UK Metrology Board Scheme

Module D and D1 NAWI Regulation 2016 (S.I. 2016/1152)
Modules A2, D, D1 and E1 for the Measuring Instruments Regulations 2016 (SI 2016/1153) and Approved Verification under Section 11A of the Weights and Measures Act 1985

Introduction

The Non-Automatic Weighing Instrument Regulations 2016 create the obligations relating to the placing on the market of non-automatic weighing instruments in the UK. This scheme incorporates the requirements for the approval of a manufacturers quality system by a UK approved body in accordance with these Regulations.

The Measuring Instrument Regulations 2016 create the obligations relating to the placing on the market of measuring instruments in the UK. This scheme incorporates the requirements for the approval of a manufacturers quality system by a UK approved body in accordance with these Regulations.

Section 11A of the Weights and Measures Act 1985 permits persons that are approved by the Secretary of State to become Approved Verifiers. This entitles them to pass as fit for use for trade measuring equipment that they have been approved for. The approval is issued by the Secretary of State and this scheme facilitates the auditing process to ensure compliance with Section 11A and schedule 3A of the Weights and Measures Act 1985 are met. The approved body will make a recommendation to the Secretary of State as to whether the certification under section 11A can be issued who will then decide if the certification can be issued.

UKAS accreditation for the purpose of appointment as an Approved Body under the Non-automatic Weighing Instruments Regulations 2016 and the Measuring Instruments Regulations 2016 confirms that the conformity assessment standard applicable for the relevant modules based on quality assurance of the production process is ISO/IEC 17065. For the purpose of the assessment of Approved Verifiers it is ISO/IEC 17021-1.

Module A2 is based on the internal production control plus supervised instrument checks at random intervals.

Module D is based on quality assurance of the production process whereby the manufacturer operates an approved quality system for production, final product inspection and testing of the UKCA type approved instrument(s) concerned.

Module D1 is based on quality assurance of the production process for instruments that the manufacturer declares conformity with the requirements of the Regulation.

Module E1 is based on the quality assurance of final instrument inspection and testing.

Approved verification under section 11A of the Weights and Measures Act 1985 is based on schedule 3A of that Act.

The quality system shall ensure that instruments are in conformity with the type described and comply with the requirements of the Regulations and requirements that apply to them.

The Scheme

The scheme implements the functional approach for product certification and is primarily addressing the UK Office for Product Safety and Standards (OPSS) Non-Automatic Weighing Instruments Regulations 2016, the Measuring Instruments Regulations 2016 and Section 11A of the Weights and Measures Act 1985 which requirements are applicable and this scheme.

The functional approach for the scheme is based upon the requirement for the manufacturer to demonstrate a quality system in place as the means of confirming the specified instruments comply with the requirements of the Regulations and is approved by a UK Approved Body accordingly following

Selection –The relevant modules in the Regulations or the Sections of the Weights and Measures Act 1985.

Determination - an audit (and where required instrument checks) to confirm the quality system applied is effective.

Independent Review of the report and *Decision*, approval.

Attestation (certification award) and

ongoing *Surveillance* as detailed below.

The manufacturer shall lodge an application for assessment of the quality system with an Approved Body of his choice. The Body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer. Additionally, the Approved Body may pay unexpected visits to the manufacturer. During such visits, the Approved Body may, if necessary, carry out product tests, or have them carried out, to verify that the quality system is functioning correctly. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

Manufacturers records of complaint.

The scheme requires all applicants/clients keep a record of all complaints made known to it relating to compliance with certification requirements and makes these records available to the certification body when requested during audits of the quality system and

1) takes appropriate action with respect to such complaints and any deficiencies found in products that affect compliance with the requirements for certification.

2) documents the actions taken.

MODULE A2

INTERNAL PRODUCTION CONTROL PLUS SUPERVISED INSTRUMENT CHECKS AT RANDOM INTERVALS

Internal production control plus supervised instrument checks at random intervals is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 4, and 5 (annex II of MI Regulations), and ensures and declares on his sole responsibility that the measuring instruments concerned satisfy the requirements of this Directive that apply to them.

Technical documentation

The manufacturer shall establish the technical documentation as described in the regulations. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture, and operation of the instrument.

Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured instruments with the technical documentation and with the requirements of the regulations that apply to them.

Instrument checks

At the choice of the manufacturer, either an accredited in-house body or an approved body, chosen by the manufacturer, shall carry out instrument checks or have them carried out at random intervals determined by the body, in order to verify the quality of the internal checks of the instrument, considering, inter alia, the technological complexity of the instruments and the quantity of production. An adequate sample of the final measuring instruments, taken on-site by the body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the designated

standard, and/or normative document, and/or equivalent tests set out in other relevant technical specifications, shall be carried out to verify the conformity of the instruments with the relevant requirements of the Regulations . In the absence of a relevant designated standard or normative document, the accredited in-house body or approved body concerned shall decide on the appropriate tests to be carried out.

MODULE D

CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS

Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down for manufacturing and conformity marking and ensures and declares on his sole responsibility that the instruments concerned are in conformity with the type described in the UKCA type examination certificate and satisfy the requirements of this Directive that apply to them.

Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the instruments concerned, and shall be subject to routine surveillance.

Quality System

The manufacturer shall lodge an application for assessment of his quality system with an approved body of his choice, for the measuring instruments concerned.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

(b) a written declaration that the same application has not been lodged with any other notified body,

(c) all relevant information for the instrument category envisaged.

(d) the documentation concerning the quality system.

(e) the technical documentation of the approved type and a copy of the type-examination certificate.

The quality system shall ensure that the measuring instrument are in conformity with the type described in the type-examination certificate and comply with the requirements of the Regulations that apply to them. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of

written policies, procedures, and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals, and records.

It shall contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities, and powers of the management about product quality.

(b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used.

(c) the examinations and tests that will be carried out before, during, and after manufacture, and the frequency with which they will be carried out.

(d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned.

(e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

The auditing team shall review the technical documentation referred to above, to verify the manufacturer's ability to identify the relevant requirements of the regulations and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

The quality system shall ensure that the measuring instrument are in conformity with the type described in the type-examination certificate and comply with the requirements of the Regulations that apply to them. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures, and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals, and records.

MODULE D1

QUALITY ASSURANCE OF THE PRODUCTION PROCESS

Quality assurance of the production process is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down and ensures and declares on his sole responsibility that the instruments concerned satisfy the requirements of the Directive that apply to them.

Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements and shall include an adequate analysis and assessment of the risk(s).

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument. The technical documentation shall, wherever applicable, contain at least the following elements:

(a) a general description of the instrument.

(b) conceptual design and manufacturing drawings, schemes of components, sub-assemblies, circuits, etc.

(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the instrument.

(d) a list of the designated standards applied in full or in part the references of which have been published in the *designated standards database issued by the UK Government*, and, where those designated standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of the Regulations, including a list of other relevant technical specifications applied. In the event of partly applied designated standards, the technical documentation shall specify the parts which have been applied.

(e) results of design calculations made, examinations carried out, etc.

(f) test reports.

Quality Systems

The manufacturer shall lodge an application for assessment of his quality system with an approved body of his choice, for the measuring instruments concerned.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well.

(b) a written declaration that the same application has not been lodged with any other approved body.

(c) all relevant information for the instrument category envisaged.

(d) the documentation concerning the quality system.

(e) the technical documentation referred to above

The quality system shall ensure compliance of the measuring instruments with the requirements of the regulations that apply to them.
All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures, and instructions.
This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals, and records.

It shall contain an adequate description of:
(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality.
(b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used.
(c) the examinations and tests that will be carried out before, during, and after manufacture, and the frequency with which they will be carried out.
(d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned.
(e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

The auditing team shall review the technical documentation referred to above, to verify the manufacturer's ability to identify the relevant requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

MODULE E1

QUALITY ASSURANCE OF FINAL INSTRUMENT INSPECTION AND TESTING

Quality assurance of final instrument inspection and testing is the conformity assessment procedure whereby the manufacturer fulfils the obligations of the Regulations and declares on his sole responsibility that the measuring instruments concerned satisfy the requirements of the Regulations that apply to them.

Technical documentation

The manufacturer shall establish the technical documentation as described in the Regulations. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture, and operation of the instrument.

Manufacturing

The manufacturer shall operate an approved quality system for final product inspection and testing of the measuring

Quality system

The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the measuring instruments concerned.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well.

(b) a written declaration that the same application has not been lodged with any other notified body.

(c) all relevant information for the instrument category envisaged.

(d) the documentation concerning the quality system.

(e) the technical documentation.

The quality system shall ensure compliance of the measuring instruments with the requirements of the Regulations that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures, and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals, and records.

It shall contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities, and powers of the management with regard to product quality.
(b) the examinations and tests that will be carried out after manufacture.
(c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned.
(d) the means of monitoring the effective operation of the quality system.

APPROVED VERIFICATION

SECTION 11A SCHEDULE 3A THE WEIGHTS AND MEASURES ACT 1985

An approved verifier shall prepare and keep up to date a quality system manual, that is to say, a document:

(*a*) showing how his quality system satisfies the requirements of these requirements.

(*b*) setting out the objectives of that system.

(*c*) containing details of his organisational structure, including details of:

(i) the persons who have management responsibility for that system, including their names and individual responsibilities.

(ii) the persons who are authorised to test, pass or stamp weighing or measuring equipment with which the verifier is concerned, including their names and qualifications.

(d) containing details of the equipment and other items required for the testing of weighing or measuring equipment with which the verifier is concerned.

(*e*) containing a description of the regulations made under this Act, and certificates of approval issued under section 12 of this Act, which are applicable to the testing, passing or stamping of weighing or measuring equipment with which the verifier is concerned.

(*f*) containing a description of the verifier's procedures:

(i) for the testing of weighing or measuring equipment.

(ii) for ensuring that weighing or measuring equipment passed as fit for use for trade conforms with any such regulations, and (where applicable) any such certificates of approval.

(iii) for ensuring that weighing or measuring equipment which does not conform with any such regulations, or (where applicable) any such certificates of approval, is prevented from being passed as fit for use for trade.

(iv) for ensuring that any persons conducting tests of weighing or measuring equipment have the necessary skills and qualifications to do so.

(v) for ensuring that the verifier exercises control over and retains responsibility for the actions of any sub-contractor of his in relation to the testing of weighing and measuring equipment.

(vi) for enabling identification of individual items or batches of weighing or measuring equipment.

(vii) for the control of the equipment used for the testing of weighing or measuring equipment.

(viii) for the control and use of the prescribed stamp.

(ix) for the control of documents and data.

(x) for undertaking internal reviews and audits of the verifier's quality system; and

(*g*) containing a description of the verifier's system of records for showing that any weighing or measuring equipment passed as fit for use for trade conforms with any such regulations and (where applicable) any such certificates of approval.

The UK Metrology Board Ltd (UKMB)

The UKMB is a separate independent legal entity, wholly owned by the United Kingdom Weighing Federation (UKWF), and in accordance with ISO/IEC 17065 and17021-1 undertakes all certification (approval) activities impartially with arrangements in place that ensure conflicts of interest are identified and resolved to prevent any risks to impartiality and all activities are conducted to ensure objectivity, independence, and fairness throughout. UKMB are the Scheme owner and ensure it is developed and maintained by technically competent persons as detailed in procedure PD1

NB. It is not a requirement that manufacturers are members of the UKWF in order to seek approval of their quality system by UKMB, the costs of assessment are the same for members and non- members, and membership does not influence the impartiality, independence and objectivity of the assessment and approval by UKMB.

Application for approval of the quality system.

The manufacturer shall complete the UKMB application form:

SD5 for new certification applications

SD6 for changes to UKMB certification

SDXX for transfer of accredited certification

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well.

(b) a written declaration that the same application has not been lodged with any other notified body.

(c) all relevant information for the instrument category envisaged.

(d) the documentation concerning the quality system; and

(e) the technical documentation of the instrument, and where applicable a copy of the type examination certificate.

The quality system shall ensure that the instruments are in conformity with the type described and comply with the requirements of the Regulations that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality.

(b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used.

(c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out.

(d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

(e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

UKMB will provide an estimation for the assessment process.

The agreement entered into between UKMB, and the applicant will be recorded in a separate contract agreement.

UKMB Assessment process.

Once UKMB has received an order for a quality system audit the planning process will assign an audit team consisting of at least one lead auditor. In addition, one or more auditors and/or technical assessors may be added to the team. All auditors and technical assessors are required to act impartially and keep confidential all information relevant to the audit and any manufacturer's information that is not in the public domain.

The applicant will be advised of the audit team members for acceptance or otherwise. Non-acceptance must be in writing with reasons provided. The Managing Director of UKMB will consider the reasons and if considered valid will make the necessary changes accordingly.

The initial assessment process consists of:

Stage 1 are view of the documents submitted with the application and a site visit to confirm/evaluate site specific conditions and obtain an overview of available information before initiating stage 2. The main objective of stage 1 is to determine the readiness of the manufacturer /quality system for the approval audit.

Non-conformances will not be recorded but areas of concern which may result in reported non- conformances during stage 2 will be communicated to the manufacturer.

NB. Stage1 may be dispensed with for organisations transferring their approval from an accredited (IAF recognised) certification body. Copies of approval certificates and schedules must be provided on application.

Stage 2 an operational audit of the quality systems on-site in accordance with a visit plan supplied. Any non-conformances identified will be recorded and reported on completion of the audit and categorised accordingly.

Major non-conformance

- Lack of or failure to implement a process.
- Information which casts doubt on the product integrity and conformance with specified requirements.
- A series of minor non-conformances relating to the same issue.
- Misuse of marks.

Minor non-conformance

- Isolated examples of implementing requirements which do not cast doubt on the product integrity or performance.

A suitable corrective action is required from the manufacturer following a root cause analysis. UKMB shall require the client to analyse the cause and describe the specific correction and corrective actions taken, or planned to be taken, to eliminate detected non-conformances, within the specified time.

Any major non-conformities should be reviewed, a root cause analysis and corrective action plan provided to the auditor within one month from the date of the audit and resolved and verified by UKMB within a further two months.

Any minor non-conformities should be reviewed, a root cause analysis and corrective action plan provided to UKMB for acceptance within one month. The auditor will ensure the corrective action has been implemented at the next audit. A failure to resolve a minor non-conformity will result in that non-conformity being elevated to a major non-conformity.

In the event of any major or minor non-conformities a root cause analysis must also be provided by the client within the time frames detailed above. Root cause analysis forms part of the non-conformity resolution process and is required by UKMB to close out and complete certification.

No response is required for observations, but it is recommended that the company responds to them in a positive manner to improve the implementation of the quality system.

Verification of non-conformances.

All non-conformances both major and minor must be verified before a recommendation for approval/certification of the quality system can proceed.

Minor non-conformances reported during surveillance: An acceptable root cause analysis and corrective action plan must be provided to UKMB within one month following a routine surveillance visit and will be verified at the next visit.

Suitable documentation may be submitted to confirm satisfactory implementation of corrective action for a major non-conformance BUT a further site visit may be necessary, and this will be confirmed at the closing meeting.

Verification of any major non-conformities after three months will require a re-assessment of the complete quality management system.

Review, decision, and certification.

A report of the audit will be provided and following verification of corrective actions will be submitted for independent review and decision, following a positive decision a certificate of approval of the quality system confirming the instruments listed continue to be manufactured in accordance with the Regulation and signed by the UKMB Managing Director will be issued.

The validity of the certificate shall be three years from date of issue and normally subject to annual surveillance/recertification visits to confirm the ongoing approval/certification of the quality system to support the applicable instruments validity.

Appeal.

When an applicant or a certificate holder disagrees with a certification decision, then UKMB has an appeals process, a copy of the appeals procedure can be requested. The appeal must be in writing, for the attention of the UKMB Managing Director, and detail the basis of the appeal which will then be considered by two independent members of the Advisory Board. The results of the appeal will be communicated in writing to the appellant.

Complaints.

Complaints about the UKMB process delivery or scheme assessment criteria, will be treated in accordance with the UKMB complaints procedure, logged accordingly, investigated and when appropriate the results provided accordingly.

Manufacturer's responsibility.

The manufacturer shall comply with the certification agreement (SD7) which also includes the use of marks when approval of the quality system is confirmed via award of certification. The manufacturer shall immediately inform the management of UKMB of any organisational changes, manufacturing changes or other circumstance which could result in the quality system failing and the instruments continued compliance with the applicable requirements of the Regulation/Directive.

Sanctions.

An approval certificate may be suspended or withdrawn by the UKMB if the manufacturer does not comply with the requirements of the certification scheme, including timely corrective action and verification of non-conformities. When approval/certification is suspended or withdrawn (or expired) the manufacturer shall cease any reference to UKMB approval and use of marks.

Certification amendment.

If the manufacturer wishes to amend certification to include additional instruments or locations an application to UKMB must be submitted (SD6). UKMB will undertake a review and advise on actions necessary regarding any further assessment of the manufacture/quality system considered necessary in order to amend the approval/certification accordingly.