HOKLAS Supplementary Criteria No. 9

Physical and Mechanical Tests under the Test Category of "Physical and Mechanical Testing" and "Toys and Children's Products"

1 INTRODUCTION

1.1 This criteria document serves to clarify and supplement the requirements of ISO/IEC 17025: 2017 for the accreditation of physical and mechanical tests under the test category of 'Physical and Mechanical Testing' and 'Toys and Children's Products'. This document should be read in conjunction with ISO/IEC 17025: 2017 and other relevant criteria documents.

1.2 Laboratories shall comply with all specific requirements of the test standards in addition to the requirements specified in this document.

2 SCOPE OF ACCREDITATION

2.1 This document is applicable to accreditation of laboratories for physical and mechanical tests excluding gemstone testing under the test category of 'Physical and Mechanical Testing' and 'Toys and Children's Products'.

3 TERMS AND DEFINITIONS

3.1 The terms and definitions given in ISO/IEC Guide 99 and ISO 9000 are applicable to this document.

3.2 The term "shall" is used throughout this document to indicate those provisions which are mandatory. The term "should" is used to indicate guidance which, although not mandatory, is provided by HKAS as a recognised means of meeting the requirements.

4 RESOURCE REQUIREMENTS – PERSONNEL

4.1 Each staff member of the laboratory at supervisory level or above, including the officer-in-charge of the laboratory or each section leader in the case of a larger laboratory, shall hold at least a higher diploma in an engineering or physical science subject or a higher qualification conferred by a recognised higher education institution in Hong Kong or an equivalent or higher academic qualification and shall have not less than three years relevant work experience. If such staff member does not possess the required academic qualification but has extensive work experience (e.g. ten years) in his/her responsible testing area, the laboratory shall keep record to substantiate that such staff member has the required technical knowledge and skills to supervise the operation of related test area(s).

4.2 Each test operator shall have sufficient technical knowledge of the technology as stipulated in related test standards. He/she shall have satisfactorily completed the required training before he/she is authorised for performing specific tests independently.

4.3 Each laboratory shall nominate at least one staff member at supervisory level as the signatory for a specific test. The nominated signatory shall have at least six months of supervisory experience in the testing area(s) for which signatory approval is being sought.

4.4 The training program for new testing operator shall at least cover the following areas:

(a) Principles and practice of basic physical and mechanical tests, including factors that may affect test results and precautions to be taken for minimising such effects;
(b) Understanding related test standards and terminology;
(c) Principles, limitations and operation of common equipment/fixture and the criteria for selection of equipment/fixture, including the method for selecting an appropriate instrument for performing a specific test;
(d) Preparation of test items, pre-conditioning requirements and specific testing conditions (if any);
(e) Identifying appropriate locations of the test item to be tested;
(f) Understanding equipment calibration and metrological traceability;
(g) Understanding measurement uncertainty;
(h) Recording of test results;
(i) Drawing conclusion based on test results; and
(j) Understanding laboratory management system.

4.5 Where necessary, the laboratory shall provide refresher training on infrequently performed tests to test operators.

5 RESOURCE REQUIREMENTS – FACILITIES AND ENVIRONMENTAL CONDITIONS

5.1 Critical environmental conditions shall be controlled continuously and recorded. Acceptable ranges for the conditions such as temperature and humidity shall be defined. Cases where environmental conditions fall outside the acceptable ranges shall be recorded and the effects on test results shall be evaluated. Appropriate actions shall be initiated if the cases are identified as nonconforming work.

6 RESOURCE REQUIREMENTS – EQUIPMENT

6.1 The laboratory shall assign at least one staff member at supervisory level to be responsible for ensuring that its equipment is properly calibrated or verified against the test standard’s requirements.

6.2 Upon completion of calibration, the responsible staff member shall evaluate the equipment's calibration results against a set of documented criteria to determine whether the equipment is still acceptable for performing specific tests.

7 RESOURCE REQUIREMENTS – METROLOGICAL TRACEABILITY

7.1 If a laboratory establishes metrological traceability of measurement results through its in-house calibrations, the competence of staff member(s) performing in-house calibrations, the associated reference standards, related calibration procedures, the evaluation of measurement uncertainty for each calibration activity and the corresponding calibration records will be assessed by HKAS assessment team. HKAS Executive may require the laboratory to provide the in-house calibration procedures and related technical records to HKAS assessment team for preparation.

8 PROCESS REQUIREMENTS – REVIEW OF REQUESTS, TENDERS AND CONTRACTS

8.1 Where multiple test items (e.g. of different design or construction) of a specific product are submitted by a customer for testing, the laboratory shall perform tests for all test items unless it can demonstrate how to select certain representative test item(s) to obtain reliable test results for all the test items.

8.2 Upon the failure of certain test item(s) to demonstrate conformity with the test requirements, a customer resubmits the test item(s), i.e. the retest item(s), for testing, the laboratory shall ensure that the customer has provided the information which shows all modifications made to the retest item(s) so that the laboratory can determine the specific tests to be repeated on the retest item(s).

9 PROCESS REQUIREMENTS – SELECTION, VERIFICATION AND VALIDATION OF METHODS

9.1 Each laboratory shall ensure that all test standards which are shown in the scope of activities accredited or seeking accreditation including all normative references mentioned in those standards are readily available to its personnel.

9.2 Each laboratory shall have a mechanism to monitor the release of a new or revised test standards and to implement the new or revised standard accordingly. If only electronic version of the test standards including the standard amendment sheets is used, the laboratory shall demonstrate how its test operators can get a holistic view of the amended test standards at the test locations.

9.3 Many national and international standards specify similar tests. However, the detailed requirements may vary. If a test standards does not specify the detailed test procedures, the laboratory should prepare step-by-step test procedures as well as work sheets for its

test operators.

9.4 Where there are ambiguities in the test standard such that there are various ways to perform a test to achieve the required performance, the laboratory shall document the appropriate way to perform the test.

9.5 Many test standards specify the safety requirements for toys which are designed for children of various age groups. The laboratory shall have a procedure to determine the play value of a toy prior to performing specific tests for the toy. Reference may be made to "Age Determination Guidelines: Relating Consumer Product Characteristics to the Skills, Play Behaviors and Interests of Children" issued by US CPSC or an equivalent guidance document.

9.6 If a laboratory is seeking accreditation for compliance testing to legislation, accreditation is normally granted only on the following conditions:

(a) If the compliance test method is specified in legislation, the laboratory shall use such test method.

(b) If no compliance test method is not specified in legislation, the laboratory shall obtain formal approval from the corresponding regulatory authority for using either:
   i. a relevant test standard (e.g. ISO, EN, ASTM), or
   ii. an in-house test method which is developed and properly validated by the laboratory.

10 PROCESS REQUIREMENTS – HANDLING OF TEST ITEMS

10.1 The test item disposal system should be designed to protect the confidentiality of customer information. Before a test item is disposed, it shall be destroyed to an extent such that the customer information will not be disclosed during the disposal process.

11 PROCESS REQUIREMENTS – TECHNICAL RECORDS

11.1 Pro-forma worksheets should be designed for recording the original observations and test results. A clear instruction such as the number of significant figures to be used for recording numerical test results should be given. Space should be provided for showing the exact location of the test item on which a test was performed.

11.2 The laboratory shall record the rationale for determining the play value of each toy test item.

11.3 When more than one test items are used for performing different tests as specified in a test standard, the record shall indicate clearly which test item was used for performing a specific test.

11.4 The date of submission of a retest item and specific tests performed for the retest item shall be clearly recorded.

12 PROCESS RQUIREMENTS – EVALUATION OF MEASUREMENT UNCERTAINTY

12.1 Each laboratory shall have a procedure for evaluation of measurement uncertainty for all tests which have numerical results. In general, the measurement uncertainty for physical and mechanical tests shall be evaluated in accordance with ISO/IEC Guide 98-3.

13 PROCESS REQUIREMENTS – ENSURING THE VALIDITY OF RESULTS

13.1 Each laboratory shall participate in proficiency testing activities, which include proficiency testing scheme or interlaboratory comparison, at least once every four years for each major sub-area. The frequency of participation shall commensurate with the volume of work for each major sub-area. Where practicable, at least one of the participating laboratories shall have been accredited for the tests performed under an interlaboratory comparison.

13.2 Each laboratory shall have a documented procedure for rectifying unsatisfactory performance in its proficiency testing activities. All findings in connection with the unsatisfactory performance shall be recorded.

13.3 Each laboratory shall implement a mechanism for reviewing its reported results to ensure the validity of the results and the person who is assigned to review the results ('the reviewer') shall not be directly involved in performing the tests. In addition, the reviewer, who should preferably at supervisory level, shall have the required competence to perform the review. Sufficient technical records shall be provided to the reviewer for conducting the review.