HOKLAS Supplementary Criteria No. 48

Qualitative Screening of Consumer Products for Radioactivity Within Laboratory under the Test Category of "Physical and Mechanical Testing"

0 INTRODUCTION

(a) This criteria document serves to clarify and supplement the requirements of ISO/IEC 17025: 2017 and HKAS Policy Document No. 1 for accreditation of laboratories for qualitative screening of consumer products for radioactivity within laboratory under the test category of 'Physical and Mechanical Testing'. This document should be read in conjunction with ISO/IEC 17025: 2017, HKAS Policy Document No.1 and other relevant criteria documents.

(b) The following items are excluded from the scope of accreditation:
   i. on-site monitoring or screening of samples, goods, cargoes, etc. for radioactivity;
   ii. screening of food samples for radioactivity.

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

(d) 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.

1 SCOPE

(No additional explanation)

2 NORMATIVE REFERENCE

(No additional explanation)

3 TERMS AND DEFINITION

(No additional explanation)

4 GENERAL REQUIREMENTS

(No additional explanation)

5 STRUCTURAL REQUIREMENTS

(a) The technical management of the laboratory shall have in-depth knowledge of and extensive experience in radioactivity monitoring and shall be responsible for the technical operation of the laboratory with respect to radioactivity monitoring and calibration of related instruments.

6 RESOURCE REQUIREMENTS

6.1 GENERAL

(No additional explanation)

6.2 PERSONNEL

(a) Staff shall have adequate training in the correct performance of the tests concerned. A training programme shall be outlined. The programme shall include training in operating, maintaining and performance checking instruments, test procedures as well as quality assurance. Staff members are only allowed to perform tests independently after their performance has been assessed to be satisfactory. Competence assessment, including any raw data and authorization record shall be maintained. Their performance shall be evaluated regularly to ensure their continued competence. Records of initial training and continued competence assessment, including all raw data, shall be maintained.

(b) If handling of radioactive materials is involved, the staff shall be familiar with the laboratory's operational procedures in the handling and use of radioactive materials. Specialized training shall be given to staff operating, maintaining and checking of performance of relevant instruments as

appropriate. If applicable, staff handling unsealed radioactive materials shall be classified as radiation worker and protected according to the requirements of the Radiation Ordinance.

(c) Each laboratory shall nominate at least one staff member at supervisory level as the signatory for a specific test. The nominated signatory shall have a university degree in relevant science or engineering subjects and formal academic training in radioactivity monitoring. He/she shall have at least three years general laboratory experience and at least six months of supervisory experience in the testing area(s) for which signatory approval is being sought.

6.3 FACILITIES AND ENVIRONMENTAL CONDITIONS

(a) The laboratory shall provide appropriate environmental conditions and controls necessary for particular tests, including temperature, humidity, lighting, etc. Reference should be made to manufacturer's manuals of instruments or relevant standard methods. Critical environmental conditions shall be controlled continuously and recorded. Cases where environmental conditions fall outside the acceptable ranges shall be recorded and the effects, if any, shall be evaluated. Appropriate actions shall be taken if the cases are identified as nonconforming work.

(b) It is the responsibility of the laboratory to implement necessary radiation safety measures to ensure compliance with the requirements of the Radiation Ordinance as well as to provide adequate radiation protection to its operating staff.

(c) Designated areas should be defined for the safe storage, handling and use of radioactive materials according to the requirements of the Radiation Ordinance.

6.4 EQUIPMENT

(No additional explanation)

6.5 METROLOGICAL TRACEABILITY

(a) The calibration of radiation monitoring instruments can be conducted initially and checked periodically according to the Tests Before First Use and Periodic Tests requirements as stipulated in the Measurement Good Practice Guides No. 14 published by The Society for Radiological Protection or equivalent requirements as stipulated in other national / international guidelines such as the Safety Report Series No. 16 published by International Atomic Energy Agency (IAEA), using suitable reference sources or relevant reference instruments. When the calibration procedure is specified in a test standard, such calibration procedure shall be followed.

6.6 EXTERNALLY PROVIDED PRODUCTS AND SERVICES

(No additional explanation)

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

(a) Laboratories shall adopt relevant national/international standard test methods, e.g. ISO 7503 Part 1 to 3 Measurement of radioactivity - Measurement and evaluation of surface contamination, as far as possible. Laboratory-developed methods or non-standard methods shall not be used until laboratories have performed proper method validation to validate that each particular method is adequate for its intended purpose and the needs of the customers. For compliance testing or testing against guideline levels, it is essential that the limits of detection are well below the compliance limits and that the method gives reliable results at the compliance limits.

(b) Laboratories shall verify their competence to perform the test to achieve satisfactory performance against the documented performance characteristics of the standard method such as Minimum Detectable Activity (MDA), false compliant rate at the screening limit, repeatability, etc. as appropriate before any tests are performed. The verification work to be carried out should be appropriate to the purpose of the method, e.g. screening of surface contamination caused by a particular type of radiation emitters in a particular energy range.

7.2.2 Validation of methods

(a) Although validation is not required for standard test methods, laboratories should pay particular attention to the limitations of the methods.

(b) Laboratory-developed methods and non-standard methods shall be validated and authorised before use. The validated laboratory-developed methods and non-standard methods shall be documented and scope of application, performance characteristics, quality control plans and calibration shall be well defined.

(c) Laboratory-developed methods and non-standard methods shall be developed with reference to relevant national/international standard test methods or guidelines as far as possible. Method performance characteristics such as MDA, screening limit, false compliant rate, applicable sample types etc. shall be established. The monitoring protocol for the screening (e.g. locations of representative monitoring points within a sample and the monitoring time at each point) for different sample types shall be defined. The method shall be validated through inter-laboratory comparison to provide independent evidence that the test results obtained by the proposed method are comparable to those obtained by other laboratories. Only screening methods that have been shown to have a false compliant rate of less than 5% at the level of interest shall be used, albeit a more stringent false compliant rate may be required in some cases. Other method characteristics such as the types of radiation monitored (e.g. α, β or γ) and their approximate energy ranges shall be defined.

(d) The performance of a validated method may change due to many reasons. It is therefore necessary to review the performance characteristics of test methods on a regular basis and revise, if necessary. Such reviews may also be required when the performance of the method is affected by changes in equipment or environmental conditions, etc.

7.3 SAMPLING

(a) Sampling from sample lot or site is excluded from the scope of accreditation. Customers taking their own samples should be made aware of proper storage, sampling and transportation procedures. In particular, it is strongly recommended that customers be made aware of the fact that the test results only relate to the sample as submitted. Inference of the sample test results to production lots or batches may be subject to other factors such as variations of the raw materials, variation of the production processes, etc. Similarly, the test results cannot take into account batch to batch variations.

7.4 HANDLING OF TEST ITEMS

(a) Laboratories shall prepare and implement a plan for detecting and handling test items of high radioactivity. Such plan shall be documented.

7.5 TECHNICAL RECORDS

(No additional explanation)

7.6 EVALUATION OF MEASUREMENT UNCERTAINTY

(No additional explanation)

7.7 ENSURING THE VALIDITY OF RESULTS

(a) Laboratories shall establish and implement quality control plans to ensure and demonstrate that the monitoring process is in-control and the results generated are accurate and reliable. The quality control measures shall

include, as a minimum, (i) determination of background; (ii) verification of the correct performance of the instrument using suitable check source; (iii) repeat screening of the same sample by different operators. The quality control plans shall include frequency of performing the quality control measures, their acceptance criteria and actions to be taken in cases of acceptance criteria not being met. Laboratories shall document their quality control plans and procedures for each test or monitoring method.

(b) Control charts shall be used where appropriate to monitor the performance of the laboratory. Control and warning limits of such charts shall be based on statistical principles. Laboratories shall also observe any trend that is indicated in control charts. Recommendations given in relevant national or international standards should be followed, if appropriate.

(c) A written corrective action programme and documentation of corrective actions are essential. The corrective action programme is a written procedure detailing the steps to be followed when the monitoring system is judged to be out of control. The documentation of corrective actions is a written record of actions taken to bring the system back into control along with data that demonstrates system control.

(d) Laboratories shall establish schedules for verifying their performance by analysing relevant reference materials as far as possible and participating in proficiency testing programmes or inter-laboratory comparisons. Participation in proficiency testing programmes or inter-laboratory comparisons, when proficiency testing programmes are not available, at least once a year is required.

(e) Laboratories shall document procedures for rectifying unsatisfactory performance in proficiency testing programmes or inter-laboratory comparisons. If unsatisfactory results are obtained, the laboratory shall promptly investigate the cause(s) for this and rectify the problem(s) and demonstrate that it can achieve satisfactory performance for the test/method in question. All findings in connection with unsatisfactory performance shall be recorded.

7.8 REPORTING OF RESULTS

(a) A description of the items for screening as received shall normally be given in test reports. The description shall include, where relevant to the interpretation of test results, a description of the number/set, appearance,

type of items and condition when received. Any deviation from the test standard requirements shall be given.

(b) Quality control results shall be reported when they are required for the proper interpretation of test results, the customers requested them, or the test standards concerned require them to be reported. Qualifying statements on test results shall be given, if necessary.

(c) The information to be reported shall include, as a minimum, the following:
(i) Type of monitoring e.g. direct surface contamination monitoring;
(ii) monitoring protocol;
(iii) instrument used with model and serial number;
(iv) instrument coefficient and calibration date;
(v) details of measurement traceability;
(vi) screening limit (reporting limit);
(vii) background, as appropriate;
(viii) results of monitoring;
(ix) other information (e.g. instrument settings, monitoring procedure) as appropriate for results interpretation.

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 A
(informative)

REFERENCE DOCUMENTS

1 ISO 7503 Part 1 to Part 3 *Measurement of radioactivity -- Measurement and evaluation of surface contamination*

2 ISO 8769 *Measurement of radioactivity — Alpha-, beta- and photon emitting radionuclides — Reference measurement standard specifications for the calibration of surface contamination monitors*

3 The Society for Radiological Protection, UK *Measurement Good Practice Guides No. 14 The examination, testing and calibration of portable radiation protection instruments*

4 International Atomic Energy Agency *Safety Report Series No. 16 Calibration of Radiation Protection Monitoring Instruments*

5 Public Health England, UK *NRPB-R326 Guidance on the Choice, Use and Maintenance of Hand-held Radiation Monitoring Equipment*

6 International Atomic Energy Agency *Practical Radiation Technical Manual No. 1 Workplace Monitoring for Radiation and Contamination*

7 *Radiation Ordinance* (Cap 303), Hong Kong