UKWF Seminar on Module D

6th June 2023

Overview

- To place a weighing instrument on the market or put it in to service
- Must have a module B type examination certificate
- Then followed by a second module which can be Module F
- This has historically been a Weights and Measures Inspector
- Can be module D
- This is a manufacturer initially conformity assessing their own instruments
- Can be a manufacturer re-qualifying their own instruments

Overview

- There has a been a reduction of the number of Inspectors of Weights and Measures offering the service of initial verification and re-qualification
- Difficult to get Inspectors in a timely manner to meet the needs of customers
- Many UK Weighing Federation members have either already obtained module D certification or considering a module D certification
- This seminar is outlining some of the things that need to be considered if you wish to obtain it
- Focuses on NAWI’s

Overview

- You must have a quality management system that meets the requirements of Schedule 7 of the Non-automatic Weighing Instruments Regulations 2016
- Same as Annex II of the Directive 2014/31
- The system will be audited by an approved body
- If it is demonstrated that the quality system meets the requirements of schedule 7 – will be issued a certificate
- Will be subject to annual audits
- The certification is based around the type examinations that you have approval to verify

Overview

- You do not need to be the owners of the type-examination certificates that you are certified to undertake verifications and re-qualifications
- If you are not the owner- it is accepted practice that you should have the permission of the owner
- This will take the form of written consent which should be updated annually
- The rationale is that you must have ”access to technical information” for the purposes of this certification
- This can be required by either the market surveillance authorities or the certification body undertaking module D

Legal Background – Module D

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 in points 2.2 and 2.5 and ensures and declares on his sole responsibility that the instruments concerned are in conformity with the type described in the EU-type examination certificate(*GB type-examination certificate)* and satisfy the requirements of this Directive that apply to them.

Legal Background – Module D

2.3.2 Quality System:

- The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate(*GB type examination certificate)* and comply with the requirements of this Directive(*Regulation)* 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

Legal Background – Module D

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

Legal Background – Module D

- The basis of the clause 2.3.2 is ISO 9001-2015

- Must also look at the WELMEC Guide 8.6 –”Measuring Instruments Directive 2014/32 EU, Presumption of Conformity of the Quality Systems of Manufacturers with module D or H1 when ISO 9001:2015 is applied”

- This has been updated to include the NAWI Directive 2014/31 and will mirror the requirements of schedule 7

Internal Auditing

9.2 –Internal audit

The organization shall conduct internal audits at the planned intervals to provide information on whether the quality management system:

a) conforms to:

1. the organization’s own requirements for its quality management system;
2. the requirements of this International Standard;

b) is effectively implemented and maintained.

7.5 Documented information

- The organization must have documented information determined by the organisation as being necessary for the effectiveness of the quality management system
- This will include the necessary procedures
- The necessary technical and legal documents
- Must have a sufficient document control process

7.5 Documented information

5.1 Leadership and commitment

- Top management shall demonstrate leadership and commitment with respect to the quality management system
- Very important in large organisations

5.2.1 Establishing the quality policy

- Must have a clear statement that the objectives of the business are focused on the process
- Quality policy will ensure that the review will take place at the management review process

6.2 Quality objectives and planning to achieve them

- Should have a specific quality objective which will feed into the management review
- Should be measurable

7.5 Documented information

8.4 Control of externally provided processes , products and services

- This will cover procedures for purchasing processes that are necessary.
- Should consider the external auditing of suppliers
- Must remember suppliers of software and load cells

8.5 Production and service provision

- This will cover the verification procedure and the issuing of the Declaration of Conformity
- It will be necessary to carry out a witnessed verification
- Ensure that the process complies with the essential requirements and the harmonized standards

7.5 Documented information

9.2 Internal audit

- Must have an effective internal audit schedule

9.3 Management review

- Should have a management review input that relates to the module D processes
- Must have an operating management review process and recorded minutes

Examples of Non-Compliance

- Insufficient understanding of the verification process for NAWIs,
- Unclear definitions of management responsibility
- Unclear quality objectives with regard to the process
- Inappropriate calibration records for the equipment used-weights
- Insufficient testing of purchased goods-water meters
- Insufficient random sampling-length measures
- Insufficient testing of software