2 Company LLC Application for Commission Consideration as a
Firewalled Conformity Assessment Body

I. Introduction

CPSC staff recommends that the Commission accredit The Step 2 Company LLC laboratory as a firewalled conformity assessment body (firewalled testing laboratory) to perform specified product testing required by the Consumer Product Safety Act (CPSA). The regulation at 16 CFR part 1112 sets forth the firewalled laboratory application and acceptance procedures. This memorandum describes the process CPSC staff used to evaluate the application.¹

II. Background

CPSA: Third Party Laboratory Requirements and Conditions Applicable to Firewalled Laboratories

Section 14 of the CPSA, as amended by the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires manufacturers and importers of children's products subject to applicable children's product safety rules to use third party conformity assessment bodies (third party

¹ The application and related supporting materials are not attached to this memorandum but are available for review upon request by any Commissioner.

testing laboratories), which have been accredited under CPSC requirements, to test children's products for compliance with children's product safety rules. Manufacturers and importers must use test results to certify compliance with any applicable "children's product safety rule." A "children's product safety rule" is defined as a "consumer product safety rule under the CPSA or similar rule, regulation, standard or ban under any other Act enforced by the Commission, including a rule declaring a consumer product to be a banned hazardous product or substance." 15 U.S.C. § 2063(f)(1). The CPSA also requires the Commission to establish requirements for accreditation of third party testing laboratories.

The CPSA defines a "third party conformity assessment body" as a testing laboratory that is not owned, managed, or controlled by the manufacturer or private labeler of a product assessed by such testing laboratory, except that a laboratory that is owned, managed, or controlled by the manufacturer or private labeler, under certain specified conditions, may be recognized as accredited by the Commission as a third party testing laboratory. Testing laboratories that comply with these specified conditions are said to be "firewalled" against the possibility of undue influence.

The Commission may accredit a laboratory under the CPSA's firewalled provision, if the Commission finds, by order, that:

A) accreditation of the laboratory would provide equal or greater consumer safety protection than the manufacturer or private labeler's use of an independent third party conformity assessment body; and

B) the laboratory has established procedures to ensure that –

i) its test results are protected from undue influence by the manufacturer, private labeler, or other interested party;

ii) the Commission is notified immediately of any attempt by the manufacturer, private labeler, or other interested party to hide or exert undue influence over test results; and

iii) allegations of undue influence may be reported confidentially to the Commission.

15 U.S.C. § 2063(f)(2)(D). The Commission has issued regulations implementing the statutory provisions concerning CPSC's accreditation of third party conformity assessment bodies. 16 CFR part 1112 (effective June 10, 2013). These regulations include baseline requirements for independent laboratories and the process for firewalled laboratory application and acceptance procedures. The application and acceptance procedures for independent and firewalled third party testing laboratories are found in § 1112.13 and § 1112.17 (Appendix A).

III. Discussion

Under CPSC's regulation, one of the requirements for CPSC acceptance of a testing laboratory is that the laboratory must be accredited to ISO/IEC Standard 17025: "General requirements for the

competence of testing and calibration laboratories” (ISO 17025). The ISO 17025 standard has technical requirements and management requirements on topics such as organization, management systems, document control, audits, and management reviews. Several of these management requirements address impartiality and safeguards against conflicts of interest.

If the laboratory is part of an organization that performs activities other than testing, the responsibilities of key personnel in the organization, who are involved with, or who influence the testing and/or calibration activities of the laboratory, must be defined to identify potential conflicts of interest. The laboratory must have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial, or other pressures and influences that may adversely affect the quality of their work. Furthermore, the laboratory must have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity.

To ensure continued compliance, accredited laboratories are reexamined regularly by their accreditation bodies to verify that they maintain their standards of independence and technical expertise.

ISO 17025 accredited laboratories must have arrangements to ensure that their management and personnel are free from any undue internal and external commercial, financial, or other pressures and influences that may affect adversely the quality of their work. These arrangements apply to commercial laboratories, manufacturers’ laboratories, and government laboratories.

ISO 17025 accreditation of a laboratory includes assessing whether the laboratory has the technical competence to conduct testing for a given scope of test methods and standards, and ensure that the laboratory’s management and organization maintains safeguards against undue influence. Given these factors, the Commission included, among other requirements, ISO 17025 accreditation by an ILAC-MRA signatory accreditation body as a requirement for approval under the CPSA firewalled provisions. 16 CFR § 1112.13(b).

In addition, 16 CFR part 1112 requires laboratory applicants for firewalled status to submit additional documentation demonstrating to the Commission that the laboratory complies with criteria establishing safeguards against undue influence.

During the rulemaking proceedings promulgating 16 CFR part 1112, the Commission noted in the preamble² regarding proposed § 1112.13(b) (providing the requirements for firewalled laboratories):

“If the Commission determines that the firewalled-specific documents indicate that the laboratory has sufficient safeguards against and procedures concerning undue influence in place, and the laboratory satisfies the baseline criteria, including ISO/IEC 17025 accreditation by an ILAC–MRA signatory body, then the Commission will consider that the applicant laboratory would provide equal consumer safety protection than the manufacturer’s or private labeler’s use of an independent laboratory.”

² 77 FR 31086, at 31112 (May 24, 2012) - <http://www.gpo.gov/fdsys/pkg/FR-2012-05-24/pdf/2012-10923.pdf>.

Proposed § 1112.13(b) was unchanged in the final rule issued by the Commission.

Staff Review of Firewalled Laboratory Application

CPSC staff reviewed the application seeking Commission accreditation as a firewalled laboratory. Staff summarizes the application and review process below:

1. The laboratory applied for firewalled acceptance via the CPSC online registration form. The applicant submitted training materials and other information to show conformity with the criteria for acceptance of firewalled laboratories.
2. The Firewalled Laboratory Review Committee (Review Committee), comprised of three senior CPSC staff members, reviewed the application. The Review Committee members individually examined the application materials according to the criteria for firewalled laboratories set forth in 16 CFR part 1112. After individual members conducted their independent assessments, the Review Committee met as a group to discuss whether the laboratory met the baseline requirements for CPSC acceptance and satisfied the additional firewalled laboratory criteria.
3. After the Review Committee examined documents from the laboratory, the committee members concluded that the applicant satisfied the baseline requirements for CPSC acceptance, as well as the criteria for firewalled laboratories set forth in the CPSA and accompanying regulations at 16 CFR part 1112. Specifically, the Review Committee determined:
 - i) The applicant provided valid and current copies of ISO 17025 accreditation certificates and accreditation by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation-Mutual Recognition Arrangement (ILAC-MRA). The applicant also submitted a statement of scope that clearly identified each CPSC rule and/or test method for which CPSC acceptance was being sought. These documents satisfy the baseline criteria required for all CPSC-accepted laboratories.
 - ii) The applicant submitted documents that explained how the laboratory will protect test results from undue influence by the manufacturer, private labeler, or other interested party.
 - iii) The applicant provided documentation evidencing laboratory operating procedures or quality manuals with clear policies stating that attempts to exert undue influence must be immediately reported to the CPSC and that allegations of undue influence may be reported confidentially to the CPSC. CPSC contact information is included in each of these documents.
 - iv) The applicant provided training documents, including a description of the training program content, demonstrating how the applicant provided training, at least annually for the laboratory staff, explaining procedures for addressing undue influence and CPSC reporting policies. The records included training dates and a list of employees who received such training.

- v) The applicant submitted organizational charts for the laboratory, and for the broader organization as well, showing the reporting relationship of the laboratory within the broader organization.
4. Based on the information supplied by the applicant, the Review Committee concluded that the laboratory's established procedures satisfy the statutory criteria for accreditation as a firewalled laboratory. The Review Committee further determined that the applicant would provide equal or greater consumer protection than the use of an independent third party assessment body, and that the applicant had established procedures to ensure that its test results are protected from undue influence by the manufacturer, private labeler, or other interested party. Lastly, the Review Committee determined that the applicant established procedures to notify the Commission immediately of any attempt to exert undue influence over test results, and allegations of undue influence may be reported confidentially to the Commission.

IV. Firewalled Laboratory Review Committee Conclusions

The Review Committee recommended that the Commission accredit the following laboratory applicant as a firewalled laboratory:

The Step 2 Company LLC

10010 Aurora-Hudson Rd
Streetsboro
Ohio
United States
44241

The Review Committee recommended accreditation of the laboratory for the following scope:

- 16 CFR Part 1501, Small Parts Regulation
- 4.6 (ASTM F963-17), Small Objects
- 4.7 (ASTM F963-17), Accessible Edges
- 4.8 (ASTM F963-17), Projections (except bath toy projections)
- 4.9 (ASTM F963-17), Accessible Points
- 4.12 (ASTM F963-17), Plastic Film
- 4.13 (ASTM F963-17), Folding Mechanisms and Hinges
- 4.14 (ASTM F963-17), Cords, Straps, and Elastics (Except 4.14.12, 4.14.4 Strings and Lines for Flying Devices)
- 4.15 (ASTM F963-17), Stability and Overload Requirements
- 4.16 (ASTM F963-17), Confined Spaces
- 4.17 (ASTM F963-17), Wheels, Tires, and Axles
- 4.18 (ASTM F963-17), Holes, Clearances, and Accessibility of Mechanisms
- 4.32 (ASTM F963-17), Certain Toys with Nearly Spherical Ends
- 4.36 (ASTM F963-17), Hemispheric-Shaped Objects
- 4.39 (ASTM F963-17), Jaw Entrapment in Handles and Steering Wheels
- 4.41 (ASTM F963-17), Toy Chests (Except 4.41.1)

V. Recommendation

Staff recommends that the Commission accredit the laboratory in accordance with the firewalled procedures described in 16 CFR part 1112. This recommendation is based on the assessment conducted by the CPSC Firewalled Laboratory Review Committee, which examined the application materials and agreed that the applicant's documentation supported the conditions for accreditation as a firewalled laboratory.

Delegation Approval Requested

If the Commission accredits this firewalled laboratory by order, staff recommends that the Commission authorize the Deputy Executive Director for Operations, Office of the Executive Director, to approve any future applications by this laboratory.

Such applications would include, for example, applications to conduct testing for additional CPSC children's product safety requirements, or applications to renew the applicant's accreditation information and CPSC acceptance as a firewalled laboratory. Future applications typically would involve CPSC staff review of technical scope competency and accreditation status by its ILAC-MRA accreditation body and would involve review of any changes in undue influence policies. Authorizing the Deputy Executive Director for Operations, Office of the Executive Director, to approve future applications by this laboratory would be consistent with prior Commission practice regarding other firewalled laboratories the Commission has previously accredited.

VI. Commission Options

- (1) The Commission can vote to accredit the applicant laboratory for recognition as a firewalled laboratory for the specified testing scope. To do so, the Commission must issue an order finding that the the laboratory has met the necessary regulatory requirements for firewalled laboratories.
- (2) The Commission can vote not to accredit the applicant laboratory for recognition as a firewalled laboratory for the specified testing scope, if the Commission decides that an applicant's documentation is not sufficient to support a Commission finding to accredit the applicant laboratory under the firewalled provisions. Under this option, the Commission also could decide to direct staff to obtain additional information relevant to whether the Commission should accredit the applicant.
- (3) If the applicant is accredited as a firewalled laboratory for the specified testing scope, the Commission could accept or reject the staff recommendation that the Commission delegate to the Deputy Executive Director for Operations, Office of the Executive Director, the authority to approve subsequent applications by the same firewalled laboratory.
- (4) Take other action deemed appropriate, based on the information presented in the briefing materials, and as approved by a majority vote of the Commission.

The Office of the General Counsel has prepared a ballot vote sheet presenting these options and has provided a draft order for the applicant laboratory for the Commission's consideration.

Appendix A – Excerpt from CPSC’s Regulations at 16 CFR Part 1112

§1112.13³ How does a third party conformity assessment body apply for CPSC acceptance?

(a) Baseline Requirements. Each third party conformity assessment body seeking CPSC acceptance must:

(1) Submit a completed Consumer Product Conformity Assessment Body Registration Form (CPSC Form 223 or Application). In submitting a CPSC Form 223, the third party conformity assessment body must attest to facts and characteristics about its business that will determine whether the third party conformity assessment body is independent, firewalled, or governmental. The third party conformity assessment body also must attest that it has read, understood, and agrees to the regulations in this part. The third party conformity assessment body must update its CPSC Form 223 whenever any information previously supplied on the form changes.

(2) Submit the following documentation:

(i) Accreditation certificate.

(A) The third party conformity assessment body must be accredited to the ISO/IEC Standard 17025:2005(E), “General requirements for the competence of testing and calibration laboratories.”

(B) The accreditation must be by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation-Mutual Recognition Arrangement (ILAC-MRA).

(ii) Statement of scope. The third party conformity assessment body’s accreditation must include a statement of scope that clearly identifies each CPSC rule and/or test method for which CPSC acceptance is sought. Although a third party conformity assessment body may include more than one CPSC rule and/or test method in its scope in one application, it must submit a new application if the CPSC has already accepted the third party conformity assessment body for a particular scope, and the third party conformity assessment body wishes to expand its acceptance to include additional CPSC rules and/or test methods.

(b) Additional Requirements for Firewalled Third Party Conformity Assessment Bodies.

(1) A third party conformity assessment body may be accepted as a firewalled third party conformity assessment body if the Commission, by order, makes the findings described in §1112.17(b).

(2) For the Commission to evaluate whether an applicant firewalled third party conformity assessment body satisfies the criteria listed in §1112.17(b), and in addition to the baseline accreditation requirements in paragraph (a) of this section, a firewalled third party conformity assessment body applying for acceptance of its accreditation must submit copies of:

(i) The third party conformity assessment body’s established policies and procedures that explain:

³ The complete rule is linked at: www.ecfr.gov. Browse Title 16 - Commercial Practices. Go to part 1112, “REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES.”

- (A) How the third party conformity assessment body will protect its test results from undue influence by the manufacturer, private labeler, or other interested party;
- (B) That the CPSC will be notified immediately of any attempt by the manufacturer, private labeler, or other interested party to hide or exert undue influence over the third party conformity assessment body's test results; and
- (C) That allegations of undue influence may be reported confidentially to the CPSC;

- (ii) Training documents, including a description of the training program content, showing how employees are trained annually on the policies and procedures described in paragraph (b)(2)(i) of this section;
- (iii) Training records, including a list and corresponding signatures, of the staff members who received the training identified in paragraph (b)(2)(ii) of this section. The records must include training dates, location, and the name and title of the individual providing the training;
- (iv) An organizational chart(s) of the third party conformity assessment body that includes the names of all third party conformity assessment body personnel, both temporary and permanent, and their reporting relationship within the third party conformity assessment body;
- (v) An organizational chart(s) of the broader organization that identifies the reporting relationships of the third party conformity assessment body within the broader organization (using both position titles and staff names); and
- (vi) A list of all third party conformity assessment body personnel with reporting relationships outside of the third party conformity assessment body. The list must identify the name and title of the relevant third party conformity assessment body employee(s) and the names, titles, and employer(s) of all individuals outside of the third party conformity assessment body to whom they report;

§1112.17 How will the CPSC respond to each application?

(a) CPSC staff will review each application and may contact the third party conformity assessment body with questions or to request submission of missing information.

(b) The application of a firewalled third party conformity assessment body will be accepted by order of the Commission, if the Commission finds that:

- (1) Acceptance of the accreditation of the third party conformity assessment body would provide equal or greater consumer safety protection than the manufacturer's or private labeler's use of an independent third party third party conformity assessment body; and
- (2) The third party conformity assessment body has established procedures to ensure that:
 - (i) Its test results are protected from undue influence by the manufacturer, private labeler, or other interested party;
 - (ii) The CPSC is notified immediately of any attempt by the manufacturer, private labeler, or other interested party to hide or exert undue influence over test results; and
 - (iii) Allegations of undue influence may be reported confidentially to the CPSC.

(c) The CPSC will communicate its decision on each application in writing to the applicant, which may be by electronic mail.