Minimum Requirements for Measurement Standards for Laboratory Certification

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1.0 Introduction

- 1.1 Laboratories certified by the CLAS program shall use measurement standards that enable the laboratory to provide traceability to the International System of Units (SI) or to standards acceptable to the CLAS program, as described in <u>CLAS Requirements Document 9</u>, *Traceability Requirements for CLAS Certification*. These measurement standards shall have the demonstrated uncertainty and stability for the intended use. This is a requirement to assure that the calibrations carried out by the laboratory meet an acceptable quality level.
- 1.2 Quality in this context is related to whether the calibration results meet or does not meet expectations. The maximum allowable collective uncertainty for measurement standards to provide an acceptable quality level depends on several factors. These factors are all related to the three types of services recognized by CLAS. A laboratory can offer more than one type of service.

2.0 Measurement Standards for Type I Service

- 2.1 Type I service is intended primarily for the calibration of measurement standards. Laboratories providing Type I calibration services are often referred to as standards or standards calibration laboratories. A laboratory providing Type 1 calibration services has the appropriate reference standards, working standards, check standards, and calibration systems to assess dynamically and to quantify its measurement uncertainty. The measurement process is monitored continually and results documented. A high level of environmental control and monitoring is in place.
- 2.2 Calibration certificates for Type I services include a measurement result accompanied by a statement of uncertainty at a stated level of confidence. The statement of uncertainty implies that the laboratory is confident at the quoted level (approximately 95% for the CLAS program) that the value of the measurand is within the stated limits of uncertainty.
- 2.3 Reference standards used to support Type I services must have full redundancy. That means that a physical quantity represented by a reference standard must be duplicated by another standard held by the laboratory so that the measurement system can be systematically assessed. Usually, the adequacy of the measurement standards will not need to be a separate concern since their uncertainty contributions are fully accounted for in the uncertainty **budgets** of the calibration or measurement systems.

3.0 Measurement Standards for Type II Service

- 3.1 Type II service is intended primarily for the calibration and adjustment of test, measurement, and diagnostic equipment for use in such areas as product testing, manufacturing, and servicing. Laboratories providing Type II calibration services are often referred to as test equipment calibration laboratories. Equipment that is calibrated through a Type II service usually constitutes the end of the traceability chain and is generally not used to calibrate other calibration standards.
- 3.2 A laboratory providing Type II calibration services has the appropriate working standards and calibration systems to calibrate to a specification/tolerance, usually a manufacturer's specification/tolerance or a published standard. This type of calibration is usually called **compliance testing** and is usually carried out in a suitably controlled and monitored environment. See Recommended Practices for Calibration Laboratories.
- 3.3 In order for a laboratory to qualify for **Type II** service, it must have calibrated working standards with known measurement uncertainty. The laboratory must assess any additional significant uncertainty components in the measurement system that contribute to the measurement result. These additional components of uncertainty must be estimated, documented, and combined with the uncertainty in the assigned value of the standard to determine the uncertainty of the measurement system. See <u>CLAS Requirements Document 5</u>, General Requirements for Evaluating and Expressing the Uncertainty of Measurement Results.
- 3.4 To maintain confidence in the performance of the calibration system, the laboratory will verify the calibration status of reference, primary, transfer and working standards according to defined procedures and schedules.
- 3.5 In some cases, the uncertainty in the reference standard is taken as the uncertainty in the entire measurement system. The laboratory then needs to demonstrate that all other influences on the measurement system are negligible. A list of such influences can include: a) non-representative sampling in time; b) personal biases in reading instruments; c) imperfect approximations or assumptions incorporated into the measurement procedure; d) variations in repeat measurements that cannot necessarily be attributed to the instrument under test; e) influences of the environment; and f) inexact values of constants and other parameters used in calculations.
- 3.6 The calibration certificate for compliance testing must include a statement that the uncertainty of the measurement system has been accounted for by indicating an acceptable test uncertainty ratio (TUR) or a combination of TUR and **guardbands** or similar techniques. Laboratories performing compliance testing/calibration with measurement system uncertainties that are at least four times less than the tolerance limits of the equipment being calibrated do not need to use **guardbands** or special techniques. For this condition, equipment can be considered to be in-tolerance, if the results are within the specification limits of the equipment. See <u>CLAS Requirements Document 6</u>, *Requirements for Calibration Certificates issued by CLAS Laboratories*, for additional requirements for calibration certificates.

- 3.7 Other forms of reporting are also possible, including reporting a measurement uncertainty at a level of confidence, depending on the requirements of the client. This would be the case when using a Type II calibration service to calibrate a device with no tolerance or specification assigned.
- 3.8 Generally, as long as the collective uncertainty of the measurement system does not exceed 25% of the designated tolerance of the characteristic being calibrated (minimum 4:1 TUR), then there is a high probability (as high as 99% or more subject to the form of the distribution and how much of the population is being considered) that the correct decision will be made as to whether the equipment is within tolerance. A TUR criterion is usually based on the trade-off between the risk to the client and the cost to the laboratory, not to mention the limitations imposed by state-of-the-art measurements. It is readily apparent that the higher the TUR, the lower the risk to the client and the higher the cost to the laboratory, and vice versa (for additional information on the balance of these risks see <u>ILAC G8</u>: 1996 Guidelines on Assessment and Reporting of Compliance with Specification).
- 3.9 In cases when a minimum 4:1 TUR is not achieved, the laboratory shall document such deviations in their calibration certificates and be prepared to demonstrate to CLAS that the acceptable quality level has not been adversely affected.
- 3.10 The following examples and techniques show how to satisfy the intent of the requirement when a 4:1 TUR cannot be achieved directly:
 - 3.10.1 The measurement value extended by the uncertainty of the measurement is required to fall within the specified limits of the equipment being calibrated. This form of guardbanding minimizes consumer risk and is discussed in ILAC G-8.

For example, if the tolerance of the equipment is \pm 90 ppm and the uncertainty of the measurement system is \pm 30 ppm, compliance is reported only when the measured value falls within the interval of \pm (90 ppm - 30 ppm) = \pm 60 ppm of the expected value.

- 3.10.2 The equipment being calibrated can be de-rated (tolerances increased) to maintain a minimum 4:1 TUR. The calibration certificate and the calibration status label on the equipment shall indicate clearly this de-rated condition.
- 3.10.3 The tolerance or specification limits can be narrowed to compensate for the uncertainty of the measurement system. A simple algebraic correction can be made by reducing the limits by the amount that the system uncertainty exceeds 25% of the specification limits for the equipment being calibrated. A more appropriate approach would be to reduce the limits by the technique shown below. This guardbanding approach gives approximately the same consumer risk as that associated with a TUR of 4:1.

Newlimits =
$$\sqrt{(Oldlimits)^2 - (U_{sys})^2}$$

Where,

- *Oldlimits*: original tolerance of the equipment under test
- *Newlimits* : reduced tolerance to use for testing compliance of the equipment
- U_{sys} : uncertainty of the measurement system.

For example, if the tolerance of the equipment is \pm 90 ppm and the uncertainty of the measurement system is \pm 30 ppm, then the TUR is 90:30 or 3:1. To obtain approximately the same consumer risk as that given by a 4:1 TUR, one would test the equipment to the new tolerance of $\pm \sqrt{90^2 - 30^2} = \pm 85$ ppm

- 3.10.4 Several other techniques using guardbands have also been developed and some of these might be worth considering. Users of these techniques should be careful that the assumptions made in these procedures apply to their measurements.
- 3.11 For some equipment, the value and uncertainty of the measurement standard could be transferred directly to the equipment being calibrated. For example, a single value equipment could be adjusted to the value of the standard. Here, a minimum 4:1 TUR is not required.
- 3.12 It is occasionally possible to demonstrate that a specific system performs better than published specifications that are intended to represent a large group of similar systems when used under a wider range of measurement conditions. The improved performance can be demonstrated through statistical process control, or through actual performance verified against higher echelon standards, or through other suitable means. In this case, the demonstrated uncertainty in the specific measurement system can be used (in lieu of the published specifications) to satisfy the minimum 4:1 TUR criterion, keeping in mind that this claimed improvement would have to be assessed.

4.0 Measurement Standards for Type III Service

4.1 This service is the same as Type II service except that the laboratory is not expected to have the capability to verify thoroughly the calibration status of its measurement standards. Instead, the laboratory assures the quality of the measurement results through such other quality control techniques as interlaboratory comparison, replication, retesting, and correlation with other

measurement characteristics. Measurement standards used for Type III services are robust and are generally not subject to large drift or change within the laboratory's scope of measurement.