ČESKÝ METROLOGICKÝ INSTITUT

Czech Metrology Institute
Notified Body no. 1383
Okružní 31, 638 00 Brno, CR

Information as regards:

Transition of conformity assessment under the EU Directives 2004/22/EC and 2009/23/EC to the new Directives 2014/32/EU (MID) and 2014/31/EU (NAWID)

module D, D1

Based on consultations with the European Commission DG Grow and national notifying authority CMI, as Notified Pointy no. 1383 (further referred to as CMI NB) for the above mentioned directives, has adopted the following principles of a unified and correct approach to the transition of conformity assessment under current directives 2004/22/EC and 2009/23/EC to the new ones 2014/32/EU (MID) and 2014/31/EU (NAWID) concerning the EU type examination which was published as an information leaflet signed by General Director on February 23rd , 2016. In the framework of procedures to put measuring instruments on the market module B is often followed by a declaration of conformity with approved type on the basis of quality assurance of the production process (module D). For manufacturers whose quality system for production, final product inspection and testing has been certified by NB CMI this NB herewith adopts principles, specified below, of the approach to the transition to directives 2014/32/EU and 2014/31/EU. These principles are to be applied to module D1 as appropriate. (Where appropriate, the corresponding provisions of the directives as an original source of the information are given in square brackets).

1) Certification activities of NB CMI not finished by April 19th, 2016 at the latest will be reviewed and finalized in accordance with directive 2014/31/EU, resp. 2014/32/EU, inclusive provisions of the harmonized standard EN 45501:2015 for NAWID.

   [MID art. 51 point 1, art. 52, art. 50; NAWID art. 44 point 1, art. 45, art. 43, art. 12, art. 6 point 4, art. 3 point 1]

2) Starting on April 20th, 2016 measuring instruments being made available on the market have to be in compliance with the requirements of directives 2014/31/EU, resp. 2014/32/EU. When making measuring instruments available on the market any time after April 19th, 2016, whether in reality or as given in the documentation, manufacturers and importers should follow the new directives.

   [MID art. 51 point 1, art. 52, art. 50, art. 19 point 2; NAWID art. 44 point 1, art. 45, art. 43, art. 3 point 1, art. 14 point 2]

3) Since April 20th, 2016 supply (distribution) and putting on the market and into use of measuring instruments compliant with the old directives (2009/23/ES a 2004/22/ES) is permitted provided that they have been put on the market before April 20th, 2016 (so that there is, at least, documentary evidence that they have been delivered from the manufacturer or importer to another subject = to a distributor or a user).

   [MID art. 50, art. 4 point 5 and 6, art. 51 point 1, art. 52, point 61 preambule; NAWID art. 43, art. 2 point 3 and 4, art. 3 point 1, art. 44 point 1, art. 45, point 46 preambule]

4) Certificates of quality system for production, final product inspection and testing (module D) having been issued under current directives remain valid until their expiry, even after April 20th, 2016. However, the transition of declaration of conformity to a new directive will require an implementation of the corresponding changes (inclusive new elements in the quality management system) as follows:

- implementation of the provision of a continuous review of changes in instrument design or characteristics and of changes in the harmonised standards or in other technical specifications by reference to which conformity of an instrument is made and taking measures for the production to remain in conformity with the directive;

  [MID art. 8 point 4, art. 7 point 2; NAWID art. 6 point 4, art. 3 point 2 and 3]

- implementation of the provision to identify economic operators to whom they have supplied a measuring instrument and who have supplied them with a measuring instrument and to store this information for the period of 10 years since the delivery of those instruments (if such practice has not already been in place before April 20th, 2016);

  [MID art. 13, art. 51 point 1, art. 52, art. 50; NAWID art. 11, art. 44 point 1, art. 45]

- a response to changes regarding the marking of measuring instruments under both MID and NAWID – indication of their name, registered trade name or registered trade mark and the postal address at which they can be contacted, a change in the supplementary metrology marking in NAWID;

  [MID art. 8 point 6, art. 10 point 3, art. 51 point 1, art. 52, art. 50; NAWID art. 6 point 6, art. 8 point 3, art. 44 point 1, art. 45, art. 3 point 1]

- changing the EU Declaration of conformity, both in relation to the directives 2014/31/EU, resp. 2014/32/EU, resp. in relation to national transposition legal documents and in a structure given by the mandatory template in the corresponding directive;

  [MID art. 19 point 2, art. 51 point 1, art. 52, art. 50; NAWID art. 14 point 2, art. 44 point 1, art. 45, art. 43, art. 3 point 1]

- in cooperation with NB CMI to reflect the changes having been made in corresponding EU type examination certificates (module B) to module D certificates (not applicable to D1).

  [MID art. 3.2 for module D Annex II, art. 51 point 1; NAWID art. 2.3.2 Annex II, art. 44 point 1]

5) To achieve a continuous validity of the certificates of quality system for production, final product inspection and testing having been issued under the current directives even after the date of April 20th, 2016 manufacturers have the following options:

A) <u>A manufacturer whose intention is to legalize a transition of his quality management system without any delay</u>

This manufacturer would send to NB CMI a written application for a legalization of the transition of his quality management system to the directives 2014/31/EU, resp. 2014/32/EU together with:

- a declaration that the quality management system has been modified to be in line with the directive 2014/31/EU, resp. 2014/32/EU and
- a description of changes in the quality management system which have been made to achieve this goal;

NB CMI would review this documentation and if the result of the review is positive the NB would issue a revised certificate for a fee of 114 EUR (the period of validity of the original certificate would remain the same). NB CMI would then check the correct and full implementation of the changes in the quality management system on spot during the next audit.

B) A manufacturer who would leave the legalization of the transition of his quality management system to the next audit to be made by NB CMI

NB CMI would review, during the next (usually planned) audit, among others the implementation of the changes in the quality management system resulted from the transition to the directive 2014/31/EU, resp. 2014/32/EU. Following this audit NB CMI would issue a revision of the certificate of quality system for production, final product inspection and testing.

[MID art. 8 point 4, art. 3.2 for module D Annex II ; NAWID art. 6 point 4, art. 2.3.2 Annex II]

In Brno on February 24th, 2016

Pavel Klenovský

General Director and Head of NB CMI