
❖SPC&B Safety News❖

A Newsletter for Clients of Sharretts, Paley, Carter & Blauvelt, P.C.

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CPSC Issues Proposed Rules on Testing and Certification for Non-Children's and Children's Products



As required by the Consumer Product Safety Improvement Act (CPSIA), the Consumer Product Safety Commission (CPSC) has published proposed rules that would establish the requirements for reasonable testing programs for non-children's products, third party compliance testing for children's products, and for component testing. The proposed rules currently are scheduled for a vote by the Commission on April 21, 2010.

We have briefly summarized the major provisions of the reasonable testing program and children's product third-party testing program requirements below. Component testing is referenced throughout, but our discussion does not go into all of the requirements the CPSC proposes for testing different types of components. As a general rule, the proposed rule will require that component parts be traceable and that the party certifying compliance must have all appropriate documentation, including identification of the component part, identification of the applicable rules, bans, standards, and regulations for the component part, description of the testing methods and sampling protocols used, the date of testing, the results, and identification of the testing party. Anyone interested in a complete summary of the proposed regulation on component testing should contact us.

We strongly encourage companies to review their own procedures in light of the detailed requirements in the proposals. We stand ready to assist you in developing programs and procedures that will help your company to attain the standards that will soon be required by the CPSC for all manufacturers and importers of consumer products subject to its rules, regulations, standards, and bans.

Reasonable Testing Programs for Non-Children's Products

The proposed regulations establish five elements required for a reasonable testing program, which must be documented in written procedures and protocols: (1) product specification; (2) certification tests; (3) production testing plan; (4) remedial action plan; and (5) recordkeeping requirements.

(Continued on page 2)

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(Continued from page 1)

Product Specification

This element consists of a document that describes the article being certified and lists the applicable rules with which it must comply and which will form the basis for a general conformity certificate. The document should describe the article and whether the testing is to be conducted on the finished product or on components and any further information, including the style name or number, composition, etc., that is necessary to adequately identify the product and its components. Products that are not materially different may have the same product specification.

Certification Tests

The CPSC states that a sufficient number of samples would have to be submitted for testing to provide a “high degree of assurance” that the product is compliant. Furthermore, if a product (or its components if utilizing component testing) fails, the importer would not be able to certify the product until a high degree of assurance is achieved, based on additional testing. Any time there is a material change such as different manufacturing process, different specifications, etc., the product or its components must be retested.

Production Testing Plan

A production testing plan is a set of procedures and processes intended to demonstrate that consumer products manufactured after the initial certification continue to comply with the applicable rules. This can be accomplished either by conducting periodic ongoing testing or by the use of “process management techniques” to control any variations in production that could affect the product’s compliance to the applicable rules. In other words, the production testing plan is designed to confirm that the product is the same as the one that was tested for certification purposes. The plan must be able to detect noncompliant products as effectively as the tests required for certification testing. The plan should describe the tests or measurements that will be part of the program, the intervals at which the tests or measurements will be made, the number of samples to be tested, and the basis for concluding that such tests provide a high degree of assurance of compliance.

Remedial Action Plan

A remedial action plan is a written set of procedures describing the steps to be taken whenever results from any tests used to assess compliance yield failing results. The remedial action plan is required to re-establish compliance. Once the remedial action takes place, re-testing is required. For failing product that has not been introduced into commerce, there is no need to report the failure to the CPSC, but the manufacturer/importer must notify the agency of products distributed in commerce for which there is a failure.

Recordkeeping Requirements

Previously, the CPSC only stated that records (test reports, certificates, etc.) must be maintained for a period of 3 years by a designated person in the United States. The new publication has much more stringent requirements.

The records that must be maintained, in English, for each consumer product are as follows:

- Copy of the general conformity certificate
- Record of the product specification for the product.
- Description of how the product was certified as being in compliance, such as how each requirement was evaluated, the testing facility that conducted the test (if used), and the test results
- Records to demonstrate compliance with the production testing plan requirements, including details of the applicable rules, the types of production tests conducted, the number of samples tested, the

(Continued on page 3)

(Continued from page 2)

- production intervals selected and the test results.
- Records of any remedial actions required and taken

The product specification and the general conformity certificate must be maintained for as long as the certified product is being distributed plus 3 years. Other records must be maintained for 3 years after they are generated. A new product specification will initiate a new record set for the product. The records must be kept in the “main office of the certifier.”

Third-Party Testing for Children’s Products

The proposed rule would require the submission of “sufficient samples” to an accredited third-party testing facility to provide a high degree of assurance that the tests demonstrate compliance. The CPSC confirmed that in some circumstances component testing can be used in lieu of finished product testing, such as testing for lead or phthalate content. In testing for other standards, such as the use and abuse tests conducted on small parts, the finished product may have to be tested. If there are failing results on one sample of the product, the product cannot be introduced into commerce, even if other samples did pass the same test. Remedial action must be taken after identifying nonconforming features. The failure is not required to be reported to the CPSC unless the products have already entered commerce.

Periodic Testing

The proposed rule specifies the conditions for periodic ongoing testing of products that continue to be produced after the initial certification, absent material changes that would trigger a requirement for new testing. Such periodic testing must be conducted by an accredited third-party testing facility and does not have to be the same facility that conducted the initial certification testing. The frequency of periodic testing depends on whether the children’s product manufacturer/importer has implemented a reasonable testing program (as described above for non-children’s products). When a reasonable testing program is in place, the minimum frequency for the periodic testing is once per year, although more frequent periodic testing might be required for certain products or tests.

If no reasonable testing plan is in place, the manufacturer/importer would have to develop a periodic test plan listing the tests that will be conducted, the intervals at which the test will be conducted, the number of samples to be tested, and the basis for determining that the plan provides a high degree of assurance of compliance. The periodic testing should be done at intervals short enough to provide such an assurance, after evaluating the following factors:

- High variability in test results should result in shorter intervals;
- Measurements that are close to a numerical limit (e.g., lead content limits) should result in shorter intervals;
- Known manufacturing process factors that may affect compliance should result in the adjustment of the intervals to those factors
- Consumer complaints or warranty claims indicating potential noncompliance should result in shorter intervals
- Non-material changes may be used as a factor.

Other factors that may require shorter intervals between periodic tests include when:

- Noncompliance could result in “serious bodily injury”
- The number of products produced annually is very large
- Products are not similar to products with which the manufacturer/importer is normally familiar and/or have many different components

(Continued on page 4)

(Continued from page 3)

- Noncompliance cannot be determined easily, such as by visual inspection

The timing for the interval between periodic tests begins when the children's product certificate is issued. Finally, absent a material change in the product or any other circumstances that would trigger a requirement for more frequent testing, low-volume (less than 10,000 units) manufacturer/importers of children's products should only be required to conduct periodic testing after 10,000 units have been produced since the initial certification test.

Testing of Random Samples

The CPSC advises that the samples chosen for periodic testing should be selected using a simple random sample technique. For greater assurance of compliance, the certifier should select additional samples as required by the product and its production. The agency provides the following example of random selection:

For example, if the planned production quantity in a period is 50,000, and 12 random samples are to be selected for periodic testing, before the products are made, a random process identifies which 12 of the 50,000 will be selected for periodic testing. If the products continue to be distributed in commerce as they are manufactured, the certifier may wish to test the samples as they are selected to minimize the potential quantity of noncompliant products in circulation if a test returns failing results.

Material Changes

Whenever a children's product undergoes a "material change" in the product design, manufacturing process, or sourcing of component parts, that could affect the product's ability to comply with the applicable rules, sufficient samples of the changed product must undergo accredited third-party testing and a new certificate must be issued. Only the applicable rules affected by the material change need be tested. If the material change is limited to a component, the children's product certificate could be based on the initial accredited third-party test of the pre-changed product plus the new accredited third-party test of the changed component.

Verification of Third-Party Test Results

Not only must manufacturer/importers of children's products have their products tested by an accredited third-party testing facility, but the CPSC would now require them to verify the results obtained from that facility by sending product samples for testing to an alternate accredited third-party testing facility on a recurring basis: "The certifier, in the exercise of due care, should send sample(s) of the same children's product to an alternate CPSC-recognized third party conformity assessment body at a frequency that provides a high degree of assurance that the children's product complies to the applicable children's product safety rules." This verification process can be accomplished with periodic testing, described above.

If a product fails any test, whether for certification, material change, or periodic testing, the product cannot be distributed in commerce until remedial actions are taken. If the product has already been distributed in commerce, the CPSC must be notified. If two accredited third-party testing facilities have differing results, one compliant and one non-compliant, the certifier must investigate the discrepancy and if one of the testing facilities' test results were due to error, the certifier must notify the CPSC.

Safeguarding Against Undue Influence

The CPSC requires that all certifiers exercise due care to establish procedures to prevent attempts to exercise "undue influence" on a third-party testing facility by the manufacturer, private labeler or other inter-

(Continued on page 5)

(Continued from page 4)

ested party, including a written policy statement from company officials and annual training of appropriate staff on avoiding undue influence.

Remedial Action Plan

Following a failing test result, if some or all of the product has already been distributed in commerce, the certifier must notify the CPSC. Remedial actions must be taken after any failure, to ensure with a high degree of assurance that future production of the children's product will comply with all applicable rules, such as redesign, changes in the manufacturing process, or changes in component sourcing. For any existing product, remedial action may include rework, repair, or scrap, with subsequent retesting and certification of any redesigned or remanufactured product.

Recordkeeping Requirements

The records that must be maintained, in English, for as long as the product is being distributed plus three years, for each children's product tested by an accredited third-party testing facility are as follows:

- Copy of the certificate with all the required information. The product covered by the certificate should be readily identifiable and distinguishable from any other products.
- Certification test results showing compliance to applicable rules. The certifier must have separate certification test results for each manufacturing site.

The records for periodic testing of children's products that must be maintained are:

- Periodic testing plan, which should be maintained for as long as the product is being distributed plus 3 years and
- Copies of the periodic testing results, which should be maintained for 3 years after their generation.

The records that must be maintained for material changes, for as long as the product is in distribution plus 3 years, are:

- Descriptions of all material changes
- Certification tests that were conducted and the test values

Verification test documentation should be maintained for as long as the product is being distributed plus 3 years. Records of remedial action plans also must be maintained, including the failing test results, the remedial actions taken, the dates of those actions, and the person who authorized the remediation. Copies of the procedures to safeguard against undue influence, including training materials and records indicating the names of the employees who were trained and the dates of such training also must be maintained.

Anyone with questions regarding these matters should contact Gail T. Cumins at gcumins@spcblaw.com or Donna L. Shira at dshira@spcblaw.com, or by calling 212-425-0055.
