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Method to account for measurement uncertainties when performing metrological tests within the scope of the German X-ray Ordinance (RoeV) and the German Radiation Protection Ordinance (StrlSchV)

Recommendation by the German
Commission on Radiological Protection

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Empfehlung der Strahlenschutzkommission

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1 Background

During the Radiology Standards Committee's revision of the standard DIN 6815:2005-05, 'Medical X-ray equipment up to 300 kV – Rules for testing of radiation protection after installation, maintenance and essential modification', a suggestion was put forward to add a new section on how to handle technical test measurement results and their associated uncertainties. Standard DIN 6815 is of particular importance because the guideline for expert tests performed in line with the German X-ray Ordinance (RoeV) and various other standards refer to DIN 6815. The new section recently added to the draft containing stipulations on measurement uncertainty was met by a number of objections which led to the addendum being removed from the version released in 2013. Nevertheless, it was deemed necessary to account for measurement uncertainties when performing metrological tests in the future, and to continue the discussion irrespective of the standard.

As a result, the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB) commissioned the German Commission on Radiological Protection (SSK) to prepare a recommendation on accounting for measurement uncertainties when performing metrological tests associated with radiological protection. In doing so, particular attention was to be paid to the following aspects:

> Requirements may arise due to statutory limits and protection requirements to be met in keeping with the latest advances in technology or the latest advances in science and technology;
>
> The extent to which specifications regarding measurement uncertainties are required, and who should stipulate them from a technical perspective.

Beyond the above scope, measured quantity values are to be compared with required values multiple times when performing practical radiological protection measurements and when monitoring environmental radioactivity. In all of these cases, the present SSK recommend-dation should resolve any lack of clarity during implementation and enable a standard method to be used when verifying conformity with requirements.

2 Problem

The requirements placed upon metrological tests conducted within the scope of radiation protection are often defined by tolerance intervals that are stipulated by way of statutory limits or minimum technical requirements set out in guidelines and standards. A metrological test is designed to determine whether a tolerance interval, and hence a requirement, have been complied with.

In doing so, the measured quantity value may well be within the tolerance interval, yet the true value of the measurand may in fact lie outside of the tolerance interval. The full measurement result is therefore needed in order to assess this situation, and this requires a measurement uncertainty along with the measured quantity value as an estimate for the true value underlying the measurement.

First it is important to determine how the measurement uncertainties are to be taken into account in order to be able to assess whether the measurement results comply with the requirements.

3 Recommendations

The SSK has compiled the following recommendations to account for measurement uncertainty when performing metrological tests designed to ensure conformity with requirements:

1. The result of a metrological test must contain the measured quantity value y and the standard measurement uncertainty $u(y)$.[1]

2. The calculation of a standard measurement uncertainty should be based on the "Guide to the expression of uncertainty in measurement" (GUM) (JCGM 100) or GUM Supplement 1 (JCGM 101).

   As an alternative to calculating standard measurement uncertainty based on the GUM or GUM Supplement 1, transparent conservative estimates of measurement uncertainties can be assumed by drawing on information from other sources (guidelines, standards, recommendations from specialist societies, etc.).

   The tester should determine the standard measurement uncertainty of the measured quantity value and document the entire procedure.

   Where requirements to determine standard measurement uncertainties are not fully available at present, it is recommended that information be compiled in order to elaborate the standard measurement uncertainties while accounting for every possible contribution to uncertainty.

3. Requirements always refer to the true value $\tilde{y}$ of a measurand Y. However, since the true value of a measurand is unknown and unrecognisable, and can only be estimated by way of a measured quantity value y, it is only possible to provide probability statements about the true value. A requirement is deemed met if there is a high probability of it being the case. By stipulating the coverage probabilities in keeping with the following recommendations, the probabilities of making correct decisions in favour of conformity are at least 95 % each, meaning the probabilities of making incorrect decisions are no more than 5 % in each case. The SSK considers this to be appropriate (please refer to the scientific justification).

4. If requirements are stipulated by a single-sided upwards-limited tolerance interval with an upper limit T_{U}, which shall not be exceeded by the true value of the measurand with a high probability, then a decision in favour of conformity should be taken if the upper bound[2] of the probabilistically symmetric coverage interval[3] with a 90 % coverage probability is lower than the limit T_{U}.

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[1] Here, the symbols are used as placeholders for symbols of physical quantities. The given symbols of quantities should be used when implementing this recommendation; please refer to the examples provided in the Annex.

[2] The upper bound of the probabilistically symmetric coverage interval with a 90 % coverage probability is the 95th percentile of the probability density function $f_Y(\tilde{y} \mid y, \mathfrak{I})$; please refer to Section 4.

If the GUM (JCGM 100) is used to determine the measurement uncertainty, the condition for conformity

$$y + 1.65 \cdot u(y) \leq T_{\mathrm{U}}$$

applies if the relative measurement uncertainty is less than 25 %.

For larger relative uncertainties, please refer to DIN ISO 19929 (ISO 11929) regarding calculation of the coverage interval bounds.

5. If requirements are stipulated by a single-sided downwards-limited tolerance interval with a lower limit T_{L} , below which the true value of the measurand shall not lie with a high probability, then a decision in favour of conformity should be taken if the lower bound[4] of the probabilistically symmetric coverage interval with a 90 % coverage probability is higher than the limit T_{L} .

   If the GUM (JCGM 100) is used to determine the measurement uncertainty, the condition for conformity

$$y - 1.65 \cdot u(y) \geq T_{\mathrm{L}}$$

   applies if the relative measurement uncertainty is less than 25 %.

   For larger relative uncertainties, please refer to DIN ISO 19929 (ISO 11929) regarding calculation of the coverage interval bounds.

6. If requirements are stipulated by a two-side-limited tolerance interval $[T_{\mathrm{L}}, T_U]$, in which the true value of the measurand shall lie with a high probability, then a decision in favour of conformity should be taken if the probabilistically symmetric coverage interval with a 95 % coverage probability lies within the tolerance interval.[5]

   If the GUM (JCGM 100) is used to determine the measurement uncertainty, the conditions for conformity

$$y - 1.96 \cdot u(y) \geq T_{\mathrm{L}} \text{ and } y + 1.96 \cdot u(y) \leq T_{\mathrm{U}}$$

   apply if the relative measurement uncertainties is less than 25 %.

---

[3] In order to highlight the underlying Bayesian approach, the term “coverage interval” is used here instead of “confidence interval”, which is often used in frequentist statistics. The probabilistically symmetric coverage interval for the probability (1-γ) is defined by the constraint that there is a probability of γ/2 that the true value will be below the lower bound and above the upper bound of the coverage interval in each case. Here the term is used to distinguish it from the shortest coverage interval.

[4] The lower bound of the probabilistically symmetric coverage interval is the 5th percentile of the probability density function $f_Y(\tilde{y} \mid y, \Im)$; please refer to Section 4.

[5] The stipulation of a 95 % coverage probability is conservative and it ensures that the 5 % probability of making incorrect decisions is complied with for each relative measurement uncertainty.

For larger relative uncertainties, please refer to DIN ISO 19929 (ISO 11929) regarding calculation of the coverage interval bounds.

7. The question set out in the advisory mandate concerning the extent to which specifications regarding permissible measurement uncertainties are required, and who should stipulate them from a technical perspective can be answered as follows:

   Requirements set out in regulations have been stipulated[6] or are to be stipulated by way of tolerance intervals. Based on the approach used in this recommenddation, requirements in terms of permissible measurement uncertainties are not deemed necessary.

8. The stipulation of an acceptance interval $[K_L, K_U]$ requires knowledge of the standard measurement uncertainty as a function of the primary measurement results along with sufficient reproducibility of the measurements and standard measurement uncertainties.[7] The acceptance interval is then defined by way of implicit equations:

   a. For a single-sided upwards-limited tolerance interval:

   $$P(\tilde{y} > T_U \,|\, y = K_U, u(y = K_U)) = 0.05\,.$$

   If the GUM (JCGM 100) is used to determine the measurement uncertainty, the condition for the upper bound of the conformity interval

   $$K_U = T_U - 1.65 \cdot u(y = K_U)$$

   applies if the relative measurement uncertainties is less than 25 %.

   For larger relative uncertainties, please refer to DIN ISO 19929 (ISO 11929) regarding calculation of the coverage interval bounds.

   b. For a single-sided downwards-limited tolerance interval:

   $$P(\tilde{y} < T_L \,|\, y = K_L, u(y = K_L)) = 0.05\,.$$

   If the GUM (JCGM 100) is used to determine the measurement uncertainty, the condition for the upper bound of the conformity interval

   $$K_L = T_L + 1.65 \cdot u(y = K_L)$$

   applies if the relative measurement uncertainties is less than 25 %.

   For larger relative uncertainties, please refer to DIN ISO 19929 (ISO 11929) regarding calculation of the coverage interval bounds.

   c. For a two-side-limited tolerance interval:

   $$P(\tilde{y} < T_L \,|\, y = K_L, u(y = K_L)) + P(\tilde{y} > T_U \,|\, y = K_U, u(y = K_U)) = 0.05$$

[6] A tolerance interval is a range of permissible values for a quantity. The bounds of a tolerance interval must be stipulated in regulations; this depends on the consequences of a deviation from the specified interval.

[7] Information about measurement uncertainty as a function of the primary measurement result can, for example, originate from independently performed measurements or they can be stipulated in standards. However, in individual cases they can also be arrived at by calculating the given measurement uncertainties.

Without a limitation of the relative measurement uncertainty of the measurement procedure, the conditions for the conformity interval bounds

$$P(\tilde{y} < T_{\mathrm{L}} \,|\, y = K_{\mathrm{L}}, u(y = K_{\mathrm{L}})) = 0.025 \text{ and } P(\tilde{y} > T_{\mathrm{U}} \,|\, y = K_{\mathrm{U}}, u(y = K_{\mathrm{U}})) = 0.025$$

apply.

If the GUM (JCGM 100) is used to determine the measurement uncertainty, the conditions for the conformity interval bounds

$$K_{\mathrm{L}} = T_{\mathrm{L}} + 1.96 \cdot u(y = K_{\mathrm{L}}) \text{ and } K_{\mathrm{U}} = T_{\mathrm{U}} - 1.96 \cdot u(y = K_{\mathrm{U}})$$

apply if the relative measurement uncertainties are less than 25 %.

For larger relative uncertainties, please refer to DIN ISO 19929 (ISO 11929) regarding calculation of the coverage interval bounds.

4 Scientific justification

4.1 Basic principles

Current developments within metrology have led to an internationally accepted approach to define and quantify measurement uncertainties. It began in the 1990s with the ISO Guide to the Expression of Uncertainty in Measurement (GUM) (ISO 1993) and the DIN 1319 (DIN 1996, 1999) standards. A Bayesian theory of measurement uncertainty (Weise and Wöger, 1993) served as a theoretical basis for the GUM. This theory uses Bayes' theorem and the product rule to provide and build upon the requisite probability densities. Following a few initial acceptance problems and various discussions, the Joint Committee on Guides in Metrology (JCGM) reissued the GUM (JCGM 100) while also adding to it (JCGM 101). Today, the method presented in the GUM and its annexes are recognised internationally and reflect the latest advances in science and technology when it comes to uncertainties within metrology.

The JCGM has also issued recommendations to account for measurement uncertainties when assessing the conformity of measured values with requirements (JCGM 106). The present SSK recommendation conforms with JCGM 106.

In the field of ionising radiation metrology, the implementation of the GUM and its use to determine characteristic limits such as detection limit, decision threshold and limits of the coverage interval have been specified in ISO 11929 and DIN ISO 11929. Reference is made to these standards, both in standards used to monitor environmental radioactivity and in German and international regulations. ISO 11929 and DIN ISO 11929 provide the tools needed to implement the approach recommended in Section 3.

The uncertainty concept is as follows in the field of metrology: A measurement provides an uncertain estimate y (measurement result) of the unknown and unrecognisable true value $\tilde{y}$ of the measurand *Y*. The conditional probability density function (PDF) $f_Y(\tilde{y}\,|\,y, \mathfrak{I})$, i.e. the probability that, given measurement result y and any other available information $\mathfrak{I}$, the true value of measurand Y is $\tilde{y}$, then expresses in full the uncertainty attributed to the measurement result y. $f_Y(\tilde{y}\,|\,y, \mathfrak{I})$ is the probability density function of a random variable serving as an estimator of *Y*. As a PDF, it is normalized to one $\int_{-\infty}^{\infty} f_Y(\tilde{y}\,|\,y, \mathfrak{I})\,\mathrm{d}\tilde{y} = 1$. Instead of the PDF

$f_Y(\tilde{y}|y,\Im)$, which expresses the uncertainty in full, the uncertainty can also be characterised by a coverage interval $[y^{\triangleleft}, y^{\triangleright}]$ containing the true value of the measurand with a preselected coverage probability $(1-\gamma)$. The root of the variance of the PDF $f_Y(\tilde{y}|y,\Im)$ is known as the so-called standard measurement uncertainty $u(y)$.

The PDF depends on the information available. The GUM, to some extent, and the GUM Supplement 1 (JCGM 101) in particular use the Principle of Maximum Entropy (PME) or Bayes' Theorem to derive a number of different PDFs depending on the information available in each case. If only measurement result y and its associated standard measurement uncertainty $u(y)$ are available, the resulting PDF is characterised by the normal Gaussian distribution $\mathrm{N}(y,u(y))$.

The SSK follows the JCGM recommendations and recommends that the GUM and GUM Supplement 1 ((JCGM 100, JCGM 101) be used to quantify measurement uncertainties. The SSK recommends the methodology set out in (JCGM 106) when assessing conformity with requirements.

Requirements in terms of technical testing are derived from protection requirements reflecting the latest advances in science and technology as well as statutory thresholds. Such requirements can be stipulated as single-side-limited or two-side-limited tolerance intervals for various parameters. Metrological proof is required to ensure compliance with these requirements. Accounting for measurement uncertainty is critical to being able to provide a reliable statement. Here, measurement uncertainty means the standard measurement uncertainty $u(y)$ as per (JCGM 100, JCGM 101) associated with the measured value y.

A requirement can be confirmed as having been met, i.e. the measured quantity value conforms with the requirements, if, in the case of a stipulated tolerance interval, the true value of the measurand lies within the tolerance interval at a level of probability to be stipulated.

The scientific assessment of a measurement task can only be used to derive boundary conditions for the required probabilities. The regulator is responsible for stipulation, which is then adopted as a social convention.

The SSK recommends (recommendation 3) stipulating a 95 % probability of making a correct decision with conformity tests. This, in turn, means a 5 % probability of making an incorrect decision. This 5 % figure is often quoted in international standards and considered reasonable given the limited opportunities available to reliably determine very high percentiles of probability density functions.

Tolerance interval bounds are to be stipulated in such a way that the 5% probability of making an incorrect decision in favour of conformity is tolerable in terms of the protection objective.

Quantiles of the PDF $f_Y(\tilde{y}|y,\Im)$ were used with the GUM and GUM Supplement 1 measurement uncertainties concept to specify the decision-making rules set out above.

A requirement is deemed as having been met, i.e. the measured value conforms with the requirements

1. if, in the case of a stipulated single-sided downwards-limited or upwards-limited tolerance interval, the lower respectively upper bound of the coverage interval with a 90 % coverage probability is higher respectively lower than this limit,
2. if, in the case of a stipulated two-side-limited tolerance interval, the coverage interval with a 95 % coverage probability lies within the tolerance interval.

If the GUM is applied, the coverage intervals can be calculated using the standard measurement uncertainties $u(y)$ and quantiles of the standard normal distribution $k_{1-\alpha}$, e.g. as per DIN ISO 11929 (ISO 11929). If GUM Supplement 1 is applied, numerical procedures are required to calculate the coverage interval bounds.

In order to account for measurement uncertainty when performing metrological tests to ensure conformity with requirements, the SSK provides recommendations in Section 3 which are described and justified in the present Section 4. Fig. 1 illustrates the decision-making rules set out in the recommendations provided in Section 3.

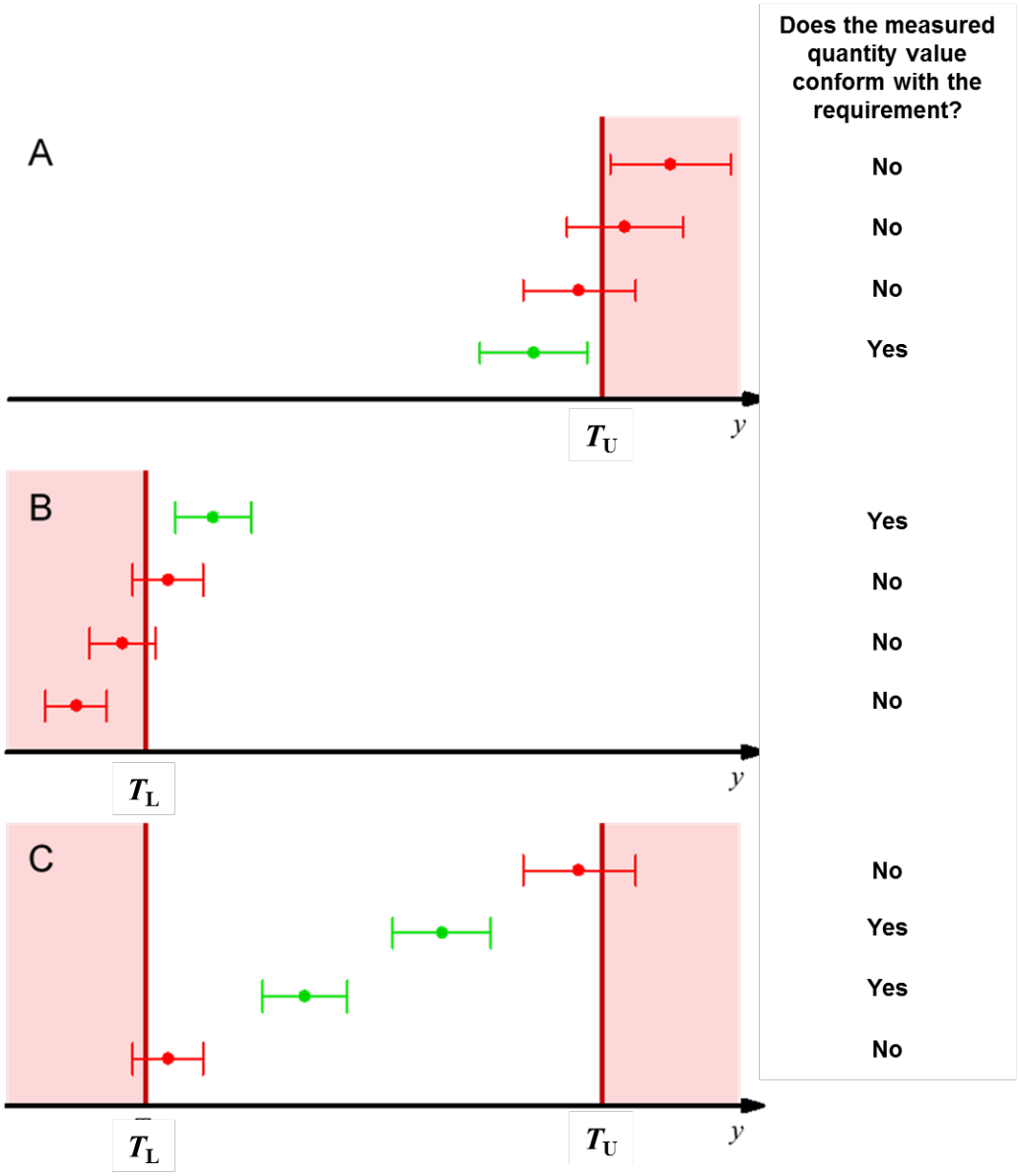

Fig. 1: Conformity test with requirements for a single-sided upwards-limited tolerance interval (A), a single-sided downwards-limited tolerance interval (B) and a two-side-limited tolerance interval (C). The SSK recommends coverage probabilities (shown above as a range of measuring points) of 90 % in cases A and B, and 95 % in case C. This recommendation is based on the criterion that the probability level for a correct decision in favour of conformity should be at least 95 %, while the probability level for an incorrect decision should not exceed 5 %.

4.2 Derivation and explanations of the recommendations

Requirements are often stipulated by defining tolerance intervals $[T_L, T_U]$ for the true values of a measurand. The true value of the measurand $\tilde{y}$ must lie within this interval. As the true value of a measurand is unknown and unrecognisable, it is only possible to provide probability statements about it. A conformity interval $[K_L, K_U]$ is also often stipulated. If a measured value y lies within the conformity interval, the decision is taken that it conforms with the requirements. Fig. 2 illustrates the tolerance interval and conformity interval concepts for a two-side-limited tolerance interval.

The stipulation of an acceptance interval $[K_L, K_U]$ to assess conformity with requirements requires knowledge of the standard measurement uncertainty $u(y)$ as a function of the primary measurement results along with sufficient reproducibility of the measurements and measurement uncertainties. The acceptance interval is then defined by way of implicit equations; please refer to Sections 4.2.3 and 4.2.4.

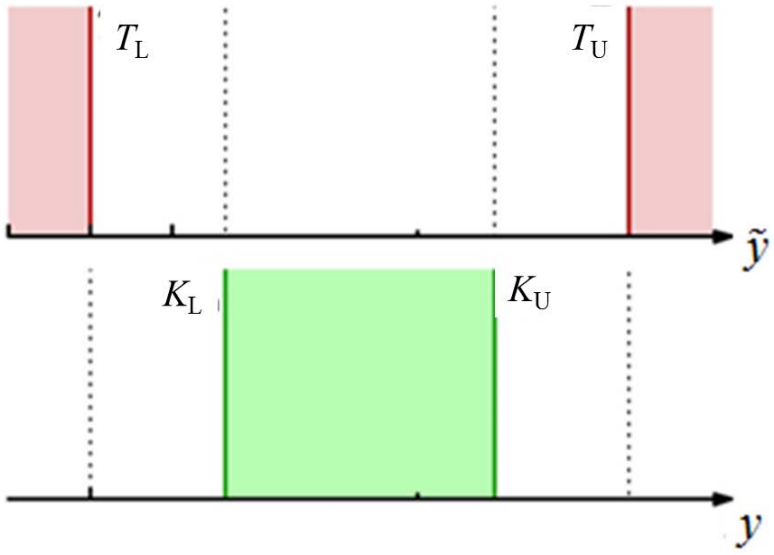

Fig. 2: Tolerance interval for the true value $\tilde{y}$, expressed by the bounds T_L and T_U, and acceptance interval for measured values y, expressed by K_L and K_U; cf. also Fig. 1 in (JCGM 106).

4.2.1 Conformity involving single-side-limited tolerance intervals

If requirements are stipulated by a single-sided upwards-limited tolerance interval with an upper limit T_U, which shall not be exceeded by the true value of the measurand with a high probability, then a decision in favour of conformity should be taken if the upper bound of the probabilistically symmetric coverage interval with a 90 % coverage probability is lower than the limit T_U.

If the GUM (JCGM 100) is used to determine the measurement uncertainty, the condition for conformity

$$y + 1.65 \cdot u(y) \leq T_U$$

applies if the relative measurement uncertainty is less than 25 %.

For larger relative uncertainties, please refer to DIN ISO 19929 regarding calculation of the coverage interval bounds.

If requirements are stipulated by a single-sided downwards-limited tolerance interval with a lower limit T_L, below which the true value of the measurand shall not lie with a high probability, then a decision in favour of conformity should be taken if the lower bound of the probabilistically symmetric coverage interval with a 90 % coverage probability is higher than the limit T_L.

If the GUM (JCGM 100) is used to determine the measurement uncertainty, the condition for conformity

$$y - 1.65 \cdot u(y) \geq T_L$$

applies if the relative measurement uncertainty is less than 25 %.

For larger relative uncertainties, please refer to DIN ISO 19929 (ISO 11929) regarding calculation of the coverage interval bounds.

In order to explain the stipulations for proving conformity set out in recommendations 4 and 5, Fig. 3 below provides graphs illustrating the extreme cases for the various conformity tests which ensure that the respective coverage probabilities should provide at least a 95 % probability of taking a correct decision in favour of conformity, and therefore a maximum 5 % probability of taking an incorrect decision.

The need for a symmetric coverage interval for a probability of just 90 % stems from the fact that one side of the distribution can only ever supply true values below or above the tolerance bound T_L or T_U. The other side also provides true values outside of the coverage interval that conforms with the requirements.

The question set out in the advisory mandate concerning the extent to which specifications regarding permissible measurement uncertainties are required, and who should stipulate them from a technical perspective can be answered as follows:

Requirements set out in regulations have been stipulated or are to be stipulated by way of tolerance intervals. For this reason, requirements in terms of permissible measurement uncertainties are not deemed necessary.

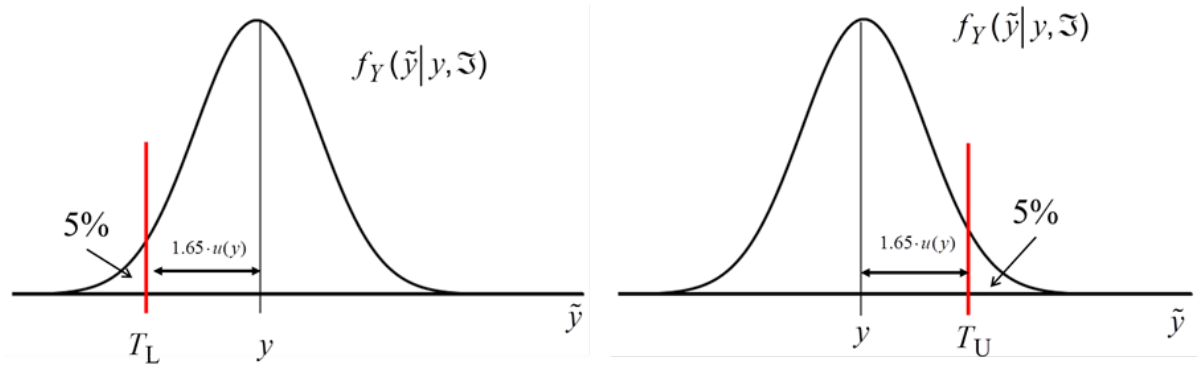

Fig. 3: Extreme cases involving single-side-limited tolerance intervals. With single-side-limited tolerance intervals, a 90 % coverage probability is sufficient for the probabilistically symmetric coverage interval in order to keep the probability of making incorrect decisions in favour of conformity at a level below 5 %.

4.2.2 Conformity involving two-side-limited tolerance intervals

If requirements are stipulated by a two-side-limited tolerance interval $[T_L, T_U]$, in which the true value of the measurand shall lie with a high probability, then a decision in favour of conformity should be taken if there the probabilistically symmetric coverage interval with a 95% coverage probability lies within the tolerance interval:

$$P(\tilde{y} < T_L \vee \tilde{y} > T_U | y, u(y)) \leq 0.05\,.$$

If the GUM (JCGM 100) is used to determine the measurement uncertainty, the conditions for conformity

$$y - 1.96 \cdot u(y) \geq T_L \text{ and } y + 1.96 \cdot u(y) \leq T_U$$

apply if the relative measurement uncertainty is less than 25 %.

For larger relative uncertainties, please refer to DIN ISO 19929 (ISO 11929) regarding calculation of the coverage interval bounds.

The stipulation of a 95 % coverage probability is conservative and it ensures that the 5 % probability of making incorrect decisions is complied with for each relative measurement uncertainty. Fig. 4 shows the borderline case for the implicit maximum possible standard measurement uncertainty and the resulting demand for a 95 % coverage probability. Measurement procedures with a higher level of measurement uncertainty are not in a position to prove conformity with requirements.

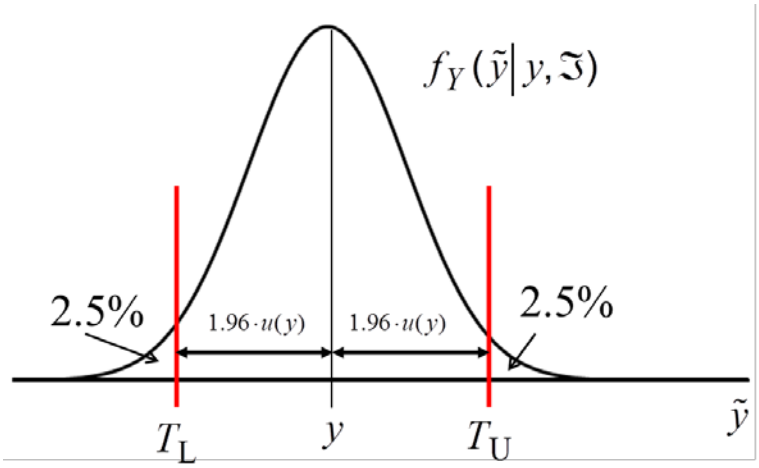

Fig. 4: Extreme case involving a two-side-limited tolerance interval that renders it necessary to apply the 95 % coverage probability for this requirement. In this extreme case, the uncertainty is so high that the probabilistically symmetric coverage interval for the 95 % probability almost fills the entire tolerance interval.

4.2.3 Acceptance interval involving single-side-limited tolerance intervals

The stipulation of an acceptance interval $[K_L, K_U]$ requires knowledge of the standard measurement uncertainty as a function of the primary measurement result along with sufficient reproducibility of the measurements and standard measurement uncertainties. The acceptance interval is then defined by way of the following implicit equation:

– For a single-sided downwards-limited tolerance interval $[T_L, +\infty]$, only the lower bound of the acceptance interval K_L is required:

$$P(\tilde{y} < T_L \,|\, y = K_L, u(y = K_L)) = 0.05\,.$$

If the GUM (JCGM 100) is used to determine the measurement uncertainty, the condition

$$K_L = T_L + 1.65 \cdot u(y = K_L)$$

applies to relative measurement uncertainties < 25% (please refer to Fig. 5).

– For a single-sided upwards-limited tolerance interval $[0, T_U]$, only the upper bound of the acceptance interval K_U is required:

$$P(\tilde{y} > T_U \,|\, y = K_U, u(y = K_U)) = 0.05\,.$$

If the GUM (JCGM 100) is used to determine the measurement uncertainty, the condition $K_U = T_U - 1.65 \cdot u(y = K_U)$ applies to relative measurement uncertainties < 25 % (please refer to Fig. 5).

For larger relative uncertainties, please refer to DIN ISO 19929 (ISO 11929) regarding calculation of the coverage interval bounds.

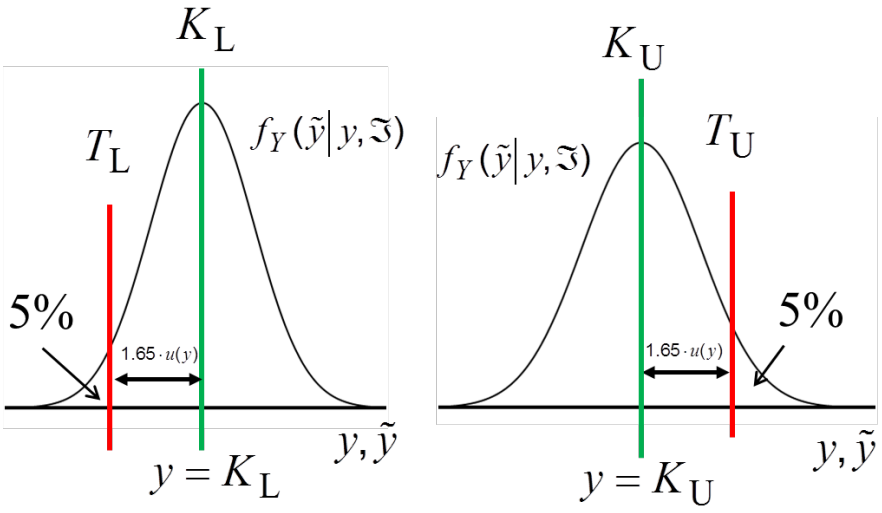

Fig. 5: Graph illustrating the acceptance interval stipulations for single upper or lower tolerance limits.

4.2.4 Conformity involving a two-side-limited tolerance interval

The following observations refer to the conservative stipulation set out in Section 4.2.2.

In the case of a two-side-limited tolerance interval $[T_L, T_U]$, the following equations apply to the acceptance interval $[K_L, K_U]$:

$$P(\tilde{y} < T_L \,|\, y = K_L, u(y = K_L)) = 0.025 \text{ and } P(\tilde{y} > T_U \,|\, y = K_U, u(y = K_U)) = 0.025 .$$

This accounts for the fact that the probability of making incorrect decisions in favour of conformity are distributed symmetrically (please refer to Fig. 6).

If the GUM (JCGM 100) is used to determine the measurement uncertainty, the conditions

$$K_L = T_L + 1.96 \cdot u(y = K_L) \text{ and } K_U = T_U - 1.96 \cdot u(y = K_U)$$

apply if the relative measurement uncertainties are less than 25 %.

For larger relative uncertainties, please refer to DIN ISO 19929 (ISO 11929) regarding calculation of the coverage interval bounds.

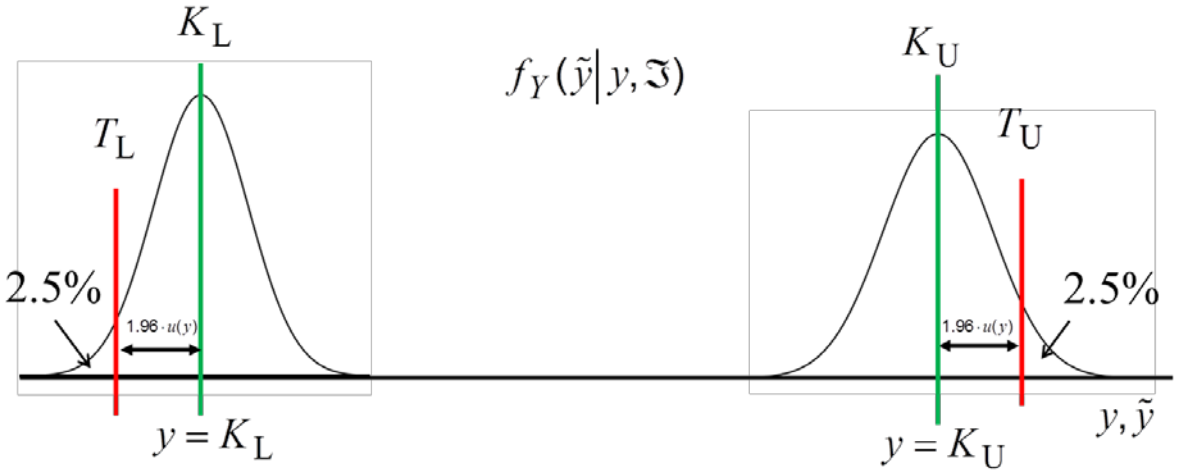

Fig. 6: Graph illustrating the acceptance interval stipulations.

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Annex

A-1 Definitions

Acceptance interval $[K_L, K_U]$ (JCGM 106):

Interval of permissible measured true quantity values

Measurement result (JCGM 200):

Set of quantity values attributed to a measurand together with any other available relevant information ((JCGM 200), 2.9)

NOTE 1[8] (JCGM 200): A measurement result generally contains "relevant information" about the set of quantity values, such that some may be more representative of the measurand than others. This may be expressed in the form of a probability density function (PDF).

NOTE 2 (JCGM 200): A measurement result is generally expressed as a single measured quantity value and a measurement uncertainty. If the measurement uncertainty is considered to be negligible for some purpose, the measurement result may be expressed as a single measured quantity value. In many fields, this is the common way of expressing a measurement result.

Measurement uncertainty (JCGM 200):

non-negative parameter characterising the dispersion of the quantity values being attributed to a measurand, based on the information used

NOTE 1 (JCGM 200): Measurement uncertainty includes components arising from systematic effects, such as components associated with corrections and the assigned quantity values of measurement standards, as well as the definitional uncertainty. Sometimes estimated systematic effects are not corrected for but, instead, associated measurement uncertainty components are incorporated.

NOTE 2 (JCGM 200): The parameter may be, for example, a standard deviation called standard measurement uncertainty (or a specified multiple of it), or the half-width of an interval, having a stated coverage probability.

Measured quantity value y (JCGM 200):

Quantity value representing a measurement result

NOTE 4 (JCGM 200): In the GUM, the terms "result of measurement" and "estimate of the value of the measurand" or just "estimate of the measurand" are used to express 'measured quantity value'.

Standard measurement uncertainty $u(y)$ (JCGM 200):

Measurement uncertainty expressed as a standard deviation

Tolerance interval $[T_L, T_U]$ (JCGM 106):

[8] Note numbering corresponds to the section quoted.

Interval of permissible true values of a quantity

Coverage interval (JCGM 200):

Interval containing the set of true quantity values of a measurand with a stated probability, based on the information available

NOTE 2 (JCGM 200): A coverage interval should not be termed “confidence interval” to avoid confusion with the statistical concept (see (JCGM 100), 6.2.2).

NOTE 3 (JCGM 200): A coverage interval can be derived from an expanded measurement uncertainty (see JCGM 100), 2.3.5).

Coverage interval, probabilistically symmetric $\left[y^{\triangleleft}, y^{\triangleright} \right]$:

Coverage interval with the property $P(\tilde{y} < y^{\triangleleft} \left| y, u(y)) = P(\tilde{y} > y^{\triangleright} \right| y, u(y)) = \gamma / 2$

Coverage probability (JCGM 200):

Probability $1-\gamma$ that the set of true quantity values of a measurand is contained within a specified coverage interval

True quantity value $\tilde{y}$ (JCGM 200):

Quantity value consistent with the definition of a quantity

NOTE 1 (JCGM 200): In the Error Approach to describing measurement, a true quantity value is considered unique and, in practice, unknowable. The Uncertainty Approach is to recognise that, owing to the inherently incomplete amount of detail in the definition of a quantity, there is not a single true quantity value but rather a set of true quantity values consistent with the definition. However, this set of values is, in principle and in practice, unknowable. Other approaches dispense altogether with the concept of true quantity value and rely on the concept of metrological compatibility of measurement results for assessing their validity.

NOTE 3 (JCGM 200): When the definitional uncertainty associated with the measurand is considered to be negligible compared to the other components of the measurement uncertainty, the measurand may be considered to have an “essentially unique” true quantity value. This is the approach taken by the GUM and associated documents, where the word “true” is considered to be redundant.

A-2 Quantities and symbols

Quantities are represented by upper-case letters. They must be carefully distinguished from their values, which are represented by lower-case letters. To this end, the quantities and symbols provided by ISO 11929 and DIN ISO 11929 (ISO 11929) were used.

Y	Random variable as an estimator for the measurand; also used as the symbol for the non-negative measurand which quantifies the observed physical effect
$\tilde{y}$	True quantity value of the measurand. If the observed physical effect is not given, then $\tilde{y} = 0$; otherwise $\tilde{y} > 0$.
y	Measured value of the estimator Y; primary measurement result for the measurand
$u(y)$	Standard measurement uncertainty of the measurand for the primary measurement result y
$y^{\triangleleft}$, $y^{\triangleright}$	Lower or upper limit of the coverage interval for the measurand
$1-\gamma$	Probability for the coverage interval of the measurand
k_p, k_q	Quantiles of the standard normal distribution for the probability p or q (e.g. $p = 1-\alpha$, $1-\beta$ or $1-\gamma/2$)
K_{L}, K_U	Lower or upper bound of the acceptance interval
T_{L}, T_U	Lower or upper bound of the tolerance interval
$f_Y(\tilde{y}\,\vert\, y, \mathfrak{I})$	Conditional probability density function for the true value $\tilde{y}$; given a measured value y of measurand Y and any other available information $\mathfrak{I}$.

A-3 Examples

A-3.1 Measuring the dose rate with a single-sided upwards-limited tolerance interval

A measurement of the ambient dose rate $\dot{H}^*(10)$ should be performed on the edge of an exclusion area to determine compliance with the criterion set out in the German Radiation Protection Ordinance (StrlSchV) which states that the ambient dose rate on the edge of an exclusion area may not exceed 3 mSv/h. This therefore involves a single-sided upwards-limited tolerance interval where $T_U(\dot{H}^*(10)) = 3\ \text{mSv/h}$.

A calibrated survey meter fitted with a Geiger-Müller counter was used to perform measurements. The relative uncertainty of the measurement was determined by independent repeated measurements performed in a comparable radiation field as a relative standard deviation of the indicated measured quantity values for $u_{rel}(\dot{H}^*(10)) = 0.08$.[9]

The measurement provided a ambient dose rate of $\dot{H}^*(10) = 2.70\ \text{mSv/h}$. The attributed standard measurement uncertainty is

$$u(\dot{H}^*(10)) = \dot{H}^*(10) \cdot u_{rel}(\dot{H}^*(10)) = 2.70\ \text{mSv/h} \cdot 0.08 = 0.22\ \text{mSv/h}\ .$$

As set out in recommendation 4, conformity with the requirement is acknowledged if $y + 1.65 \cdot u(y) \le T_U$ is met. This means the following must apply:

$$\dot{H}^*(10) + 1.65 \cdot u(\dot{H}^*(10)) \le T_U(\dot{H}^*(10)) = 3\ \text{mSv/h}\ .$$

This is not the case since

$$2.70\ mSv/h + 1.65 \cdot 0.22\ \text{mSv/h} = 3.06\ \text{mSv/h} > T_U(\dot{H}^*(10)) = 3\ \text{mSv/h}$$

After broadening the exclusion area, an ambient dose rate of $\dot{H}^*(10) = 2.50\ \text{mSv/h}$ was measured on the edge of the exclusion area with a standard measurement uncertainty of

$$u(\dot{H}^*(10)) = \dot{H}^*(10) \cdot u_{rel}(\dot{H}^*(10)) = 2.50\ \text{mSv/h} \cdot 0.08 = 0.20\ \text{mSv/h}\ .$$

Thus

$$2.50\ mSv/h + 1.65 \cdot 0.20\ \text{mSv/h} = 2.83\ \text{mSv/h} \le T_U(\dot{H}^*(10)) = 3\ \text{mSv/h}$$

means that the boundaries of the exclusion area conform with the requirement set out in the German Radiation Protection Ordinance (StrlSchV).

Based on the information that the relative standard measurement uncertainty is $u_{rel}(\dot{H}^*(10)) = 0.08$ under these measurement conditions, an acceptance interval can also be provided. For a single-sided upwards-limited tolerance interval, the following equation applies to the acceptance interval as per recommendation 8.a:

$$K_U = T_U - 1.65 \cdot u(y = K_U)\ .$$

[9] When using a calibrated survey meter, the question of how well the meter maps the measurand is irrelevant to the standard measurement uncertainty of a measured quantity value.

This example for the upper bound of the acceptance interval

$$K_{\mathrm{U}}(\dot{H}^{*}(10)) = 3\ \mathrm{mSv/h} - 1.65 \cdot K_{\mathrm{U}}(\dot{H}^{*}(10)) \cdot 0.08 = \frac{3\ \mathrm{mSv/h}}{1 + 1.65 \cdot 0.08} = 2.65\ \mathrm{mSv/h}$$

conforms with the requirements of the German Radiation Protection Ordinance (StrlSchV).

A-3.2 Measurement of patient entrance surface dose rates for fluoroscopic X-ray equipment pursuant to DIN 6868-150 with a single-sided upwards-limited tolerance interval

When performing acceptance testing for medical X-ray equipment, the patient entrance surface dose rate is measured as set out in DIN 6868-150[10]. According to DIN 6868-150, X-ray equipment with a flat-panel detector and a panel length of 25 cm (longest side) as well as X-ray equipment with a 25 cm image intensifier must comply with a 0.6 µGy/s patient entrance surface dose rate limit $\dot{K}_{\mathrm{B}}$. This therefore involves a single-sided upwards-limited tolerance interval where $T_{\mathrm{U}}(\dot{K}_{\mathrm{B}}) = 0.60\ \mu\mathrm{Sv/s}$.

A calibrated diagnostic dosimeter is used to measure the patient entrance surface dose rate. The relative uncertainty of the measurement was determined by independent repeated measurements performed in comparable radiation fields as a relative standard deviation of the indicated measured quantity values for $u_{\mathrm{rel}}(\dot{K}_{\mathrm{B}}) = 0.11$.

The measurement resulted in a patient entrance surface dose rate of $\dot{K}_{\mathrm{B}} = 0.42\ \mu\mathrm{Sv/s}$. The attributed standard measurement uncertainty is

$$u(\dot{K}_{\mathrm{B}}) = \dot{K}_{\mathrm{B}} \cdot u_{\mathrm{rel}}(\dot{K}_{\mathrm{B}}) = 0.42\ \mu\mathrm{Gy/s} \cdot 0.11 = 0.05\ \mu\mathrm{Gy/s}.$$

As set out in recommendation 4, a decision regarding conformity with the requirement is taken if $y + 1.65 \cdot u(y) \leq T_{\mathrm{U}}$ is met. This means the following must apply:

$$\dot{K}_{\mathrm{B}} + 1.65 \cdot u(\dot{K}_{\mathrm{B}}) \leq T_{\mathrm{U}}(\dot{K}_{\mathrm{B}}) = 0.60\ \mu\mathrm{Gy/s}.$$

In this example, the following applies:

$$0.42\ \mu\mathrm{Gy/s} + 1.65 \cdot 0.05\ \mu\mathrm{Gy/s} = 0.50\ \mu\mathrm{Gy/s} < 0.60\ \mu\mathrm{Gy/s}$$

Based on this result, the X-ray equipment conforms with the requirement.

An acceptance interval can also be provided since a constant relative measurement uncertainty can be assumed by performing independent repeated measurements in comparable radiation fields. For a single-sided upwards-limited tolerance interval, the following equation applies to the acceptance interval as per recommendation 8.a:

$$K_{\mathrm{U}} = T_{\mathrm{U}} - 1.65 \cdot u(y = K_{\mathrm{U}}).$$

This example for the upper bound of the acceptance interval

$$K_{\mathrm{U}}(\dot{K}_{\mathrm{B}}) = 0.6\ \mu\mathrm{Gy/s} - 1.65 \cdot K_{\mathrm{U}}(\dot{K}_{\mathrm{B}}) \cdot 0.11 = \frac{0.6\ \mu\mathrm{Gy/s}}{1 + 1.65 \cdot 0.11} = 0.51\ \mu\mathrm{Gy/s}$$

conforms with the requirements.

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[10] DIN 6868-150. Image quality assurance in diagnostic X-ray departments – Part 150: RoeV acceptance test of medical radiographic and fluoroscopic X-ray equipment, June 2013

A-3.3 Measuring activity with a two-side-limited tolerance interval

When performing a thyroid function test, $70\,\text{MBq}$ of Tc-99m should be filled from a generator with a two-side-limited tolerance interval of $\pm 15\,\%$. As a result, the bounds of the two-side-limited tolerance interval are

$$T_\text{L}(A) = 59.50\ \text{MBq} \text{ and } T_\text{U}(A) = 80.50\ \text{MBq}.$$

In order to verify conformity with the requirement, the filled activity is measured at a measuring station. A constant relative standard measurement uncertainty of $u_\text{rel}(A) = 0.05$ was determined when independently calibrating the measuring station.

The measurement provided a measured quantity value of $A = 67.00\,\text{MBq}$ with a standard measurement uncertainty of

$$u(A) = A \cdot u_\text{rel}(A) = 67.00\ \text{MBq} \cdot 0.05 = 3.35\ \text{MBq}.$$

As set out in recommendation 6, a decision regarding conformity with the requirement is taken if

$$y - 1.96 \cdot u(y) \geq T_\text{L} \text{ and } y + 1.96 \cdot u(y) \leq T_\text{U} \text{ apply.}$$

In the current example, the condition is therefore

$$A - 1.96 \cdot u(A) \geq T_\text{L}(A) \text{ and } A + 1.96 \cdot u(A) \leq T_\text{U}(A).$$

The above measured quantity value and its attributed standard measurement uncertainty result in

$$A - 1.96 \cdot u(A) = 67.00\ \text{MBq} - 1.96 \cdot 3.35\ \text{MBq} = 60.43\ \text{MBq} \geq T_\text{L}(A) = 59.50\ \text{MBq}$$

and

$$A + 1.96 \cdot u(A) = 67.00\ \text{MBq} + 1.96 \cdot 3.35\ \text{MBq} = 73.57\ \text{MBq} \leq T_\text{U}(A) = 80.50\ \text{MBq}.$$

Based on this, the filled activity conforms with the requirement.

An acceptance interval can also be provided since a constant relative measurement uncertainty can be assumed by performing calibration measurements. Based on recommendation 8.c,

$$K_\text{L} = T_\text{L} + 1.96 \cdot u(y = K_\text{L}) \text{ and } K_\text{U} = T_\text{U} - 1.96 \cdot u(y = K_\text{U})$$

apply.

In this example for the acceptance interval bounds, this means

$$K_\text{L}(A) = T_\text{L}(A) + 1.96 \cdot u(A = K_\text{L}(A)) = T_\text{L}(A) + 1.96 \cdot K_\text{L}(A) \cdot u_\text{rel}(A)$$
$$= \frac{59.50\ \text{MBq}}{(1 - 1.96 \cdot 0.05)} = 65.96\ \text{MBq}$$

and

$$K_\text{U}(A) = T_\text{U}(A) - 1.96 \cdot u(A = K_\text{U}(A)) = T_\text{U}(A) - 1.96 \cdot K_\text{U}(A) \cdot u_\text{rel}(A)$$
$$= \frac{80.50\ \text{MBq}}{(1 + 1.96 \cdot 0.05)} = 73.32\ \text{MBq}.$$