



Article Content

Title : Regulations Governing Accreditation and Management of Drug Abuse Urine Testing and Medical Institutions CH

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Category : Ministry of Health and Welfare (衛生福利部)

Chapter 1 General Principles

Article 1 These Regulations are enacted pursuant to Paragraph Three, article 33-1 of Statute for Narcotics Hazard Control (hereinafter referred to as "the Statute ").

Article 2 The executive institution of these Regulations is the Food and Drug Administration, Ministry of Health and Welfare (hereinafter referred to as "Ministry").

Chapter 2 Review Committee and Inspectors

Article 3 In order to conduct the accreditation and management of drug abuse urine testing and medical institutions (hereinafter referred to as "testing institutions"), the Ministry has set up the Testing Institution Accreditation Review Committee (hereinafter "the Review Committee " for short).

Article 4 The Review Committee has the following duties:

1. To provide consultation services about the policies of accreditation of testing institutions;
2. To review the operation procedures of certifying testing institutions;
3. To review the accreditation and performance test results and inspection reports of testing institutions;
4. To review the termination of testing accreditation practice, revocation and abolishment of the accreditation qualification of testing institutions as well as appeals for reexamination; and
5. To review other matters concerning accreditation of testing institutions.

Article 5 In the Review Committee shall be set nine to fifteen committee members, including a convener and a vice convener. The committee members shall be appointed by the Director-general of Ministry from the personnel engaged in narcotics analysis, medicine, pharmacy, and law.
The tenure of members of the preceding Paragraph is two years and a member may be reappointed consecutively upon expiration of

the tenure. The number of members of each gender shall not be lower than one third of the total number of the members.

Article 6 In the Review Committee shall be set one executive secretary and one to three clerks, which shall be assumed by the staff of the executive institution on a part-time basis.

Article 7 The Review Committee shall hold at least a meeting every year, and may call temporary meetings if necessary.

Article 8 The meetings of the Review Committee shall be presided over by the convener. In absence of the convener, the meeting shall be presided over by the vice convener. In absence of both convener and vice convener, one representative shall be selected by and from the committee members to be the chairman of the meeting. The opening of a meeting requires the attendance of more than one half of the committee members. When a decision is made by means of voting, it shall be approved by more than one half of the attending committee members.

Article 9 The committee members of the Review Committee are all no-pay positions.

Article 10 The executive institution may employ inspectors to conduct inspection. The inspectors shall be acquainted with the relevant provisions, attend the training held by the executive institution, and submit inspection reports. The tenure of inspectors is three years, and an inspector may be employed consecutively upon expiration of the tenure. Relevant expenses may be paid to the inspectors in accordance with relevant provisions.

Chapter 3 Accreditation and Management

Article 11 A testing institution may submit the application form, together with the following documents and information to the executive institution to apply for accreditation:

1. Photocopy of the establishment allowance certificate of the testing institution;
2. Organization, personnel and management data:
 - (1) Organizational structure, division of authority and responsibility, and mutual relationship;
 - (2) Table of positions and general statement of personnel qualification;
 - (3) Photocopy of the qualification and education background certificates of the personnel;
 - (4) Provisions on the management of documents and information of the testing institution.
3. Testing quality manual;
4. List of instruments and equipment;

5. The research data on the method validation of at least nine drugs or metabolites of those listed in Article 18, Paragraph 1 of the Regulations Governing Drug Abuse Urine Testing Operations.

6. Other documents and research data required by the executive institution.

Where the application documents and information fail to satisfy the requirements but can be supplemented and corrected, the executive institution shall notify the applicant to make supplement or correction within a given time limit; in case supplement or correction is not made in the specified time limit, the application shall be rejected.

Where the application documents and information satisfy the requirements, the executive institution shall present the same to the inspectors of the preceding Article for preliminary document review.

Article 12 The applicant testing institution, within six months after passing the preliminary document review of Paragraph 3 of the preceding Article, shall complete three times of performance test and the inspection conducted by the executive institution on the drugs or metabolites of Paragraph 1 Subparagraph 5 of the preceding Article.

Performance test shall include negative urine specimen, positive urine specimen mixed with the drug to be tested of a known concentration, and positive urine specimen with a concentration near to the cutoff value of the drug to be tested or its metabolite.

The accuracy of performance test shall reach 90% or above, and false positive result may not occur. For 80% or more of the results, the difference between the measured value of the drug to be tested and the value nominated by the executive institution shall be within 20% or two standard deviations, and in no case the difference may be 50% or more.

Where the performance test fails to satisfy the requirements in the preceding Paragraph, three times of performance test shall be conducted after the defects are corrected.

Inspection shall be conducted in accordance with the relevant regulations of the drug abuse urine testing institutions. Where an applicant testing institution fails to pass the inspection, another inspection shall be performed additionally after the defects are corrected.

Article 13 For a testing institution that has passed the performance test and inspection of the preceding Article, and the review conducted by the Review Committee, Ministry shall issue an accreditation certificate and have its name and accreditation number announced on the website of the executive institution

(hereafter referred to as the website).

The testing institution shall hang up the accreditation certificate at an obvious place in the institution.

Article 14 In case of alteration of name, address, principal, responsible person, certifying scientist, initial test method, confirmatory test method or testing instrument, the testing institution shall, within thirty days after alteration, submit the related data to the executive institution for approval, and the executive institution shall carry out inspection if necessary. When the alteration of address in the preceding paragraph is related to the relocation of testing instruments, the report of the relocating testing instruments, schedule, address and a geographical location map shall be submitted to the executive institution for approval. The executive institution shall announce the relocating schedule on the website. After the alteration is complete in the preceding paragraph, the test can be proceeded after the receiving the approval from the executive institution.

Article 15 After being accredited, the testing institution shall accept , and shall not evade, hinder, or decline the performance test conducted by the executive institution once every three months. The accuracy of performance test results shall reach 90% or above, and false positive result may not occur. For 80% or more of the results, the difference between the two consecutively measured values of the drug to be tested and the mean value of the testing institution participated in the test shall be within 20% or two standard deviations, and it is not allowable that the difference reaches 50% or more for two consecutive times. The values measured by the testing institutions that are 20% or two standard deviations above the mean value shall not be included in the calculation of the mean value.

Article 16 The performance test of testing institutions conducted by the executive institution every three months shall include at least ten urine specimens.

Article 17 The urine specimens sent by the test consignor (hereafter referred to as the consignor) to the testing institution shall include blind performance test specimens accounting for not less than 5% of the total amount. The blind performance test specimens of the preceding Paragraph shall include 80% of negative specimens and 20% of positive specimens. The positive urine specimens shall be used mainly for detecting the drugs to be tested, and the test results shall be reported based on qualitative research.

Article 18

Where the test consignor finds any error in the result of blind performance test, it shall notify the testing institution and the executive institution. The testing institution shall, within ten days commencing from receipt of the notice, explain the reasons in writing to the executive institution.

- Article 19 The executive institution shall require the testing institution to correct within a given time limit the defects found in inspection, performance test, and blind performance test. The corrections of the preceding Paragraph shall include statement of the defects and measures of remediation and prevention; where the defects are errors of testing skills or methods, the whole batch of performance test or blind performance test specimens whereof error occurs, shall be retested by the testing institution. The statement, measures, and quality control information of retest shall be submitted by the testing institution to the executive institution within the time limit of the preceding Paragraph.
- Article 20 After being accredited, where necessary, the executive institution may, at any time, dispatch personnel to conduct inspection, and the testing institution may not evade, hinder, or declines such inspection.
- Article 21 Where a testing institution doesn't conform to the provisions of Articles 15, or is unqualified in inspection, it shall, within five days following receipt of the notice, make explanation and file an improvement report to the executive institution.
- Article 22 Upon receipt of specimen, the testing institution shall conduct tests in accordance with the items designated by the consignor as soon as possible, and produce a test report within fourteen days. The results of initial test or confirmatory test shall first be confirmed by the certifying scientist, and the test report shall be approved and signed by the responsible person. A test report shall at least include the serial number of the accreditation certificate, the numbers of urine specimens, the cutoff values of drugs, and the drugs detected or not detected, and shall remark the employed test method, the limit of quantification, and other related data.
- Article 23 The testing institution shall retain the information relevant to the evaluation of the test methods and the test results.
- Article 24 The testing institution may not commission another testing institution to test the urine specimens, unless with the consent of the test consignor and the executive institution.

Article 25 The testing institutions shall submit a monthly report of all the urine test cases, before the tenth day of the next month, in designated format to the executive institution for reference.

Article 26 The executive institution may commission any relevant agency (institution) to conduct performance test and inspection activities.

Chapter 4 Staffing

Article 27 A testing institution shall designate a responsible person to take charge of the management of drug abuse urine testing activities.

The responsible person shall have any of the following qualifications:

1. Doctor's degree, major in analytical chemistry or other related natural science, and at least one year of practical experiences;
2. Master's degree, major in analytical chemistry or other related natural science in college or research institute, and at least three years of practical experiences; or
3. Graduate from chemistry or other related natural science department of university or college, and at least five years of practical experiences.

The responsible person shall undertake the following duties:

1. To ensure the testing institution has enough trained and experienced personnel to carry out drug abuse testing activities, and take charge of the on-job training, auditing of workload and technical confirmation of internal personnel;
2. To ensure the testing institution has a complete standard operation procedure, audit the revision of the procedure and record the date of revision;
3. To establish and implement quality assurance plan;
4. To supervise the implementation of quality management and quality control urine test;
5. To ensure the accuracy of the testing system and the test of each batch of test samples, and take relevant records;
6. To approve and sign the test report; and
7. To take necessary correction and prevention measures and take relevant records if any incompliance with the quality management system occurs.

Article 28 A testing institution shall designate certifying scientist to confirm all the data and quality control results.

A certifying scientist shall have any of the following qualifications:

1. Doctor's degree, major in analytical chemistry or other related natural science, and at least one year of practical experiences in testing;

2. Master's degree, major in analytical chemistry or other related natural science in college or research institute, and at least two years of practical experiences in testing; or
3. Graduate from the department of chemistry or other related natural science of university or college, and at least three years of practical experiences in testing.

Article 29 The personnel of a testing institution shall take on-job training and master the technologies required for accomplishing the work.

Article 30 The responsible person, certifying scientist, testers and other personnel of a testing institution all shall have a positional representative, and written records shall be taken about the representation.

Article 31 The testing institutions shall set up personnel data file, and the contents of the files shall include at least educational background, working experiences, training records, performance test records, and description of the current job.

Chapter 5 Facilities and Maintenance

Article 32 The facilities of a testing institution shall meet the relevant legal provisions. Electrical equipment shall be earthed appropriately, and fume hood, fire extinguisher, emergency shower, eye wash device, and other facilities ensuring the safety of the testing personnel shall be provided, and their functions shall be periodically evaluated.

Article 33 The water, electricity, lighting, temperature, humidity, spatial layout, equipment, safety and other environmental conditions of a testing institution shall meet the testing requirements, and the environmental factors that will influence the test results shall be monitored and relevant records shall be taken.

Article 34 A testing institution shall have separated and controlled specimen storage area, testing area and records storage area.

Article 35 The testing institutions shall formulate the standard operation procedures for operating, maintenance and calibration of the instruments, as well as storing implementation records.

Article 36 The testing institutions shall formulate the calibration procedures for balances, thermometers, pipettes, measuring flask, and other measuring equipments, with the content explicitly defining the calibration methods, calibration frequency, range of qualification, and restrictions on use and correction measures of unqualified equipments.

Chapter 6 File and Archive Management

Article 37 A testing institution shall formulate a file control procedure to regulate the formulation, revision, periodical examination, distribution, control, archiving and storage of the related files. The files and records relating to the test shall be stored for two years at least, and where necessary, the period may be extended according to the requirement of the consignor.

Article 38 A testing institution shall establish relevant archives, including personnel data, custody and control form, quality manual, quality management and quality assurance records, all original test data, test report, inspection and performance test reports, data printed by computer, and other relevant files and data, all in safe storage.

Chapter 7 Suspension of Testing, and Termination, Revocation and Abolishment of Accreditation

Article 39 Under any of the following circumstances of the testing institution, the executive institution may order the suspension of all or a part of its testing practice until the defect is totally corrected:

1. The testing institution has defects of Article 19 Paragraph 1.
2. The testing institution has not performed the test method validation assessment or the annual verification, or the performance is not satisfactory.

Article 40 Under any of the following circumstances of the testing institution, the executive institution may terminate its testing practice for one to six months, and a time limit shall be set for improvement:

1. Where wrong results are caused due to managerial defect;
2. Where the testing institution can not run normally since it is moved to another place;
3. Where the instrument or equipment can not work normally;
4. Where personnel change occurs and cause violation of the provisions of these Regulations or the Regulations Governing Drug Abuse Urine Testing Operations;
5. Where the testing institution evades, hinders, or declines the inspection or performance test conducted by the executive institution without any due reason , but in a manner of slight infringement;
6. Where the testing institution doesn't conduct operations in accordance with these Regulations and the Regulations Governing Drug Abuse Urine Testing Operations, slightly infringing the relevant provisions; or
7. Where any other slight violation of the provisions of these Regulations occurs.

Article 41 The testing institution, at the end of the period of termination of the preceding Article or upon expiry, may apply for inspection; the testing institution, having passed the inspection at the end of the period of termination or upon expiry, may continue the testing practice. No commission can be accepted from any consignor before the testing institution passes the inspection.

Article 42 If an accredited testing institution makes any false statement in the content of its application as specified in Article 11 or provides false documents and information, its accreditation will be revoked.

Article 43 Under any of the following circumstances, the accreditation of a testing institution will be abolished:

1. Where serious circumstance of false positive test result occurs;
2. Where it is confirmed the test operation violates the law;
3. Where the testing institution exposes any secret about the tester known in the operation;
4. Where the testing institution, after being terminated of its testing practice, does not file an application for inspection according to Article 41 or fails to pass the inspection;
5. Where the testing institution evades, hinders, or declines the inspection or performance test without any due reason shown;
6. Where serious circumstance in which the testing institution doesn't conduct operations in accordance with these Regulations and the Regulations Governing Drug Abuse Urine Testing Operations occurs;
7. Where the testing institution abandons accreditation or shut downs operation; or
8. Where serious circumstance of any other violation of these Regulations occurs.

Article 44 Under any of the following circumstances of the testing institution, the executive institution shall notify relevant government agencies of its decisions in written form:

1. Suspension of testing according to Article 39.
2. Termination of testing practice, revocation or abolishment of accreditation of the testing institution in accordance with Articles 40, 42, or the preceding Article.

Article 45 Where the testing institution finds itself dissatisfied with the decisions of suspension of testing practice, termination or revocation or abolishment of accreditation, it may file an appeal in writing within fifteen days following the arrival of the notice of decision.

Article 46

Within one year after the accreditation is cancelled or abolished, the testing agency may not apply for accreditation again in the same name or at the same place, and the chief in charge of testing operations may not assume the responsible person of any testing institution within two years.

Article 47 Upon the decisions of revocation or abolishment testing institution, the competent authority shall announce the name of the institution and the decisions on the website.

Chapter 8 Supplementary Provisions

Article 48 The executive institution shall include in the annual budget the expenses for accreditation and management of testing institutions.

Article 49 These Regulations shall come into force on 1 July 2021.