



ACCREDITATION SCHEME FOR FUNCTIONAL FOOD TESTING

Technical Notes FFT 01 General Criteria for Testing of Health- Related Properties of Foods

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1. INTRODUCTION & SCOPE

- 1.1 This document describes the specific requirements to be complied by facilities performing testing of health-related properties of foods before they can be accredited.
- 1.2 This document shall be used in conjunction with the standard, ISO/IEC 17025- General Requirements for the Competence of Testing and Calibration Laboratories and other documents such as, SAC 01 - *Terms and Conditions for Accreditation*, SAC 02 - *Rules for Use of SAC Accreditation Marks and Mutual Recognition Arrangement (MRA) Marks*, SAC-SINGLAS 001 – *Accreditation Process*, SAC-SINGLAS 006 – *Traceability of Measurements*, and PROF 001 - *Proficiency Testing Technical Notes*.

2. TEST FACILITY, ORGANISATION AND PERSONNEL

- 2.1 Each test facility management shall ensure that requirements in ISO/IEC 17025 and relevant documents are complied with, in its test facility.

- 2.2 Test facility management shall ensure:

- a) that a sufficient number of qualified personnel, appropriate facilities, equipment, and materials are available for the timely and proper conduct of the study;
- b) the maintenance of a record of the qualifications, training, experience and job description for each professional and technical individual;
- c) that personnel clearly understand the functions they are to perform and, where necessary, provide training for these functions;
- d) that appropriate and technically valid Standard Operating Procedures (SOPs) are established and followed, and that all original and revised SOPs are approved for use;
- e) that for each study an individual with the appropriate qualifications, training, and experience is designated by the management as the Study Director before the study is initiated. The covering and/or replacement for Study Director shall be done according to established procedures, and shall be documented;
- f) documented approval of the study plan by the Study Director;
- g) the maintenance of a historical file of all SOPs;
- h) that retention of archived records for an appropriate period of time;
- i) that an individual is identified as responsible for the management of the archive(s);
- j) the maintenance of a master schedule of all the studies for tracking purposes;
- k) that test facility supplies meet requirements appropriate to their use in a study.

2.3 Study Director's Responsibilities

- 2.3.1 The Study Director is the single point of study control and has the responsibility for the overall conduct of the study and for its final report.

- 2.3.2 These responsibilities shall include, but not limited to, the following functions. The Study Director shall:

- a) approve the study plan and any amendments to the study plan by dated signature;
- b) ensure that study plans and amendments and SOPs are available to study personnel;
- c) ensure that the study plan and final report for single-site or multi-site study identify all test facilities and test sites involved in the conduct of the study;

- d) ensure that the study plan and final report which involve multi-site study shall also define the role(s) of all Principal Investigator(s);
- e) ensure that the procedures specified in the study plan are followed, and assess and document the impact of any deviations from the study plan on the quality and integrity of the study, and take appropriate corrective action if necessary; acknowledge deviations from SOPs during the conduct of the study;
- f) ensure that all raw data generated are fully recorded and documented;
- g) ensure that customised computerised systems and/or softwares used in the study have been validated;
- h) sign and date the final report to indicate acceptance of responsibility for the validity of the data;
- i) ensure that after completion (including termination) of the study, the study plan, the final report, raw data and supporting material are archived.

2.3.3 For multisite studies, the Study Director's responsibility for the overall conduct of the study shall not be delegated to the Principal Investigator(s). This includes the approval of the study plan and its amendments and approval of the final report.

2.4 Principal Investigator's Responsibilities

2.4.1 The Principal Investigator will ensure that the delegated phases of the multi-site study are conducted in accordance with the requirements of ISO/IEC 17025 and other documents as outlined in section 1.2.

2.5 Study Personnel's Responsibilities

2.5.1 All personnel involved in the conduct of the study must be knowledgeable in ISO/IEC 17025 and relevant SAC-SINGLAS requirements which are applicable to their involvement in the study.

2.5.2 Study personnel will have access to the study plan and appropriate SOPs applicable to their involvement in the study. It is their responsibility to comply with the instructions given in these documents. Any deviation from these instructions shall be documented and communicated directly to the Study Director, and/or if appropriate, the Principal Investigator(s).

2.5.3 All study personnel are responsible for recording raw data promptly and accurately and in compliance with ISO/IEC 17025 and other documents as outlined in section 1.2 and are responsible for the quality of their data.

2.6 Ethics Committee Approval

2.6.1 The test facility shall obtain written ethics clearance from an appropriate Ethics Committee, and shall consider and address relevant issues (e.g. handling of post examination samples, handling of subjects' data, etc) before the conduct of the study.

3. **ACCOMMODATION, ENVIRONMENTAL CONDITIONS AND SAFETY**

3.1 Physical Facilities

- 3.1.1 Work areas in which the analysis is done shall preferably be separated from all other laboratory operations. Separate work areas shall be available for the following operations:
- a) food preparation area;
 - b) food consumption area;
 - c) collection of primary samples (e.g. plasma, serum, urine);
 - d) analysis of primary samples;
 - e) adequate and appropriate storage facilities must be available for:
 - i) the storage of food sample before and after preparation;
 - ii) the storage of materials used in the course of analysis;
 - iii) the safe storage of hazardous and non-hazardous wastes prior to disposal;
 - f) de-contamination of laboratory personnel and protective clothing;
 - g) cleaning of glassware, purification of reagents and solvents.

3.2 Facilities for Handling Test and Reference Items

- 3.2.1 To prevent contamination or mix-ups, there shall be separate rooms or areas for receipt and storage of the test and reference items, and mixing of the test items with a suitable medium.
- 3.2.2 The facilities shall be adequately equipped to preserve the identity, concentration, purity, and stability of the test and reference items.

3.3 Staff Facilities

- 3.3.1 The test facility shall have adequate access to washrooms, supply of drinking water and facilities for storage of personal protective equipment and clothing.

3.4 Archive Facilities

- 3.4.1 Archive facilities shall be provided for the secure storage and retrieval of study plans, raw data, final reports, samples of test items and specimens. Archive design and archive conditions shall protect contents from untimely deterioration.

3.5 Waste Disposal Facilities

- 3.5.1 Handling and disposal of wastes shall be carried out in such a way as not to jeopardise the integrity of studies. This includes provision for appropriate classification and labelling, collection, storage and disposal.

3.6 Safety

- 3.6.1 It shall be a safe working place for its personnel and for the test subjects participating in the study plan. It shall comply with the safety regulatory requirements. The test facility shall ensure that test subjects, employees, and visitors are protected from laboratory hazards.

- 3.6.2 There shall be written safety policies and procedures. Procedures on safety practices of the test facility shall be part of new employees' orientation program. This shall be documented when completed.
- 3.6.3 The safety procedure manual shall be available on the workbench and a safety officer shall be appointed to ensure safety measures as contained in the manual is implemented.
- 3.6.4 There shall be appropriate first aid materials available and maintained for both test subjects and staff at the sample collection facility.
- 3.6.5 The test facility shall report serious accidents and laboratory acquired illnesses to the relevant authorities.
- 3.6.6 All injuries that require medical treatment or time lost from work shall be reviewed as part of the laboratory's quality assurance programme.
Note: This includes every sharp injury requiring appropriate treatment according to the documented protocol.
- 3.6.7 Injuries or occupational illnesses shall be documented and follow-up action recorded.
- 3.6.8 Appropriate immunisation program shall be administered for all laboratory personnel.
- 3.6.9 Test facility shall ensure that its personnel wear protective clothing and safety equipment appropriate to the duties being performed. Personnel protection equipment e.g. gowns, gloves, masks, goggles shall be made available to staff who require such protection when at work, e.g. when working with known hazardous gases such as formaldehyde.
- 3.6.10 There shall be a safety shower or other emergency source of water in all areas where quantities of concentrated caustics are handled. Piped eyewash fountains or the equivalent shall also be present. All of these and the protective equipment shall be easily accessible and shall not be obstructed by equipment, furniture, etc. Test facility shall also provide fire extinguishers at appropriate places.
- 3.6.11 All dangerous and poisonous chemicals used in the laboratory must be contained, labelled and kept in a locked cabinet by a designated safety officer. The laboratory shall follow the guidelines from the relevant authorities.
- 3.6.12 Material safety data sheets shall be documented for each hazardous chemical in the laboratory. The designated safety officer shall maintain the location of such documentation.
- 3.6.13 Proper signs shall be placed at significant hazard areas. Reagent vessels containing hazardous substances shall be labelled appropriately with warnings.
- 3.7 Biological Hazards And Control Safety

- 3.7.1 The laboratory shall institute standard precautions against infectious hazards of blood and body fluids. Reference shall be made to the following guidelines from the relevant regulatory bodies.

Note: Staff, whose work is likely to involve contact with body substances, shall use gloves and other appropriate personal protective devices. Gloves must fit properly; cleaning or disinfecting of disposable gloves for reuse is prohibited. Gloves, aprons, or laboratory coats and protective eyewear must be provided and are required for those activities likely to splash the skin.

- 3.7.2 For example, used pipette tips, sample cups, etc. shall not be washed and reused.

- 3.7.3 All needles and sharps shall not be re-used and shall be placed into puncture-resistant containers.

4. LABORATORY EQUIPMENT

- 4.1 Table 1 in this document sets out the recommended minimum frequency for calibrations and performance checks of general equipment.

- 4.2 Where requirements specified in the test method or equipment manual deviate from Table 1, the laboratory shall adopt the more stringent requirement.

4.3 Reagents

- 4.3.1 All laboratory personnel shall be made aware of their responsibilities on the use of suitable chemical reagents, solvents, reference materials and laboratory ware in terms of the types of analysis they conduct.

- 4.3.2 Proper storage of all reagents shall be observed according to the requirements set up by the manufacturers to ensure integrity and safety.

- 4.3.3 The appropriate grades of chemical reagents and solvents as specified in the methods or procedures shall be used.

- 4.3.4 All reagent containers shall be labelled to ensure traceability of the reagent. They shall be labelled minimally with: reagent name, date of preparation, date of opening, concentration, solvent (if not water), any special precautions or hazards and date of expiry. The person responsible for the preparation of the reagent shall be identifiable either from the label or from records.

- 4.3.5 Laboratories shall establish written procedures for preparation of reagent solutions. Records of such preparations shall be maintained for later reference in case of doubtful test result. Records for reagent solutions shall include measured weights and volume, pH readings, calculation of standardization factor and solution concentration.

4.3.6 For substances that are classified as scheduled poisons under the Poisons Act and its rules, they shall be kept separately from other reagents and held in locked cabinets. These substances shall be handled in accordance to the rules and guidelines set out in the Poisons Act.

5. PRE-EXAMINATION PROCEDURES

5.1 Sample Collection from the Test Subject

5.1.1 Where primary sample collection facilities are provided, consideration shall be given to the accommodation of test subjects' comfort and privacy, in addition to the optimisation of collection conditions. The environment shall not invalidate the results, or adversely affect the required quality of any measurement.

5.1.2 The laboratory shall confirm with the test subject their name and identification number prior to sample collection. In cases whereby special test subject preparation is required, the laboratory shall ensure that the test subject is aware of the preparation procedure before sample collection.

5.1.3 A primary sample collection manual shall include the following:

a) Copies of, or references to:

- i) consent forms;
- ii) information and instructions provided to the test subject to their own preparation before primary sample collection;

b) Procedures for:

- i) preparation of the test subjects (e.g. instructions provided to the phlebotomists);
- ii) identification of the primary sample;
- iii) primary sample collection (e.g. phlebotomy, skin puncture, blood, urine and other body fluids), with descriptions of the primary sample containers and any necessary additives;
- iv) any acclimatising, if required for the test subject;

c) Instructions for:

- i) type and amount of primary sample to be collected;
- ii) special timing of collection, if required;
- iii) any special handling needs between time of collection and time received by the laboratory;
- iv) labeling of primary samples;
- v) gathering of clinical information (e.g. history of administration of drugs);
- vi) positive identification, in detail, of the test subject from whom the primary sample is collected;
- vii) recording of the identity of the person collecting the primary sample;
- viii) storage of the examined samples;
- ix) repeat examination due to analytical failure or further examinations of the primary sample;
- x) safe disposal of materials used in the collection;

5.1.4 The primary sample collection manual shall be part of the document control system.

- 5.1.5 All primary samples received shall be recorded in accession books, worksheets, computers or other comparable systems. The date and time of receipt of samples, as well as the identity of the receiving officer shall be recorded.
- 5.1.6 Criteria shall be developed and documented for the acceptance or rejection of primary samples. If samples which do not meet all the criteria (i.e. compromised samples) are accepted by the Study Director or designate, the final report shall indicate the nature of the problem and, if applicable, that caution required when interpreting the results.

5.2 Sample Preparation for Test Food

- 5.2.1 The facility shall have documented procedures for the sample preparation for the test food. The procedures shall specify pertinent information such as the handling of the control food item and the experimental protocol. These information shall be documented in a study plan.

6 **STUDY PLAN**

6.1 Content of the Study Plan

- 6.1.1 The study plan should contain, but not be limited to the following information:
- a) Identification of the Study, the Test Item and Reference Item
 - i) A descriptive title;
 - ii) A statement which reveals the nature and purpose of the study;
 - iii) Identification of the test item by code or name (IUPAC; CAS number, biological parameters, etc.);
 - iv) The reference item to be used.
 - b) Information Concerning the Sponsor and the Test Facility
 - i) Name and address of the sponsor;
 - ii) Name and address of any test facilities and test sites involved;
 - iii) Name and address of the Study Director;
 - iv) Name and address of the Principal Investigator(s), and the phase(s) of the study delegated by the Study Director and under the responsibility of the Principal Investigator(s).
 - c) Dates
 - i) The date of approval of the study plan by signature of the Study Director. The date of approval of the study plan by signature of the test facility management;
 - ii) The proposed experimental starting and completion dates.
 - d) Test Subjects
 - i) Inclusion and exclusion criteria e.g. known food allergies, known diabetes mellitus, etc;
 - ii) Management of test subjects e.g. participants' information, consent forms, etc;
 - iii) Test conditions e.g. fasting before test.
 - e) Test Food
 - i) Preparation.
 - f) Reference Food (where applicable)
 - i) Acceptable/alternative reference foods;

- ii) Preparation.
- g) Test Methods
 - i) Reference to the test guideline to be used. Please refer to section 7 of this technical note – examination procedures.
- h) Other Issues
 - i) The dose levels and/or concentration(s), frequency, and duration of administration/ application;
 - ii) Detailed information on the experimental design, including a description of the chronological procedure of the study, all methods, materials and conditions, type and frequency of analysis, measurements, observations and examinations to be performed, and statistical methods to be used (if any);
 - iii) Adverse reactions such as allergy during the course of the study.
- i) Records
 - i) A list of records to be retained.

7. EXAMINATION PROCEDURES FOR TESTING OF PRIMARY SAMPLES COLLECTED FROM TEST SUBJECTS

- 7.1 The laboratory shall use examination procedures, including those for selecting/taking sample portions from test subjects that are appropriate. Preferred procedures are those that have been published in established/ authoritative textbooks, peer-reviewed texts or journals, or in international, national or regional guidelines. If in-house procedures are used, they shall be appropriately validated for their intended use.
- 7.2 All analytical procedures shall be validated against specified requirements and their limits defined.
- 7.3 Where applicable, the method of quantification shall be evaluated using solutions of the analyte in a suitable solvent. An internal standard shall be included where possible.
- 7.4 The stability of the analyte in the sample matrix during storage and throughout the analysis procedure shall be evaluated.
- 7.5 Test procedures shall include start-up instructions, precautions, pre-treatment, analysis, detection limit, lower and higher limit, disposal of waste, remarks and trouble shooting and safety of the personnel and environmental aspects. The study director or designate shall be responsible for ensuring that the contents of examination procedures are complete and have been thoroughly reviewed.
- 7.6 The appropriate test procedure shall also address the reporting of results, units, calculation, interfering substances, report values, critical limits, reference limits for the appropriate tests.
- 7.7 All procedures shall be documented, understood by the relevant staff and be available at the workstation.
- 7.8 The procedure shall be based on the instructions for use (e.g. package insert) written by the manufacturer. Any deviation shall be reviewed, documented and approved by study director. Additional information that could be required to perform the examination shall also be documented. Each new version of examination kits with

major changes in reagents or procedure shall be checked for performance and suitability for intended use. Any procedural changes shall be dated and authorised as for other procedures.

- 7.9 In addition to document control identifiers, documentation shall include, when applicable, the following:
- a) Purpose of the examination;
 - b) Principle of the procedure used for examinations;
 - c) Performance specifications (e.g. Linearity, precision, accuracy express as uncertainty of measurement, detection limit, measuring interval, trueness of measurement, analytical sensitivity and analytical specificity);
 - d) Primary sample system (e.g. plasma, serum, urine);
 - e) Type of container and additives;
 - f) Required equipment and reagents;
 - g) Calibration procedures (metrological traceability);
 - h) Procedural steps;
 - i) Quality control procedures;
 - j) Interferences and cross reactions;
 - k) Principle of procedure for calculating results, including measurement uncertainty;
 - l) Biological reference intervals;
 - m) Alert/critical values, where appropriate;
 - n) Laboratory interpretation;
 - o) Safety precautions;
 - p) Potential sources of variability.

8. ASSURING QUALITY OF EXAMINATION PROCEDURES – QUALITY CONTROL AND PROFICIENCY TESTING

- 8.1 The effectiveness of the quality control programs for testing of primary samples shall be measured and be included in the management review of the laboratory.
- 8.2 The laboratory's internal quality control programs shall include tolerance limits and corrective action procedures to use when limits are exceeded. The quality control data shall be reviewed at regular intervals that may detect trends in examination performance that may indicate problems in the examination system.
- 8.3 Participation in Proficiency Testing (PT) programs shall cover the extent and complexity of analytical procedures. Where such PT programs are not available, the laboratory shall embark on alternative means of ensuring proficiency (e.g., by a process of inter-laboratory comparison with laboratories doing similar work or the development of a mechanism of internal quality control). Test facilities shall refer to Technical Note PROF 001 for details on participation in PT programmes.
- 8.4 The Study Director or designate shall review and monitor the results of PT and participate in the documentation of corrective actions.

9. POST-EXAMINATION PROCEDURES

9.1 Retained Samples

- 9.1.1 A retained sample refers to the tested sample or part of the original sample, which is preserved at the laboratory for future use in case of dispute over the findings. A retained sample applies to both the food test sample and test subject's primary sample.
- 9.1.2 Where applicable, a representative sample with sufficient quantity shall be retained for a specified period. It shall be properly sealed, appropriately identified and stored under appropriate conditions.

9.2 Waste Disposal

- 9.2.1 The laboratory shall have policies and procedures for waste management for the disposal of all solid and liquid and gaseous wastes. These methods shall be in compliance with applicable local regulations and reviewed annually.
- 9.2.2 Waste shall be disposed of at regular intervals not exceeding a week.
- 9.2.3 Infectious waste shall be placed into biohazard disposal bags for appropriate disposal in a government-approved incinerator by licensed waste contractors.
- 9.2.4 Safe disposal of samples no longer required by the examination shall be carried out in accordance with local regulations or recommendations for waste management.

RETENTION OF RECORDS

- 10.1 Records required to establish an audit trail and to verify quality and reliability of test data as listed below shall be retained for a minimum period of 6 years:
- a) Study Plan;
 - b) Records of Ethics Committee Approval;
 - c) Subject consent forms;
 - d) Subjects' medical screening records;
 - e) Examination results and reports;
 - f) Raw data including instrument printouts;
 - g) Laboratory work-books or work-sheets;
 - h) Examination procedures for primary samples;
 - i) Sample identification records;
 - j) Instrument calibration records and conversion factors;
 - k) Quality control records;
 - l) Deviations and amendments to the study plan;
 - m) Proficiency testing / inter-laboratory comparisons;
 - n) Incident / accident records and action taken;
 - o) Staff training and competency records.
 - p) Lot documentation, certificates of supplies, package inserts;
 - q) Instrument maintenance records including internal and external records;
 - r) Quality improvements records

- s) Records of internal and external audits;
- t) Complaints and action taken

REFERENCES :

1. ISO/IEC 17025: 2017 – General Requirements for the Competence of Testing and Calibration Laboratories
2. OECD Principles on Good Laboratory Practice - document number 1
3. ISO 15189: 2012 Medical laboratories – Requirements for Quality and Competence
4. SAC-SINGLAS Technical Notes MED 001, General Criteria for Medical Testing Laboratories
5. SAC 01, Terms and Conditions for Accreditation
5. SAC 02, Rules for Use of SAC Accreditation Marks and Mutual Recognition Arrangement (MRA) Marks
6. Technical Notes PROF 001 – Policies on Proficiency Testing

GLOSSARY :

Health-related property of a food	Any property of natural or processed food resulting from presence of biologically-active compound(s) which in defined amount(s) provides (provide) clinically proven and documented health benefit that makes the food an important source in the prevention, management and treatment of chronic diseases (e.g. diabetes, osteoporosis, cancer).
Study Director	The individual responsible for the overall conduct of the study.
Primary Sample	Biological sample taken from a subject for testing (e.g. blood, urine, plasma, serum).
Principal investigator	The individual at the test site who acts on behalf of the study director and has defined responsibility for delegated phase(s) of the study.
Test Site	The location within the organisation at which a phase of the study is conducted.
Test food	Food for which health-related properties are being determined.
Sponsor	An entity who requests for the study to be conducted.
Test Subject	Participants selected for the study based on the study criteria.
Study Plan	A document which defines the objectives and experimental design for the conduct of the study and includes any amendments.
Reference Food	Any item used to provide a basis for comparison with the test food (e.g. glucose is used as reference food for glycemic index).

TABLE 1: RECOMMENDED CALIBRATION AND PERFORMANCE CHECK OF EQUIPMENT COMMONLY USED IN LABORATORIES PERFORMING TESTING OF HEALTH-RELATED PROPERTIES OF FOODS

S/N	Equipment	Maximum period between successive calibrations or performance checks
1	Automated, semi-automated and portable clinical analysers	Check using appropriate controls and standard materials with frequency depending on the particular use of the equipment and manufacturer's recommendation.
2.	Balances and scales	(a) When used: Level of balance and zero point (taring) (b) Monthly: One-point check for accuracy using reference weights. Calibration procedures should be documented (c) Yearly: Calibration by accredited calibration laboratory for repeatability, linearity and accuracy.
3.	Reference Weights	Once every 3 years by an accredited laboratory or a National Metrology Institute (NMI).
4.	pH Meters	Daily or when used: Check for accuracy and repeatability using standard buffer solutions. Bracket pH value expected as closely as possible with buffers.
5	Pipettes	Every half-yearly: For accuracy and repeatability using an internal verification using a calibrated balance.
6.	Refrigerators/freezers	(a) Daily: Temperature checks, using calibrated thermometer. (b) Yearly: Temperature checks, using reference thermometer.
7.	Height Measuring Equipment	Verified to intended accuracy.
8.	Stop Watches / Timing Devices	Yearly: Check for accuracy by a calibrated stop-watch
9.	Thermocouples	Yearly: calibration by accredited calibration organisation.
10.	Thermometers	(a) Reference : Once every 5 years: Full calibration by an accredited organisation

S/N	Equipment	Maximum period between successive calibrations or performance checks
		<p>Yearly: Specific points check including melting point.</p> <p>(b) Working : Half-yearly: Temperature is checked at specific point using a calibrated reference thermometer.</p>
11.	Incubators, ovens and other temperature-controlled equipment	<p>Temperature checks within the load space of such equipment must be performed and documented when used to ensure compliance with the temperature requirements of test methods.</p> <p>Calibrated thermometers used to monitor the performance of the equipment must be of sufficient accuracy to ensure that this equipment complies with the temperature tolerances specified in the test methods. If in-built temperature measuring devices are used, these must be checked at yearly intervals against a reference thermometer and these results are to be recorded.</p> <p>Yearly calibration of equipment by an accredited organisation.</p>
12.	Water Bath	<p>(a) Daily or depending on usage frequency: Check the temperature using a calibrated thermometer contained in water bath. Record water bath thermometer correction factor and attach to water bath. Maintain bath to an accuracy of $\pm 1^{\circ}\text{C}$ of the requirement.</p> <p>(b) Yearly: Calibration by an accredited organisation.</p>
13.	Water purification system	<p>(a) Daily or depending on usage frequency: In-line check for conductivity. For instruments without in-line checks: weekly off-line check for conductivity.</p> <p>(b) For tests that require sterile water, sterility checks to be performed 6 monthly.</p>
14	Biological Safety Cabinet & Laminar Flow Cabinet	Monthly, quarterly or annually depending on the class of cabinet. : Certified to ensure filters are functioning properly and that airflow rate meet specifications.
15	Thermohydrograph	Yearly: Calibrated for temperature and humidity.