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Content

Title：	Regulations Governing the Recognition of Designated Laboratory for Measuring Instrument Ch
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Content：

Article 1

These Regulations are enacted pursuant to Paragraph 2, Article 26 of the Weights and Measures Act.

Article 2

The terms used in these Regulations are defined as follows:

1.Laboratory: laboratory to conduct testing;

2.Designated laboratory: laboratory recognized by the dedicated weights and measures authority under these Regulations to conduct testing for type approval of measuring instrument.

Article 3

To apply for recognition, a laboratory or its subordinate institution shall be one of the following:

1.Government agency (institution) of the Republic of China;

2.Domestic public or registered private college or higher school;

3.Domestic public-welfare juridical person; or

4.Other juridical person entitled to apply for recognition and made known to the public by the dedicated weights and measures authority, in reference to the international convention and according to the region, testing area, test items, category of measuring instrument or other requirements.

Article 4

A laboratory applying for recognition shall satisfy the following requirements:

1.Conform to the following requirements:

(1)General standards: CNS 17025 or ISO/IEC 17025;

(2)Special standards: special regulations on the technical requirements and quality management requirements for various categories of measuring instrument, different from the general standards listed above.

2.Have the necessary testing equipment, place, personnel and management system, and be sufficiently acquainted with the technical specifications on type approval of the category of measuring instrument; and

3.Designate the following directors with the following qualifications to take charge of the laboratory and quality management:

(1)Laboratory director: graduated from science or engineering department of college or higher educational institution, having accepted relevant professional training, and having worked in related practical testing for two years or more;

(2)Quality director: graduated from quality management specialty of college or higher educational

institution, and having worked in practical quality management in the related testing fields for two years or more.
4.Designate a report signer; the report signer may not concurrently hold the position of quality director.
The special requirements referred to in Subparagraph 1 of the preceding Paragraph shall be prescribed by the dedicated weights and measures authority in respect of the categories of measuring instrument.

Article 5
A laboratory satisfying the qualification and requirements set forth in the preceding two Articles may prepare an application form, and submit it enclosed with the following documents together with the assessment fee and certification fee to the dedicated weights and measures authority to apply for recognition:
1.Evidential documentation on compliance with the qualification set forth in Article 3;
2.Quality Manual of the laboratory;
3.System architecture and list of quality files;
4.Calibration tracing system chart of the testing equipment and list of instruments;
5.Organizational chart and laboratory layout map;
6.Geographic location map of the laboratory;
7.Evidential documentation on the compliance of laboratory director and quality directory with the conditions set forth in Subparagraph 3, Paragraph 1 of the preceding Paragraph; and
8.Other documents designated by the dedicated weights and measures authority.
In case the applicant referred to in the preceding Paragraph is not in the Republic of China, a representative who has dwelling or business office in the Republic of China shall be commissioned to apply for recognition.

Article 6
A laboratory that has passed the examination of documents and field assessment conducted by the dedicated weights and measures authority shall be recognized in respect to the examined category and scope of measuring instrument, and granted a recognition certificate of designated laboratory.

Article 7
Where any defect is found in the assessment of a laboratory, the dedicated weights and measures authority may notify the laboratory to develop an improvement plan within a specified time limit and apply for reexamination; in case no improvement plan is made after the time limit expires or any defect is found in the reexamination, the laboratory may not be recognized, and the certification fee shall be handed back.

Article 8
The validity period of a recognition certificate of designated laboratory shall be three years commencing from the date of issuance. Within six to two months before the validity expiration date, a designated laboratory may prepare an application form, and submit it enclosed with the relevant documents together with the assessment fee and certification fee to the dedicated weights and measures authority to apply for extension. If the laboratory passes the re-assessment, a replacement of the recognition certificate shall be granted.
The validity period of a replacement of recognition certificate as referred to in the preceding Paragraph shall be three years commencing from the day after expiration of the validity period of the original certificate. Nonetheless, if application for replacement is filed two months

before the original validity expiration date and the replacement is not finished before the period expires, the validity period of the replacement shall be three years commencing from the date of issuance.

Article 9
A designated laboratory shall perform the testing activities in the recognized testing field by itself. However, with the consent of the dedicated weights and measures authority, it may commission
any other laboratory to conduct a part of the testing activities.

Article 10
The dedicated weights and measures authority shall, periodically or non-periodically, dispatch personnel to the designated laboratories to implement monitoring assessment.

Article 11
Where any defect is found in monitoring assessment, the dedicated weights and measures authority may notify the designated laboratory to accomplish improvement within thirty days, and then apply for reexamination.

Article 12
Under any of the following circumstances, the designated laboratory shall, within fifteen days commencing from the occurrence, submit the relevant documents to the dedicated weights and measures authority for reference:
1.Alteration of the name of laboratory or its subordinate institution;
2.Change of quality director; or
3.Consecutive suspension of business for thirty days or longer.

Article 13
Under any of the following circumstances, the designated laboratory shall, within fifteen days commencing from the occurrence, submit the relevant documents to the dedicated weights and measures
authority to apply for reexamination:
1.Alteration of the subordinate institution of the laboratory;
2.Alteration of the organization or management of the laboratory;
3.Change of laboratory director or report signer;
4.Alteration of laboratory address, environment or equipment;
5.Alteration of the quality manual of the laboratory;
6.Alteration of the scope of recognition; or
7.Any other alteration likely to affect the capacity of the laboratory.

Article 14
During the testing for type approval of measuring instrument, the designated laboratory shall detailedly
record the test records and related technical documents.
The test records and related technical documents referred to in the preceding Paragraph shall be kept
for ten years at least. Nonetheless, if it is otherwise prescribed in the specification in respect of the category of measuring instrument, such prescription shall apply.

Article 15
The dedicated weights and measures authority may view and examine the relevant documents of any designated laboratory, and may dispatch personnel to the designated laboratory for investigation. Without good reason shown, the designated laboratory may not evade, hinder or refuse the investigation.

Article 16
For a laboratory that conforms to the following qualification requirements, the procedure of application
for recognition and management may be simplified:
1.Laboratory accredited by the Taiwan Accreditation Foundation (hereinafter referred to as "the Foundation"), wherein the certificate is still in force; or
2.Laboratory whose compliance with the provision of Paragraph One, Article 4 is proved by the Foundation.
The simplification of procedure as referred to in the preceding Paragraph is as follows:
1.Exemption from submission of the documents listed in Subparagraphs 2~4, Paragraph One of Article 5;
2.Exemption from the field assessment set forth in Article 6;
3.Exemption from re-assessment when applying for extension in accordance with the provision of Article 8;
and/or
4.Exemption from the monitoring assessment set forth in Article 10.
The simplification set forth in Subparagraphs 3 and 4 of the preceding Paragraph may be applied to the
designated laboratories that are recognized by the dedicated weights and measures authority and conform
to the qualification requirement set forth in the first Paragraph.
Before the Foundation referred to in the first Paragraph is established, the provisions of the preceding
two Paragraphs shall be applied to the laboratories that conform to the following qualification requirements:
1.Laboratory accredited by the Chinese National Laboratory Accreditation (hereinafter "CNLA" for short),
wherein the certificate is still in force; or
2.Laboratory whose compliance with the provision set forth in Paragraph One of Article 4 is proved by CNLA.

Article 17
Under any of the following circumstances, the dedicated weights and measures authority may temporarily
deprive a designated laboratory of the right to sign test report in the name of designated laboratory in respect of the recognized category of measuring instrument; and recover the right after it is confirmed through reexamination that improvement has been made within the specified time limit:
1.Where the designated laboratory does not apply for reexamination in accordance with the provision
of Article 11;
2.Where any defect that is not likely to cause test failure or only happens by chance is found in the

reexamination conducted under Article 11;
3.Where the designated laboratory does not submit the relevant documents to the dedicated weights and
measures authority for reference as prescribed in Article 12;
4.Where the designated laboratory does not apply for reexamination in accordance with the provision
of Article 13;
5.Where the designated laboratory refuses or fails to provide the data without good reason shown or within a given time limit;
6.Where the designated laboratory does not take measures to provide convenience for the dedicated weights
and measures authority to deal with monitoring assessment, appeal, complaint or dispute cases, and still
does not cooperate after the authority has given a notice to order the laboratory to do so; or
7.Where the recognition is terminated by the Foundation; or terminated by CNLA before the Foundation
is established.
Where a designated laboratory violates the provision set forth in Article 15 to prohibit evasion, hindering
or refusal of investigation, the dedicated weights and measures authority may temporarily deprive the laboratory of the right to sign test report in the name of designated laboratory in respect of the recognized category of measuring instrument within a certain period.

Article 18
Where it is found that a designated laboratory acquires the recognition by way of fraud, the dedicated
weights and measures authority shall cancel the recognition, and notify the original applicant or his successor to hand back the recognition certificate within a specified time limit; in case that the certificate is not handed back in the specified time limit, the dedicated weights and measures authority
shall directly issue a public notice to write it off.

Article 19
Under any of the following circumstances, the dedicated weights and measures authority may abolish the
recognition of a designated laboratory:
1.Where the laboratory applies for abolishment on its own initiative;
2.Where any defect that is likely to cause test failure or significantly reduce the performance is found in the reexamination conducted under Article 11;
3.Where any false or incorrect statement is found in the test records or related technical documents;
4.Where the laboratory losses the ability to do business or can not justly and effectively conduct testing activities;
5.Where the laboratory signs a test report in the name of designated laboratory beyond the scope of recognition or after it is deprived of this right under Article 17.
6.Where the laboratory does not finish improvement within the time limit specified in Paragraph One of Article 17, and pass the reexamination conducted by the dedicated weights and measures authority;
7.Where the laboratory does not pay the fees according to the relevant provisions or within a given

time limit;
8.Where the accreditation is cancelled or abolished by the Foundation; or by CNLA before the Foundation
is established; or
9.Other violations of the provisions set forth in these Regulations, which are deemed serious by the dedicated weights and measures authority.

Article 20
After the recognition of a laboratory is cancelled or abolished, no application may be filed for the same or a similar laboratory to apply for recognition of designated laboratory for the same category of measuring instrument within three years, unless in a circumstance as prescribed in Subparagraph 1,
Paragraph One of the preceding Article or other special circumstances approved by the dedicated weights and measures authority.

Article 21
A laboratory that has acquired the recognition of the dedicated weights and measures authority by right of international cooperation or mutual acknowledgement agreement or convention shall be regarded as a designated laboratory.

Article 22
A laboratory that has acquired the recognition under the Fundamentals for the Recognition of Designated
Laboratory for Measuring Instrument before these Regulations come into force shall be regarded as a
designated laboratory.

Article 23
These Regulations shall come into force from the date of promulgation.

Data Source：Ministry of Economic Affairs R.O.C.(Taiwan) Laws and Regulations Retrieving System