Guidance and examples for monitoring periods of testing equipment for laboratories in the fields of consumer protection, agricultural sector, chemistry and environment, veterinary medicine and pharmaceutics

71 SD 4 027_e | Revision: 1.2 | 25 October 2017

Scope of application:

This document is intended for laboratories in the fields of consumer protection, agricultural sector, chemistry and environment, veterinary medicine and pharmaceutics. It contains guidance and examples for an implemented program for inspection and functional checks of testing equipment of laboratories as required by DIN EN ISO/IEC 17025. The indicated periods (intervals) are based on experience and shall therefore be treated as a recommendation.

Date of confirmation by the advisory accreditation board: 10/06/2017

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The document 71 SD 4 027 of revision 1.1, confirmed on 02/08/2014, was fundamentally revised. Due to the extensive changes and to preserve readability, highlighting the changes was forgone.

1 Purpose

In testing laboratories in the above fields, measurement uncertainty is usually established by means of the overall procedure. In light of the proportion of the measurement uncertainty resulting from calibration with regard to a relevant measured variable, it may usually be assumed that it does not make a significant contribution to the overall measurement uncertainty, e.g.
for mass and temperature. In this case, proof of feedback does not have to be provided (DIN EN ISO/IEC 17025, ILAC P 10). This means that it is not necessary to apply calibration procedures (as defined in 71 SD 0 005) for functional checks of testing equipment.

Usually, measurement standards are used for functional checks. A working standard (most significant representation of the SI device in the testing laboratory) must have proof of metrological feedback (feedback certificate) complying with the requirements of the regulation 71 SD 0 005. The laboratory may define/deduce additional working standards for a measured variable if applicable by aligning them with the working standard having a feedback certificate (without using a calibration procedure). It uses working standards to check the testing equipment. Figure 1 illustrates the procedure.

If the contribution of calibration to the overall measuring certainty is not negligible in an exceptional case, rule 71 SD 0 005 may be applied beyond the working standard. In such cases, calibration procedures must be used for the functional checks.

The decision about intervals established on obtaining feedback certificates of working standards is the laboratories' responsibility and is not addressed in this guidance document. Likewise, the inspections of testing equipment before its initial use required by DIN EN ISO/IEC 17025 are not addressed hereunder.

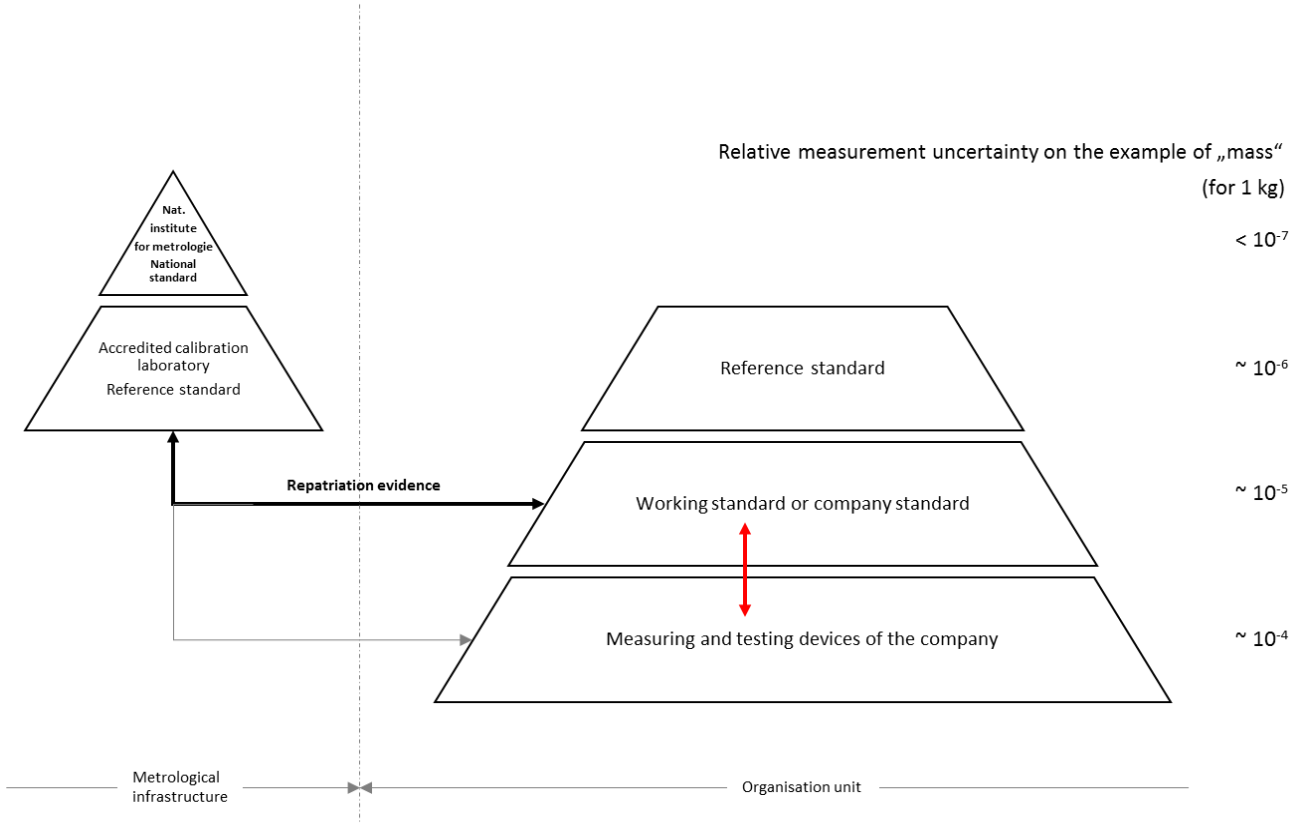

Figure 1 Calibration hierarchy (71 SD 0 006; according to VIM 2012)

If reference materials are used, designation of their measurement uncertainty is of vital importance. This contribution may not be disregarded in the overall measurement uncertainty. Wherever possible, laboratories should use certified reference materials by competent manufacturers.

DIN EN ISO/IEC 17025 requires that the laboratory must have an implemented and documented program for the inspection/functional check of its devices. Such program must describe

- the respective procedure,
- tolerances and
- the frequency of inspections/functional checks

These procedures must provide unambiguous specifications for the case in which the checked device shows results outside of the tolerance limit.

The following table contains examples for measures and frequencies which might be included in such program. They are not exhaustive and do not include all requirements for monitoring of testing equipment possibly set down in standards or equivalent documents (e.g. AQM data sheets; VDI). If the field of activity of the laboratory calls for further/additional requirements, it shall comply with

such requirements (e.g. requirements of GLP or GMP for examinations of medications or pharmaceutically active substances). The frequencies (periods, intervals) quoted in this guidance document are based on experience. The frequencies to be determined by the laboratory vary depending on the frequency of use, usage provisions, setup characteristics, etc. **The laboratory bears the sole responsibility for such determination.**

Before start-up of any equipment first used in the laboratory, an appropriate initial inspection must be performed.

2 Terms

Measurement standard	Realisation of a definition of a dimension, with a stated quantity valued and associated measurement uncertainty, used as a reference (International Vocabulary of Metrology, VIM 2012, 5.1)
Reference standard	Measurement standard for calibration of other measurement standards for a kind of quantity in an organisation or a location (VIM 2012, 5.6)
Working standard	Measurement standard used routinely to calibrate or verify measuring devices or measuring systems (VIM 2012, 5.7)
Reference material	Material, sufficiently homogeneous and stable with respect to one or more specific properties, which has been established to be fit for its intended use in a measurement process (DIN EN ISO 17034:2017)
Certified reference material	Reference material characterised by a metrological valid procedure for one or more specified properties, accompanied by a reference material certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability (DIN EN ISO 17034:2017)
Reference	Material, substance, item or micro-organism with known attributes which is checked for fulfilment of a requirement on testing equipment as defined in this document

3 Description

No.	To be examined	Type of device/item	Measures	Recommended period
1.a	**Mass**	**Scales**	Loading a working standard with a known and unchanging mass Check-up with higher-value working standard in various weighing ranges, alternatively: Maintenance by the manufacturer or service provider	On each day of use Annually
1.b	**Mass**	**Test weights (working standards: Unit weights, suitable weights)**	Comparison with a suitable working standard	Annually
1.c	**Mass or volume**	**Air displacement pipettes digital burettes dispensers; dilutors**	Gravimetric check	Semi-annually
1.d	**Mass or volume**	**Automatic pipettes including automatic micro-titer plate pipettes**	Check-up by the manufacturer or service provider or according to the manufacturer's instructions	Semi-annually

No.	To be examined	Type of device/item	Measures	Recommended period
2.a	**Temperature**	**Thermometers (liquid glass thermometers incl. min/max, electronic thermometers, temperature loggers, temperature sensors, display thermometers)**	Check-up by comparison with a suitable working standard	2 years
2.b	**Temperature**	**Drying cabinets heating cabinets water quenches with thermometers**	Actual temperature/temperature control	On each day of use
2.c	**Temperature**	**Refrigerators/refrigeration rooms Deep-freeze cabinets/rooms; ultralow freezers**	Actual temperature/temperature control	On each day of use or weekly
2.d	**Temperature and moisture**	**Air-conditioned rooms/chambers Emission testing cabinets**	Actual temperature/temperature control and actual humidity control	On each day of use
2.e	**Temperature**	**Incubators/incubation rooms Incubators**	Actual temperature/temperature control Additionally for anaerobic incubators: Check-up of anaerobic conditions	Continuously over the period of incubation During each check-up

No.	To be examined	Type of device/item	Measures	Recommended period
2.f	**Temperature**	**Annealing furnaces** **Muffle furnace**	Check-up by means of a suitable reference	Annually
2.g	**Temperature and reference**	**Hot-air steriliser**	Indicators and T recorders or T loggers suitable for hot-air sterilisers Functional check (sterility check) by means of bioindicators	Per batch Semi-annually
2.h	**Temperature and reference**	**Autoclaves**	Indicators and recorders or loggers suitable for autoclaves for pressure, temperature and time Functional check (sterility check) by means of bioindicators	Per batch Semi-annually
2.i	**Temperature**	**Heating blocks**	Actual temperature control	Annually
2.j	**Temperature and reference**	**Thermal cyclers** **Block cyclers**	Indirect functional check, e.g. by applying a suitable reference strain/material	On each day of use
2.k	**Temperature and reference**	**Real-time cyclers**	For plate systems (e.g. 96-well plate) exclusion of boundary effects by means of homogeneous same sample over all cavities with the channels used for diagnostics	Annually
3.a	**Volume or density of liquids**	**Araeometer** **Butyrometer**	Visually for damage	On each day of use

No.	To be examined	Type of device/item	Measures	Recommended period
3.b	**Volume**	**Plate casting units**	Check filling volume	Semi-annually
4	**Density liquids**	**Oscillation-type density meters (DIN EN ISO 15212-1)**	Determination of density of water or any other usually used matrix	On each day of use
5	**Pressure**	**Barometers Manometers Hygrometers**	Comparison with a working standard	3 years
6	**Time**	**Mechanical clocks Mechanical chronometers**	Comparison with PTB time server (https://uhr.ptb.de/)	Annually
7	**Gas or water volume per time**	**Water meters Gas meters**	Comparison with a working standard	Annually
8.a	**Length**	**Scanning electron microscope (SEM)**	Comparison with a working standard	Semi-annually
8.b	**Length**	**Transmission electron microscope (TEM)**	Comparison with a working standard	Semi-annually
9	**Viscosity**	**Viscometers**	Test oil with manufacturer's certificate	Annually

No.	To be examined	Type of device/item	Measures	Recommended period
10	**Reference**	**Photometers**	Measuring of independent control solution Testing of wavelength accuracy and photometric accuracy with appropriate references (e.g. filters, solutions)	With each series of analyses Annually
11	**Reference**	**Polarimeters**	Check-up with appropriate reference (e.g. sucrose concentration series)	Annually
12	**Reference**	**ELISA readers**	Use of a device-specific validation plate	Annually
13	**Reference**	**pH meters**	Check-up within the range to be expected with pH buffers, if applicable, adjustment with two pH buffers and back measurement with third buffer; the buffers used for the check-up must cover the whole working range	On each day of use
14	**Reference**	**Conductivity meters**	Check-up with at least one KCI standard in the range to be expected using the temperature compensation	On each day of use
15	**Length or reference**	**Test sieves for determination of particle sizes for sampling in the environmental field**	Visual inspection and sieving with standard sand according to DIN 3310 (for test sieves for which no standard sand is available: Testing with precision jet gauge or use of a set of reference sieves)	Annually

No.	To be examined	Type of device/item	Measures	Recommended period
16	**Reference**	**Liquid chromatographic devices** **general** **LC specific:** **e.g.** **HPLC-MS, -FLD, -DAD;** **IC-CD, -UV;** **SFC**	Measuring of independent control solution Calibration within the working range Determination of sensitivity/blank value e.g. control of the vacuum and the mass tunes (transmission of ion optics), flows and detector signal quantity, constancy of temperature of the column oven	With each series of analyses Independently decided by the laboratory Independently decided by the laboratory
17	**Reference**	**Gas chromatographs general** **GC specific:** **e.g.** **GC-MS, -WLD, -ECD, -FID, -NPD, -PID;** **GC Headspace, Purge & Trap**	Measuring of independent control solution Calibration within the working range Determination of sensitivity/blank value e.g. control of the vacuum, gas flow and the mass tunes (transmission of ion optics), the temperature program and detector signal quantity, incubator (e.g. incubator shaker, thermistor, heating block, etc.)	With each series of analyses Independently decided by the laboratory Independently decided by the laboratory
18	**Reference**	**Portable FID/PID**	Check-up with calibration gas Zero adjustment	Annually On each day of use and if necessary in the unloaded range
19	**Reference**	**DC**	Standards/reference substances in the examination procedure	With each examination procedure or sequence

No.	To be examined	Type of device/item	Measures	Recommended period
20	**Reference**	**AAS general** **AAS specific:** **e.g.** **Flame, graphite furnace, hybrid, cold vapour AAS**	Measuring of independent control solution, calibration within the working range Determination of sensitivity/blank value e.g. gas flows, temperature, dosage flows	With each series of analyses Independently decided by the laboratory Independently decided by the laboratory
21	**Reference**	**IPC general** **IPC specific:** **e.g.** **-OES, -MS**	Measuring of independent control solution, calibration within the working range Calibration within the working range Determination of sensitivity/blank value e.g. control of the vacuum, gas flow, wave length accuracy and the mass tunes (transmission of ion optics)	With each series of analyses Independently decided by the laboratory Independently decided by the laboratory
22	**Reference**	**GDMS, GDOS, spark emission spectrometers**	Functional check: Measurement of standards/reference substances	With each series of analyses
23	**Reference**	**Optical spectrometers IR-, FT-IR-, RAMAN spectometers**	S/N or band intensity plus wavelength accuracy or band condition plus optical resolution or full width at half maximum (use of appropriate references)	Annually
24	**Reference**	**NMR spectrometers**	Sensitivity, line shape	Quarterly

No.	To be examined	Type of device/item	Measures	Recommended period
25	**Reference**	**X-ray fluorescence analyser**	Measurement of reference substances	On each day of use
26	**Reference**	**X-ray diffraction (XRD)**	Position of lines and intensity	Monthly
27	**Reference**	**Energy dispersive X-ray spectroscopy (EDX)**	Energy resolution	Semi-annually
28	**Reference**	**Micro probes or WDX systems**	Line position per spectrometer crystal by means of a calibration standard	Semi-annually
29	**Reference**	**Electron spectroscopy systems (XPS, ESCA)**	Energy resolution and linearity of the energy axis; Sputtering rate	Quarterly
30	**Reference**	**Secondary ion mass spectrometry (SIMS)**	Mass resolution in the relevant mass range and space resolution	Quarterly
31	**Reference**	**Hg porosimeters**	Reference material for pore radial distribution	Quarterly
32	**Reference**	**Gas adsorption measuring systems (e.g. BET)**	Reference material (specific surface and radial pore distribution)	Quarterly
33	**Reference**	**Clean benches**	Microbiological check-up by means of air settlement plates (sedimentation)	Weekly
34	**Reference**	**Spiral platers**	Checking dispensing volume Depending on the model: Checking for carry-over (e.g. by blank samples)	Monthly Manufacturer’s recommendation

No.	To be examined	Type of device/item	Measures	Recommended period
35	**Reference**	**Air samplers**	Checking of suction volume/time unit	Annually
36	**Reference**	**Electrophoresis devices**	Check-up of levelling	On each day of use
37	**Reference**	**Colony count devices**	Plausibility check	On each day of use
38	**Reference**	**Nucleic acid isolation and filtration system with automated PCR sample preparation (robot)**	Check-up by means of manufacturer kits or reference strain/material	Extent and time interval according to the information provided by the manufacturer
39	**Reference**	**Next Generation Sequencing and SNP typification platforms**	The instruments can be monitored by means of appropriate monitoring programs (e.g. evaluation of read lengths, quality parameters of data analysis software, confirmation of analysis data by other methods if such data are generated anyway). The results of regularly analysed checking samples may also be used for monitoring devices.	Independently decided by the laboratory
40	**Reference**	**Oxygen measurement devices for sampling in the environmental field**	Check-up with a 100% air-saturated measuring medium, alternatively check-up in water vapour-saturated air for water analytics	On each day of use
41	**Reference**	**Gas measurement equipment for permanent gases**	Check-up with calibration gas	Annually
42	**Reference**	**Metal detectors**	Functional check	On each day of use
43	**Reference**	**Redox measurement equipment**	Check-up within the range to be expected with redox buffers	On each day of use

4 Further applicable documents

71 SD 0 005	Data sheet on metrological feedback within the scope of accreditation procedures
71 SD 0 006	Feedback of measurement and testing equipment to national measurement standards