

Scale Manufacturers Association

® *



Conformity Assessment Program Production Meets Type

* SMA PRODUCTION MEETS TYPE DEVICE MANUFACTURER Conformance Logo and Design are a registered trademark of the Scale Manufacturers Association

MANUFACTURERS BILL OF RIGHTS

We, the manufacturers of weighing devices, reserve the right to declare a device metrologically different from that certified. As owner of the applicable Certificate we reserve the right to declare these devices no longer traceable to the certificate.



Definitions Of Terms Used In This Document And/Or Procedures

Applicant – The manufacturer of a metrological device (load cell, weighing element, indicating element, complete device) that is applying to the SMA for Production Meets Type certification.

Auditing Body – The Scale Manufacturers Association, Board of Directors.

Candidate devices – devices that the applicant is requesting be certified for production meets type.

Certified - attested by an official agency that the device evaluated meets applicable standards.

Corrective Action - Action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence.

Declaration of Conformance - a document testifying to the fulfillment of a stated requirement.

Design File – Engineering records describing the device and containing a history of device changes.

ECN/ECO – Engineering Change Notice/Engineering Change Order.

Facilities Evaluation – A review of the applicant to demonstrate that their facilities, quality system, process control, and audit program ensure that metrological devices produced perform at the same levels as when the device was type approved.

Metrological Component - a part, assembly, material, design, or procedure that has a direct influence on the performance or operation of a weighing device.

Metrological Device - a device that is designed for an installation and operation which facilitates the accuracy and validity of a measurement.

Metrological integrity of a device - is the design, features, operation, installation, or use of a device that facilitates: (1) the accuracy and validity of a measurement or transaction, and (2) conformance of the device with statutory requirements..

Model/Type - the device evaluated by an official agency and found compliant with applicable legal metrological standards.

NCWM – National Conference of Weights and Measures.

NIST – National Institute of Standards and Technology.

Objective Evidence -Design data and test data which supports that a device operates within the guidelines of its certification.

Performance - the operational characteristics of a metrological device.

Preventive Action - Action taken to eliminate the causes of a potential nonconformity, defect or other undesirable situation in order to prevent occurrence. This is done by analysis of records and other relevant sources of information for trends that may adversely affect quality.

Produced - assembled and performance validated by the device manufacturer.

Production Unit - is a device shipped directly from the manufacturer and represented as new.

Sampling Plan – A schedule of product sampling schemes for producing objective evidence that production meets type.

SMA - Scale Manufacturers Association.

Second Party Audits – audits performed by the Third Party on behalf of the SMA (including Application Review and the Facilities Evaluation).

Third Party – a person, company, organization, association other than the SMA or the original equipment manufacturer.

TABLE OF CONTENTS

| | |
|--|---|
| 1. SCOPE | 3 |
| 2. CONDITIONS OF TERMS | 3 |
| 3. SELF ADMINISTRATION | 3 |
| 4. METROLOGICALLY SIGNIFICANT COMPONENTS | 3 |
| 5. SUBSTITUTION OF METROLOGICALLY SIGNIFICANT COMPONENTS | 4 |
| 6. CONFORMANCE APPLICATION PROCEDURE | 4 |
| 7. DEMONSTRATION OF CONFORMANCE | 4 |
| 8. METHODS OF DECLARATION AND NOTIFICATION | 5 |
| 9. SMA CONFORMANCE LOGO | 5 |
| 10. RECOURSE AND CORRECTIVE ACTION PROCEDURE | 6 |
| EXHIBIT A - DECLARATION OF CONFORMANCE, SAMPLE | 7 |



1.0 Scope

- 1.1 The scope of this standard is to define the requirements of a Conformity Assessment Program (CAP) necessary to ensure that metrological devices and/or components produced perform at a level consistent with that of the device and/or component certified.

2.0 Conditions of Terms

- 2.1 Members of the Scale Manufacturers Association believe it is important to define for the entire weighing industry a procedure or set of standards that validate that production devices perform at a level consistent with that of the device certified. This validation, that production meets type, is unconditional for the first 30 days after the device is placed into service and conditional for the remainder of the first year. This validation is subject to specific criteria defined by this standard and is limited in scope or void as defined by this standard.

3.0 Self Administration

- 3.1 The Scale Manufacturers Association designed this standard to be self administrating. It is the responsibility of each manufacturer to validate his claim that production meets type. This validation must be done by:
 - 3.2 Keeping an up to date design file that defines the metrologically significant components of the device that was certified. This design file must be complete enough that each significant parameter is included. During the life of the product, when changes to the metrological significant components take place, the manufacturer is obligated to retest the product and place objective evidence in the design file to assure conformance with applicable standards.
 - 3.3 During the years of production of a given device, the manufacturer is obligated to regularly test a portion of production devices against the performance of the device certified. This objective evidence shall include the design file and the test records maintained for a period of three years after the last month of production.
 - 3.4 The manufacturer must at all times be able to produce the objective evidence to validate the process through systems audits.

4.0 Metrologically Significant Components

- 4.1 A metrologically significant component is a part, assembly, material, design or procedure that has a direct influence on the performance or operation of a device or component thereof as identified by the device manufacturer.
- 4.2 Metrological integrity is maintained by verification that the applicable characteristics of those components identified as metrologically significant are unchanged from those used in the device certified.
- 4.3 The following list contains components that may or may not be identified by the device manufacturer as metrologically significant. This list shall not be considered exhaustive and is included as examples.
 - 4.3.1 Load Cell, Analog
 - 4.3.1.1 Sensor spring element design
 - 4.3.1.2 Sensor material and heat treat
 - 4.3.1.3 Strain gauge
 - 4.3.1.4 Temperature compensating means
 - 4.3.1.5 Environment sealing design
 - 4.3.2 Load Cell, Digital
 - 4.3.2.1 Components listed in clause 4.3.1
 - 4.3.2.2 Bridge excitation voltage regulation components
 - 4.3.2.3 Temperature sensitive components used to establish gain of amplification stage or reference voltage(s)
 - 4.3.2.4 Metrologically significant embedded software
 - 4.3.2.5 Temperature sensing component
 - 4.3.2.6 Analog to Digital converter type
 - 4.3.3 Load Receiving Element, Mechanical
 - 4.3.3.1 Suspension type
 - 4.3.3.2 Restraint system
 - 4.3.3.3 Bearing design
 - 4.3.3.4 Weighbridge construction
 - 4.3.4 Load Receiving Element, Electronic
 - 4.3.4.1 Components listed in clause 4.3.3
 - 4.3.4.2 Load cell type
 - 4.3.4.3 Load application to load cell
 - 4.3.5 Indicating Element, Mechanical
 - 4.3.5.1 Beam notch geometry and location

- 4.3.5.2 Fulcrum design
- 4.3.5.3 Temperature compensated springs
- 4.3.5.4 Spring constants
- 4.3.5.5 Bearing design
- 4.3.6 Indicating Element, Electronic
 - 4.3.6.1 Excitation voltage regulation components
 - 4.3.6.2 Temperature sensing elements
 - 4.3.6.3 Metrologically significant embedded software
 - 4.3.6.4 Reference voltage components
 - 4.3.6.5 Analog to Digital converter
 - 4.3.6.6 Temperature sensitive components in amplification stage used to establish gain or offset
 - 4.3.6.7 Active filter components
 - 4.3.6.8 Some clock components

5.0 Substitution of Metrologically Significant Components

- 5.1 It may become necessary over the production life of a device that components used in the production device need to be substituted for certification. When making such substitutions, the following requirements shall be met to ensure that production meets type.
- 5.2 If the component is of metrological significance, an engineering evaluation is made to determine the effect that the component will have on the performance of the device.
- 5.3 If there is a potential for adversely affecting the metrological performance of the device, then an engineering test shall be performed to validate or reject the replacement component.
- 5.4 Upon completion of engineering and testing, the design file shall be updated.

6.0 Conformance Application Procedure

- 6.1 Conformance Application Submittal
 - 6.1.1 Complete the application form and sent with non-refundable application fee to SMA for processing.
 - 6.1.2 The application fee covers the review and processing of the application by the SMA Auditing Body.
 - 6.1.3 Upon review the Auditing Body may

request further documentation be submitted at the expense of the applicant.

- 6.1.4 On approval of the application documents the initial audit will be scheduled with the applicant. The cost of the initial audit and all subsequent audits are the responsibility of the applicant.

6.2 Initial Audit

- 6.2.1 All applicants prior to final accreditation will require an audit.
- 6.2.2 The manufacturer will grant the Auditing Body access for inspection and all necessary information required to perform its duties.

- 6.2.2.1 Quality system documentation

- 6.2.2.2 Manufacturing processes

- 6.2.2.3 Testing Equipment

- a. For accuracy

- b. For calibration

- c. For applicable influence factors

- 6.2.2.4 If deficiencies are discovered Corrective and Preventive Action will be required.

- 6.2.3 100% of production sample must meet type after approved Corrective and Preventive Action is implemented.

6.3 Subsequent Audits

- 6.3.1 All accredited manufacturers shall be audited at a minimum of once every five years.

- 6.3.2 Special audits may be requested by the Auditing Body.

- 6.3.2.1 For procedural violations discovered by the auditing body. (The manufacturer will be given reasonable amount of time to correct the deficiency.)

- 6.3.2.2 As a result of formal complaints.

7.0 Demonstration of Conformance

- 7.1 The auditing body shall consider conformance to this standard when the requirements of the underlying procedures are met.

- 7.2 Quality handbook

- 7.2.1 The quality process which guarantees

the correctness of the declaration of conformance shall be described in the quality handbook of the manufacturer who declares conformance. The minimum information shall include the process, procedures, test methods and results and the pre-determined percentage of tested patterns. If tests are carried out in a modified manner other than that required by respective certificates and standards the conformance with the required procedure has to be proven.

7.3 Test data

7.3.1 Test results corresponding to the serial number of the tested pattern shall be maintained and available for a least three years following the last month of production.

8.0 Methods of Declaration and Notification

8.1 In general there are different parties involved in the quality process, which are the manufacturer of the device, the user and the SMA or its authorized agent. A minimum of methods of declaring and notifying follows:

8.2 Method of declaration to user of conformance to this standard:

8.2.1 SMA conformance logo

8.2.1.1 The SMA conformance logo shall be fixed on the device and/or associated documentation.

8.2.2 Year of declaration of conformance:

8.2.2.1 Together with the SMA conformance logo the device must bear the year of production. The declaration of conformance refers to the valid standard of that year.

8.2.3 Declaration of conformance

8.2.3.1 Different type certifications exist and may apply to the device. It is up to the manufacturer to declare the conformance to one or more of these type certifications by using the SMA conformance logo. To identify which these are and to take official responsibility for the correctness of this information a written declaration of conformance has to be issued either in the official

manual of the device or in form of an added sheet of paper. The declaration has to include the following information as a minimum:

- a. name or trademark of the manufacturer who declares conformance
- b. model and/or type of device
- c. list of applicable type certifications and the certificate number
- d. date of declaration

8.2.3.2 Refer to exhibit A for an example of this document.

9.0 SMA Conformance Logo

9.1 The SMA Conformance Logo may be applied to applicable devices or accompanying documentation to serve as indication that the device manufacturer has complied with the terms and conditions of this standard. The logo shall be applied to the device in a location that does not interfere with its operation.

9.2 The logo shall be a maximum of 51 mm (2 inches) in diameter and shall be green Pantone 348U in color with black printing on printed material. Text font shall be Arial. Smaller labels are acceptable provided they maintain the same format and are legible. Black & white and shades of gray are acceptable for other applications.

9.3 The logo shall include the following information:

- 9.3.1 The Scale Manufacturers Association logo
- 9.3.2 "Product Meets Type"
- 9.3.3 "Device Manufacturer"

9.4 The logo shall appear in the format shown below:



Figure 1 - SMA Conformance Logo

* SMA PRODUCTION MEETS TYPE DEVICE MANUFACTURER Conformance Logo and Design are a registered trademark of the Scale Manufacturers Association

10.0 Recourse and Corrective Action Procedure

10.1 SMA

10.1.1 The SMA as the creator and owner of this standard, its requirements, and the SMA Conformance Logo has the right to recourse for its improper use. Recourse action may only be initiated by the Auditing Body.

10.1.2 Examples of improper use of the information contained in this standard are listed below. This list is only an example and is not intended or implied to be a complete list:

10.1.2.2 Use of the SMA Conformance Logo for a device which is known to not meet all requirements of this standard.

10.1.2.3 Intentionally provide false test data or corrective action information for the purpose of continued use of the SMA Conformance Logo.

10.1.3 In the event that the Auditing Body learns of improper use of this information or its logo the SMA shall immediately inform the manufacturer, in writing, of the improper use. The Auditing Body may take additional actions as deemed necessary.

10.2 Manufacturer

10.2.1 In the event a manufacturer determines an error has occurred in a device(s) placed in service of a nature which questions the conformance of the device(s) to the standard, the manufacturer shall immediately inform the SMA in writing as to the nature of the non-conformance and the corrective action taken.

10.2.2 The report of non-conformance must include:

10.2.2.1 the number of units effected,

10.2.2.2 the model designation effected,

10.2.2.3 the error, and

10.2.2.4 the corrective and preventive action taken or a request to SMA for conformance assistance

10.2.3 It is required that the manufacturer have a corrective action procedure as part of their quality manual. This procedure should include the following

information. (A copy of this procedure may be requested for review.)

10.2.3.1 Definition of procedure

10.2.3.2 Who can take corrective actions

10.2.3.3 What constitutes non-conformance

10.2.3.4 References to any forms and information required to complete the form

10.2.3.5 Define the error or failure

10.2.3.6 Corrective and preventive actions taken or required

10.2.3.7 Closure and reporting of final actions

10.3 Third Party

10.3.1 In the event a third party determines an error has occurred in device(s) placed in service of a nature which questions the conformance of the device(s) to the standard, the third party shall immediately inform the SMA of the suspected non-conformance.

10.3.2 The report of non-conformance must include:

10.3.2.1 the number of units believed effected,

10.3.2.2 the model designation and serial number(s) suspected,

10.3.2.3 the location of the suspected unit(s), and

10.3.2.4 the suspected error

10.3.3 Once informed, the SMA will take the necessary actions to inform the Board of Directors and the manufacturer of the reported non-conformance. All efforts will be taken to maintain the confidentiality of the third party.

10.3.4 The manufacturer will be responsible to report back to the Auditing Body all findings regarding this suspected non-conformance. It will then determine the need for additional action, if necessary.

10.3.5 The SMA will inform the third party of any corrective actions taken by the manufacturer or of actions recommended by the Auditing Body.

10.3.6 If excessive Correction Action Reports are filed further testing may be requested at an approved Testing Laboratory.

EXHIBIT A - Declaration of Conformance, sample

Name of manufacturer

**Declaration of Conformance to SMA Standard
Year of Declaration XXXX
Production Meets Type**



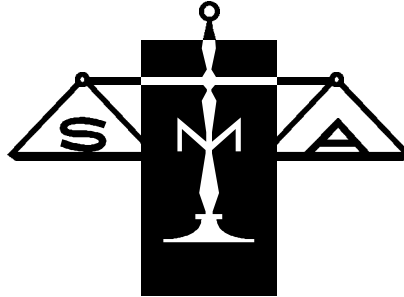
We the manufacturer of

| Model | Type | Certificate and Number | Issued by |
|--------------|-------------|-------------------------------|------------------|
| XXXX | YYY | NTEP CC 99-999 | NIST |
| | | | |
| | | | |

Declare in our responsibility the conformance of the above listed models and types to the mentioned certificates and the requirements of the SMA standard.

This declaration becomes valid when the SMA Conformance Logo, having our name or trademark is applied to the device or its accompanying documentation.

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