HOKLAS Supplementary Criteria No. 51

'Chemical Testing' - Doping Control Testing Laboratories

0 Introduction

(a) This document serves to clarify and supplement the requirements of ISO/IEC 17025:2017 and HKAS PD001 for the accreditation of laboratories performing doping control testing. Applicant or accredited laboratories shall operate under a management system conforming to ISO/IEC 17025:2017 and HKAS PD001. For areas not covered in this document, ISO/IEC 17025:2017, HKAS PD001, HKAS 002 and other relevant HKAS/HOKLAS Supplementary Criteria documents shall apply.

(b) This document shall be read in conjunction with HOKLAS SC-20. This document contains pointers to HOKLAS SC-20. Users shall refer to the corresponding clauses of HOKLAS SC-20 for the applicable criteria as appropriate.

(c) The technical criteria specified in this document apply to accreditation of laboratories performing doping control testing under the 'Chemical Testing' Test Category. However, these criteria are not applicable to accreditation of laboratories performing gene doping control testing by polymerase chain reaction (PCR). Laboratories performing gene doping control testing by PCR shall refer to HOKLAS SC-21 for the applicable criteria. For chemical testing of other nature, laboratories shall refer to HOKLAS SC-20 or HOKLAS SC-44 for the applicable criteria as appropriate.

(d) Laboratories should also note that fulfilling the requirements in this document might not necessarily meet the requirements of all test standards. Individual test standards may have specific requirements which shall be met when conducting the tests.

1 Scope

(No additional explanation)

2 Normative references

(No additional explanation)

3 Terms and definitions

(No additional explanation)

4 General requirements

(No additional explanation)

5 Structural requirements

(a) The technical management of the laboratory shall include at least a member with in-depth knowledge of and extensive experience in analytical chemistry and doping control testing. He/she shall be or part of the technical management that is responsible for the technical operation of the laboratory with respect to the testing.

6 Resource requirements

Please refer to Clause 6 of HOKLAS SC-20.

7 Process requirements

7.1 Review of requests, tenders and contracts

(No additional explanation)

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

Please refer to Clause 7.2.1 of HOKLAS SC-20.

7.2.2 Validation of methods

Please refer to Clause 7.2.2 (a) to (g) of HOKLAS SC-20.

(h) For establishing the presence of prohibited substances in doping

control testing, a laboratory may wish to modify an existing accredited test procedure or introduce a technically equivalent test procedure such that the modified or new test procedure is still considered as covered by its accreditation scope. In such case, the requirements as given in the Appendix apply.

7.3 Sampling

Please refer to Clause 7.3 of HOKLAS SC-20.

7.4 Handling of test or calibration items

Please refer to Clause 7.4 of HOKLAS SC-20.

7.5 Technical records

(No additional explanation)

7.6 Evaluation of measurement uncertainty

Please refer to Clause 7.6 of HOKLAS SC-20.

7.7 Ensuring the validity of results

Please refer to Clause 7.7 of HOKLAS SC-20.

7.8 Reporting of results

Please refer to Clause 7.8 of HOKLAS SC-20.

7.9 Complaints

(No additional explanation)

7.10 Nonconforming work

(No additional explanation)

7.11 Control of data and information management

(No additional explanation)

8 Management system requirements

(No additional explanation)

Appendix

Requirements for a laboratory making modification to an accredited test procedure, or introducing a technically equivalent procedure which adopts analytical techniques or measurement principles already covered by accreditation, for establishing the presence of prohibited substances in doping control testing

(i) The bounds within which the laboratory may modify its test procedures shall be clearly defined and approved by the HKAS Executive, and normally, the laboratory may only modify its accredited test procedures to (a) include additional analytes which are of the same or similar chemical nature (e.g. drugs in the same class) to those already within its scope of accreditation; (b) change the method performance characteristics for a given sample matrix and a given parameter, e.g. modification of screening limit; and (c) include additional technically equivalent procedures which adopt analytical techniques or measurement principles already covered by accreditation.

(ii) Any modification or addition of technically equivalent procedures shall not involve new analytical technique or measurement principle not previously covered in the scope of accreditation of the laboratory.

(iii) The laboratory shall have demonstrated good system maturity and stability and meet the accreditation criteria for Monitoring Plan B or C (as given in HKAS SC-04). Nevertheless, the laboratory may not necessarily be adopting Plan B or C.

(iv) The laboratory shall demonstrate technical competence by obtaining satisfactory results in the latest two of any relevant proficiency test programmes or inter-laboratory comparisons participated by the laboratory within the previous two years using the accredited test procedures.

(v) The laboratory shall have gone through at least one assessment visit for the test procedures to be modified, with no significant nonconformity identified in related activities.

(vi) The staff who are responsible for the development and modification of test procedures shall have the sufficient technical understanding of the test and the technology used.

They shall be able to judge the suitability of the test and the validity of the results obtained. They shall be approved signatory in the test concerned and have at least 1 year of experience in the test area 'Race Control Analysis'. HKAS Executive will specifically assess the competence of the staff who are authorised to undertake method development and modification during assessments, taking into consideration factors such as the staff's (a) formal education and training received; (b) experience within the field; (c) participation in research or development projects; (d) participation in standardization committees; and (e) participation in scientific or authoritative committees.

(vii) The process for developing, validating and authorising modified or new test procedures shall be controlled and documented. The process shall be reviewed at suitable intervals for adequacy and the related activities shall be monitored by incorporation into the laboratory's internal audit programme.

(viii) The laboratory shall maintain a record system that can demonstrate how a test procedure was modified (or developed), validated and accepted, the justification for any procedure modification and development, and who was responsible for each key activity. The information recorded shall be sufficient to allow audits to clearly follow the events leading to the introduction of each modified test procedure.

(ix) The laboratory shall demonstrate their technical competence to validate modified or new procedures in accordance with Clause 7.2.2 of ISO/IEC 17025:2017 as well as Clause 7.2.2 of HOKLAS SC-20.

(x) The laboratory shall ensure that any modified or new procedures have been fully validated before they are introduced in its scope of accreditation.

(xi) The laboratory shall implement sufficient quality control measures to ensure the validity of the test results obtained from the modified or new procedures.

(xii) If nonconforming testing work is identified in association with the use of any modified or new procedures, the work shall be handled in accordance with Clause 7.10 of ISO/IEC 17025:2017, and in this connection, if any invalid results are suspected or found to have been reported to customers, the laboratory shall report the

matter to HKAS Executive immediately.

(xiii) The laboratory shall notify HKAS Executive of any modified or new test procedure for incorporation into its scope of accreditation by submitting the modified or new procedure, the proposed scope and also the duly completed HKAS 009 form within 10 working days from the effective date of the modified or new procedure to HKAS Executive for review. If the 10-working day condition cannot be met, proper justification shall be provided.

(xiv) The laboratory shall keep an updated scope of the tests the laboratory is accredited to perform, including any modified or newly added procedures, the associated product/matrix types and target analytes.

(xv) The laboratory shall submit in full the validation report with relevant raw data records, uncertainties and other pertinent information as appropriate e.g. staff training records, for any modified or new test procedures since the last reassessment visit for review by HKAS Executive upon request.

(xvi) HKAS Executive will closely monitor the performance of the laboratory, e.g. through unannounced or scheduled visits to the laboratory, matters arising as per Clause (xii) above, etc., and may amend or delete any items proposed by laboratory for inclusion into its scope of accreditation or terminate the practice of the laboratory under Clause 7.2.2 (h) at its discretion.

Annex

(Informative)

Bibliography

1 ILAC G7 : *Accreditation requirements and operating criteria for horseracing laboratories*

2 ILAC G18 : *Guideline for describing scope of accreditation*

Please also refer to the Annex of HOKLAS SC-20.