TO: The Commission
Alberta E. Mills, Secretary

THROUGH: Austin C. Schlick, General Counsel
Jason Levine, Executive Director

FROM: Daniel R. Vice, Assistant General Counsel, Regulatory Affairs
David M. DiMatteo, Attorney, Regulatory Affairs

SUBJECT: Renewal of Accreditation of the Step2 Company LLC
Conformity Assessment Body as a "Firewalled" Third Party Laboratory

DATE: July 13, 2022

BALLOT VOTE DUE: Tuesday, July 19, 2022

CPSC staff is forwarding a memorandum to the Commission recommending that the Commission renew the accreditation of the Step 2 Company LLC conformity assessment body as a firewalled third party laboratory.

Please indicate your vote below:

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

_________________________________   _________________
(Signature)    (Date)
2. _____ Approve the accreditation order, with the specified changes:

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

_________________________________    ___________________
(Signature)    (Date)

3. _____ Do not approve accreditation and order.

___________________________________________________________________________

___________________________________________________________________________

(Signature)    (Date)

4. _____ Take other action specified below.

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

_________________________________    ___________________
(Signature)    (Date)
ORDER

Having considered the application for renewal of the Step2 Company LLC (the renewal applicant) to continue its accreditation by the U.S. Consumer Product Safety Commission (CPSC or 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 recommendation of CPSC staff, the Commission, by order, finds that:

1. The renewal applicant is owned, managed, or controlled by the manufacturer or private labeler of products that would be assessed by the renewal applicant if the renewal applicant is accredited as a third party conformity assessment body.

2. The renewal applicant is accredited by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation-Mutual Recognition Arrangement.

3. The renewal 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. 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

c. allegations of undue influence may be reported confidentially to CPSC; and

4. In view of the findings numbered 2 and 3 above, the accreditation of the renewal applicant will provide equal or greater consumer safety protection than the manufacturer 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 renewal 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 4.15, *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 renewal applicant will be placed on the list of entities on the CPSC’s 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 renewal applicant does not continue to meet the requirements of 16 CFR part 1112, the renewal applicant would be subject to suspension or withdrawal in accordance with the procedures provided in 16 CFR part 1112.
Order issued on the ____ day of ________, 2022.

BY ORDER OF THE COMMISSION:

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

TO: The Commission
    Alberta E. Mills, Secretary

DATE: July 13, 2022

THROUGH: Austin C. Schlick, General Counsel
          Jason Levine, Executive Director
          DeWane Ray, Deputy Executive Director for Safety 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: Audit Application for Commission Consideration to Renew
         Acceptance of The Step2 Company LLC as a Firewalled
         Conformity Assessment Body

I. Introduction

CPSC staff recommends that the Commission approve the CPSC Audit application from the
Step2 Company LLC (Step2) to renew its approval as a firewalled conformity assessment body
(firewalled testing laboratory) authorized to perform specified children’s 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

The Commission voted to approve Step2 as a CPSC firewalled testing laboratory on January 28,
2020. Step2 has now submitted a CPSC Audit application to request CPSC renewed
accreditation as a firewalled laboratory. There are 41 firewalled laboratories in the CPSC
program. For all but two of these laboratories, the Commission voted to delegate approvals of all
future applications by each laboratory to the Deputy Executive Director for Operations, Office of
the Executive Director. For Step2, the Commission vote to delegate authority to staff was 2-2,

¹ The supporting materials related to the application are not attached to this memorandum but are
available for review upon request by any Commissioner.
and therefore, authority to approve future applications such as this was not approved. Staff recommends renewed CPSC accreditation of Step2 as a CPSC firewalled laboratory.

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 testing laboratories), that have been accredited in a manner satisfying CPSC requirements, to test children’s products for compliance with children’s product safety rules. Manufacturers and importers must use test results from a CPSC-accepted, third party testing laboratory 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). Section 14 of 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. 15 U.S.C. § 2063(f)(2). Testing laboratories that comply with these specified conditions are considered to be “firewalled” against the possibility of undue influence.

The Commission may accredit a laboratory considered to be firewalled 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’s 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 at §§ 1112.13 and 1112.17. (Appendix A).

The regulations at 16 CFR part 1112 require all CPSC-accepted testing laboratories to submit an “Audit application” if their status changes with their accreditation body and no less than every 2 years. Section 1112.13 defines Audit as two parts:

1. An examination by an accreditation body to determine whether the third party conformity assessment body meets or continues to meet the conditions for accreditation (a process known more commonly as a “reassessment”); and

2. The resubmission of the “Consumer Product Conformity Assessment Body Acceptance Registration Form” (CPSC Form 223) and accompanying documentation by the third party conformity assessment body and the Consumer Product Safety Commission's (CPSC's) examination of the resubmitted CPSC Form 223 and accompanying documentation.

III. Discussion

Under 16 CFR part 1112, one of the requirements for CPSC acceptance of a testing laboratory is that the laboratory must be accredited by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation-Mutual Recognition Arrangement (ILAC-MRA) to ISO/IEC Standard 17025: “General requirements for the competence of testing and calibration laboratories” (ISO/IEC 17025).

ILAC is an organization that was formed in 1977 to promote international acceptance of test results performed by accredited laboratories. A series of standards developed by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) provides specifications for organizations that conduct conformity assessment activities. The ISO/IEC is a specialized system for worldwide standardization. Technical committees comprised of members from across the globe (including the United States) collaborate to develop these conformity assessment standards to facilitate acceptance of testing results among countries. These standards were developed expressly to be used by accreditation bodies that have entered mutual recognition arrangements (MRAs) with equivalent bodies in other countries.

Throughout the world, many industry and public stakeholders rely on laboratory accreditation to independently evaluate laboratory competence. Laboratory accreditation is based upon criteria and procedures from ISO/IEC 17025 to determine the technical and management competence of laboratories. Technical assessors conduct a thorough evaluation of all factors of facility operations that affect the production of technical data.
The technical assessors of laboratories are members of ILAC MRA accreditation bodies. Acceptance into the ILAC MRA requires an intensive peer evaluation from other accreditation bodies to determine compliance with ISO/IEC 17011 – “General requirements for bodies providing assessment and accreditation of conformity assessment bodies” (ISO/IEC 17011). The peer evaluators also witness the performance of assessors during actual laboratory assessments to determine if the laboratory is in compliance with ISO/IEC 17025. This evaluation is a recurring one, for accreditors to maintain their credentials.

ISO/IEC 17025 enables laboratories to demonstrate that they operate competently and generate valid results, thereby promoting confidence in their work both nationally and around the world. ²

Technical assessors evaluate a laboratory to all requirements in ISO/IEC 17025, including impartiality criteria in the standard:

The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial, or other pressures to compromise impartiality.

The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality.

NOTE A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new customers, etc.

If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk.

All laboratories, including third party independent and first party (manufacturer owned) laboratories, must identify risks to impartiality and demonstrate how they minimize these risks. Based on discussions with experienced assessors, particular emphasis is placed on these risks for first party laboratories. For example, the assessor will examine the organizational structure of the laboratory and parent organization. The laboratory must demonstrate how it minimizes impartiality risks. This may be accomplished through official laboratory procedures, corporate policies, code of ethics, or other methods.

In addition, assessors utilize the entirety of ISO/IEC 17025 since the standard is designed for laboratories to enable them to demonstrate they operate competently and are able to generate valid and impartial results. For example, under the Process Requirements section in the standard, an assessor may evaluate if there were deviations requested by the customer (the parent manufacturer for first party laboratories). Examples of deviations could include modifications to test methods, modifications to sampling plans, or other deviations from standards. These deviations could be identified by the assessor by document reviews, ² ISO Information Document on ISO/IEC 17025: https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100424.pdf
interviews and/or other investigatory means. The standard requires that such requests must not impact the integrity of the laboratory or the validity of the results.

To ensure continued compliance, accredited laboratories are reassessed regularly by their accreditation bodies to verify that they maintain their standards of independence and technical expertise. Laboratories across the world have had their accreditations suspended or withdrawn by their accreditation bodies if the laboratories did not make corrective actions to nonconformities identified in a reassessment.

ISO/IEC 17025 accreditation includes an assessment to ensure the laboratory has the technical competence to conduct testing for a given scope of test methods and standards, and to ensure that the laboratory activities are structured and managed to safeguard impartiality. The Commission included, among other requirements, ISO/IEC 17025 accreditation by an accreditation body that is a signatory to the ILAC-MRA as a requirement for approval under the CPSA firewalled provisions. 16 CFR § 1112.13(a)(2) and (b).

During the rulemaking proceedings promulgating 16 CFR part 1112, the Commission noted in the preamble 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 17025:2005 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.

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

16 CFR part 1112 further 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.

Staff Review of Firewalled Laboratory Application

CPSC staff reviewed the CPSC Audit application from Step2, which is seeking Commission renewal of 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 and an OGC observer, reviewed the application. The Review Committee

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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 independent assessments, the Review Committee convened 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 section 14 of 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/IEC 17025 accreditation certificates and accreditation by an accreditation body that is a signatory to the 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 laboratories 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 that explain procedures for addressing undue influence and reporting allegations of undue influence to the CPSC. The records included training dates and a list of employees who received such training. The procedures included a requirement for annual training.

   v) The applicant submitted organizational charts for the laboratory, and for the broader organizations as well, showing the reporting relationship of the laboratory within the broader organization.

   vi) The applicant showed that there are no laboratory staff with reporting relationships outside of the laboratory.

4. Based on the information supplied by the applicant as described above, the Review Committee concluded that Step2 has established procedures to 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 has 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 renew the CPSC accreditation of the following laboratory applicant as a firewalled laboratory:

The Step2 Company LLC  
10010 Aurora-Hudson Rd  
Streetsboro, OH  44241  
USA

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
- 4.9 (ASTM F963-17), Accessible Points
- 4.12 (ASTM F963-17), Plastic Film
- 4.13 (ASTM F963-17), Folding Mechanisms and Hinges
- 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 approve the Step2 application for renewal of accreditation, 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 submitted application materials and agreed that the applicant’s documentation supported the conditions for accreditation as a firewalled laboratory.

VI. Commission Options

(1) The Commission can vote to approve the Step2 application for renewal of accreditation for recognition as a firewalled laboratory for the specified testing scope. To do so, the Commission must issue an order finding that the laboratory has met the necessary regulatory requirements for firewalled laboratories.

(2) The Commission can vote to approve Step2’s renewal of accreditation, with specified changes as approved by a majority vote of the Commission.
(3) The Commission can vote to not approve the renewal of accreditation of Step2 for recognition as a firewalled laboratory.

(4) The Commission could take other action deemed appropriate, such as directing staff to obtain additional information, and as approved by a majority vote of the Commission.

The OGC has prepared a ballot vote sheet presenting the above 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

§1112.13 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, “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:

5 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.