GOVERNMENT NOTICE NO. 60

METROLOGY ACT

(No. 10 OF 2016)

METROLOGY (TYPE APPROVAL ADMINISTRATIVE) REGULATIONS, 2021

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IN EXERCISE of the powers conferred by section 30 of the Metrology Act, I, ROY AKAJUWE KACHALE-BANDA, Minister of Industry , hereby make the Regulations—

1. These Regulations may be cited as the Metrology (Type Approval Administrative) Regulations, 2021. Citation

2. In these Regulations, unless the context otherwise requires— Interpretation

"family of measuring instruments" means an identifiable group of measuring instruments or modules belonging to the same manufactured type that have the same design features and metrological principles for measurement but which might differ in some metrological and technical performance characteristics, for example, maximum capacity or accuracy class;

"ILAC" means the International Laboratory Accreditation Cooperation; and

"module" means an identifiable part of a measuring instrument that performs a specific function or functions, and that can be separately evaluated according to specific metrological and technical performance requirements prescribed in the regulation pertaining to the instrument of which it will form part.

Submission of measuring instruments for type approval

3.—(1) Any measuring instrument used for a measurement regulated under the Act shall be subject to type approval.

(2) A person who desires to sell or make available any new model of a measuring instrument of a type which is required to be type approved in terms of the Act, shall, with a view to obtain a type approval certificate, make a submission for such type approval to Malawi Bureau of Standards.

(3) The submission in subregulation (2) shall be accompanied by a completed submission form obtained from Malawi Bureau of Standards and relevant documentation and specimens required under these Regulations or by Malawi Bureau of Standards.

(4) Malawi Bureau of Standards shall be entitled to request further information or assistance from the person who makes the submission at any stage of the type approval process.

Technical documentation

4.—(1) A competent authority shall prescribe technical documentation required for the type approval process in any regulation pertaining to the type of measuring instrument being submitted or in a national or international standard or other document as required under the regulations pertaining to the type of measuring instrument.

(2) Where the competent authority does not prescribe the required documents, Malawi Bureau of Standards shall specify the documents required which may include—

(*a*) description of the instrument, for example, detailed specifications relating to construction, assembly, adjustment, internal operation of the measuring instrument or its devices and self-adjusting mechanisms; and

(*b*) assembly drawings, detailed drawings, layouts, and schematic diagrams, and sales literature, photographs, drawings, and documents intended for users, including instructions for installation and preparation of an instrument for service, and operating, maintenance, and repair manuals.

(3) The person who makes the submission may submit any additional documentation pertaining to the measuring instrument that may assist in the type approval process.

(4) Malawi Bureau of Standards shall be entitled to request a declaration, signed by a competent person and acceptable to Malawi Bureau of Standards, confirming that the measuring instrument complies with any requirement for

design, construction or operation required by any regulation pertaining to the type of measuring instrument and for which no test for conformity is provided.

Specimen of measuring instruments to be submitted for type approval

5.—(1) A person who submits documents for type approval of instrument shall submit a specimen for testing which is representative of the type produced during normal production processes unless the person agrees with Malawi Bureau of Standards, that a prototype of a measuring instrument may be submitted prior to replicas of the measuring instrument being produced.

(2) The person shall also attach a statement to the submission relating to the measuring instrument, indicating whether it is a prototype, from a production line test run or from an established production line.

(3) The person shall ensure that the specimen submitted for testing is correctly adjusted as any failures during testing may result in refusal of the type approval and Malawi Bureau of Standards may, at its discretion, permit the correction of any faults that are found during testing or request a new specimen for testing.

(4) Malawi Bureau of Standards may request the person who makes a submission to dismantle and reassemble any measuring instrument as necessary, in order to evaluate such measuring instrument.

(5) The person making the submission shall submit at least one specimen for type approval testing where no requirements for the number of specimens required are prescribed in any regulation pertaining to the type of measuring instrument being submitted or in a national or international standard or other document required under the regulations pertaining to the type of measuring instrument.

(6) Where destructive testing is part of process, the person making the submission shall submit several samples to enable all tests to be carried out.

(7) In consultation with the person making the submission, Malawi Bureau Standard may request additional specimens for testing, where the testing of compliance to different requirements can be done simultaneously to reduce the time required for testing.

(8) Where Malawi Bureau of Standards accepts the type approval test results issued by a conformity assessment body, recognised and acceptable for the purposes of type approval of a measuring instrument, Malawi Bureau of Standards shall require that at least one specimen be submitted for its inspection and any testing deemed necessary.

(9) Where the measuring instrument referred to in subregulation (8) is not self-contained, the person making the submission shall have the instrument fully installed at a test site acceptable to Malawi Bureau of Standards.

Type approval of a new type of a measuring instrument

6.—(1) Where a person making a submission submits a family of similar measuring instruments at one time for type approval, Malawi Bureau of Standards shall decide if all instruments within the family will be covered by a single type approval certificate or if certain of the measuring instruments within the family shall be subjected to a separate type approval.

(2) Malawi Bureau of Standards shall use the criteria specified below to make the decision regarding the type approval process to be followed—

(*a*) different measuring instrument types produced by a particular manufacturer that are identical in design, materials, components and measurement ranges but that differ superficially in their non-metrological characteristics, for example, colour or housings, shall be covered by a single type approval;

(*b*) measuring instruments produced by a specific manufacturer which have different metrological characteristics such as measuring range, scale intervals of measured quantities or different size components of the same type, for example, load cells, may be covered by a single type approval provided that such differences preserve the performance of the measuring instrument variants within permissible error limits; and

(*c*) where guidance on a single or multiple type approvals for a family of measuring instruments is provided in any regulation pertaining to the type of measuring instrument being submitted or in a national or international standard or other document as is required by the regulations pertaining to the type of measuring instrument.

(3) Where Malawi Bureau of Standards decides to have a single type approval for a family of measuring instruments, Malawi Bureau of Standards shall decide on which variants, within the family, shall be tested with a view to type approving the whole family.

(4) Where guidance on the selection of variants for testing is provided in any regulation pertaining to the type of measuring instrument being submitted or in a national or international standard or other document as is required under the regulations pertaining to the type of measuring instrument, Malawi Bureau of Standards shall make a decision based on such guidance.

(5) Where a new variant within a family of measuring instruments is submitted after the original type approval for the family has been granted, Malawi Bureau of Standards shall decide, based on the criteria in regulation 5 (1), on what type approval tests shall be carried out to confirm compliance with requirements and whether a new type approval certificate will be issued or if the original type approval certificate for the family shall be endorsed to include the new variant.

(6) In these Regulations, where the term "measuring instrument" is used, it applies also to a family of measuring instruments that have been submitted for type approval unless otherwise stated.

(7) Where seemingly similar measuring instruments are submitted for type approval by different persons, Malawi Bureau of Standards shall subject the measuring instruments to separate type approval processes and allocate unique type approval marks.

Type approval of modules of measuring instruments

7.—(1) Malawi Bureau of Standards may agree to the type approval of a separate module where any regulation or a national or international standard or other document makes provision for the separate type approval of modules that form part of the type of measuring instrument to which such regulation pertains.

(2) Where Malawi Bureau of Standards accepts test results for the type approval of separate modules of a measuring instrument from a competent test laboratory or laboratories recognised and acceptable to Malawi Bureau of Standards, Malawi Bureau of Standards may request a complete instrument made up of separately type approved modules to be submitted to any tests deemed necessary to ensure compatibility of the separate modules.

(3) In this case, Malawi Bureau of Standards shall decide if a single type approval will be granted for the complete instrument or if separate type approvals will be granted for each module

Type approval of modified measuring instruments

8.—(1) A person shall not sell or make available for use for any regulated measurement any type approved model of a measuring instrument that has been modified unless the modified measuring instrument has been submitted to Malawi Bureau of Standards for evaluation and type approval as deemed necessary.

(2) The person making a submission of the modified measuring instrument for type approval shall also submit a completed submission form required under regulation 3 and the applicable technical documentation required under regulation 4 which shall include a signed statement detailing the modifications to the originally type approved measuring instrument and where available: any data, analysis and conclusions concerning the technical or metrological consequences of the modification.

(3) Where a modified version of a previously type approved measuring instrument is submitted for type approval, Malawi Bureau of Standards shall decide whether—

(*a*) the modification is superficial and shall not require any testing and the original type approval certificate will be extended by means of an addendum to cover the modified measuring instrument;

(*b*) the modification is sufficient to require limited testing or all tests specified for the type approval of the subject measuring instrument before the original type approval certificate is extended by means of an addendum to cover the modified measuring instrument; or

(*c*) the modification is so radical that a new type approval must be obtained for the new type of measuring instrument.

Technical requirements and type approval test procedures

9.—(1) Malawi Bureau of Standards shall ensure that type approval testing is performed according to requirements and test procedures contained in any regulation pertaining to the type of measuring instrument being submitted or in a national or international standard or other document as required under the regulations pertaining to the type of measuring instrument.

(2) Where Malawi Bureau of Standards deems it necessary, it shall require that additional tests be carried out to ensure compliance with the relevant requirements.

(3) Where a measuring instrument is intended to be used for a regulated measurement and no suitable requirements exist in any regulation, Malawi Bureau of Standards may, in consultation with the person who had made the

submission, use applicable technical requirements and type approval test methods contained in an international standard and set any conditions deemed necessary for the use of the measuring instrument until such time that suitable requirements are prescribed in a regulation.

Particulars to be submitted

10. A person who submits a measuring instrument for type approval shall, at the request of Malawi Bureau of Standards—

(*a*) provide sufficient labour for the proper and expeditious handling of test standards or any material which may be used in the testing of the measuring instrument;

(*b*) provide sufficient calibrated test standards of appropriate denominations or other equipment to perform the prescribed tests;

(*c*) transport test equipment to the site at which the tests will be performed; and

(*d*) provide suitable facilities for the measuring or re-measuring of the weight, length, area or volume of any material, liquid, gas or other product used for the testing of a measuring instrument.

Test site and authorization for use of type approval specimens

11.— (1) Where a measuring instrument needs to be installed at test site for type approval testing, the suitability of the test site shall be approved by Malawi Bureau of Standards.

(2) Where the type approval test requires a durability test over a period of use, a person selecting the site shall do so based on its ability to ensure the required use of the measuring instrument under normal conditions of use over the prescribed period.

(3) Where the type approval test requires a durability test over a period of use, Malawi Bureau of Standards shall, subject to such conditions, limitations or requirements and for such period as Malawi Bureau of Standards may deem fit, authorize in writing the use, for a regulated measurement, of one or more measuring instruments being subjected to type approval testing, for the prescribed test period.

Nomination of test laboratories for measuring instruments submitted for type approval testing

12.—(1) Where Malawi Bureau of Standards does not have access to the necessary test facilities, Malawi Bureau of Standards may, in consultation with a person who makes the submission, select test laboratories or other conformity assessment bodies acceptable to the person who has made the submission to perform some or all of the required tests.

(2) The laboratories or conformity assessment bodies referred to in subregulation (1) may be within the country or in another country.

(3) Malawi Bureau of Standards shall determine the competency of test laboratories or conformity assessment bodies referred to in subregulation (1) based on—

(*a*) accreditation to ISO/IEC 17025 for the applicable or equivalent tests by the national accreditation body or equivalent or an ILAC affiliated accreditation body; or

(*b*) in the absence of accreditation to ISO/IEC 17025, on the provision of satisfactory evidence of compliance with the requirements of ISO/IEC 17025 and competency to perform the required tests, for example by having participated in a successful peer review with another competent body or being assessed by a person nominated by Malawi Bureau of Standards; and

(*c*) compliance with the requirements under subregulation 13 (*c*).

Use of test results from acceptable test laboratories

13. Malawi Bureau of Standards may accept a certificate of conformity and type approval test results obtained from a recognised and acceptable laboratory or conformity assessment body for the type approval of a measuring instrument:

Provided that—

(*a*) at least one complete specimen of the measuring instrument shall be submitted for inspection;

(*b*) where the submitted test results are found to be incomplete or where one or more tests have been performed using different criteria to the requirements contained in any regulation pertaining to the measuring instrument, Malawi Bureau of Standards shall perform the necessary tests to ensure compliance with all requirements pertaining to the type of measuring instrument submitted for type approval; and

(*c*) Malawi Bureau of Standards may also consider a laboratory belonging to a national legal metrology authority in another country after it has evaluated, by any means deemed necessary, and found such laboratory competent to perform the required tests and issue a test report in the format required by the International Organization for Legal Metrology pertaining to the measuring instrument submitted for type approval or in a format specified in a regulation or by Malawi Bureau of Standards; and—

(i) the conformity assessment body that issues the International Organization for Legal Metrology test reports that are validated by an the International Organization for Legal Metrology Certificate issued by the International Organization for Legal Metrology Issuing Authority in a country that is a signatory to the International Organization for Legal Metrology Declaration of Mutual Confidence within the International Organization for Legal Metrology Framework for a Mutual Acceptance Arrangement on Type Evaluations; and

(ii) the conformity assessment body issues test reports that are used by an International Organization for Legal Metrology registered Issuing Authority to issue certificates under the International Organization for Legal Metrology Basic Certification System for the International Organization for Legal Metrology Type Evaluation of Measuring Instruments.

Conditions of type approval and requested alterations

14.—(1) Malawi Bureau of Standards may, before issuing a type approval certificate, require an alteration to be made to the type of measuring instrument evaluated for type approval, as Malawi Bureau of Standards may deem necessary.

(2) Malawi Bureau of Standards may, by means of the type approval certificate, limit the use of a measuring instrument or set such conditions for its use or requirements for verification, as Malawi Bureau of Standards may deem necessary.

Refusal to type approve an instrument or modified instrument and appeal

15.—(1) Where Malawi Bureau of Standards is satisfied that a measuring instrument or family of measuring instruments submitted for type approval does not comply with all requirements in a regulation pertaining to it, Malawi Bureau of Standards shall refuse to type approve the instrument and shall inform, in writing, a person who made the submission reasons for refusing to type approve the measuring instrument or family of measuring instruments.

(2) Subregulation (1) shall be applicable where a module of a measurement submitted for type approval is found not comply with all requirements in a regulation pertaining to it.

(3) A person who submitted a measuring instrument, or a module of a measuring instrument that Malawi Bureau of Standards refuses to type approve may appeal to the Board where he believes that the regulatory requirements have been incorrectly applied when evaluating the measuring instrument or module and he has failed to resolve the dispute with Malawi Bureau of Standards.

Issue of type approval certificates and supporting documentation

16.—(1) Where Malawi Bureau of Standards finds that a specimen of a new type of measuring instrument or module submitted for type approval complies in all respects with the requirements in a regulation pertaining to it, Malawi Bureau of Standards shall type approve the measuring instrument or module by issuing a type approval certificate which contains the allocated type approval mark.

(2) Subregulation (1) shall apply where Malawi Bureau of Standards deems that the modification to a measuring instrument or module to be so radical that a new type approval must be obtained.

(3) Where Malawi Bureau of Standards finds that a specimen of a previously type approved but modified measuring instrument or module, submitted for type approval, complies in all respects with the requirements in a regulation pertaining to it and such modification is of such a nature that the original type approval is applicable, Malawi Bureau of Standards shall type approve such modified measuring instrument or module by issuing an addendum to the original type approval certificate to include the modified variant of the measuring instrument or module.

(4) The type approval certificate or an addendum to a type approval certificate shall be an official document and contain at least the following information—

(*a*) name and address of the person making the submission;

(*b*) name and address of the manufacturer;

(*c*) identification of applicable regulations against which compliance was assessed;

(*d*) type approval mark;

(*e*) name and signature of an officer from Malawi Bureau of Standards;

(*f*) date of type approval;

(*g*) date of type approval expiry;

(*h*) any conditions or restrictions for use for a regulated measurement;

(*i*) a description of the technical and metrological characteristics of the type of measuring instrument and its variants in enough detail to clearly identify the instrument; and

(*j*) any other details such as position of verification mark, required protective seals and special checks at the time of verification, to enable the correct verification of the measuring instrument.

(5) Where Malawi Bureau of Standards deems it necessary, the information required in paragraphs (*h*), (*i*) and (*j*) may be put in a separate document and form part of the type approval certificate.

Type approval mark

17.—(1) Where Malawi Bureau of Standards issues a type approval certificate under these Regulations for any measuring instrument which is a replica of a measuring instrument, the measuring instrument shall be clearly and indelibly marked with the type approval mark, in the form "M 1", where "M" denotes the "Republic of Malawi" and the number is a sequential number corresponding to the number of type approvals granted at the time of issue.

(2) Malawi Bureau of Standards shall ensure that the type approval mark is placed on a measuring instrument in a position required by any regulation pertaining to such measuring instrument and is visible, legible, and indelible.

Period of validity of type approval certificates and extension of validity

18.—(1) A type approval certificate issued by Malawi Bureau of Standards shall be valid for a period of ten (10) years after which time no new measuring instruments of the type covered by the certificate may be sold for use for a regulated measurement unless an application has been made for a review and extension of validity.

(2) Before the expiry of a type approval certificate, the person who made the submission may apply for a review and extension of the certificate.

(3) Malawi Bureau of Standards may, in order to carry out a review to determine that the measuring instrument and its variants, covered by the type approval certificate, still complies with requirements pertaining to it at the time of original approval and that no unauthorized modifications have been made, request for inspection, such specimens of the measuring instrument and its variants and any documents, including signed declarations, deemed necessary.

(4) Where Malawi Bureau of Standards is satisfied that the measuring instrument and its variants still complies with all applicable requirements, Malawi Bureau of Standards shall extend the validity of the type approval certificate for a further 10 years.

Publication of type approval documents

19. Malawi Bureau of Standards shall, upon a type approval certificate or an addendum to a previously issued certificate, and any supporting documents being issued, make the document publically available in any manner that Malawi Bureau of Standards deems fit, for use by inspectors, verification officers and other interested persons.

Confidentiality of information regarding type approval

20. Malawi Bureau of Standards (and legal metrology officials responsible for type approval evaluations) shall keep confidential all proprietary information and test results pertaining to a measuring instrument submitted for type approval:

Provided that all information deemed necessary to facilitate verification or inspection, including the means of checking that a measuring instrument is not in a calibration mode, shall be included in the type approval certificate or any supporting documents which are made public.

Withdrawal of type approval certificates

21.—(1) Where Malawi Bureau of Standards is satisfied that a type of measuring instrument, module or a type approved modification to a measuring instrument or module, no longer satisfies the requirements pertaining to the type of measuring instrument at the time of type approval, Malawi Bureau of Standards may withdraw such type approval certificate and shall publicize the withdrawal in any manner Malawi Bureau of Standards deems fit.

(2) At the time of the withdrawal of a type approval certificate, Malawi Bureau of Standards may prohibit any person from using the measuring instruments of the particular type currently being used for a regulated measurement or may impose some conditions for continued use.

Verification of type approved measuring instruments

22. A legal metrology official or verification officer shall not refuse to verify any particular measuring instrument that is a replica of the type or modified type in respect of which a type approval certificate has been issued and has not been withdrawn, on the grounds that the material of construction or the principle according to which such measuring instrument has been made is such that it is unsuitable for use for any regulated measurement for which it was type approved.

Made this 30th day of September, 2021.

ROY. AKAJUWE KACHALE-BANDA
Minister of Industry

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