



## **OIML Seminar on Conformity to Type (CTT)**

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**Mechanisms in place in various countries to ensure that  
measuring instruments comply with the approved type**

(texts provided by the countries)

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## Japan

In Japan, there is a "Verification System" by an official body such as a national or prefectural authority in which the verification mark is fixed when a product passes the examination of structure and instrumental error. In addition, another verification system called "Designated Manufacturer System" went into effect when Measurement Law was revised in 1993. In this system, the Minister of Ministry of Economy, Trade and Industry (METI) designates a manufacturer that has a certain level of quality control. The designated manufacturer is allowed to perform the initial inspection of their products and to fix an inspection (verification) mark that indicates conformity to the metrological requirements.

This system aims to exempt the manufacturer with a certain level of quality control from initial verification by the national/prefectural authority. The manufacturer is designated through a rigorous and comprehensive examination of quality control system. The requirements imposed on the manufacturer in the examination are specified based on the Measurement Law. These requirements are actually compatible with those specified by the ISO 9000. In addition, periodical annual examinations are conducted in order to continuously monitor the competence of the designated manufacturer.

The manufacturers in Japan maintain conformity of their products to the requirement under the Measurement Law through such a severe quality control system. Therefore, quality and conformity to type for all specified measuring instruments produced in Japan are secured enough by "Verification System" and "Designated Manufacturer System."

Specified measuring instruments produced in foreign countries also need to be verified. In addition, the Measurement Law in Japan allows oversea manufacturers to be designated and to fix the "verification mark." At present, twenty-six (26) factories in six (6) countries have been authorized by the government (METI) as the designated manufacturers.

Therefore, we have a strong concern that establishment of a new system of conformity to type may lead to imposing an additional cost and duties on national/ prefectural metrological authorities and the manufacturers.

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## Kenya

Kenya has in place a mechanism for this programme. It starts from type approval . It is by law established that all weighing and measuring equipment intended for trade use in the country must be of the approved type or if not yet approved they must undergo type approval before being put to trade use.

All type approvals are done at the Weights and Measures Departmental headquarters. Conformity to type tests (otherwise known as initial verification) are undertaken by the regional offices around the country. These tests are undertaken on the basis of open directives from the Headquarters which include the database and essential tests for each equipment. Therefore all equipment intended for approval are submitted to the office of Director, at the Weights and Measures Headquarters. Equipment of the type approved models are submitted at any regional office for purposes of undertaking conformity to type tests.

In this respect, the responsible organization has in place surveillance programs to ensure compliance in this area. The regional offices personnel frequently carry out inspection visits to industries and trade premises to ensure compliance.

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## The Netherlands

In the Netherlands, legal metrology is restricted to those areas of use of measuring instruments where it is expected that there is a substantial risk that the free market mechanism provides insufficient protection against unfair transactions and trade..

The concept of this framework is:

1. To only implement those areas of use for which regulation by legislation is considered absolutely necessary,
2. Keep the costs of administrative burden low,
3. Harmonize the existing regimes as much as possible,
4. Regulate on a high level of abstraction,
5. Strict separation of tasks between bodies designated for certification (NB's) and market surveillance bodies.

Where possible and/or desirable and where a sufficient level of competence and degree of organization is available, self-regulation under strict conditions is accepted and promoted.

This conceptual framework has been implemented in the Dutch law on Metrology which contains separate chapters comprising:

- ▲ Those transactions employing measurements for which legal requirements apply,
- ▲ Conformity assessment,
- ▲ The placing on the market and use of measurement devices and sanctions in case of offence,
- ▲ Surveillance and inspection.

Concerning conformity assessment the applicable European directives have been implemented. For certain instruments covered by MID, but of which their use is outside the measurement areas covered by NL legislation the enforcement still is applicable in case those measuring instruments are marked to state compliance with the MID requirements.

Further additional national regulation is in place for those types of instruments not covered by European directives but included in the scope of the legally regulated areas of use.

The national law also covers the requirements of enforcement with respect to the EU regulation for market surveillance.

The certification of measuring instruments on basis of performance of conformity assessment is executed by nominated private organizations, which have been notified to EU and other member states.

Surveillance is performed by a nominated authority. Execution of the surveillance task of which is 100 % covered by the government resources based on a multi-annual contract. The surveillance activity comprises in principle a random unannounced inspection on metrological aspects but taking into account a risk analysis on the kind of measuring instrument. The inspections include tests on compliance to the applicable accuracy requirements. In general all measuring instruments will pass in review in an about 4-year period. The contractor (government) requires annual reports on instruments inspected and detected abnormalities. Databases cover all individual measurement devices in use under legal metrology control.

Subsequent verification on a regular basis is in general not applied in NL. Only for taximeters this system of verification is implemented and for the other measurement instruments within legal control a subsequent verification is mandatory only after a repair whereby the seal has been broken. Organizations certified by a notified conformity assessment body are allowed to perform such verifications.

Concerning utility metering the legal metrological control is performed on a statistical basis and executed by the utility metering branch organization. The previous mentioned nominated surveillance body evaluates the statistical approach and reports to the Ministry on this approach and the results of the execution of this metrological control. Where necessary batches of instruments may be rejected on basis of these reports and are exchanged.

Since the certification of measuring instruments within the framework of legal metrological control is performed by nominated private organizations the approval and evaluation reports need to become available to the surveillance body in order to verify the metrological requirements. Hence this information is stored in a protected database maintained by the surveillance body on behave of the government.

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## Poland

In Poland our law regulation controls measuring instruments which are used in following areas: in protection of health, life and environment; in protection of safety and law and order; in protection of consumers' rights; in collecting fees, taxes and non-tax budget dues as well as in establishing discounts, penalties, remuneration and compensations, and in charging and establishing dues and services alike; in customs control; in trade.

Forms of legal metrological control in Poland are:

- ⤴ Type Approval - carried out by GUM only;
- ⤴ Initial Verification - carried out by Regional Verification Offices, Local Verification Offices or authorized third-party companies (certain kinds of measuring instruments only);
- ⤴ Subsequent Verification - carried out by Regional Verification Offices, Local Verification Offices or authorized third-party companies (certain kinds of measuring instruments only).

In general legal metrological control in Poland consists of three steps: type approval, initial verification and subsequent verification. Measuring instruments subject to all three steps are listed in annex 1.

Mechanism used in Poland to ensure that measuring instruments comply with the approved type is the initial verification required before placing the instrument on the market.

According to the Law on measures (art. 8m) during initial verification there are following checks:

- ⤴ verification of compliance with approved type (construction, materials, metrological characteristics),
- ⤴ verification of markings and symbols,
- ⤴ verification of compliance with technical documentation if apply.
- ⤴ After certain of time period defined in legal regulations subsequent verification is being conducted.

During subsequent verification there are following checks:

- ⤴ verification if markings are present, verification if the instrument is not broken,
- ⤴ verification of metrological characteristics (MPE etc. ).

Subsequent verification has its period of validity defined in law for every category of instrument. Subsequent verification can be every year like for some measuring instruments for liquids, every two or three years like for weighing instruments, every five or even ten years like for heat or gas meters. As a result of subsequent verification in case of positive result of inspection (for example testing whether measuring errors are within MPE prescribed in technical regulations) inspector leaves mark (sticker) or paper document (certificate) showing that instrument was positively verified.

Result of verification allows to use the instrument for next period.

Metrological surveillance plays also an important role as a mechanism used to ensure that measuring instrument complies with the approved type.

On the territory of Poland we have Metrological Surveillance inspectors that check some percent of measuring instruments in:

- ⤴ shops and other places where products are sold for customers and price is given as a result of measurement,

- ▲ filling stations,
- ▲ taxis,
- ▲ drugstores/pharmacies,
- ▲ other areas under legal metrological control.

Every year Bureau of Metrological Surveillance publishes the report showing how many instruments were checked, the percentage of good instruments, how many tickets were given, how many shops, pharmacies and other points were controlled.

Apart from this there is also market surveillance inspection, in Poland it is not metrological authority, but they can control points of sale, shops and producers, and they also check if measuring instruments have a proof of verification. If necessary, market surveillance inspection contacts metrological surveillance.

Comparing legal metrological control in Poland to the legal metrological control systems presented in OIML D16 "Principles of assurance of metrological control" we can evaluate the Polish system to be at the market stage highly restrictive with an element of balanced system (initial verification in some cases can be performed by authorized manufacturer).

## Annex 1

Measuring instrument subject to type approval, initial verification and subsequent verification

1. Fixed storage tanks;
2. Instruments for measuring the speed of vehicles in traffic (radar, laser, control speedometers);
3. Weighbridges for weighing road vehicles in motion;
4. Road measuring tankers;
5. Tyre pressure gauges for motor vehicles;
6. instrument for measuring the standard mass per storage volume of grain: standard 20 L, usable 20 L, 1 L i ¼ L.

Measuring instrument subject to type approval and initial verification

1. Metal barrels;
2. Glass hydrometers - alcoholmeters and alcohol hydrometers.

## Serbia

Currently in the Republic of Serbia there is no specific (national) program or system that addresses the issue of conformity to type. To be precise, in our country two mechanisms are deployed, i.e. type approval and verification of measuring instruments used for purposes under legal control. Verification of an individual measuring instrument is mainly performed if the type of the measuring instrument has been examined and a type approval certificate issued.

Verification of individual measuring instruments together with the supervision of measuring instruments brought about detection of non-conforming measuring instruments. This resulted in withdrawal of issued type approval certificate, about which it was reported in the relevant OIML enquiry some years ago.

In order to ensure that measuring instruments comply with the approved type some ways of analysis of production of measuring instruments or examination of quality system applied in such a production has been considered with intention to prevent non-conforming measuring instruments to be produced.

As Republic of Serbia is the country in transition that signed SAA with the European Union we are in process of harmonizing our legislation in field of metrology with the EU legislation. Consequently we are committed and we are making great efforts to adopt the mechanisms that are in place in EU to ensure that measuring instruments comply with the approved type or that addresses the issue of conformity to type.

## United Kingdom

Conformity to Type (CTT) is established in the UK through the implementation of the two EC metrology Directives; the Non-automatic Weighing Instruments Directive (2009/23/EC) and the Measuring Instruments Directive (2004/22/EC).

The two EC Directives provide a number of commonly used conformity assessment procedures to ensure that measuring instruments comply with the approved type and the Directive. Other conformity assessment procedures are also available in the MID that establish conformity with the requirements of the Directive without the requirement to first conduct a type approval (these are not described below).

### NAWI

There are two conformity assessment procedures in the NAWI Directive relating to CTT; EC verification and EC declaration of type conformity (guarantee of production control).

EC verification is the procedure whereby the manufacturer ensures and declares that the instruments, which are checked (tested and examined) by a Notified Body, are in conformity with the type described in the EC type-examination certificate and that they satisfy the requirements of the Directive. The manufacturer shall take all necessary measures in order that the manufacturing process ensures conformity of the instruments.

EC declaration of type conformity (guarantee of production quality) is the procedure whereby the manufacturer, who has adequately implemented a quality system, declares that the instruments concerned are in conformity with the type as described in the EC type-approval certificate and that they satisfy the requirements of the Directive. A Notified Body shall examine and evaluate the quality system to determine whether it ensures conformity of the instruments with the type as described in the EC type-approval certificate and with the requirements of the Directive. All the elements, requirements and provisions adopted by

the manufacturer shall be documented in a systematic and orderly manner in the form of written rules, procedures and instructions (covering the manufacturing process, quality control and assurance techniques, examinations and tests, etc.).

## **MID**

The conformity assessment procedures in the MID relating to CTT are:

- △ Annex D – Declaration of Conformity to Type based on Quality Assurance of the Production Process
- △ Annex E – Declaration of Conformity to Type based on Quality Assurance of Final Product Inspection and Testing
- △ Annex F – Declaration of Conformity to Type based on Product Verification

Annex B is the applicable conformity assessment procedure for EC type-examination, so the conformity assessment procedures are usually denoted as B + D, B + E and B + F.

In terms of the procedures, Annex D is broadly equivalent to the EC declaration of type conformity (guarantee of production quality) and Annex F is broadly equivalent to the EC verification as described above for NAWIs. Annex E also utilises the concept of an approved quality system, except for Annex E the quality system relates to final product inspection and testing (instead of the production process) and is typically only used for (electro-)mechanical or 'simple' measuring instruments, e.g. capacity serving measures.

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