Annex 4

CLINICAL THERMOMETER EXAMPLE

This example is intended to illustrate how metrological control for clinical thermometers can be assessed, not to recommend legal requirements for them. In some countries, voluntary standards (norms) with which all thermometer manufacturers comply and a general policy of users to buy only thermometers guaranteed by the manufacturer to comply with these standards may reduce the need for legal controls. Let us consider controls on liquid-in-glass clinical thermometers and/or on their use. Their accuracy is almost entirely determined by their quality at the time of manufacture and, provided the liquid column has not separated and the glass is not broken, their accuracy does not generally deteriorate. When thermometers have been checked at the factory and are used in hospitals only by trained nurses or technicians, the probability of incorrect measurements due to operator error, environmental conditions, etc., is low and one can dispense with initial and subsequent verification. In such cases, one usually does not impose legal metrology requirements on operator training or environmental requirements. It is more usual to control liquid-in-glass thermometers by pattern evaluation following the OIML Recommendation No. 7 and/or by either 100 % verification or lot sampling at the factory (R 7 does not specify what constitutes adequate assurance of metrological control based on pattern evaluation, lot sampling, and testing according to R 7) without any subsequent verification. If officials are satisfied with a manufacturer's quality assurance, their verification may be limited to periodically witnessing lot sampling and testing at the factory (quality surveillance). It is inefficient and unnecessary for the officials to duplicate the manufacturer's quality assurance if it continues to be adequate.

Legal metrology officials and thermometer manufacturers should ensure temperature measurement accuracy by monitoring the errors of the temperature measurement process used to evaluate the liquid-in-glass thermometers. Regular measurements on stable control thermometers and the keeping of control charts can provide information on the process precision. Calibrations of standard thermometers by a higher level laboratory and interlaboratory comparisons with other laboratories involved in temperature measurements at comparable levels of accuracy can provide information on systematic errors.

When, for example, the maximum permissible error for thermometers is + 0.1 °C, - 0.15°C, as recommended in R 7, the uncertainty of the temperature measurement process used to test these thermometers should be quantified and shown to be much less than 0.1 °C. If R 7 is chosen as the basis for thermometer pattern evaluation and for factory qualification, and this is supplemented with production lot sampling, a

valid procedure for production lot sampling is still necessary even if a submitted pattern meets all the requirements[*]. Legal metrology officials should also be concerned with whether rejected thermometers are destroyed, remanufactured or repaired, or relabelled and sold for less demanding applications. In any case, it should be ensured that, following the tests, complying thermometers are not confused with non-complying thermometers. If marks are affixed to those that comply, immediately following the tests, this should not be a problem. Also, one should ensure that unscrupulous manufacturers do not include rejected thermometers in lots later submitted for testing, in the hope that the sampling process will miss them.

The situation changes when one considers electronic, digital readout clinical thermometers. Subsequent verification is generally not needed for liquid-in-glass thermometers as already mentioned because of their stable properties, but should be considered for electronic devices whose performance may change as components age or fail. This is particularly true for a new technology for which pattern evaluation may not adequately assess all relevant factors.

In one instance, a hospital purchased a large number of electronic thermometers that had performed accurately and reliably in laboratory tests but which, when placed in service, frequently produced erroneous readings. The problem was traced to the electromagnetic fields of a nearby radio station (see also Annex 8). This suggests that, to achieve assurance of metrological control for electronic devices, control techniques should take electromagnetic interference (EMI) into account. Legal requirements could specify the ability of the instrument to reject EMI. One could then evaluate instrument patterns for susceptibility to EMI and other environmental variables. Another approach is to control the environment of device use by prohibiting device use in locations where EMI exceeds a specified threshold. But because most hospitals have no capability for measuring or controlling EMI levels, this is impractical. Because electronic thermometers may also be sensitive to other environmental conditions (ambient temperature, etc.) their subsequent verification, where required, should be performed under realistic conditions of use, for example, by checking them at regular intervals at the user location (for example, hospital, clinic, or doctor's office) against calibrated standards (for example, liquid-in-glass thermometers). Placing requirements on the user, rather than relying only on official inspections, conserves the resources of the legal metrology service.

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[*] Examples of standards providing guidance on lot sampling are:

- ISO 2859 « Sampling procedure and tables for inspection by attributes » (see also ISO Guide 3319).
- United States - ANSI Standards Z1.4 and Military Standard 105D.