1.4.4 SELF-VERIFICATION

European Self-verification or UK Weights and Measures Act 1985 Self-verification?
The term “self-verification” has become the colloquial expression for the process whereby an organisation that is suitably accredited/authorised can carry out the conformity assessment and performance testing on weighing instruments that it has manufactured or, in certain circumstances, has repaired, installed or distributed. In contrast, “verification” is the term used when weighing equipment undergoes performance testing and conformity assessment carried out by a Notified Body such as a Trading Standards Department or an accredited third party organisation.

There are now three types of self verification:

- UK national self verification, which has its origins under the Weights and Measures Act 1985
- EC Declaration of Type Conformity which has its origins in the Non-Automatic Weighing Instruments Directive (NAWI) 2009/23/EC
- Declaration of Conformity to Type based on quality assurance of the production process, with its origin in the Measuring Instruments Directive (MID) 2004/22/EC

In practice, there is little difference between the last two, and the obligations that have to be met by the manufacturer are very similar. It should be noted, however, that there is a subtle difference in the way these requirements have been implemented in UK legislation. A manufacturer who is accredited as a “self-verifier” under the NAWI Directive is also allowed to carry out re-verification of the products that he can initially verify, because the NAWI concerned do not fall under the control of the Weights and Measures Act 1985 after they have been placed on the market and taken into service. However, the MID has been implemented in the UK on a different basis; Automatic Weighing Instruments (AWI) that are subject to the MID do become subject to the Weights and Measures Act 1985 once they have been placed on the market and taken into service, therefore re-verification can be carried out either by a Notified Body or by a manufacturer, repairer, installer or distributor that is accredited under the UK national self-verification system. A table showing who can verify is given at the end of this document.

European Self-verification (EC Declaration of Type Conformity under NAWI Directive 2009/23/EC)
Non Automatic Weighing Instruments (NAWI’s), (weighing instruments that require the action of gravity to determine the mass and require the intervention of an operator during weighing), which are first placed on the EU market and put into use in EU member states must comply with the NAWI Directive.

NAWI’s used for controlled applications must have gone through EC type-examination and been given an EC Type Approval Certificate. They must be manufactured in conformity with the EC Type Approval Certificate and must be labelled and CE marked in accordance with the NAWI Directive and other applicable directives.

These NAWI’s must be subject to initial conformity assessment (verification) procedures whereby either:

- a NAWI notified body examines and tests the instrument and applies the conformity assessment mark (i.e. TSO Verification) or
- a manufacturer who has in place a quality system which has been approved by a NAWI notified body as complying with the Directive gives his own EC Declaration of Type Conformity and applies the conformity assessment mark (i.e. self-verification)

Getting Quality System approval to make EC Declarations of Type Conformity
An organisation, in the EU or outside it, who is the "manufacturer" of NAWI's can apply in writing to a European Commission Notified Body that has NAWI Directive Annex II(2) approval to assess their quality management system, as complying with the Annex II paragraph 2.3 of the Directive. In the UK, these notified bodies include:

BSI Management Systems
SGS UK Ltd
NMO

The "manufacturer" must undertake to carry out the obligations arising from the approved quality system and to maintain the approved quality system to ensure its continuing suitability and effectiveness. They must make available all relevant information including the documentation of the quality system presented in a systematic and orderly manner in the form of written rules, procedures and instructions with a view to ensuring a proper understanding of the quality programmes, plans, manuals and records and the "design documentation" of the instruments.

The Notified Body will evaluate the quality system to determine whether it satisfies the requirements referred to in paragraph 2.3.2 of Annex II to the NAWI Directive. If it does, the Notified Body will grant to the "manufacturer" an approval of the quality system; which then permits the "manufacturer" to make EC Declarations of Type Conformity.

Making EC Declarations of Type Conformity
Providing the "manufacturer" adequately implements the approved quality system; carries out all the examinations and tests consistent with his obligations in the quality system and is satisfied that the instruments conform with the Type Approval Certificate and meet the requirements of the NAWI Directive, he can apply the CE marking including the green M and the identification number of the notified body that approved the quality system. If the manufacturer has appointed authorised representatives within an EU Member State then they may also carry out these functions, provided that they are operating under the manufacturers control and approved quality system. The manufacturer or his authorised representative shall draw up a written declaration of conformity detailing compliance with the NAWI Directive and any other applicable directives.

Note: the Directive uses terminology that is sometimes confusing and this is a good example:

"EC Declaration of Type Conformity" is the process whereby the approved manufacturer carries out the activities defined in his quality system, and applies the CE mark, the green M and the Notified Body number

"Declaration of Conformity" is the document that identifies the model type and declares that it complies with all the relevant identified directives.

Keeping the approval to make EC Declarations of Type Conformity
Notified Bodies that have approved the quality systems carry out what is known as EC surveillance. They periodically carry out audits in order to ensure that the manufacturer is maintaining and applying the quality system and provide the manufacturer with an audit report. They carry out visits at the places of manufacture, inspection, testing and storage. They can carry out full or partial audits, announced or unannounced. The "manufacturer" is required, in respect of each instrument, to keep available for inspection the documentation of the quality system; the design documentation of the instrument; and all related quality records. The manufacturer is also required to inform the notified body of any changes in his quality system.

Self-verifying repaired NAWI Directive Instruments
Once a NAWI Directive weighing instrument has had its first conformity assessment, i.e. EC Declaration of Type Conformity or EC Verification (see section 1.4.2) and has been put into use, it ceases to come under the full first-placed-on-the-market arrangements detailed above. If it has undergone any repair or maintenance process which has affected its metrological

integrity or accuracy it should be submitted for re-qualification. Manufacturers who have an approved quality system can also re-qualify any instruments included in the scope of their approval that have been rejected by an authorised officer and repaired, or that underwent significant repair such that they should be re-qualified before being placed back into use.

They follow the same basic process for examination and conformity assessment but finish the process by applying a re-qualification crown and alongside it the notified body number of the notified body that approved their system. Additionally they are not required to issue a declaration of conformity.

Definition of a manufacturer
Unfortunately, the scope of the legislation for EC self-verification is significantly different to that for UK national self-verification as the EC system is limited to only manufacturers, whereas the UK system included installers and repairers (and therefore the distinction is less of an issue). It will be up to the notified body that assesses the company for self-verification to determine whether it qualifies as a manufacturer for a range of instruments and hence be eligible for approval.

When a company has the design, component production and instrument assembly all completely under their direct control then it is more than likely that they will be considered a manufacturer. However, the situation has become blurred from both sides in that traditional manufacturer's contract out many services and, especially with the modular approach, an organisation may well be able to assemble an instrument from components without actually being the manufacturer.

To satisfy an assessor that they qualify as a manufacturer, the company will have to show that they have exercised control over the design of the instrument, even if they have assembled an indicator sourced from another manufacturer holding the TAC to a platform with load cells from another manufacturer holding test certificates. In any case, they will have to show that they have the full support of the component manufacturers in attaining approval for self-verification so that they can demonstrate that they will be able to keep the necessary information up to date. Other actions that will support qualification as a manufacturer include:

- labelling the instrument under the companies own name or own brand
- holding the type approval certificate or test certificate (either as the manufacturer or as a parallel approval)
- making the full CE declaration of conformity and hence taking full legal responsibility for compliance with all applicable EC directives

European Self-Verification (Declaration of conformity to type based on quality assurance of the production process under MID 2004/22/EC)
Automatic Weighing Instruments that are used for applications that come under the heading "Use for Trade", as defined in Section 7 of the Weights and Measures Act 1985, must either be type approved under Section 12 of that Act and be stamped either by a Weights and Measures Inspector or an authorised self-verifier under Section 11 of the Act; or be manufactured under a European Type Approval granted under the MID and then be initially verified either by a Notified Body or an accredited manufacturer.

The process and requirements for a manufacturer to become accredited under the MID are essentially the same as those under the NAWI Directive. The same rules relating to documentation of the Quality System, record keeping, auditing, training and so on apply. The accreditation to be a self-verifier under this Directive however does not extend to the re-verification of instruments that have been repaired following either rejection by a Trading Standards Officer or failure such that a repair was necessary that could have impacted on the metrological performance of the instrument. (See the Table "Who can verify?")

Who can verify?

	INITIAL VERIFICATION				REVERIFICATION			
	TSO	Notified Body	Manufacturer	Repairer, Installer or adjuster	TSO	Notified Body	Manufacturer	Repairer Installer or adjuster
Any Weighing Instrument Type Approved under Sec 12 of the Weights and Measures Act 1985	Yes	No, unless the Notified Body is also a Trading Standards Department in which case they act as a TSD and not as a Notified Body	Yes if he is an "authorised verifier" under Section 11A of the Weights and Measures Act 1985	Yes if he is an "authorised verifier" under Section 11A of the Weights and Measures Act 1985	Yes	No, unless the Notified Body is also a Trading Standards Department in which case they act as a TSD and not as a Notified Body	Yes if he is an "authorised verifier" under Section 11 of the Weights and Measures Act 1985	Yes if he is an "authorised verifier" under Section 11 of the Weights and Measures Act 1985
Non-automatic weighing instrument Type Approved under the NAWI Directive	No	Yes	Yes, if accredited for that purpose by a Notified Body	No	No	Yes	Yes, if accredited for initial verification by a Notified Body	No
Automatic Weighing Instrument Type Approved under the Measuring Instruments Directive	No	Yes	Yes, if accredited for that purpose by a Notified Body	No	Yes	No, unless accredited as an "authorised verifier" under Sec 11 of the Weights and Measures Act 1985	No, unless he has an accreditation as an "authorised verifier" under Sec 11 of the Weights and Measures Act 1985	No, unless he has an accreditation as an "authorised verifier" under Sec 11 of the Weights and Measures Act 1985