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KAN TECHNICAL NOTES FOR CHEMICAL TESTING LABORATORY

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APPROVAL SHEET

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LIST OF AMENDMENT

No.	Date	Part number revised	Brief description of changes	Part revision number
1.	January 2008	All	Change of identification	2
2.	April 2016	All	Change of identification and change of address	3

SPECIFIC REQUIREMENT FOR CHEMICAL LABORATORY

1. INTRODUCTION

a. This Specific requirements are an interpretation of the general requirements of ISO/IEC 17025-2005.

b. This accreditation requirements are applicable to field of chemical testing, testing technical, type of test, and or specific test in chemical area, as extra information to the already generally stated requirements in each of the clauses ISO/IEC 17025-2005.

c. Chemical testing is qualitative, semi-quantitative or quantitative procedure designed to prove the existence of a chemical compound or chemical group with the aid of a specific reagent.

d. Chemical testing is taken to include chemical quality and purity, chemical ingredients, trace chemical detection, identification of chemical contamination, identification of chemical impurities, trace chemical unknowns, chemical component analysis, chemicals formulation from all product or material tested, such as product or material of pharmaceutical, food, beverage, agricultural, petrochemical, environmental, waters, metals and alloys, ores and minerals, bituminous materials, plastics, leather, rubber, paper, cosmetics & perfumes, detergents, fats, oils and waxes, gases & aerosols, pigments, resins etc.

2. PERSONNEL

a. Technical Manager, Laboratory Supervisors and chemical laboratory analysis shall possess a basic education in chemistry vocation or a related science.

b. Chemical laboratory analysis must be carried out by, or under the supervision of a qualified, experienced and competent analyst.

c. Laboratory management shall ensure that laboratory personnel have the knowledge, skills, and abilities based on education, experience, demonstrated skills, and training. to perform their duties.

d. Laboratory shall establish and define an internal training program and ensure the competency of laboratory personnel.

e. Laboratory shall have training procedure that used to ensure that training has taken place with each employee for procedures and methods that the employee performs. The procedure applies to on-the-job training, in-house training and new-hire training.

f. The training is verified and documented. The training procedure is applicable to new employees, for the introduction of new procedures and methods, for retraining of employees, and for re verification of employee performance.

g. The laboratory shall maintain an up-to-date record of the training that each member of staff has received.

h. Before starting any work related duties, the employee should be familiar with all work related documents. These documents include procedures, work instructions, applicable manuals and regulations.

3. ACCOMMODATION AND ENVIRONMENTAL CONDITIONS

a. The laboratories are designed to provide space, engineering controls, and proper environmental conditions for optimal sample storage, sample handling, and analysis, in accordance with general laboratory practice.

b. Laboratory facilities meet the required environmental conditions, including any needed separation of work areas to ensure that analyses will not be adversely affected within resources provided.

c. Laboratory storage areas provide proper storage of samples, reagents, microbiological media, chemicals, select agents, standards and reference materials, and radioactive wastes and hazardous waste.

d. The temperature and humidity within the laboratory are maintained within limits for the proper performance of each test or analysis and maintained according to the manufacturer's specifications for the proper operation of instruments.

e. Floors in the laboratories are constructed from a material that is resistant to most chemical spills and easily disinfected.

f. Microbiology labs are designed to minimize areas with cracks or fibers that could serve to accumulate debris and serve as an area for growth of microorganisms. Floors are clean, dry, and in sound condition so there are no tripping hazards.

g. In laboratories that perform metal analysis, benches, hoods and glassware are monitored periodically for metal contamination.

h. Sample receiving and storage is conducted in designated areas which are separate from the main part of the laboratory.

4. TEST METHOD AND METHOD VALIDATION

a. The method number and title used in the laboratory the same as the scope of testing.

b. The method contain the title, scope and field of application, references, principles and definitions, reagents and materials, apparatus, analytical methodology, expression of results, performance criteria, revision history, page numbering, total number of pages, issuing authority.

c. A method should be validated when it is necessary to verify that its performance parameters are adequate for use for a particular analytical problem:

   i. new method developed for particular problem;

   ii. established method revised to incorporate improvements or extended to a new problem;

   iii. when quality control indicates an established method is changing with time;

   iv. established method used in a different laboratory, or with different analysts or different instrumentation;

   v. to demonstrate the equivalence between two methods, e.g. a new method and a standard.

d. Methods developed in-house must be adequately validated, documented and authorized before use.

e. Where they are available, matrix matched reference materials should be used to determine any bias, or where this is not possible, results should be compared with other technique(s), preferably based on different principles of measurement.

f. Measurement of the recovery of gravimetrically added spike analyte, measurement of blanks and the study of interferences and matrix effects can also be used to check for bias or imperfect recovery.

g. Estimation of uncertainty must form part of this validation process and in addition to covering the above factors, should address issues such as sample homogeneity and sample stability.

h. In-house methods are fully documented, appropriately validated and

authorized for use.

i. Copies of published and official methods are available. The most up-to-date version of the method is available to the analyst.

j. Analyses are supervised to follow the methods specified.

k. Methods have an appropriate level of advice on calibration and quality control.

l. The validation of the method contain (depending on the type of method (qualitative, semi quantitative, etc) :

   i. criteria for determining the required number of samples to be tested. validation of test method performed under same conditions as those of a real assay;
   ii. precision;
   iii. repeatability;
   iv. recoveries of spiked samples;
   v. specificity of the method in a given matrix;
   vi. analytical range;
   vii. linearity;
   viii. limit of detection;
   ix. limit of quantification;
   x. accuracy;
   xi. confirmation techniques;
   xii. statement that the method used in the validation is fit for the intended use.

5. EQUIPMENT AND MEASUREMENT TRACEABILITY

a. All equipment used in laboratories should be of a specification sufficient for the intended purpose, and kept in a state of maintenance and calibration consistent with its use.

b. The use of appropriate reference materials can provide:

   i. essential traceability;
   ii. enable analysts to demonstrate the accuracy of results;
   iii. calibrate equipment and methods;
   iv. monitor laboratory performance and validate methods; and
   v. enable comparison of methods by use as transfer measurement standards.

c. Hotplates, stirrers, no volumetric glassware and glassware used for rough volume measurements such as measuring cylinders and laboratory heating or ventilation

systems are equipment not used for making measurements or with minimal influence on measurements.

d. General service equipment will typically only be maintained by cleaning and safety checks as necessary. Calibrations or performance checks will be necessary where the setting can significantly affect the test or analytical result (e.g. the temperature of a muffle furnace or constant temperature bath). Such checks need to be documented.

e. The performance of pyknometers, U-tube viscometers, pipettes, and burettes is dependent on "wetting" and surface tension characteristics. Cleaning procedures must be chosen so as not to compromise these properties.

f. Cleaning procedures, storage, and segregation of volumetric equipment may be critical, particularly for trace analyses where leaching and adsorption can be significant.

g. The frequency of such performance checks may be specified in manuals or operating procedures. If not, then it will be determined by experience and based on need, type and previous performance of the equipment. Intervals between checks should be shorter than the time the equipment has been found, in practice, to take to drift outside acceptable limits.

h. It is often possible to build performance checks - system suitability checks – into test methods (e.g. based on the levels of expected detector or sensor response to reference materials, the resolution of component mixtures by separation systems, the spectral characteristics of measurement standards, etc.). These checks must be satisfactorily completed before the equipment is used.

i. Laboratory shall have a procedure specifies the schedule and requirements for maintenance, performance, calibration, and verification of laboratory testing equipment that meet the criteria of the maintenance and calibration parameters needed to achieve the accuracy of instruments used for analytical testing.

j. Laboratory shall have a procedure specifies the schedule and requirements for maintenance, performance, calibration, and verification of laboratory testing equipment that meet the criteria of the maintenance and calibration parameters needed to achieve the accuracy of instruments used for analytical testing.

k. Laboratory shall have equipment records containing description of the instrument, critical accessories and software, manufacturer's name, type identification and serial number; Laboratory number; installation qualification (IQ) and operational qualification

(OQ) records obtained from the installer or manufacturer; and other related material such as instrument service and repair, warranty information, service contract conditions and specifications.

l. Laboratory shall have operating instructions for each instrument, including starting and shutting down the instrument.

m. Equipment is operated by authorized personnel; authorized personnel are identified per laboratory.

n. The overall programmed for calibration in the chemical laboratory shall be designed to ensure that all measurements that have a significant effect on test or calibration results are traceable to a measurement standard, preferably a national or international measurement standard such as a reference material.

o. Traceability of Measurement Results is property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.

p. Mechanisms for achieving Chemical Measurement Traceability results are :

i. Use of physical standards and devices exist to establish traceability for measurement of fundamental properties, such as mass, length and time or derived properties, such as area, volume, and pressure;

ii. Use of chemicals of known and adequate purity or reference materials of known composition (probably solutions of pure chemicals).for calibrated of Instruments such as chromatographs and spectrometers, which require calibration as part of their normal operation;

iii. Use of a national or international standard method and traceable reference materials for calibration purposes of equipment where a test is used to measure an empirical property of a sample, such as flashpoint.

q. New or newly acquired equipment must be checked by the laboratory before use to ensure conformity with specified design, performance and dimension requirements.

r. Procedures for performing calibrations shall be adequately documented, either as part of specific analytical methods or as a general calibration document. The documentation should indicate how to perform the calibration, how often calibration is necessary, action to be taken in the event of calibration failure. Frequency intervals for recalibration of physical measurement standards should also be indicated.

s. Calibration of weights set shall by calibration laboratory that accredited by KAN or by accreditation body signatory to a APLAC MRA.

t. Calibration of thermometers and thermocouples set shall by calibration laboratory that accredited by KAN or by accreditation body signatory to a APLAC MRA.

u. Calibration of hygrometers (where humidity is important to the outcome of the test). shall by calibration laboratory that accredited by KAN or by accreditation body signatory to a APLAC MRA.

v. Laboratory shall have of pH standards at least two buffer to cover the range of pH needed in the tests methods for pH meter.

w. Laboratory shall checked and recorded regularly of temperatures for Ovens, Refrigerators, Water baths, that used in the tests methods.

x. Laboratory shall have a procedure that ensures adequate response so that the performance of the Gas Chromatograph instrument meets the critical criteria to assure confidence in the results.

y Laboratory shall have a procedure that ensures adequate response so that the performance of the HPLC instrument meets the critical criteria to assure confidence in the results.

z. Equipment that is not operating properly is clearly marked to show that it is out of service.

aa. When an instrument is discovered to be improperly operating, it is tagged and taken out of service.

ab. Equipment is not returned to service until performance checks and verification have been performed and documented.

ac. Each instrument has an established schedule specifying performance checks, including the testing frequency and acceptable performance specifications. These performance checks ensure the instrument is operating properly and consistently prior to analysis.

ad. Verification of Balances Depends on use for Linearity, Zero point, Accuracy using calibrated weights.

ae. Verification of Volumetric Glassware (pipettes/burettes) depends on Use for Accuracy, Precision.

af. Parameter of Chromatographs to be checked, depending on the methods:

i. Overall system checks, precision of repeat sample injections, carry-over;

ii. Column performance (capacity, resolution, retention);
iii. Detector performance (output, response, noise, drift, selectivity, linearity);
iv. System heating/thermo statting (accuracy, precision, stability, ramping characteristics);
v. Autosampler (accuracy and precision of time routines).

ag. Parameter of Spectrometers and spectrophotometers to be checked, depending on the methods, including atomic absorption, fluorimetric, inductively coupled plasma – optical emission, infra-red, luminescence, mass, nuclear magnetic resonance, ultra-violet/visible and X-ray fluorescence:
i. Selected wavelength accuracy, precision, stability;
ii. Source stability;
iii. Detector performance (resolution, selectivity, stability, linearity, accuracy, precision);
iv. Signal to noise ratio;
v. Detector calibration (mass, ppm, wavelength, frequency, absorbance, transmittance, bandwidth, intensity etc.);

ah. Internal temperature controllers and indicators where applicable.

6. REAGENTS AND REFERENCE MATERIALS

a. The quality of reagents and other consumable materials must be appropriate for their intended use. Consideration needs to be given to the selection, purchase, reception and storage of reagents.

b. The grade of any critical reagent used including distilled water should be stated in the method, together with guidance on any particular precautions which should be observed in its preparation, storage and use.

c. These precautions include toxicity, flammability, stability to heat, air and light; reactivity to other chemicals; reactivity to particular containers; and other hazards.

d. Reagents and reference materials prepared in the laboratory should be labeled to identify substance, strength, solvent (where not water), any special precautions or hazards, restrictions of use, and date of preparation and/or expiry.

e. The person responsible for the preparation shall be identifiable either from the label or from records.

f. Solutions of reagent, standard and any other such as mobile phase properly labeled with solution name, concentration, date of preparation, expiration date, and identity of person who prepared.

g. Stored reagents, reference materials and supplies shall be under the appropriate conditions and in a secure manner to ensure the separation of incompatible materials.

h. Disposed of reagents and standards solutions appropriately followed to National and or local regulation.

i. Laboratory shall have documented verification or comparison of standards and/or reference materials before use and the protocol when non-conforming results are encountered.

j. Where the quality of a reagent is critical to a test, the quality of a new batch should be verified against the outgoing batch before use, provided that the outgoing batch is known to be still serviceable.

k. Where the quality of a reagent is critical to a test, the quality of a new batch should be verified against the outgoing batch before use, provided that the outgoing batch is known to be still serviceable.

l. Chemical, standards and reference materials are stored separately from samples. Reference materials and measurement standards should be handled in order to safeguard against contamination or degradation. Staff training procedures should reflect these requirements.

m. The measurement standards required for the tests are readily available.

n. The measurement standards are certified or are the "best" available.

o. The preparation of working measurement standards and reagents is documented.

p. Measurement standards, reference materials and reagents are properly labeled and correctly stored. Where appropriate “opening” and “use-by” dates are used.

q. New batches of measurement standards, and reagents critical to the performance of the method are compared against old batches before use.

r. The correct grade of materials is being used in the tests.

s. Where measurement standards, or reference materials are certified, copies of the certificate are available for inspection.

7. ASSURING THE QUALITY OF TEST RESULTS

a. Laboratory Quality Control is an essential aspect of ensuring that data released is fit for the purpose determined by the quality objectives.

b. Approach of quality control is the principal recourse available for ensuring that only quality data is released.

c. The Principe of the laboratory quality control program is its internal quality control, composed of day-to-day and sample-set to sample-set monitoring of analytical performance, and its external QC based on the laboratory's performance in proficiency testing programs.

d. Laboratory Management is responsible for establishing a Laboratory Quality Control Program and ensures that quality control is performed and reviewed of quality control data for acceptability.

e. Analysts are responsible for conducting quality control analyses in accordance with The Laboratory Quality Control Program.

f. Internal quality control is used to measure accuracy, precision, contamination, and matrix effects. The laboratory determines, where feasible, the accuracy and precision of all analyses performed.

g. Accuracy and precision control charts are used to determine if the measurement system process is in control and whether the results generated by the measurement system are acceptable.

8. SAMPLING MANAGEMENT

a. Laboratory shall have procedure for sample reception, procedure contain acceptance/rejection criteria for samples received, procedure for ensuring no cross contamination during sub sampling or when the sample is split between chemistry, procedure contain a sample control system within the laboratory especially for legal samples, procedure contain the selection of test portions such as grinding, mixing and sub sampling.

b. Laboratory sample shall stored under conditions to protect the integrity of the sample.

c. When samples are held under environmental conditions specified in the test method, those conditions are maintained, monitored and recorded. Monitoring records are collected according to established procedures.

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