

White Paper: SimpleQuE's Explanation of Firewalled Laboratory Requirements For Toy Testing

Written by Jim Lee, President of simpleQuE

Background

ISO 17025 has requirements for any accredited lab regarding identification and avoidance of adverse influence on testing results. The standard specifically states, "The accredited testing laboratory should not engage in any activities that may endanger the trust in its independence of judgment and integrity in relation to its testing activities."

Accredited testing laboratories have typically been independent from private labelers, manufacturers, importers, distributors and retailers, and are able to demonstrate autonomy and freedom from any influence over the lab's test results. When a laboratory is owned (at least 10%) and/or operated by the private labeler, manufacturer, importer, distributor or retailer, then the independence from influence falls into scrutiny. The Consumer Product Safety Commission (CPSC) calls these "Firewalled Laboratories" and adds additional requirements to assure independence.

With new CPSC regulations for toy testing by accredited laboratories, many manufacturers and private labelers are looking to add or enhance their own in-house test capabilities to better control costs while complying with increased testing requirements. This is compounded by concerns that the existing third-party testing labs do not have the capacity to support the test demands.

The problem is to understand what a Firewalled Laboratory needs to do to gain CPSC acceptance.

Existing Requirements in ISO 17025

ISO 17025 already addresses Firewalled Laboratory Accreditation without using that name. Clause 4.1.4 states:

If the laboratory is part of an organization performing activities other than testing, the responsibilities of key personnel in the organization that have an involvement or influence on the testing activities of the laboratory shall be defined in order to identify potential conflicts of interest.

Where a laboratory is part of a larger organization, the organizational arrangements should be such that departments having conflicting interests, such as production, commercial marketing or financing do not adversely influence the laboratory's compliance with the requirements of this International Standard.

If the laboratory wishes to be recognized as a third-party laboratory, it should be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgment. The third-party testing laboratory should not engage in any activities that may endanger the trust in its independence of judgment and integrity in relation to its testing activities.

There are additional ISO 17025 requirements (Clauses 4.1.4, 4.1.5, 4.2.1, 4.8, 4.9, 4.11 4.13.2.3, 5.1.2 j) that relate to Firewalled Laboratory Accreditation to prevent any conflicts of interest.

- Having managerial and technical personnel who have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests, and to initiate actions to prevent or minimize such departures;
- Having arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;
- Having policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity;

- Defining the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services;
- Specifying the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests;
- Providing adequate supervision of testing staff, including trainees, by persons familiar with methods and procedures, purpose of each test, and with the assessment of the test results;
- Having technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;
- Appointing a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources;
- Appointing deputies for key managerial personnel;
- Ensuring that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.
- Ensuring that all test reports are reviewed and approved by the appropriate personnel

ISO 17025 further adds to Firewalled Laboratory independence from undue influence by:

- Requiring a procedure and policy for dealing with complaints that can include conflict of interest or undue influence;
- Having an appropriate corrective action process and procedure that takes into account the root causes as it might relate to conflict of interest or undue influence;
- Having a procedure for corrective action that assures corrective actions are effectively implemented as it might relate to conflict of interest or undue influence;
- Having a process and procedure for dealing with test reports that do not meet requirements, and how corrections and amendments are made.

CPSC Requirements And Expectations

A laboratory owned or controlled by a manufacturer or private labeler of products to be tested by the laboratory is subject to additional requirements intended to assure that the CPSC is immediately and confidentially notified of any attempt by the manufacturer, private labeler or other interested party to hide or exert undue influence over the laboratory's test results.

The CPSC has additional requirements for Firewalled Laboratories in addition to being accredited to ISO 17025 with an appropriate toy testing lab scope, by an ILAC-MRA signatory accreditation body

- Must submit to the CPSC 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 laboratory's test results. This additional requirement applies to any laboratory in which a manufacturer or private labeler of a children's product to be tested by the laboratory owns a ten percent or more interest.
- This insinuates there is a procedure and process for identifying undue influence, training on these procedures that includes training on how to notify the CPSC,
- The Commission must formally accept the accreditation application before the laboratory can become an accredited firewalled laboratory.

The CPSC may accredit a laboratory under the Act's firewalled provision if the CPSC finds that:

- 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

- the laboratory has established procedures to ensure that-
 - its test results are protected from undue influence by the manufacturer, private labeler or other interested party;
 - 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
 - allegations of undue influence may be reported confidentially to the Commission.

The process the CPSC utilizes is as follows.

- Laboratories apply for firewalled acceptance via the CPSC on-line registration form. Each applicant submits training materials and other information to show conformance with the criteria for acceptance for firewalled laboratories.
- Firewalled Laboratory Review Committee comprised of four senior level CPSC staff members reviews the applications. The committee members individually compared the applications for each laboratory with the criteria for firewalled laboratories as described in the CPSIA and in the Commission-published requirements for laboratory accreditation. After individual members conducted their assessments, the committee met as a group to discuss each person's reasoning with regard to a laboratory's conformity or non-conformity with the firewalled laboratory criteria. The team reviewed documentation that included elements of training programs and records of training attendance, policies stated in laboratory quality manuals and operating manuals related to prohibition on acts of undue influence, organizational charts, and certification and scope documents associated with ISO 17025 accreditation.
- The Review Committee concluded, by majority vote/ that the documentation supplied by the applicants supported requirements for acceptance as firewalled laboratories. The Review Committee recommended that a memorandum be prepared for Commission review with a recommendation to accept the applicants as firewalled laboratories and to list the laboratories on the CPSC Web site for the testing scopes approved by the Review Committee.

As of August 27, 2009 there are seven firewalled labs owned by Mattel that got approved. It is possible to put firewall protections in place to assure an in-house laboratory has appropriate safeguards and protections against undue influence. The question is whether it is economically feasible to implement and accredit an internal lab to ISO 17025, or outsource the testing to the large number of existing labs that are already accredited and approved. You can find the existing list of CPSC approved labs at <http://www.cpsc.gov/cgi-bin/labapplist.aspx>.