GB

NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

ICS 03.120.10

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GB/T 27404-2008

Criterion on quality control of laboratories - Chemical testing of food

实验室质量控制规范　食品理化检测

Issued on: May 04, 2008 **Implemented on: October 01, 2008**

Issued by: General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China;

Standardization Administration of the People's Republic of China.

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1 Scope

This Standard specifies the management requirements, technical requirements, process control requirements and quality assurance requirements for the quality control of food physical and chemical testing laboratories.

This Standard applies to the quality control of food physical and chemical testing laboratories engaged in the testing of food quality (including sensory, physical and chemical), chemical substances (including active ingredients, pesticide and veterinary drug residues, food additives, heavy metals, toxins, environmental pollutants, etc.). Chemical testing laboratories in other fields can also refer to it.

2 Normative references

The provisions in following documents become the provisions of this Standard through reference in this Standard. For dated references, the subsequent amendments (excluding corrigendum) or revisions do not apply to this Standard, however, parties who reach an agreement based on this Standard are encouraged to study if the latest versions of these documents are applicable. For undated references, the latest edition of the referenced document applies.

GB/T 1.1, *Directives for standardization -- Part 1: Rules for the structure and drafting of standardizing documents* (GB/T 1.1-2000, ISO/IEC Directives, Part3, 1997, NEQ)

GB 8170, *Rules of rounding off for numerical values and expression and judgement of limiting values*

GB/T 15483.1, *Proficiency testing by interlaboratory comparisons -- Part 1: Development and operation of proficiency testing schemes* (GB/T 15483.1-1999, idt ISO/IEC Guideline 43-1:1997)

GB/T 19000, *Quality management systems -- Fundamentals and vocabulary* (GB/T 19000-2000, idt ISO 9000:2000)

GB/T 20000.1, *Guide for standardization -- Part 1: Standardization and related activities -- General vocabulary* (GB/T 20000.1-2002, ISO/IEC Guide 2:1996, MOD)

Laboratory quality control work associated with control analysis and subsequent necessary corrective activities.

4 Management requirements

4.1 Organization and management

4.1.1 The food physical and chemical testing laboratory (hereinafter referred to as the laboratory) or its organization shall be an entity capable of assuming legal responsibility. A non-independent legal entity shall have its status in the parent organization, and the above parent organization has promised not to interfere with its inspection work.

4.1.2 When the laboratory works in its fixed facilities or in other places outside the fixed facilities it is responsible for, including temporary or mobile facilities, it shall meet the relevant requirements of this Standard.

4.1.3 If the organization where the laboratory is located is also engaged in activities other than testing, in order to identify potential conflicts of interest, the responsibilities of key personnel involved in testing or having an impact on testing activities in the organization shall be defined.

4.1.4 Management personnel of laboratory shall be responsible for the planning, establishment, implementation, maintenance and improvement of the management system, including:

a) Laboratory management and technical personnel shall have the necessary authority and resources to perform responsibilities including implementing, maintaining and improving the management system, identifying deviations from the management system or testing procedures, and taking measures to prevent or reduce these deviations.

b) Measures are in place to ensure that laboratory management and laboratory personnel are free from any improper internal and external commercial, financial and other pressures and influences that adversely affect the quality of work.

c) Establish client information confidentiality policies and procedures to protect client confidential information and proprietary rights, including procedures for securing electronic transmission and storage of results.

d) Develop policies and procedures for impartiality education to personnel and avoid involvement in any activity that may diminish the credibility of their competence, impartiality, judgment, or operational integrity.

e) Clarify the organization and management of the laboratory, its position in the parent organization, and the relationship between quality management, technical

operations, and support services.

f) Define the responsibilities, authorities and interrelationships of all management, operational and verification personnel who have an impact on the quality of testing.

g) Personnel who are familiar with detection methods, procedures, objectives and result evaluation shall provide timely training and effective supervision to laboratory personnel according to their responsibilities, experience and ability.

h) There are technical management personnel who are fully responsible for technical operations to ensure the resources required for the quality of laboratory operations.

i) Appoint a person in charge of quality, grant him responsibility and authority, and ensure the operation and implementation of the management system. The quality manager shall report directly to management personnel of laboratory, who is responsible for determining laboratory policy and resource assurance.

j) Designate an agent for key functions of the laboratory.

k) Ensure that laboratory personnel understand the interrelationship and importance of their activities and how they can contribute to the achievement of the quality objectives of the management system.

4.1.5 The top management of the laboratory shall ensure that an appropriate communication mechanism is established within the laboratory to ensure the effective operation of the management system.

4.2 Management system

4.2.1 Laboratories shall establish, implement and maintain a management system commensurate with their scope of activities. Its policies, systems, procedures, plans and instructions shall be documented and communicated to all relevant personnel to ensure that these documents are understood, accessed and implemented.

4.2.2 The quality-related policies of the laboratory management system, including the quality policy statement, shall be articulated in the quality manual. Overall objectives shall be established. The operational effectiveness shall be reviewed during management reviews. The top management of the laboratory shall publicize the quality policy, goals and commitments to all employees. This quality policy statement includes:

a) Commitment by management personnel of laboratory to good professional conduct and quality of service;

b) Statement from management personnel of laboratory regarding laboratory service standards;

n) Measurement traceability;

o) Environmental protection and safety and health (when applicable);

p) Research and development (where applicable);

q) Verification of testing procedures and preparation of standard operating instructions;

r) Testing acceptance and sample collection, transport, storage and handling (disposal);

s) Quality control of test results;

t) Test result report;

u) Laboratory information system (where applicable) and security;

v) Laboratory's quality management control process.

NOTE 2: The management personnel of laboratory can designate quality management personnel to establish and implement a verification (calibration) plan for measuring instruments, standard materials and analysis systems (if necessary, including an inspection plan for auxiliary equipment), analyze and confirm the verification (calibration) and inspection results, so as to ensure the status meets job requirements.

4.2.6 The responsibilities of technical management personnel and quality management personnel, including the responsibility to ensure compliance with this Standard, shall be specified in the quality manual.

4.2.7 When planning and implementing changes to the management system, the top management of the laboratory shall ensure the integrity of the management system.

4.3 Document control

4.3.1 The laboratory shall establish and maintain procedures to control all management system documents (internal and external). Controlled documents can be kept on paper or non-paper media. They shall be backed up and archived. The retention period shall be stipulated.

NOTE: External documents include laws and regulations, government management documents, norms, international, national and regional standards, procedures, methods, instrument and equipment instruction manuals, documents provided by customers and related information, materials, manuals, etc. Internally formulated documents include quality manuals, management procedures, technical procedures, operating instructions, record forms, charts, plans, etc.

4.3.2 The laboratory shall establish an effective and smooth mechanism to ensure timely access to laws, regulations, instructions and management requirements of government management agencies, and to ensure timely updates of technical standards.

4.3.3 Document control procedures ensure that:

a) All documents incorporated into the management system are reviewed and approved for use by authorized personnel prior to release.

b) Establish an easily accessible control list of all management system documents to identify their current revision status and distribution.

c) Authorized versions of the appropriate documents are available at all locations that are essential to the efficient operation of the laboratory.

d) Carry out periodic review of documents. Amend as necessary to ensure continued applicability.

e) Expired and obsolete documents shall be removed in time, or other methods shall be used to ensure that they are not misused. Obsolete documents retained for legal or intellectual preservation purposes shall be appropriately marked.

f) All management system documents shall be uniquely identified, including date of issue, edition and/or revision identification, page number, total number of pages, document end mark and issuing agency.

g) Establish a change or modification control procedure for paper documents and documents stored in computer systems. Specify how to change and specify appropriate labels.

h) Changes to documents shall be reviewed and approved by the person in charge of the original review. Designated persons shall be provided with relevant background information on which to base their review and approval.

i) If the laboratory's document control system allows for handwritten revisions of documents prior to republication, procedures and authorities for revisions shall be established. Modifications shall be clearly marked, initialed and dated. Modified documents shall be officially published as soon as possible.

4.4 Quality and technical records

4.4.1 The laboratory shall establish and maintain procedures to control the identification, collection, access, filing, storage maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews and records of corrective and preventive actions.

4.4.2 All records shall be legible and kept in an easily accessible manner. The storage facility has a suitable environment to prevent damage, deterioration and loss of records. All records shall be kept secure and confidential.

4.4.3 The laboratory shall clearly stipulate the retention period of various quality and

4.6 Complaint handling

4.6.1 The laboratory shall have policies and procedures for handling customer complaints or other feedback. Records shall be maintained of all complaints, as well as of investigations and corrective actions taken by the laboratory in response to complaints.

4.6.2 For complaints related to the quality of laboratory test results, the laboratory shall organize investigation and analysis in a timely manner to determine the cause and reply in time. After investigation and verification, if it is a problem in the quality of laboratory testing, the laboratory shall immediately implement the non-conformance testing work control procedures specified in 4.7. If damage has been caused to the customer, it is necessary to recover and reduce the loss and impact on the customer as much as possible.

4.7 Control of non-conformance

4.7.1 When any aspect of the testing process, or the results of the work, does not conform to established procedures or agreed with the client, the laboratory shall implement established policies and procedures for the control of non-conformance work to ensure that:

a) The quality management personnel have the responsibility and right to deal with the non-conformance testing work, and stipulate the measures to be taken when the non-conformance work is determined (including suspending work when necessary, withholding test reports);

b) Evaluate the severity of the non-conformance testing work;

c) Make corrections immediately, and stipulate the measures to be taken according to the evaluation results;

d) If necessary, notify the client and cancel the job;

e) If the inspection report has been released, appropriate remedial measures shall be taken immediately;

f) Identify responsibilities for stopping and approving resumption of work;

g) Keep records of every non-conformance inspection work. Management personnel of laboratory shall periodically review records of non-conformance testing work to identify non-conformance trends and take appropriate preventive measures.

NOTE: The identification of non-conformance testing work can be carried out in all aspects of the management system and technical operations, such as reports from quality supervisors, customer complaints, instrument calibration and period checks, inspections of consumables, inspections of reports or certificates, internal audits, management reviews, external audits, proficiency testing and

quality control, etc.

4.7.2 If it is confirmed that the non-conformance testing work may recur or doubt the laboratory's compliance with its policies and procedures, the corrective action procedures specified in 4.9 shall be implemented immediately.

4.8 Measures for correction

4.8.1 The laboratory shall have policies and procedures and the authority to implement measures for correction when non-conformance with work, deviations from policies and procedures of the management system or technical operations are identified.

4.8.2 The procedure of measures for correction shall include an investigation process to determine the root or potential cause of the problem. Where appropriate, preventive measures shall be instituted.

4.8.3 When measures for correction are required, the laboratory shall determine the measures for correction to be taken. Select and implement the measures that will best eliminate the problem and prevent its recurrence. The intensity of measures for correction shall be commensurate with the severity of the problem and the degree of risk. When measures for correction taken result in changes to operating procedures, these changes shall be documented and notified to the appropriate personnel for implementation.

4.8.4 After measures for correction have been implemented, the laboratory shall monitor the results of the measures for correction or conduct a dedicated audit of the relevant areas to assess the effectiveness of the actions.

4.8.5 Additional audits shall be performed when identification of non-conformance work or deviations casts doubt on the laboratory's conformity with policies and procedures or with the management system. The results of measures for correction shall be submitted to laboratory management for review and necessary improvements to the management system shall be implemented.

4.9 Precautions

4.9.1 Implement preventive actions when identifying potential non-conformance detection work causes and opportunities for improvement in management systems or technical activities.

4.9.2 When the laboratory needs to take preventive measures, it shall formulate, implement and monitor the preventive measure plan to reduce the possibility of similar non-conformance work and take the opportunity to improve. The preventive action procedure shall include the initiation, control and documented improvement of actions to ensure their effectiveness.

h) Laboratory internal quality control activities;

i) Changes in workload and type of work;

j) Feedback from customers or internal staff and others;

k) Complaints;

l) Suggestions for improvement;

m) Other relevant factors such as resources and training needs and plans for employees.

4.11.2 Issues identified and actions taken during management reviews shall be documented. Management personnel shall ensure that these actions are implemented within an appropriate and agreed schedule.

4.12 Continuous improvement

The laboratory shall continuously improve the effectiveness of the management system through implementation of the quality policy and objectives, application of audit results, analysis of data, corrective and preventive actions, and management reviews.

5 Technical requirements

5.1 Purchasing services and supplies

5.1.1 The laboratory shall develop policies and procedures for selecting and purchasing supplies and services, including procedures for the purchase, acceptance, and storage of reagents and consumables.

5.1.2 The laboratory shall ensure that all purchased supplies, reagents and consumables that affect the quality of the test are put into use only after they have been checked or confirmed to meet the standard specifications or requirements specified in the relevant test method. The selected service shall meet the specified requirements. Records of compliance checks shall be kept.

5.1.3 The laboratory shall formulate quality control measures for important reagents and consumables (including standard substances, chemical reagents, experimental water, etc.) and services that have an important impact on test results. Or prepare a work instruction for compliance inspection, including compliance inspection items and compliance inspection standards.

5.1.4 Laboratory procurement documents shall be reviewed and approved for technical content prior to issuance. The content of the procurement documents may include: the

form, category, grade, specification, drawings, inspection instructions, quality requirements and management system standards on which the work mentioned above is carried out, for supplies and consumables.

5.1.5 The laboratory shall evaluate the suppliers of important consumables, supplies and services that affect the quality of the test. Keep records of evaluations and lists of approved suppliers.

5.2 Personnel

5.2.1 The laboratory shall have sufficient human resources to meet the needs of testing work and implementation of the quality management system. Permanently employed or contracted personnel shall be used. The laboratory shall ensure that these personnel are competent and supervised, and work in accordance with the requirements of the laboratory's quality system.

5.2.2 The laboratory shall formulate job descriptions for the qualifications and job responsibilities of personnel in each position. It shall ensure the ability of all personnel to operate specific equipment, engage in testing (including the physical fitness requirements for personnel engaged in sensory evaluation and physical performance testing), evaluate test results and sign test report certificates. Personnel shall be authorized to perform specific technical work.

5.2.3 Management personnel of laboratory shall maintain records of the education, training, professional qualifications, work experience and competencies of all technical personnel. The records shall be easy for relevant personnel to check and update in time. The laboratory shall set permissions to prevent unauthorized access to these archival records.

5.2.4 Management personnel of laboratory shall be composed of personnel with management and professional technical capabilities. The scope of professional technology shall include food sensory, physical properties, chemistry, food engineering, food nutrition, food hygiene, food safety, etc. The top management of the laboratory shall be responsible for the overall operation and management of the laboratory to ensure the quality of the testing work.

5.2.5 The laboratory shall formulate the education, training and skill objectives of laboratory personnel for different levels of laboratory personnel. There shall be policies and procedures for identifying training needs and for providing training and assessment of personnel. The training program shall be appropriate to the current and anticipated tasks of the laboratory.

5.3 Facilities and environmental conditions

5.3.1 Facilities configuration

room, balance room, sensory evaluation room, chemical (physical) analysis room, instrument analysis room, standard product storage area, reagent storage area, high-pressure gas cylinder placement area, utensil washing area, etc. Constant analysis and drug residue analysis shall be relatively separated in physical space. The organic analysis room shall be relatively isolated from the inorganic analysis room.

5.3.3.3 Non-laboratory personnel are not allowed to enter the working area without permission. At the entrance of the working area, there shall be obvious signs that no random entry is allowed. Contacting work or visiting shall be approved and accompanied by a special person.

5.3.3.4 All personnel entering the experimental area shall wear work clothes to prevent pollution sources from being brought in.

5.3.3.5 There shall be no items unrelated to experiments in the laboratory, and activities unrelated to work shall not be carried out, so as to protect personal safety and equipment safety.

5.3.4 Safety and health

5.3.4.1 When chemical analysis and pretreatment experiments involve organic solvents and volatile gases, they shall be operated in a fume hood. Pay attention to the waste gas and liquid generated by the analytical instruments. Discharge or collect them in time.

5.3.4.2 Comply with the relevant national regulations on the safety management of hazardous chemicals. Strictly control the storage of flammable, explosive, toxic and harmful reagents in the laboratory. Highly toxic reagents shall be stored in a safe, managed uniformly, and registered for use. When using toxic, harmful or corrosive reagents and standards, protective gloves or protective masks shall be worn.

5.3.4.3 High-pressure gas cylinders shall be placed fixedly. Always check for air leaks or unsafe factors during use.

5.3.4.4 When using instruments and equipment with radiation sources, strictly follow the radiation protection regulations.

5.3.4.5 The laboratory shall be kept tidy and clean. Clean up the experimental waste in time after the experiment. Clean used items, utensils, instruments and equipment in time. Do a good job in environmental sanitation. Experimental glassware shall be cleaned according to procedures.

5.3.4.6 There shall be a person in charge of safety and health in the work area, who is responsible for the safety and health in the area of responsibility.

5.3.4.7 Laboratory personnel shall learn how to use various safety devices and fire-fighting equipment so that they can be used correctly in emergency situations. The effectiveness of safety devices and fire-fighting equipment shall be checked regularly.

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