# Nuclear industry M&TE calibration accuracy requirement status and management

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## **1. Introduction**

Regarding of nuclear quality assurance requirements: KEPIC-QAP-1, one of the changes since the 2011 supplement, compared to the 2005, is that the calibration management requirements for measurement and test equipment(M&TE) have been added to Requirement 12 302. In this requirement, the Reference standard used for calibration must have at least 4 times more accuracy than that of the being calibrated, and if it cannot be maintained, technical justification is required.

However, it is not described a detailed explanations or definitions for reference standard, accuracy, and technical justification. Therefore, it may be difficult to understand and apply the requirements for whom without professional knowledge and ability on the calibration service or accuracy of measurements. In addition, the perception of accuracy management in the calibration academic community has changed constantly according to technology development. there may also be differences in the calibration service management status between countries. This is why there is a need to discuss the optimal safety management.

#### 2. Methods and Results

Based on the existing literature on calibration management and inquiries from related organizations, it is the object to describe requirements and introduce accuracy management methods. First of all, it deals with the interpretation of terms such as Reference standard and Required accuracy. secondly, it describes a couple of methods for comparing 4 times of accuracy and technical justification methods.

#### 2.1 Reference Standard

According to the KEPIC-QAP-1 requirements, certified equipment or reference standards can be used as standards for calibration. However, it is the reference standard has to be more than 4 times of accuracy. Although a detailed definition of reference standards is not explained, reference standards can be interpreted in the following two cases.

#### 2.1.1 Reference when calibrating equipment

According to the NIST(National Institute of Standards and Technology), A reference standard for a unit of measurement is an artifact that embodies the quantity of interest in a way that ties its value to the reference base. According to this definition, the standards used in all calibration work can be interpreted as Reference standards. At the highest level, a primary reference standard is assigned a value by direct comparison with the reference base. Secondary reference standards are calibrated by comparing with primary standards. Comparing with higher standard is the way to ensure calibration traceability for the lower standard.

According to the 'Guidelines for Maintaining Traceability of Measurement Results', the International Bureau of Weights and Measures (BIPM) develops and maintains primary standards. And traceability is guaranteed in the order of the national measurement standard (eg. KRISS), reference standard (eg, KOLAS), and working standard.

#### 2.1.2 Working Standards

The 2011 supplement clearly applies the four times of accuracy requirement to reference standards, but it is somewhat unclear whether it applies to certified equipment or not. A calibration using Primary and Secondary Standards can be considered satisfying the quality assurance requirements of 10CFR50 APPENDIX B.

On the other sides, The level of confidence in accuracy for working standards may be low, because working standards is used routinely to calibrate of equipment at laboratories themselves. Therefore, there is need to manage the accuracy of the working standards.

However, 10CFR50 APPENDIX B does not require 4 times of the accuracy. KOLAS-accredited calibration laboratories may not meet the accuracy requirement, if the purchaser does not request it. In relation to this, ANSI Z540.3 states that the accuracy requirements are met when a calibration service done by ISO-17025 accredited, including more than 4 of TUR value(Test Uncertainty Ratio).

#### 2.2 Accuracy

Accuracy is a qualitative concept, and the International Bureau of Weights and Measures (BIPM) does not use it as a quantitative concept. According to the KEPIC technical standard and the KRISS terminology, accuracy is defined as the degree to which the measured value and the true value of the measured quantity. Also, according to ANSI/IEEE100, it means the degree of agreement between the ideal device output value and the actual output value. Therefore, it is necessary to establish more specific standards for a relative comparison of 4 times accuracy.

## 2.2.1 Measuring and Testing Equipment

The required accuracy of these M&TE could be interpreted as tolerance. It is sometimes described in specifications, related industrial standards, international standards, etc. It can also be specified by customers. Therefore, when managing accuracy requirements, it should be established clear definitions. The basis for selection of the required accuracy should be documented and verifiable.

## 2.2.2 Reference Standards

To ensure accuracy of Reference standards, TAR(Test Accuracy Ratio) had been primarily used in the past. The accuracy mentioned at the time is the accuracy from manufacturer's specification(e.g.,  $\pm a\%$ ) of the equipment. It is known that firstly mentioned in MIL-STD-120 of 1950. The standard requires 5 times or more accuracy, but it is sometimes used 10 times, but in modern times it is usually used as 4 times. In the case of high-performance equipment, it may be difficult to secure 4 times of accuracy in terms of TAR.

However, ISO-17025 has required the management of expanded uncertainty as a requirement for accreditation of calibration and testing labs since 1999. The uncertainty is calculated by adding up various uncertainty factors such as that of the reference standard itself as well as that of from measurement environment, etc, with 95% level of confidence.

Accuracy and uncertainty are distinguished from each other. However, ANSI Z540.3 and NUPIC Calibration Checklist use measurement uncertainty as a comparison standard for tolerance. KEPI QAP-1 requires that the 'reference standard error' be managed to less than 1/4 of the 'calibration tolerance', and it is believed that the error can be applied as a 'measurement uncertainty' value here.

## 2.2.3. four times of the Accuracy

The errors, occurring when using M&TE calibrated, is a combination of errors from the M&TE itself and errors due to reference standards. The purpose of management these error ratio is reducing the impact of the reference standard error in the combination error and ensure economic feasibility in terms of managing TAR.

The purpose of securing an uncertainty of less than 1/4 times to the tolerance is to manage judgment errors that may occur during Pass/Fail decision making for the calibration or test acceptance. There are False Acceptance and False Reject

in decision making errors. False Acceptance is more important to reduce consumer risk, it is the error that measurement value will be within the tolerance due to uncertainty, even though expected true value is out of the tolerance.

Figure 1. describes the decision making errors,  $p_m(t-y)$  is the probability density function estimating range of the anticipated measurement value: 't' by uncertainty for a specific measurement result value: 'y'.  $p_0(t)$  is the probability that the reference value: 't' is actually distributed within the tolerance interval.

If Tolerance is set as a manufacturer's specification, information on deviation which is the criteria for the spec(eg.  $2\sigma$ ,  $3\sigma$ ) may be utilized.

Although there are special characteristics for each probability density function, statistically, if the required accuracy and uncertainty ratio is 4 or more, the probability of False Acceptance is significantly reduced.



Fig 1. Type 1.2 error probability

#### 2.2.4 Inquiries related to accuracy requirements

According to the results of inquiries to the NRC related department, the accuracy requirement is not mandatory when performing calibration based on the 10CFR50 APPENDIX B. However, if quality assurance program is committed to ANSI Z540.3, and SRP 17.1 is used for its review, it is important to manage the accuracy requirements.

## 2.3 Technical Justification

Technical justification is required if it is difficult to achieve the accuracy requirement. NRC SRP 17.1-12.6 requires calibrated equipment to be ensured within required tolerances.

## 2.3.1 Guard-Band

By excluding the uncertainty range from the tolerance, False acceptance that may occur due to uncertainty can be prevented. There are various guard band range to the value of TUR. It may depend on the criteria of manufacturer spec, and characteristics of the PDF. For example, there is simple method to reduce the tolerance interval by 1-1/TUR.

Conversely, the use of the Guard-Band mentioned above can increase the possibility of false reject. Even though the true value is within the tolerance, measured value could be out of tolerance due to uncertainty. It could lead increase of the producer's cost. Therefore, when deciding to manage such a decision error, the guard band range should be modified by applying a coefficient according to the TUR ratio.



## 2.3.2 Other methods

There may be cases where the impact of the uncertainty value is low enough, because significant margin has already been secured. and It could be difficult to implement 4 times of accuracy because of very high accuracy of equipment. Applying the requirement may also be considered depending how critical of measurement to equipment operability or reliability.

In these case, it may be possible to prove the accuracy ratio that is generally used in other industries. Reference standard needs to secure a higher accuracy than the M&TE will be calibrated according to the SRP 17.1-12.6.

M&TE needs to be identified appropriate for its end-use. In this point of view, tolerance may be set as intended use. It is different from general definition of TUR, however in terms of managing the final consumer risk, it could have same mathematical meaning. In this case, the PDF of the actual distribution for mesurerand value of product may need. Therefore, it may difficult to determine the PDF unless there are large set of data. Additionally, regarding uncertainty, test labs need to calculate its own uncertainty by taking into account the uncertainty arising from testing environment, test process, etc. Some guidance presents examples of decision making based on the measurement uncertainty value in the 'calibration certificate' to the intended-use tolerance. However, this kind of decision making refers to the error resulting from the M&TE itself, and the uncertainty from the measurement environment and process of the test is not reflected. In this regard, criteria of pass/fail decision making, and clear definition for measurement uncertainty is required to reduce the consumer risk.

EOPR (End of Period Reliability), which utilizes multiple calibration verification cases, can also be used as a method of accuracy management.

## **3.** Conclusions

A calibration services accredited to meet the ISO-17025 requirements can be considered to satisfy the measurement and test equipment accuracy management requirements of 10CFR50 Appendix B. However, the 4 times accuracy requirement of KEPIC-QAP-1 should be checked separately.

Therefore, when calibrating M&TE, it is necessary to define tolerance and prove that it will be within it. It also need to prepare technical justification, such as analysis for margin, impact of measurand, deciding uncertainty for decision making, and Guard-Band.

If such management procedures cannot be established, it may need to request the calibration labs to secure 1/4 of the uncertainty or accuracy in spec based on the M&TE tolerance of the manufacturer's specifications. Its industrial acceptance and feasibility may need to be further confirmed.

Except for the case where high accuracy is required, such as nuclear fission, safe shutdown signal, and radiation protection, the level of accuracy required by the nuclear industry may be relatively low. Therefore, additional investigation into the actual industrial accuracy management status and applicability is required to apply 4 times requirement to the Reference Standard except for the Working Standard.

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